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# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 11

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Twenty-ninth Session*

*International Conference Centre, Geneva, Switzerland, 3 – 7 July 2006*

**MATTERS ARISING FROM REPORTS OF THE COMMISSION, CODEX  
COMMITTEES AND TASK FORCES**

**Matters Arising after 17 April 2006**

## **38<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

### **Matters for action by the Commission**

#### *General Standard for Food Additives (GSFA)<sup>1</sup>*

1. The 38<sup>th</sup> CCFAC noted that due to the hierarchical nature of the GSFA Food Category System, the inclusion of the food additive provisions of Codex commodity standards with a one-to-one relationship to GSFA food categories would result in changes not only in corresponding food categories but also in parent food categories. It would consequently be necessary to revoke and/or discontinue work on and/or reassign a number of food additive provisions in the GSFA.
2. The Committee agreed to forward to the Codex Alimentarius Commission, for inclusion in the GSFA, the food additive provisions of the Codex commodity standards with a one-to-one relationship to GSFA food categories and to recommend the Commission to revoke (see Agenda Item 6) and/or reassign the corresponding food additive provisions of the GSFA that are inconsistent with these provisions, including the consequential changes in parent food categories, as illustrated in the Annex to this document (prepared by the Codex Secretariat).
3. The Commission is invited to agree to the reassignment of the food additives provisions as illustrated in the Annex.
4. The Committee further agreed to request the Codex Alimentarius Commission to replace the list of food additives of those Codex commodity standards that have a one-to-one correspondence with GSFA food categories, with text that refers to the provisions of the relevant GSFA categories.
5. It agreed to recommend to the Commission to request Codex commodity committees, when they consider new entries or revisions of food additive provisions in these commodity standards, to provide to the Committee justification of technological need for the food additives based upon Section 3.2 of the Preamble to the GSFA.

<sup>1</sup> ALINORM 06/29/12, para. 63 and Appendices VIII and IX.

Codex General Standard for Contaminants and Toxins in Foods (GSCTF)<sup>2</sup>

6. The Committee agreed to forward the Codex General Standard for Contaminants and Toxins in Foods, including Schedule I to the Commission for adoption and to recommend to the Codex Alimentarius Commission that specific reference to the GSCTF be included in the sections on contaminants of Codex commodity standards, e.g. “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 CAC”.

7. The Commission is invited to consider whether this text should be included in all Codex commodity standards as a standardised text.

FAO/WHO Expert Consultation on the health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption<sup>3</sup>

8. The 38<sup>th</sup> CCFAC agreed to forward a request to the Commission for a FAO/WHO Expert Consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption, with the following terms of reference:

Assessment of the health risks associated with the consumption of fish and other seafood:

- To identify and to consider contaminants of possible concern present in fish (methylmercury and dioxins and dioxin-like PCBs).
- To describe the pattern of contamination of the different contaminants in the relevant fish species / fish groups, such as predatory fish, oily fish, etc.
- To identify vulnerable groups of the population who might be at higher risk than the average consumer (e.g. infants, young children, pregnant women, high consumers).
- To provide guidance to countries on ways to identify regions where people are more likely to be exposed to high levels of contaminants because of differences in nutritional behaviour or local contamination.

Assessment of the health benefits of fish and other seafood consumption:

- To consider and review the evidence on the beneficial nutritional factors of eating fish (e.g. as a source of protein and essential nutrients such as vitamin D, iodine, and omega-3 fatty acids).

Comparison of the health risks and health benefits of fish and other seafood consumption:

- To develop a methodology and identify the data necessary for carrying out quantitative assessments of risks and benefits related to fish and other seafood consumption.
- To compare nutritional benefits against the possibility of adverse effects, including the uncertainties, taking into consideration all groups in the population and, if possible, allowing quantitative comparisons of human health risks and benefits of fish and other seafood consumption.

9. The Commission is invited to request FAO/WHO to consider convening the above expert consultation.

Revision of the GSFA descriptor of food category 13.6 “Food Supplements”<sup>4</sup>

10. The Committee agreed to request the Commission to revise the GSFA descriptor of food category 13.6 “Food supplements” to align it with the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005).

11. The Commission is invited to endorse the above recommendation.

<sup>2</sup> ALINORM 06/29/12, para. 119 and Appendix XVIII.

<sup>3</sup> ALINORM 06/29/12, para 191.

<sup>4</sup> ALINORM 06/29/12, para. 214 and Appendix XXXIII.

*Matters for information of Commission*General Standard for Food Additives (GSFA)<sup>5</sup>

12. The Committee agreed to discontinue work on other proposed draft and draft food additive provisions, as proposed in CX/FAC 06/38/7.

Guideline levels for Methylmercury in Fish<sup>6</sup>

13. The Committee also agreed to postpone consideration on the need to revise the guideline levels for methylmercury in fish pending the outcomes of the requested FAO/WHO Expert Consultation and to retain the current Codex guideline levels for the time-being.

14. In addition it was decided not to proceed with the development of a list of predatory fish and not to start compiling data on the ratio of methylmercury to total mercury in different fish species and to possibly consider this at a later stage with a particular focus on the different ratios for shellfish.

**16<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS***Matters for action by the Commission*Compendium of Methods of Analysis Identified as Suitable to Support Codex MRLs<sup>7</sup>

15. The Committee agreed to forward the Compendium of Methods of Analysis Identified as Suitable to Support Codex MRLs.

16. The Commission may wish to recommend that the above Compendium be not given the status of Codex Standard, Guidelines or recommendation but be maintained and updated by the Committee for use by Codex Members.

*Matters for information of Commission*Temporary Codex MRL for Tilmicosin in sheep's milk<sup>8</sup>

17. The Committee agreed to leave in place the temporary MRL for Tilmicosin in sheep's milk until JECFA had evaluated the data, in view of the strong commitment of the sponsor to make available radiolabelled residue depletion study in dairy cattle and of two residue depletion studies for further evaluation by JECFA.

**27<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING***Matters for action by the Commission*Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27-1997)<sup>9</sup>

18. The CCMAS considered the revised "International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories" developed by IUPAC/ISO/AOAC and published in the Journal of Pure and Applied Chemistry in January 2006 (CX/MAS 04/7).

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<sup>5</sup> ALINORM 06/29/12, para. 63 and Appendix XIII.

<sup>6</sup> ALINORM 06/29/12, paras 192-193.

<sup>7</sup> ALINORM 06/29/31, para. 120 and Appendix X.

<sup>8</sup> ALINORM 06/29/31, paras 42-43.

<sup>9</sup> ALINORM 06/29/23, paras 98-102.

19. The Committee noted that this Protocol was referred to in the *Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food* (CAC/GL 27-1997) and that in view of its revision it was necessary for the Committee to consider updating this reference. After some discussion on the Protocol and in view of the general agreement with the revised Protocol, the Committee agreed to ask the Commission to approve an editorial amendment to the above Guidelines to reflect the new reference to the Protocol().

20. The proposal is therefore to amend the reference in CAC/GL 27-1997, paragraph 3, third indent, to read:

Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in the “International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories”, Pure & App. Chem. Vol. 78, No.1, pp.145-196, 2006

#### Additional Background

21. The IUPAC/AOAC/ISO Protocol, mentioned in the above Guidelines (CAC/GL 27-1997), was also adopted as a specific Codex text, by reference, by the 21<sup>st</sup> Session of the Commission in 1995 (ALINORM 95/37, Appendix IV). It is presented in Appendix V of ALINORM 95/23, *Recommended Protocols for the Design, Conduct and Interpretation of Collaborative Studies and Proficiency Testing of (Chemical) Analytical Laboratories* that include two Protocols:

- ◆ Protocol for the Design, Conduct and Interpretation of Collaborative Studies
- ◆ Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories

22. The amendment of the second Protocol is proposed by CCMAS as indicated above. However, these Protocols were not identified in the list of Codex Standards and Related Texts following their adoption by the Commission.

23. The Commission is invited to consider whether one or two reference numbers should be assigned to these Protocols such as CAC/GL, xxx-1995, with a reference to Revision in 2006 if the amendment proposed by CCMAS is adopted.

#### **ADDITIONAL INFORMATION ON THE DISCUSSION ON PROTEIN CONVERSION FACTOR IN CCMMP AND CCNFSFU see ALINORM 06/29/9C, para. 18)**

24. The issue of protein conversion factor is not new on agendas of the Codex Committees on Nutrition and Foods for Special Dietary Uses (CCNFSFU) and on Milk and Milk Products (CCMMP).

25. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSFU) is currently revising the Standard for Infant Formula (CODEX STAN 72-1981). The matter of nitrogen conversion factor had been considered by the CCNFSFU for some sessions. Currently the CCNFSFU uses the conversion factor of 6.25 and there is no final agreement reached yet.

26. The CCMMP at its 6<sup>th</sup> Session in 2004 noted that the CCNFSFU was revising the Codex Standard for Infant Formula and drew the attention of the CCNFSFU to the need for a consistent application of the calculation of milk protein content in the formula i.e. Kjeldahl nitrogen x 6.38, presently in the adopted standards for milk products and in the amendment to the General Standard for the Labelling of Prepackaged Foods (Class Names), which was adopted by the 26<sup>th</sup> Session of the Codex Alimentarius Commission (ALINORM 04/27/11, para.13).

27. At the 26<sup>th</sup> Session of the CCNFSFU in 2004, the Delegation of New Zealand drew the attention of the Committee to the fact that the CCMMP highlighted the need for a consistent application of the milk protein nitrogen conversion factor of 6.38.

28. At the 27<sup>th</sup> Session of the CCNFSFU in 2005 (ALINORM 06/29/26, paras 80-83), the Committee clarified how the amount of protein is calculated in infant formula and amended text was put in square brackets. The Committee added a sentence to this footnote to clarify that protein levels set in this standard were based on a nitrogen conversion factor of 6.25.

*[For the purpose of this standard, the calculation of the protein content should be based on  $N \times 6.25$ , unless a scientific justification is provided for the use of a different conversion factor for a particular nitrogen source.] The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.*

29. Some delegations expressed their concern regarding the nitrogen conversion factor of 6.25 used for calculation of protein content. The Delegation of Germany informed the Committee that this issue had been discussed at the Working Group at length. It was proposed to use the nitrogen conversion factor of 6.25 if scientific justification was provided. The Secretariat clarified that the calculation of nitrogen conversion factor was specific to the consideration for the Standard on Infant Formula and should not be regarded as recommendation to extend this type of calculation to other standards. The Delegation of New Zealand also requested that the relevant Codex Committees, in particular the CCMMP, be informed of the decision regarding the nitrogen conversion factor for the Standard on Infant Formula. The Observers of IDF and EDA indicated that there were a number of scientific publications recommending a protein conversion factor of 6.38 for total milk protein (i.e. FAO Food and Nutrition Paper 77/2003) and supported the inclusion of this factor.

30. The Committee noted the clarification by the Observer of ESPGHAN that different food proteins contain differing amounts of nitrogen however FAO/WHO used a factor of 6.25 for all their reports on protein requirements and quality. The Observer indicated that proteins derived from cows' milk used in current infant formula are usually modified with lower conversion factors than caseins and that variations of non-protein nitrogen contents in infant formula depending on the methods of production result in further marked changes of the nitrogen conversion factor, therefore, the use of nitrogen conversion factor of 6.38 for all milk derived protein sources in infant formula was not justified.

Note: It should be noted that it is the only CCNFSDU responsibility to determine which conversion factor should be used to calculate the amount of protein in the draft revised Standard for Infant Formula which is currently named as Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Children.

## Annex

**Actions in CX/FAC 06/38/7 Appendix IV to Implement the Incorporation of GSFA Food Categories with a One-to-One Correspondence to a Single Codex Commodity Standard – Consequential Changes (Adoption or Revocation) to Parent Food Categories (see ALINORM 06/29/12, para. 63) - Proposed Revisions to Tables 1 and 2**

The 38<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed that the Codex Secretariat would prepare for the 29<sup>th</sup> Session of the Codex Alimentarius Commission a list of the consequential changes to the provisions in the General Standard for Food Additives (GSFA) for the parent food categories of those food categories that have a one-to-one relationship with Codex commodity standards, as illustrated in CX/FAC 06/38/7, Appendix IV (ALINORM 06/29/12, para. 63, first bullet). The following list contains the food additive provisions for the parent food categories to be forwarded to the Commission for adoption at step 8 and for recommendation for revocation.

| Food Category No. 01.6 |     | Cheese and analogues |       |              |        |
|------------------------|-----|----------------------|-------|--------------|--------|
| Additive               | INS | Max                  | Level | Comments     | Action |
| Pimaricin              | 235 | 40                   | mg/kg | Notes 3 & 80 | Revoke |

| Food Category No. 01.6.1 |     | Unripened cheese |       |              |                           |
|--------------------------|-----|------------------|-------|--------------|---------------------------|
| Additive                 | INS | Max              | Level | Comments     | Action                    |
| Pimaricin                | 235 | 40               | mg/kg | Notes 3 & 80 | Reassign from 01.6; Adopt |

| Food Category No. 01.6.2 |     | Ripened cheese |       |              |                           |
|--------------------------|-----|----------------|-------|--------------|---------------------------|
| Additive                 | INS | Max            | Level | Comments     | Action                    |
| Pimaricin                | 235 | 40             | mg/kg | Notes 3 & 80 | Reassign from 01.6; Adopt |

| Food Category No. 01.6.4 |     | Processed cheese |       |              |                           |
|--------------------------|-----|------------------|-------|--------------|---------------------------|
| Additive                 | INS | Max              | Level | Comments     | Action                    |
| Pimaricin                | 235 | 40               | mg/kg | Notes 3 & 80 | Reassign from 01.6; Adopt |

| Food Category No. 01.6.5 |     | Cheese analogues |       |              |                           |
|--------------------------|-----|------------------|-------|--------------|---------------------------|
| Additive                 | INS | Max              | Level | Comments     | Action                    |
| Pimaricin                | 235 | 40               | mg/kg | Notes 3 & 80 | Reassign from 01.6; Adopt |

| Food Category No. 02.1 |          | Fats and oils essentially free from water |       |          |        |
|------------------------|----------|---|-------|----------|--------|
| Additive               | INS      | Max                                       | Level | Comments | Action |
| Ascorbyl Esters        | 304, 305 | 500                                       | mg/kg | Note 10  | Revoke |
| Carotenes, Vegetable   | 160aii   | 1000                                      | mg/kg |          | Revoke |
| Guaiac Resin           | 314      | 1000                                      | mg/kg |          | Revoke |
| Polydimethylsiloxane   | 900a     | 10  | mg/kg |          | Revoke |

| Food Category No. 02.1                 |          | Fats and oils essentially free from water |       |                |        |
|--|----------|---|-------|----------------|--------|
| Additive                               | INS      | Max                                       | Level | Comments       | Action |
| Propyl Gallate                         | 310      | 200                                       | mg/kg | Notes 15 & 130 | Revoke |
| Propylene Glycol Esters of Fatty Acids | 477      | 10000                                     | mg/kg |                | Revoke |
| Stearyl Citrate                        | 484      |   | GMP   |                | Revoke |
| TBHQ                                   | 319      | 200                                       | mg/kg | Notes 15 & 130 | Revoke |
| Thiodipropionates                      | 388, 389 | 200                                       | mg/kg | Note 46        | Revoke |

| Food Category No. 02.1.2               |          | Vegetable oils and fats |       |                |                                  |
|--|----------|-------------------------|-------|----------------|----------------------------------|
| Additive                               | INS      | Max                     | Level | Comments       | Action                           |
| Ascorbyl Esters                        | 304, 305 | 500                     | mg/kg | Note 10        | Reassign from 02.1; Adopt        |
| Carotenes, Vegetable                   | 160a     | 1000                    | mg/kg |                | Reassign from 02.1; Adopt        |
| Guaiac Resin                           | 314      | 1000                    | mg/kg |                | Reassign from 02.1; Adopt        |
| Polydimethylsiloxane                   | 900a     | 10                      | mg/kg |                | Reassign from 02.1; Adopt        |
| Propyl Gallate                         | 310      | 200                     | mg/kg | Notes 15 & 130 | Reassign from 02.1; Adopt        |
| Propylene Glycol Esters of Fatty Acids | 477      | 10000                   | mg/kg |                | Reassign from 02.1; Adopt        |
| Stearyl Citrate                        | 484      |                         | GMP   |                | Reassign from 02.1; Adopt        |
| TBHQ                                   | 319      | 200                     | mg/kg | Notes 15 & 130 | Reassign from 02.0 & 02.1; Adopt |
| Thiodipropionates                      | 388, 389 | 200                     | mg/kg | Note 46        | Reassign from 02.1; Adopt        |

| Food Category No. 02.1.3               |          | Lard, tallow, fish oil, and other animal fats |       |                |                                  |
|--|----------|---|-------|----------------|----------------------------------|
| Additive                               | INS      | Max   | Level | Comments       | Action                           |
| Ascorbyl Esters                        | 304, 305 | 500   | mg/kg | Note 10        | Reassign from 02.1; Adopt        |
| Carotenes, Vegetable                   | 160a     | 1000  | mg/kg |                | Reassign from 02.1; Adopt        |
| Guaiac Resin                           | 314      | 1000  | mg/kg |                | Reassign from 02.1; Adopt        |
| Polydimethylsiloxane                   | 900a     | 10  | mg/kg |                | Reassign from 02.1; Adopt        |
| Propyl Gallate                         | 310      | 200   | mg/kg | Notes 15 & 130 | Reassign from 02.1; Adopt        |
| Propylene Glycol Esters of Fatty Acids | 477      | 10000   | mg/kg |                | Reassign from 02.1; Adopt        |
| Stearyl Citrate                        | 484      |   | GMP   |                | Reassign from 02.1; Adopt        |
| TBHQ                                   | 319      | 200   | mg/kg | Notes 15 & 130 | Reassign from 02.0 & 02.1; Adopt |
| Thiodipropionates                      | 388, 389 | 200   | mg/kg | Note 46        | Reassign from 02.1; Adopt        |

| Food Category No. 02.2 |          | Fat emulsions mainly of type water-in-oil |       |                |        |
|------------------------|----------|---|-------|----------------|--------|
| Additive               | INS      | Max                                       | Level | Comments       | Action |
| Ascorbyl Esters        | 304, 305 | 500                                       | mg/kg | Notes 10 & 113 | Revoke |

| Food Category No. 02.2.1 |     | Emulsions containing at least 80% fat |       |          |        |
|--------------------------|-----|---------------------------------------|-------|----------|--------|
| Additive                 | INS | Max                                   | Level | Comments | Action |
| Guaiac Resin             | 314 | 1000                                  | mg/kg |          | Revoke |

| Food Category No. 02.2.1.3 |          | Blends of butter and margarine |       |          |                             |
|----------------------------|----------|--------------------------------|-------|----------|-----------------------------|
| Additive                   | INS      | Max                            | Level | Comments | Action                      |
| Ascorbyl Esters            | 304, 305 | 500                            | mg/kg | Note 10  | Reassign from 02.2; Adopt   |
| Guaiac Resin               | 314      | 1000                           | mg/kg |          | Reassign from 02.2.1; Adopt |

| Food Category No. 02.2.2 |          | Emulsions containing less than 80% fat |       |          |                           |
|--------------------------|----------|--|-------|----------|---------------------------|
| Additive                 | INS      | Max                                    | Level | Comments | Action                    |
| Ascorbyl Esters          | 304, 305 | 500                                    | mg/kg | Note 10  | Reassign from 02.2; Adopt |

| Food Category No 12.1 |               | Salt and salt substitutes |       |          |        |
|-----------------------|---------------|---------------------------|-------|----------|--------|
| Additive              | INS           | Max                       | Level | Comments | Action |
| Ferrocyanides         | 535, 536, 538 | 20                        | mg/kg | Note 24  | Revoke |

| Food Category No 13.1 |          | Infant formulae, follow-up formulae, and formulae for special medical purposes for infants |       |               |        |
|-----------------------|----------|--|-------|---------------|--------|
| Additive              | INS      | Max  | Level | Comments      | Action |
| Ascorbyl Esters       | 304, 305 | 10   | mg/kg | Notes 10 & 15 | Revoke |

| Food Category No 13.1.3 |          | Formulae for special medical purposes for infants |       |               |                           |
|-------------------------|----------|---|-------|---------------|---------------------------|
| Additive                | INS      | Max   | Level | Comments      | Action                    |
| Ascorbyl Esters         | 304, 305 | 10  | mg/kg | Notes 10 & 15 | Reassign from 13.1; Adopt |

## Notes

- Note 3:** Surface treatment.
- Note 10:** As ascorbyl stearate.
- Note 15:** Fat or oil basis.
- Note 24:** As anhydrous sodium ferrocyanide.
- Note 46:** As thiodipropionic acid.
- Note 80:** Equivalent to 2 mg/dm<sup>2</sup> surface application to a maximum depth of 5 mm.
- Note 113:** Excluding butter.
- Note 130:** Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).