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codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-first Session

International Conference Centre, Geneva (Switzerland), 30 June - 4 July 2008

AMENDMENTS TO THE PROCEDURAL MANUAL

A. Proposed amendment to the Terms of Reference of the Codex *Ad hoc* Intergovernmental Task Force on Antimicrobial Resistance

1. The First Session of the *ad hoc* Task Force on Antimicrobial Resistance (October 2007) agreed to forward to the 31st Session of the Codex Alimentarius Commission an amendment to the section "Objectives" of its Terms of Reference to clarify that the Task Force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animals generated by different areas of use of antimicrobials, such as veterinary applications, plant protection or food processing, without adding a reference to human medicine.[1]

2. The proposed amendment was considered by the 60th Session of the Executive Committee (December 2007). The Executive Committee could not come to a conclusion on this matter and noted that more time was needed to consider in detail the report of the Task Force. Therefore, the Executive Committee agreed to reconsider the matter at its 61st Session and, where possible, to provide its advice to the Commission.[2]

3. The Commission is invited to consider the proposed amendment to the Terms of Reference of the Task Force, which is reproduced in Annex I to this document.

B. Proposed amendments to the "*Format for the Commodity Standards*" and to the "*Relations between Commodity Committees and General Committees*".

Background

4. The 30th Session of the Commission, while adopting the Proposed Amendments to the *Format for Codex Commodity Standards* – Food Additives – and to the *Relations between Commodity Committees and General Committees*, recognised that similar provision for contaminants should be developed for inclusion in the Relations between Commodity Committees and General Committees. The Commission therefore adopted the provisions applicable to additives as proposed, and recommended that the Committee on Contaminants in Foods develop necessary provisions for contaminants, on the basis of a draft to be prepared by the Secretariat.[3]

[1] ALINORM 08/31/42 paras 6-9

[2] ALINORM 08/31/3 paras 68-70

[3] ALINORM 07/30/REP paras 36-38

5. The Executive Committee at its 60th Session considered Proposal 9 (Relation between committees) during the discussion on the Review of Codex committee structure and mandates of the Codex committees and task forces[4].

6. The Executive Committee recognized that Proposal 9 presented in Circular Letter CL 2006/29-CAC had partly become obsolete since relations between commodity committees and general subject committees had evolved to some extent at the 30th Session of the Commission, with the amendments to "*Format for Codex Commodity Standards*" and "*Relations between Commodity Committees and General Committees*", following the decision by the 29th Session of the Commission to split the Committee on Food Additives and Contaminants into two committees.

7. As a follow-up to the above amendments, the Executive Committee agreed to recommend that:

i) all commodity committees should align contaminant provisions in commodity standards to the standard language set out in the Procedural Manual;

ii) when deviations from the standard language were needed, such text should, in principle, be submitted to relevant subject committees for endorsement, while allowing for certain flexibility, where justified; and

iii) the Secretariat should conduct an overall analysis on the content of, and relationship between "*Format for Codex Commodity Standards*" and "*Relations between Commodity Committees and General Committees*" from the viewpoint of streamlining working relations between committees and report the result to the Executive Committee, with recommendations to amend provisions in the Procedural Manual as necessary.

Proposed Amendments to the "*Format for Codex Commodity Standards*" and to the "*Relations between Commodity Committees and General Committees*"

8. The Second Session of the Committee on Contaminants in Foods considered the proposed draft provisions applied to contaminants in the "*Relations between Commodity Committees and General Committees*" and agreed to send the proposed provision applied to the contaminants with amendments to the Executive Committee for consideration.[5] The proposed provision, agreed upon by the Committee on Contaminants in Foods, is attached as Annex II.

9. Subsequently, in accordance with the recommendation of the 60th Session of the Executive Committee, the Secretariat has undertaken an analysis on the content of, and the relationship between the "*Format for Codex Commodity Standards*" and the "*Relations between Commodity Committees and General Committees*" and produced, with due regard to and incorporating where necessary the proposal of the Committee on Contaminants in Foods, further proposed amendments to the "*Format for Codex Commodity Standards*" and to the "*Relations between Commodity Committees and General Committees*", which are attached as Annex III and Annex IV respectively.

10. In order to make user-friendly these two documents with inter-related but distinct objectives, the Proposed Amendments in Annexes III and IV have been prepared observing the following principles:

i) transfer the texts directly related to the format of Codex commodity standards from the "*Relations between Commodity Committees and General Committees*" to the "*Format for Codex Commodity Standards*";

ii) amend the contaminants provision in the "*Format for Codex Commodity Standards*" in order to allow for certain flexibility that is considered necessary ;

iii) develop the provisions on residues of pesticides and veterinary drugs in the "*Relation between Commodity Committees and General Committees*" in order to recognize and clarify the roles of the Committees on Residues of Veterinary Drugs in Foods and on Pesticide Residues in relation to commodity committees;

[4] ALINORM 08/31/3 paras 24-26

[5] ALINORM 08/31/41 para. 14 and Appendix II

iv) integrate in the "*Relations between Commodity Committees and General Committees*" the proposed provisions applied to Contaminants, forwarded by the Second Session of the Committee on Contaminants in Foods with necessary adjustments;

v) replace the references to "Committees" to "Commodity Committees" where appropriate in the "*Relations between Commodity Committees and General Committees*" to clarify the scope of the document; and

vi) incorporate some linguistic and editorial changes.

11. The Proposed Amendments should be read in conjunction with the Secretariat's notes highlighted *in Italic [in square bracket]* that provide further information to be considered by the Commission. Should the Commission agree to the proposed amendments set out in Annexes III and IV, the proposal in Annex II does not need to be considered by the Commission.

C. Other Amendments

Working Instructions for the Implementation of the Criteria Approach in Codex

12. The 29th Session of the Committee on Methods of Analysys and Sampling developed the proposed amendment to the *Working Instructions for the Implementation of the Criteria Approach in Codex in Codex* in the *Principles for the Establishment of Codex Methods of Analysis* (in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts*) in order to provide specific criteria applying to the methods for the determination of trace elements[6].

13. The Commission is invited to consider the proposed amendment, which is reproduced in Annex V to this document.

[6] ALINORM 08/21/23, paras 64-79 and Appendix II

Annex I

PROPOSED AMENDMENT TO THE TERMS OF REFERENCE OF THE *AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Objectives

To develop science based guidance, taking full account of its risk analysis principles and the work and standards of other relevant international Organizations, such as FAO, WHO and OIE. The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk. The Task Force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animal generated by different areas of use of antimicrobials such as veterinary applications, plant protection or food processing.

Terms of reference

[No Change]

Time frame

[No Change]

Annex II

PROPOSED DRAFT PROVISIONS APPLIED TO CONTAMINANTS IN THE "RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES"

(for inclusion in the Procedural Manual)

(Forwarded by the 2nd Session of the Contaminants Committee to the Executive Committee)

Contaminants

Codex Commodity committees shall examine the General Standard for Contaminants and Toxins in Foods with a view toward incorporating a reference to the General Standard.

All proposals for additions or revisions to the General Standard in order to establish a reference to the General Standard shall be referred to the Codex Committee on Contaminants in Foods. The Codex Committee on Contaminants in Foods shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by the Committee on Contaminants in Foods will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.

Should the Codex commodity committee consider that a general reference to the General Standard for Contaminants and Toxins in Foods does not serve its purpose, a proposal should be prepared and forwarded to the Codex Committee on Contaminants in Foods for consideration and endorsement When doing so, the commodity committee shall provide a justification why a general reference to the General Standards would not be appropriate.

All proposals should be referred to the Codex Committee on Contaminants in Foods, preferably before the advancement of the draft commodity standards concerned to Step 5 of the Procedure for Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

In accordance with the agreed Format for Codex Commodity Standards, the section on contaminants in the Standard developed by the commodity committee should contain only the following reference to the General Standard for Contaminants and Toxins in Foods without reference to specific provisions on contaminants:

> *"The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the Commission."*

Annex III

Proposed Draft Amendments to the "Format for Codex Commodity Standards"

(Prepared by the Codex Secretariat)

Format for Codex Commodity Standards

Introduction

The Format is ~~also~~ intended for use as a guide by the subsidiary bodies of the Codex Alimentarius Commission in presenting their standards, with the object of achieving, as far as possible, a uniform presentation of commodity standards. The Format also indicates the statements which should be included in standards as appropriate under the relevant headings of the standard. The sections of the Format require to be completed in a standard only insofar as such provisions are appropriate to an international standard for the food in question.

NAME OF THE STANDARD

SCOPE

DESCRIPTION

ESSENTIAL COMPOSITION AND QUALITY FACTORS

FOOD ADDITIVES

CONTAMINANTS

HYGIENE

WEIGHTS AND MEASURES

LABELLING

METHODS OF ANALYSIS AND SAMPLING

~~Codex Commodity standards contain sections on hygiene, labelling and methods of analysis and sampling and these sections should contain all of the relevant provisions of the standard.~~ Provisions of Codex General Standards, Codes or Guidelines shall only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise. *[Secretariat's note: This text has been transferred from Paragraph 3 of the "Relations between Commodity Committees and General Committees". As the paragraph now follows the listing of sections in a commodity standard, the first sentence has become unnecessary and is therefore deleted.]*

Notes on the Headings

Name o~~O~~f t~~T~~he Standard

The name of the standard should be clear and as concise as possible. It should usually be the common name by which the food covered by the standard is known or, if more than one food is dealt with in the standard, by a generic name covering them all. If a fully informative title should be inordinately long, a subtitle could be added.

Scope

This section should contain a clear, concise statement as to the food or foods to which the standard is applicable unless this is self-explanatory in the name of the standard. In the case of a general standard covering more than one specific product, it should be made clear as to which specific products the standard applies.

Description

This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. It may also include references to types and styles of product and to type of pack. There may also be additional definitions when these are required to clarify the meaning of the standard.

Essential Composition and Quality Factors

This section should contain all quantitative and other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and requirements as to compulsory and optional ingredients. It should also include quality factors which are essential for the designation, definition or composition of the product concerned. Such factors could include the quality of the raw material, with the object of protecting the health of the consumer, provisions on taste, odour, colour and texture which may be apprehended by the senses, and basic quality criteria for the finished products, with the object of preventing fraud. This section may refer to tolerances for defects, such as blemishes or imperfect material, but this information should be contained in an appendix to the standard or in another advisory text.

Food Additives

This section should contain a general reference to the corresponding sections of the General Standard for Food Additives which should take the following form:

> *"[Food Additive functional class] used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category x.x.x.x [food category name] and/or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this standard."*

Exceptions from, or addition to, the General Standard for Food Additives that are necessary for its interpretation with respect to the product concerned should be justified fully, and should be restricted where possible. In cases where it is necessary to explicitly list food additives in a commodity standard, the names of the additives/functional classes permitted and, where appropriate, the maximum amount permitted in the food should be prepared in accordance with guidance given in the section on Food Additives in the *Relations between Commodity Committees and General Subject Committees*, and ~~may take the following form:~~

> ~~"The following provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives."~~*[Secretariat's note: The Secretariat proposes deletion of the sentence above as it is not used in practice; the requirement for endorsement is governed by, and is clearly stated in the "Relations between Commodity Committees and General Subject Committees".]*

~~Then~~ should follow a tabulation, viz:

> *"INS number, name of additive, maximum level (in percentage or mg/kg) grouped by functional classes.~~:~~"*

In this section, provisions for flavourings and processing aids should also be included.

Contaminants

This section should contain only the following reference to the General Standard for Contaminants and Toxins in Foods without reference to specific provisions on contaminants: *[Secretariat's note: The introductory sentence above has been adapted from the proposed draft provisions applied to contaminants forwarded by the Committee on Contaminants in Foods (in Annex II), with some adjustments.]*

> *"The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995)."*

For residues of pesticides and veterinary drugs, if applicable to products concerned, this section should contain a general reference which should take the following form, without reference to specific provisions on residues of pesticides and veterinary drugs: *[Secretariat's note: This inserted text is adapted from the text above.]*

> *"The products covered by this Standard shall comply with ~~and~~ the maximum residue limits for pesticides and/or veterinary drugs established by the CAC."[Secretariat's note: Reference to "/or" has been added to provide for flexibility in the application of this provision, especially for products of plant origin.]*

Hygiene

~~Any specific mandatory hygiene provisions considered necessary should be included in this section. They should be prepared in accordance with the guidance given in the section on Food Hygiene in the *Relations between Commodity Committees and General Committees.*~~ *[Secretariat's note: The context of the sentence above has been reflected in the "Relations between Commodity Committees and General Subject Committees" with some amendments, and therefore has been deleted here.]*

~~Commodity Committees should use in the commodity standards the following text~~ This Section should contain the following general reference to the *Recommended International Code of Practice – General Principles of Food Hygiene* and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* without reference to specific provisions on food hygiene:

> *"It is recommended that the products covered by the provisions of this ~~s~~Standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969~~,Rev 4-2003~~), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice."*
>
> *"The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)."[Secretariat's note: The paragraph above has been transferred from the "Relations between Commodity Committees and General Committees" with adjustments.]*

Reference should also be made to applicable codes of hygienic practice. ~~Any parts of such codes, including in particular any end-product specifications, should be set out in the standard, if it is considered necessary that they should be made mandatory.~~ *[Secretariat's note: In accordance with the decision of the 22nd Session of the Commission which endorsed the recommendation that: "In view of the confusion created by the use of the term "advisory" and as the term cannot be defined satisfactorily and the SPS and TBT Agreements do not appear to distinguish between mandatory and advisory texts, its use within the Codex framework should be discouraged, as well as the use of the term "mandatory", the sentence above has been deleted.]*

~~The following statement should also appear:~~

> ~~*"The following provisions in respect of the food hygiene of this product are subject to endorsement [have been endorsed] by the Codex Committee on Food Hygiene."*~~ *[Secretariat's note: The Secretariat proposes deletion of the sentence above as it is not used in practice; the requirement for endorsement is governed by, and clearly stated in the "Relations between Commodity Committees and General Subject Committees".]*

Weights and Measures

This section should include all provisions, other than labelling provisions, relating to weights and measures, e.g. where appropriate, fill of container, weight, measure or count of units determined by an appropriate method of sampling and analysis. Weights and measures should be expressed in S.I. units. In the case of standards which include provisions for the sale of products in standardized amounts, e.g. multiples of 100 grams, S.I. units should be used, but this would not preclude additional statements in the standards of these standardized amounts in approximately similar amounts in other systems of weights and measures.

Labelling

This section should include all the labelling provisions contained in the ~~s~~Standard. ~~and should be prepared in accordance with the guidance given in the section on Food Labelling in the *Relations between Commodity Committees and General Committees.*~~*[Secretariat's note: Consequent to the transfer of text from the "Relations between Commodity Committees and General Committees", the second half of the sentence above has been deleted.]* Provisions should be included by reference to the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985).

The section may also contain provisions which are exemptions from, additions to, or which are necessary for the interpretation of the General Standard in respect of the product concerned provided that these can be justified fully. ~~The following statement should also appear:~~

> ~~*"The following provisions in respect of the labelling of this product are subject to endorsement [have been endorsed] by the Codex Committee on Food Labelling."*~~*[Secretariat's notes: The Secretariat proposes deletion the sentence above as it is not used in practice; the requirement for endorsement is governed by, and is clearly stated in the "Relations between Commodity Committees and General Subject Committees".]*

~~The provisions on food labelling should be included by reference to the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985). Exemptions from, or additions to, the General Standard which are necessary for its interpretation in respect of the product concerned should be justified fully, and should be restricted as much as possible.~~ *[Secretariat's note: The paragraph above has been deleted as it duplicates the requirement stated elsewhere in the same section.]*

Information specified in each draft standard should normally be limited to the following:

- a statement that the product shall be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985);
- the specified name of the food;
- date marking and storage instructions (only if the exemption foreseen in Section 4.7.1 of the General Standard is applied).

Where the scope of the Codex Standard is not limited to prepackaged foods, a provision for labelling of non retail containers may be included.

In such cases the provision may specify that:

"Information on ...[7] shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.[8]

However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents."*[Secretariat's note: The above paragraphs have been transferred from the 'Relations between Commodity Committees and General Committees", with adjustments.]*

In respect of date marking (Section 4.7 of the General Standard for the Labelling of Prepackaged Foods), if a Codex commodity committee, in exceptional circumstances, determine another date or dates as defined in the General Standard, either to replace or to accompany the date of minimum durability, or alternatively decide that no date marking is necessary, a relevant provision may be included. *[Secretariat's note: The sentence above has been adapted from the current second paragraph in the Section on Food Labelling in the "Relations between Commodity Committees and General Committees".]*

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[7] Codex Committees should decide which provisions are to be included.

[8] Codex Committees may decide that further information is required on the container. In this regard, special attention should be given to the need for storage instructions to be included on the container.

Methods of Analysis and Sampling

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. ~~The following statement should also appear:~~

> ~~*"The methods of analysis and sampling described hereunder are to be endorsed [have been endorsed] by the Codex Committee on Methods of Analysis and Sampling."* [9]~~
>
> *[Secretariat's notes: The Secretariat proposes deletion of the sentence above as it is not used in practice; the requirement for endorsement is governed by, and is clearly stated in the "Relations between Commodity Committees and General Subject Committees".]*

[9] ~~Methods of analysis should be indicated as being "defining", "reference", "alternative approved" or "tentative" methods, as appropriate.~~

Annex IV

Proposed Draft Amendments to the "Relations between Commodity Committees and General Committees"

(Prepared by the Codex Secretariat)

Relations between Commodity Committees and General Subject Committees

Codex Committees may ask the advice and guidance of general subject committees having responsibility for matters applicable to all foods on any points coming within their province, in accordance with their Terms of Reference. In particular, due referral should take place between commodity committees (in this document "commodity committees" are meant to include coordinating committees and other subsidiary bodies of the Commission in so far as they elaborate commodity standards) and general subject committees during the elaboration of Codex commodity standards. *[Secretariat's note: New text is added to clarify scope of this document.]*

Codex general subject committees which include t~~T~~he Committees on Food Labelling; Food Additives; Contaminants in Foods; Pesticides Residues; Residues of Veterinary Drugs in Foods; Food Hygiene; Methods of Analysis and Sampling; ~~Food Hygiene;~~ Nutrition and Foods for Special Dietary Uses; and Food Import and Export Inspection and Certification Systems may establish general provisions on matters within their terms of reference. These general provisions should only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise (see "*Format for Codex Commodity Standards"*). *[Secretariat's note: Proposed amendments are made for clarity.]*

~~Codex Commodity standards contain sections on hygiene, labelling and methods of analysis and sampling and these sections should contain all of the relevant provisions of the standard. Provisions of Codex General Standards, Codes or Guidelines shall only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise~~ *[Secretariat's note: The two sentences above have been transferred to the "Format for Commodity Standards".]* Where ~~Codex~~ commodity c~~C~~ommittees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible general subject c~~C~~ommittees to endorse deviations from the general provisions of the Codex Alimentarius. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Sections on food additives, contaminants, hygiene, labelling, ~~food additives~~ and methods of analysis and sampling which contain specific provisions or provisions supplementing the Codex General Standards, Codes or Guidelines shall be referred to the responsible ~~Codex~~ general subject c~~C~~ommittees at the most suitable and earliest time in ~~during Steps 3, 4 and 5 of~~ the Procedure for the Elaboration of Codex Standards and Related Texts, though such referral~~ence~~ should not be allowed to delay the progress of the standard to the subsequent S~~s~~teps of the Procedure. *[Secretariat's note: Proposed amendments are for clarity.]*

~~Subject and commodity Committees should refer to the principles and guidelines developed by the Codex Committee on Food Import and Export Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time.~~ *[Secretariat's note: The paragraph above has been transferred to the end of this document, with a few minor amendments.]*

Food Labelling

Commodity committees shall refer any exemptions from, or additions to, the reference to the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) as indicated in the section on food labelling in the *Format for Codex Commodity Standards* to the Committee on Food Labelling for endorsement. *[Secretariat's note: The text above provides a link to the "Format for Codex Commodity Standards" by describing the action to be taken by the commodity committee.]*

~~The provisions on food labelling should be included by reference to the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985). Exemptions from, or additions to, the General~~

~~Standard which are necessary for its interpretation in respect of the product concerned should be justified fully, and should be restricted as much as possible.~~

~~Information specified in each draft standard should normally be limited to the following:~~

- ~~a statement that the product shall be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)~~
- ~~the specified name of the food~~
- ~~date marking and storage instructions (only if the exemption foreseen in Section 4.7.1 of the General Standard is applied)~~

~~Where the scope of the Codex Standard is not limited to prepackaged foods, a provision for labelling of non retail containers may be included.~~

~~In such cases the provision may specify that:~~

~~"Information on ...[10] shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.[11]~~

~~However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents."~~ *[Secretariat's note: The paragraphs above have been transferred to the "Format for Commodity Standards".]*

In respect of date marking (Section 4.7 of the General Standard for the Labelling of Prepackaged Foods), a ~~Codex~~ commodity c~~C~~ommittee may, in exceptional circumstances, determine another date or dates as defined in the General Standard, either to replace or to accompany the date of minimum durability, or alternatively decide that no date marking is necessary. In such cases, a full justification for the proposed action should be submitted to the ~~Codex~~ Committee on Food Labelling.

Food Additives

C~~odex c~~ommodity committees shall examine the General Standard for Food Additives (CODEX STAN 192-1995) with a view towards incorporating a reference to the General Standard. All proposals for additions or revisions to the General Standard for Food Additives in order to establish a reference to the General Standard for Food Additives shall be referred to the ~~Codex~~ Committee on Food Additives. The ~~Codex~~ Committee on Food Additives shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by the ~~Food Additives~~ Committee on Food Additives will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure. *[Secretariats' note: Some corrections have been made for clarity]*

Should the ~~Codex~~ commodity committee consider that a general reference to the General Standard for Food Additives does not serve its purpose, a proposal should be prepared and forwarded to the ~~Codex~~ Committee on Food Additives for consideration and endorsement. The commodity committee shall provide a justification for why a general reference to the General Standard for Food Additives would not be appropriate in light of the criteria for the use of food additives established in the Preamble of the General Standard for Food Additives, in particular Section 3. *[Secretariats' note: Some corrections are made for clarity]*

All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the ~~Codex~~ Committee on Food Additives, preferably before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the ~~C~~commodity ~~C~~committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

~~[10] Codex Committees should decide which provisions are to be included.~~

~~[11] Codex Committees may decide that further information is required on the container. In this regard, special attention should be given to the need for storage instructions to be included on the container.~~

All provisions in respect of food additives contained in commodity standards will require endorsement by the ~~Codex~~ Committee on Food Additives, on the basis of technological justification submitted by the commodity committees and on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions) and an estimate of the potential and, where possible, the actual intake of the food additives, ensuring conformity with the Preamble of the General Standard for Food Additives ~~General Principles for the Use of Food Additives~~. *[Secretariats' note: Some corrections are made for clarity]*

When forwarding a food additive section of a commodity standard for endorsement by the ~~Codex~~ Committee on Food Additives, the Secretariat should prepare a report to the Committee that includes the International System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives,~~,~~ technological justification, proposed level, and whether the additive was previously endorsed by the ~~Codex~~ Committee on Food Additives.

~~When commodity standards are sent to governments for comment at Step 3, they should contain a statement that the provisions "in respect of food additives are subject to endorsement by the Codex Committee on Food Additives and to incorporation into the General Standard for Food Additives."~~ *[Secretariats' note: The Secretariat proposes deletion of this text above for consistency with the provisions in Annex III.]*

When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the ~~Codex~~ Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives. When the Codex Committee on Food Additives decides not to endorse specific additives provisions, the reason should be clearly stated. The section under consideration should be referred back to the commodity committee concerned if further information is needed, or for information if the ~~Codex~~ Committee on Food Additives decides to amend the provision.

When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions for inclusion in the General Standard for Food Additives should be forwarded directly by Codex members to the ~~Codex~~ Committee on Food Additives .

Contaminants in Foods

~~Codex~~ Commodity committees shall examine the General Standard for Contaminants and Toxins in Foods with a view towards incorporating a reference to the General Standard.

~~All proposals for additions or revisions to the General Standard in order to establish a reference to the General Standard shall be referred to the Codex Committee on Contaminants in Foods.~~ The ~~Codex~~ Committee on Contaminants in Foods shall consider all ~~such~~ proposals for additions or revisions to the General Standard or ~~for~~ endorsement of proposed provisions and take action where necessary and appropriate. ~~Revisions of a substantive nature that are endorsed by the Committee on Contaminants in Foods will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.~~ *[Secretariat's note: Some amendments have been made in order to clarify the action to be taken by the Committee on Contaminants in Foods on proposals arising from other committees and to improve consistency with other sections of the document. The last sentence has been deleted as it is part of well-established procedures of endorsement applicable between commodity committees and general subject committees where the opinion of the competent General Subject Committee takes precedence over the proposal of commodity committees. To improve the logical order, the Secretariat recommends that this paragraph be moved to the very end of this section on contaminants in foods (see the place holder [##] below).*

Should the ~~Codex~~ commodity committee consider that a general reference to the General Standard for Contaminants and Toxins in Foods does not serve its purpose, a proposal should be prepared and forwarded to the ~~Codex~~ Committee on Contaminants in Foods for consideration of starting new work, revision of the General Standard for Contaminants and Toxins in Foods, or ~~and~~ endorsement of proposed provisions, as appropriate. *[Secretariat's note: As the General Standard for Contaminants and Toxins in Foods (GSCTF) should be a single reference for contaminants provisions within the Codex Alimentarius, a commodity committee, if the current contaminants provisions in GSCTF do not serve its needs, should make a request to the Committee on Contaminants in Foods for elaborating new provisions for substances concerned or for revising the current provisions in the GSCTF. The Committee on Contaminants in Foods, as is the case with the Committees on Pesticide Residues and on Residues of Veterinary Drugs in Foods which elaborate residue levels for chemicals concerned, is to be recognised as the competent committee to elaborate provisions on contaminants in the Codex Alimentarius, interacting with the Joint Expert Committee on Food Additives in accordance with the established procedure and taking into account a range of relevant food safety considerations, in particular, the exposure to contaminants in question from a variety of food sources in a broader perspective.*

On the other hand, considering the practice followed in the past where the Committee on Contaminants in Foods was requested to endorse provisions originating from commodity committees, there may need to retain certain flexibility allowing commodity committees to initiate the elaboration of provisions for contaminants or other health-related substances in the context of the elaboration of commodity standards, subject to the review by the Executive Committee through its Critical Review. It is also noted that commodity committees may develop levels for certain substances as part of quality factors, which may later need to be endorsed by the Committee on Contaminants in Foods from the food safety point of view.]

When doing so, the commodity committee shall provide a justification why a general reference to the General Standards for Contaminants and Toxins in Foods would not be appropriate for products concerned. *[Secretariat's note: For clarity, some words are added.]*

All proposals should be referred to the ~~Codex~~ Committee on Contaminants in Foods, preferably before the advancement of the draft commodity standards concerned to Step 5 of the Procedure for Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

[##]

~~In accordance with the agreed Format for Codex Commodity Standards, the section on contaminants in the Standard developed by the commodity committee should contain only the following reference to the General Standard for Contaminants and Toxins in Foods without reference to specific provisions on contaminants:~~

> ~~*"The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the Commission."*~~ *[Secretariat's note: The text above has been transferred to the "Format for Commodity Standards".]*

Pesticide residues / residues on veterinary drugs in Foods

Commodity committees shall examine the provisions on residue limits of pesticides and of veterinary drugs adopted by the Codex Alimentarius Commission with a view towards incorporating a general reference as indicated in the section on contaminants in the *Format for Codex Commodity Standards*.

Should the commodity committee consider that the general reference above does not serve its purpose, a proposal should be prepared and forwarded to the Committees on Pesticide Residues or on Residues of Veterinary Drugs in Foods as appropriate, for consideration of new work or revision of the adopted residue limits.

[Secretariat's note: The paragraphs above aim at clarifying that the Committees on Pesticide Residues and on Residues of Veterinary Drugs in Foods are the competent committees in respective areas, in accordance with their terms of reference.

Food Hygiene

Commodity committees should examine the provisions on food hygiene adopted by the Codex Alimentarius Commission, with a view towards incorporating a general reference as indicated in the section on food hygiene in the *Format for Codex Commodity Standards*. Commodity committees shall refer any exemptions from, or additions to, the general reference above to the Committee on Food Hygiene for endorsement. *[Secretariat's note: The above two sentences describe what the commodity committee should do and how exceptions from the general text as stated in the Format for commodity standards are to be handled. The first sentence has been transferred from the "Format for commodity standards", with some adjustments to make it consistent with other sections in this document.]*

~~Commodity Committees should use in the commodity standards the following text:~~

> ~~*"It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4-2003), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice."*~~
>
> ~~*"The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)."*~~ *[Secretariat's note: This deleted part is moved to the "Format for Commodity Standards".]*

Methods of Analysis and Sampling

Normal Practice

Except for methods of analysis and sampling associated with microbiological criteria, when ~~Codex~~ commodity committees have included provisions on methods of analysis or sampling in a Codex commodity standard, these should be referred to the ~~Codex~~ Committee on Methods of Analysis and Sampling at Step 4, to ensure Government comments at the earliest possible stage in the development of the standard. A ~~Codex~~ commodity ~~C~~committee should, whenever possible, provide information to the ~~Codex~~ Committee on Methods of Analysis and Sampling for each individual analytical method proposed, relating to specificity, accuracy, precision (repeatability, reproducibility) limit of detection, sensitivity, applicability and practicability, as appropriate. Similarly a ~~Codex~~ commodity c~~C~~ommittee should, whenever possible, provide information to the ~~Codex~~ Committee on Methods of Analysis and Sampling for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. "Operating characteristic" curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data.

Other criteria may be selected as required. Methods of analysis should be proposed by the ~~C~~commodity ~~C~~committees in consultation if necessary with an expert body.

At Step 4, ~~Codex~~ ~~C~~commodity ~~C~~committees should discuss and report to the ~~Codex~~ Committee on Methods of Analysis and Sampling on matters connected with:

- Provisions in Codex standards which require analytical or statistical procedure;
- Provisions for which elaboration of specific methods of analysis or sampling are required;
- Provisions which are defined by the use of Defining Methods (Type I);
- All proposals to the extent possible should be supported by appropriate documentation; especially for Tentative Methods (Type IV);
- Any request for advice or assistance.

The Committee on Methods of Analysis and Sampling should undertake a coordinating role in matters relating to the elaboration of Codex methods of analysis and sampling. The originating committee is, however, responsible for carrying out the Steps of the Procedure.

When it is necessary, the Committee on Methods of Analysis and Sampling should try to ensure elaboration and collaborative testing of methods by other recognized bodies with expertise in the field of analysis.

The Committee on Methods of Analysis and Sampling will assess the actual analytical performance of the method which has been determined in its validation. This will take account of the appropriate precision characteristics obtained in collaborative trials which may have been carried out on the method together with results from other development work carried out during the course of the method development. The set of criteria that are developed will form part of the report of the endorsement by the Committee on Methods of Analysis and Sampling and will be inserted in the appropriate Codex ~~C~~commodity ~~S~~standard.

In addition, the Committee on Methods of Analysis and Sampling will identify numeric values for the criteria for which it would wish such methods to comply.

Methods of analysis and sampling of general application to foods

When the Committee on Methods of Analysis and Sampling itself elaborates methods of analysis and sampling which are of general application to foods, it is responsible for carrying out the steps of the Procedure.

Methods of analysis of food additives as such

Methods of analysis included in Codex ~~Advisory Food Additives~~ Specifications for Food Additives (CAC/MISC 6), for the purpose of verifying the criteria of purity and identity of the food additive, need not be referred to the Committee on Methods of Analysis and Sampling for endorsement. The Committee on Food Additives is responsible for carrying out the steps of the Procedure.

Methods of analysis of pesticide residues in food

The methods for determining the levels of pesticide residues, veterinary drug residues and contaminants in food need not be referred to the Committee on Methods of Analysis and Sampling for endorsement. The Committee on Pesticide Residues is responsible for carrying out the steps of the Procedure.

Microbiological methods of analysis and sampling

When ~~Codex~~ commodity committees have included provisions on microbiological methods of analysis and sampling for the purpose of verifying hygiene provisions, they should be referred to the Committee on Food Hygiene at the most suitable time during Steps 3, 4 and 5 of the Procedure for the Elaboration of Codex Standards, which will ensure that government comments on the methods of analysis and sampling are available to the Committee on Food Hygiene. The procedure to be followed will be as in the normal practice described above, substituting the Committee on Food Hygiene for the Committee on Methods of Analysis and Sampling. Microbiological methods of analysis and sampling elaborated by the Committee on Food Hygiene for inclusion in Codex commodity standards for the purpose of verifying hygiene provisions need not be referred to the Committee on Methods of Analysis and Sampling for endorsement.

Food Import and Export Inspection and Certification Systems

General subject and commodity committees should refer to the principles and guidelines developed by the ~~Codex~~ Committee on Food Import and Export Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time. *[Secretariat's note: The fourth paragraph in the introductory section has been transferred here.]*

Annex V

PROPOSED AMENDMENT TO THE PROCEDURAL MANUAL

WORKING INSTRUCTIONS FOR THE IMPLEMENTATION OF THE CRITERIA APPROACH IN CODEX

(This document replaces the *Working Instructions for the Implementation of the Criteria Approach in Codex* in the *Principles for the Establishment of Codex Methods of Analysis*)

Any Codex Committee may continue to propose an appropriate method of analysis for determining the chemical entity and/or develop a set of criteria to which a method used for the determination must comply. In either case the specified maximum level, minimum level, any other normative level or the concentration range of interest has to be stated.

When a Codex Committee decides that a set of criteria should be developed, in some cases the Committee may find it easier to recommend a specific method and request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to "convert" that method into appropriate criteria. The Criteria will then be considered by the CCMAS for endorsement and will, after the endorsement, form part of the standard. If a Codex Committee wishes to develop the criteria, it should follow instructions given for the development of specific criteria as outlined in table 1.

Table 1: Guidelines for establishing numeric values for the criteria:

Applicability:	The method has to be applicable for the specified provision, specified commodity and the specified level(s) (maximum and/or minimum) (ML). The minimum applicable range of the method depends on the specified level (ML) to be assessed, and can either be expressed in terms of the reproducibility standard deviation (s_R) or in terms of LOD and LOQ.
Minimum applicable range:	For ML ≥ 0.1 mg/kg, [ML - 3 s_R , ML + 3 s_R] For ML < 0.1 mg/kg, [ML - 2 s_R , ML + 2 s_R] s_R[12] = standard deviation of reproducibility
Limit of Detection (LOD):	For ML ≥ 0.1 mg/kg, LOD ≤ ML · 1/10 For ML < 0.1 mg/kg, LOD ≤ ML · 1/5
Limit of Quantification (LOQ):	For ML ≥ 0.1 mg/kg, LOQ ≤ ML · 1/5 For ML < 0.1 mg/kg, LOQ ≤ ML · 2/5

[12] The s_R should be calculated from the Horwitz / Thompson equation. When the Horwitz / Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when "converting" methods into criteria then it should be based on the s_R from an appropriate method performance study.

<table>
<tr><td>Precision:</td><td>For ML ≥ 0.1 mg/kg, HorRat value ≤ 2
For ML < 0.1 mg/kg, the RSD_{TR} < 22%.
RSD_R[13] = relative standard deviation of reproducibility</td></tr>
<tr><td>Recovery (R):</td><td>
<table>
<tr><th>Concentration</th><th>Ratio</th><th>Unit</th><th>Recovery (%)</th></tr>
<tr><td>100</td><td>1</td><td>100% (100 g/100g)</td><td>98 – 102</td></tr>
<tr><td>≥10</td><td>10^{-1}</td><td>≥ 10% (10 g/100g)</td><td>98 – 102</td></tr>
<tr><td>≥1</td><td>10^{-2}</td><td>≥ 1% (1 g/100g)</td><td>97 – 103</td></tr>
<tr><td>≥0.1</td><td>10^{-3}</td><td>≥ 0.1% (1 mg/g)</td><td>95 – 105</td></tr>
<tr><td>0.01</td><td>10^{-4}</td><td>100 mg/kg</td><td>90 – 107</td></tr>
<tr><td>0.001</td><td>10^{-5}</td><td>10 mg/kg</td><td>80 – 110</td></tr>
<tr><td>0.0001</td><td>10^{-6}</td><td>1 mg/kg</td><td>80 – 110</td></tr>
<tr><td>0.00001</td><td>10^{-7}</td><td>100 µg/kg</td><td>80 – 110</td></tr>
<tr><td>0.000001</td><td>10^{-8}</td><td>10 µg/kg</td><td>60 – 115</td></tr>
<tr><td>0.0000001</td><td>10^{-9}</td><td>1 µg/kg</td><td>40 – 120</td></tr>
</table>
Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied.
</td></tr>
<tr><td>Trueness:</td><td>For the evaluation of trueness preferably certified reference material should be used.</td></tr>
</table>

The criteria in Table 1 must be approved for the determination in question.

However, the primary responsibility for supplying information about the specified Codex level(s), methods of analysis and criteria resides with the referring Committee. If the Committee fails to provide a method of analysis or criteria despite numerous requests, then the CCMAS may establish appropriate criteria as above.

CONVERSION OF SPECIFIC METHODS OF ANALYSIS TO METHOD CRITERIA BY THE CCMAS

When a Codex Committee submits a Type II or Type III method to CCMAS for endorsement, it should also submit information on the specified Codex level(s) along with the provision to enable the CCMAS to convert it into suitable generalized analytical characteristics:

- trueness
- applicability (matrix, concentration range and preference given to 'general' methods)
- limit of detection

[13] The RSD_R should be calculated from the Horwitz / Thompson equation. When the Horwitz / Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when "converting" methods into criteria then it should be based on the $RSDs_R$ from an appropriate method performance study.

- limit of quantification
- precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories), but generated from method performance study data rather than measurement uncertainty considerations
- recovery
- selectivity
- sensitivity
- linearity

These terms are defined in the Analytical Terminology for Codex Use, as are other terms of importance.

The CCMAS will assess the actual analytical performance of the method which has been determined in its validation. This will take account of the appropriate precision characteristics obtained in method performance studies which may have been carried out on the method together with results from other development work carried out during the course of the method development. The set of criteria that are developed will form part of the report of the CCMAS and will be inserted in the appropriate Codex Standard.

In addition, the CCMAS will identify numeric values for the criteria for which it would wish such methods to comply.

ASSESSMENT OF THE ACCEPTABILITY OF THE PRECISION CHARACTERISTICS OF A METHOD OF ANALYSIS

The calculated repeatability and reproducibility values can be compared with existing methods and a comparison made. If these are satisfactory then the method can be used as a validated method. If there is no method with which to compare the precision parameters then theoretical repeatability and reproducibility values can be calculated from the Horwitz equation. (M. Thompson, *Analyst*, 2000, 125**,** 385-386).