

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

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CCMAS Nodal Committee for ALL analytical methods with Codex provisions

*Prepared by SDO's (IAM)*

### Abbreviations

CAC	Codex Alimentarius Commission
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCCF	Codex Committee on Contaminants in Foods
CCPR	Codex Committee on Pesticide Residues
CCRVDR	Codex Committee on Residues of Veterinary Drugs in Foods
CCFH	Codex Committee on Food Hygiene
CCFA	Codex Committee on Food Additives
JECFA	Joint FAO/WHO Expert Committee on Food Additives

### Executive Summary

It is advisable to make CCMAS the nodal Committee for all analytical methods and sampling in the frame of Codex standards and provisions. There are several reasons why this is an important change.

In 2018 the CCMAS started new work to amend STAN 234-1999 on recommended methods of analysis and sampling. It was recognized that it is critical to keep the methods updated, and therefore a review cycle needs to be established. As part of this work STAN 234-1999 will also be formatted in such a way that competent authorities have easier access through simplified and effective search tools for "fit for purpose" methods for the various Codex provisions.

In this regard, it would be appropriate if a future single database includes recommendations for all relevant analytical methods and sampling in the frame of Codex Standards and provisions. However, present CCMAS's Terms of Reference includes the consideration of methods of analysis and sampling proposed by Codex (Commodity) Committees, but do not cover methods of analysis and sampling proposed for residues of pesticides, veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives.

This discussion paper reviews former decisions by the Codex Alimentarius Commission (CAC) and CCMAS pertaining to the scope of work for CCMAS, and areas for which currently no recommendations are given for methods of analysis in foods. These areas include contaminants, pesticides and veterinary drug residues, additives and microbiological criteria.

### Recommendations to CCMAS40

- CCMAS to become the nodal committee for ALL analytical methods and sampling in the frame of Codex standards.
- Committees (CCPR, CCRVDF, CCCF) which developed method criteria for pesticide and veterinary drug residues and mycotoxins respectively, without suggestions for analytical methods meeting the criteria, to refer proposals to CCMAS for endorsement and inclusion in STAN 234-1999.

- Committees (CCFH, CCFC), which established Standards including provisions and microbiological criteria for which no recommendations are made for analytical methods to verify compliance to Codex provisions, to refer proposals to CCMAS for endorsement and inclusion in STAN 234-1999.
- If it is not desirable to broaden the scope of CCMAS, establish dedicated analytical working groups in committees which currently do not refer methods of analysis and sampling to CCMAS. Once the methods are selected by such working groups and endorsed by its parent committee, they could be entered in STAN 234 by the Codex secretariat.

## Introduction

In 2018 CCMAS started new work to amend CODEX STAN 234-1999 on Recommended Methods of Analysis and Sampling to the normal format for a standard, including a preamble and other relevant information, scope and use of the Standard (REP17/MAS/Appendix VI).

The methods of analysis listed in Codex standards are primarily intended as methods for the verification of the provisions in Codex standards. In this context, it is critical to keep updating methods of analysis in a single document or a single database, allowing a simplified and effective search for method as well as a permanent and dynamic revision system. This brings up the question whether such a database is covering ALL methods of analysis in the frame of Codex standards. CCMAS's Terms of Reference include the consideration of methods of analysis and sampling proposed by Codex (Commodity) Committees, but do not cover methods of analysis and sampling for residues of pesticides, veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives. This document discusses the relevance to consider CCMAS as the nodal committee for ALL analytical methods. As a result, authorities can have access to a single database with recommended methods of analysis in the frame of Codex standards.

## Format for Codex commodity standards

The Codex Procedural Manual describes the format for Codex commodity standards and includes a section on methods of analysis and sampling.

CAC adopted in 2016 (REP16/CAC Appendix II) the following text to the format of Codex commodity standards.

### *Methods of Analysis and Sampling*

This section should contain the following wording:

*“For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used.”*

The methods of analysis and sampling considered necessary should be selected 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 proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives.

## History of STAN 234-1999

CCMAS held its first session in 1965. The Committee decided to establish a bibliographical collection of publications; a collection of existing analytical methods as well as a list of organizations dealing with food analyses. In subsequent sessions, decisions were made on the terms of reference (TOR) of the Committee. Below are the most important decisions which lead to the TOR in terms of inclusion/exclusion of certain groups of methods of analysis.

### *Microbiology*

The Executive Committee of the Codex Alimentarius Commission considered the question of which body would be the most appropriate for dealing with microbiological methods of analysis and sampling in their session in June 1968 (ALINORM 69/3) and decided to recommend to the Commission that responsibility in this field should be solely and exclusively that of the Codex Committee on Food Hygiene.

CCMAS took note of this recommendation and pointed out that there were certain methods of analysis of this kind which should be referred to CCMAS, such as chemical methods for toxins formed by microorganisms, the use of chemical and physical methods for the determination of certain microorganisms which are of no great concern from a health point of view (e.g. Howard mould count), the use of biological test methods for compositional criteria (e.g. vitamins, enzymatic tests), etc. The Committee agreed that there might be other aspects where overlapping was unavoidable, and the above recommendation should be clarified before a final

position could be taken by the Committee (ALINORM 69/23, January 1969). At their Fifth session, (ALINORM 70/23) CCMAS distinguished between microbiological methods related to the assessment and control of bacteriological hazards and those related to technological standards, e.g. vitamin content.

#### *Pesticides*

At the CCMAS session in June 1968 (ALINORM 69/3) the Committee noted that the Joint FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues were recommending well established methods of analysis for pesticide residues in foods. In order to avoid duplication of effort and taking into account that the Codex Committee on Methods of Analysis and Sampling had already an enormous task to fulfil, the Committee agreed that it might be better if these methods were not referred to the Committee on Methods of Analysis and Sampling for endorsement but that they should be further elaborated as international referee methods through the Procedure for the Elaboration of Codex Standards by the Codex Committee on Pesticide Residues (CCPR). The Executive Committee recommended that the opinion of the Codex Committee on Methods of Analysis and Sampling should be obtained on the acceptability of this procedure and that their views be placed before the Commission at its next session. CCMAS agreed with this proposed change of procedure (ALINORM 69/23, January 1969).

#### *Food additives*

At the CCMAS session in June 1968 (ALINORM 69/3), The Executive Committee noted that the specifications which had been submitted to governments at Step 3 of the Procedure contained methods of analysis. The Committee considered that, in view of the fact that these methods of analysis formed an integral part of the specifications, it might not be necessary to refer such methods of analysis to the Codex Committee on Methods of Analysis and Sampling, and it might be better if they were considered with the specifications by the Codex Committee on Food Additives. This might involve the need to consult the Joint Expert Committee on Food Additives which prepared the specifications. The Executive Committee recommended that the opinion of the Codex Committee on Methods of Analysis and Sampling should be obtained on the acceptability of this procedure and that their views be placed before the Commission at its next session.

CCMAS agreed with this change of procedure but recommended at the same time that the methods as elaborated by the Joint FAO/WHO Expert Committee on Food Additives would not necessarily have to be put through the Procedure for the elaboration of Codex Standards. It was understood that CCMAS would proceed with its work on the determination of additives in foods (ALINORM 69/23, January 1969).

#### *Methods for veterinary drugs in foods*

At the 16<sup>th</sup> session of CCMAS in November 1988 (ALINORM 89/23), the Committee was informed that the CAC had accepted the view of the CCRVDF that methods of analysis and sampling developed by the CCRVDF need not to be endorsed by the Committee.

The Commission (ALINORM 87/39) agreed with the view of the Committee (CCRVDF) that it was the appropriate body to develop methods of analysis and sampling for the determination of residues of veterinary drugs in foods and that, similar to pesticide residues, it was not necessary to submit these methods to the Committee on Methods of Analysis and Sampling for endorsement. The Commission noted that the Committee had taken decisions on a number of fundamental issues as follows:

- proposals to amend the terms of reference
- adoption of definitions for "veterinary drug" and "residues of veterinary drugs"
- establishment of criteria for the selection of veterinary drugs for evaluation
- priority list of veterinary drugs
- agreement on working arrangements with other Codex Committees and the Joint Expert Committee
- establishment of a working group on methods of analysis and sampling.

It also noted that methods of analysis for pesticide residues, microbiological methods, and methods of analysis included in Codex specifications for food additives did not require endorsement by the CCMAS. Two delegations queried why such methods should not require endorsement. While it was noted that more frequent sessions of the Committee or its Working Group on Endorsement might result if more methods of analysis being referred to the CCMAS for endorsement. It was also noted that it would not be possible to arrange for such a working group to meet because these meetings would have to follow all Codex rules on meetings. It was pointed out that analytical methods for pesticide residues, veterinary drug residues, and microbiological methods represented specialized fields, which might explain why such methods were not being referred to the Committee for endorsement.

## Evaluation of Codex Standards/Guidelines in areas not in scope of CCMAS, but with a potential need on recommendations for methods of analysis and sampling

### General Standard for contaminants and toxins in food and feed (STAN 193-1995)

This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed, and lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed which are recommended by the Codex Alimentarius Commission (CAC) to be applied to commodities moving in international trade.

This Standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

In this standard the maximum and guidance levels for contaminants and toxins in foods are given Table 1 summarizes the provisions in STAN 193-1995 and whether there are method criteria and/or recommended methods of analysis linked to these provisions, either in the STAN 193-1995 or in STAN 234-1999. It should be noted that some general methods of analysis for (heavy) metals are listed in STAN 228-2001 on General Methods of Analysis for contaminants.

Table 1: Contaminants for which maximum and guidance levels are included in STAN 193-1995, and references to test methods, and/or method criteria.

	Method Criteria given in STAN 193-1995?	Method given in STAN 234-1999?	Remark
Total aflatoxins	yes	Yes, for peanuts	Included language in STAN 193-1995: Analytical methods that are accepted by chemists internationally (such as AOAC) may be used  No methods in STAN 234-1999 for other commodities with ML: dried figs, pistachios, hazelnuts, almonds, brazil nuts
Aflatoxin M1	no	no	
Deoxynivalenol (DON)	yes	no	
Fumonisin (B1+B2)	yes	no	
Ochratoxin A	no	no	
Patulin	no	no	
Arsenic	no	Yes, for fats & oils, food grade salt, criteria for water,	No methods in STAN 234-1999 for arsenic in rice
Cadmium	no	Yes, food grade salt and criteria for water	No methods in STAN 234-1999 for vegetables, pulses, cereal grains, rice, chocolate, cephalopods, molluscs.  However, 'general method' for cadmium in all foods listed in STAN 228-2001.
Lead	no	Yes, food grade salt, fats and oils, butter, whey powders, edible casein products, processed fruits and vegetables, table olives, processed meat and poultry products,	No methods included in STAN 234-1999 for commodities with MLs in cereals, infant formula, formula for special medical purposes intended for infants and follow-up formula, fish, milk, wine.

		canned corned beef, cooked cured chopped meat, cooked cured ham, cooked cured pork shoulder, luncheon meat, criteria for water	However, 'general method' for lead in all foods listed in STAN 228-2001.
Mercury	no	Yes, food grade salt, fish and fishery products, criteria for water	
	Method criteria given in STAN-193-1995?	Method given in STAN 234-1999?	Remark
Methyl-mercury in certain fish species	no	Yes, criteria for commodities with ML	
Tin	no	Yes, processed fruits and vegetables, table olives, processed meat and poultry products, canned corned beef, cooked cured chopped meat, cooked cured ham, cooked cured pork shoulder, luncheon meat	
Radionuclides	no	no	GLs for infant foods and foods other than infant foods
Acrylonitrile	no	yes	
Chloropropanols (3-MCPD)	no	no	Commodities: Liquid condiments containing acid hydrolyzed vegetable proteins
Hydrocyanic acid	no	no	Commodities: gari, cassava flour
Melamine	no	Yes, infant formula, milk and milk products	ML for food and feed other than infant formula, no method included in STAN 234-1999.
Vinylchloride monomer	no	no	

### **Principles and Guidelines for the establishment and application of microbiological criteria related to foods (CAC/GL 21-1997)**

Diseases caused by foodborne pathogens constitute a major burden to consumers, food business operators, and national governments. Therefore, the prevention and control of these diseases are international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion, reflecting knowledge and experience of Good Hygienic Practice (GHP), and the impact of potential hazards on consumer health.

Analytical methods and their performance parameters are components of a microbiological criterion (CAC/GL 21 – 1997).

Depending on the microbiological limit (e.g. presence/absence of a specific foodborne pathogen), an appropriate analytical method should be selected. The methods used should be fit for purpose, meaning the method has been validated for relevant performance characteristics (e.g. limit of detection, repeatability, reproducibility, inclusivity, exclusivity). The validation study should be based on internationally accepted

protocols and include an interlaboratory study. If not available, a validation should be done by the laboratory applying the method, according to a standardised protocol.

The analytical methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.

### **Guidelines on the application of the general principles of food hygiene to the control of *Listeria monocytogenes* in foods (CAC/GL 61-2007)**

Annex I of the Guideline gives recommendations for an environmental monitoring program for *Listeria monocytogenes* in processing areas. Regarding analytical methods the following recommendation is given:

The analytical methods used to analyse environmental samples should be suitable for the detection of *L. monocytogenes* and of other defined target organisms. Considering the characteristics of environmental samples, it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately.

No recommendations for specific methods are given.

Annex II of the Guideline gives microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods. Table 1 gives a microbiological limit (100 cfu/g) for ready-to-eat foods in which growth of *L. monocytogenes* will not occur. In an asterisk to the limit it is explained that this criterion is based on the use of the ISO 11290-2 method. This is followed by the following text: "Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140)". However, it is not clear what is meant with "reliability"? This is not a formal defined performance parameter.

Table 2 gives a microbiological limit (Absence in 25 g, < 0.04 cfu/g) for ready-to eat foods in which the growth of *L. monocytogenes* can occur with the same language in an asterisk to the limit as mentioned above.

Annex III of the Guideline gives recommendations for the use of microbiological testing for environmental monitoring and process control verification by competent authorities as a means of verifying the effectiveness of HACCP and prerequisite programs for control of *Listeria monocytogenes* in ready-to-eat foods.

The following statement is included:

Overall, sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated. Methods used should be appropriately validated for the recovery of *L. monocytogenes* from environmental samples.

No specifications of analytical methods are included.

### **Codex Standard 106-1983 on General Standard for irradiated Foods**

his standard includes the following clause:

Post irradiation verification

When required and where applicable, analytical methods for the detection of irradiated foods may be used to enforce authorization and labelling requirements. The analytical methods used should be those adopted by the Codex Commission. Neither this standard nor STAN 234-1999 includes recommended methods of analysis.

### **Code of hygienic practice for powdered formulae for infants and young children (CAC/RCP 66-2008)**

The objective of this Code is to provide practical guidance and recommendations to governments, industry, health care professionals/caregivers of infants and young children, as appropriate, on the hygienic manufacture of powdered formulae (PF) and on the subsequent hygienic preparation, handling and use of reconstituted formulae. The Code supplements the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 572004), with an emphasis on the control of microbiological hazards, in particular *Salmonella* and *E. sakazakii* (*Cronobacter* species).

Annex 1 of this code on microbiological criteria for powdered infant formula, formula for special medical purposes, and human milk fortifiers gives the following recommendation:

The methods to be employed for *E. sakazakii* (*Cronobacter* species) and *Salmonella* should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

According to the current status it would be advised to include ISO 22964:2017 and ISO 6579-1 for *Cronobacter* and *Salmonella*, respectively.

### **Additives**

Analytical methods for additives form an integral part of food additives specifications as evaluated by JECFA. CCFA recommends specifications of identity and purity for food additives for adoption by the Commission. In addition, CCFA considers methods of analysis for the determination of additives in food, which are subject to endorsement by CCMAS, as discussed above. CODEX's General Standard for Food Additives (STAN 192-1995) includes a list of additives permitted for use under specified conditions in certain food categories or individual food items.

STAN 234-1999 includes only methods for the determination of additives in fruit juices and nectars: e.g. ascorbic acid, citric acid, sulphur dioxide. No method criteria nor recommended methods of analysis are available in STAN 192-1995 for the determination of additives in foods. This may indicate that there is a low priority to give recommendations on methods of analysis and sampling for additives in foods.

### **Pesticide residues**

CCPR established guidelines on performance criteria for methods of analysis for the determination of pesticides residues in food and feed (CXG 90-2017) which were adopted in 2017.

The purpose of these guidelines is to define and describe the performance criteria, which should be met by methods to analyse pesticide residues in foods and feed (hereafter referred to as food). It addresses the characteristics/parameters to provide scientifically acceptable confidence in the analytical method that is fit for the intended use and may be used to reliably evaluate pesticide residues for either domestic monitoring and/or international trade.

A difference between the performance criteria for pesticide residues and performance criteria for other analytes as published in STAN 234-1999, is the absence of suggested methods meeting the criteria.

### **Veterinary drug residues**

CCRVDF established guidelines for the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals CAC/GL 71-2009 (Revision 2012, 2014), include considerations for the selection and validation of analytical methods for veterinary drug residues in foods which must reliably detect the presence of an analyte of interest, determine its concentration, and correctly identify the analyte. The document also include performance characteristics for screening methods, quantitative and confirmatory methods. As for the area of pesticide residues, no recommendations are given for methods meeting these requirements for individual (priority) residues, or multi-residues.

It should be noted that CCRVDF had on the agenda of their last meeting a discussion paper on the revision of the criteria for the use of multi residue analytical methods for the determination and identification of veterinary drugs in foods (CXG 71-2009). However, the committee agreed to discontinue this agenda item for the time being (REP18 RVDF).

### **Discussion**

Currently within Codex there are several activities, historical decisions, and processes related to analytical methods and sampling, which may benefit from (re)alignment. Firstly, considerable work is ongoing to update STAN 234-1999 with the aim to make it an easily accessible, current, database with recommended methods of analysis and sampling to verify compliance to the provisions in Codex standards. Secondly, the current format of a Codex commodity standard refers to Codex STAN 234-1999 to identify relevant methods of analysis and sampling for checking compliance with the provisions of the standard.

As identified above, subject to several reasons and decisions in the past, recommended methods of analysis and sampling for several areas are not endorsed by CCMAS, and consequently not included in STAN 234-1999. There is also no transparency on what methods are endorsed or meet the criteria, and in some cases which criteria apply. That also calls for action and better alignment. For competent authorities it would be more efficient to have one access point to identify and recommended methods of analysis and sampling to verify compliance with the provisions in Codex commodity standards. To achieve this, it would make sense to designate CCMAS as the nodal committee in Codex for ALL relevant methods of analysis and sampling relate to Codex commodity standards.

One example how within Codex another committee was designated as "nodal committee" for a particular area is the Codex Committee on Food Additives (CCFA). Similar to Codex STAN 234-1999, there is CODEX STAN 192-1995 (General Standard for Food Additives) under Codex Committee of Food Additives (CCFA). This standard states that "The General Standard for Food Additives (GSFA) should be the single authoritative reference point for food additives. Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives (CCFA) when considering food additive provisions in similar non-standardized foods. When

a food is not covered by a commodity committee, CCFA will appraise the technological need". (Reference: General Standard for Food Additives Codex STAN 192-1995).

In the past, it was decided that methods of analysis and sampling for residues of pesticides and veterinary drugs in food, microbiological quality and safety in food, and specifications of food additives are not referred to CCMAS for endorsement and therefore not included in STAN 234-1999. In addition, provisions for a number of contaminants as included in the General Standard for contaminants and toxins in food and feed (STAN 193-1995) do not have recommended methods of analysis and sampling nor in the STAN 192-1995, nor in STAN 234-1999.

For Codex 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 (CODEX Procedural Manual).

Several committees within their responsibilities to recommend methods of analysis have established method criteria for competent authorities to identify whether an analytical method is deemed suitable to verify compliance to a Codex provision. Method criteria are established in the areas of pesticides and veterinary drug residues and mycotoxins. However, CCMAS in STAN 234-1999 suggests one or more international Standards/Official Methods meeting the criteria, whereas committees, which developed method criteria for pesticides and veterinary drug residues and mycotoxins, did not suggest any international recognized methods meeting the proposed criteria.

CCMAS considered in the past that analytical methods for pesticide residues, veterinary drug residues and microbiological methods represented specialized fields of expertise and therefore were not referred to the Committee for endorsement. If this is still the current situation, or if impossible to include additional subject matter experts to the Committee, there might be another way to collect relevant methods of analysis in one comprehensive database. This includes keeping the responsibility of methods currently outside CCMAS scope in the Codex committees concerned (CCFH, CCCF, CCPR, CCRVDR, CCFA), so as to maintain a specific expertise gathered in the same committee on both specifications/provisions and analytical methods. But, to improve their work on analytical methods, in particular the selection of appropriate methods to verify the conformity of products to Codex provisions, by setting a working group (WG) on analytical methods in each of these committees. In the case of e.g. CCFH, such a working group should at least closely liaise with ISO/TC 34/SC 9, if not even being led by this ISO committee which has a leading role for the standardization of reference methods and method validation protocols in the field of food chain microbiology at an international level. Once the methods are selected by a WG are endorsed by its parent committee, they could then be entered in the STAN 234-1999 database by the Codex Secretariat.

Considering the evaluation and discussion above, CCMAS is requested to consider the following recommendations:

- CCMAS to become the nodal committee for ALL analytical methods and sampling.
- Committees (CCPR, CCRVDF, CCCF) which developed method criteria for pesticide and veterinary drug residues and mycotoxins respectively without suggestions for analytical methods, to refer proposals to CCMAS for endorsement and inclusion in STAN 234-1999.
- Committees (CCFH, CCFC), which established Standards including provisions and microbiological criteria for which no recommendations are made for analytical methods to check compliance to Codex provisions, to refer proposals to CCMAS for endorsement and inclusion in STAN 234-1999.
- If it is not desirable to broaden the scope of CCMAS, establish dedicated analytical working groups in committees, which currently do not refer methods of analysis and sampling to CCMAS. Once the methods are selected by such working groups and are endorsed by its parent committee, they could be entered in STAN 234-1999 by the Codex secretariat.