codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/NFSDU 08/30/2-REV**
September 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

30th Session,
Cape Town, South Africa

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

A. GENERAL DECISIONS OF THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Geneva, Switzerland, 30 June – 4 July 2008)

1. The Commission **adopted** several amendments to the Procedural Manual and also adopted 35 new or revised Codex standards or related texts elaborated by the Codex Committees and Task Forces. It also approved a number of new work proposals and proposals for discontinuation of work. A complete list of these texts and details of their consideration could be found in ALINORM 08/31/REP which is available from: http://www.codexalimentarius.net

B. DECISIONS OF THE 31st SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

2. The following texts considered and adopted by the Commission have direct relation to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

STANDARDS CONSIDERED AT STEP 8

Draft Revised Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1981)[1]

3. The Commission noted the view of the European Community and its Member States that information campaigns should be encouraged in order to ensure the correct use of "gluten reduced" products by celiac patients and that further scientific work should be promoted on the risk assessment relating to oats consumption by persons intolerant to gluten, and **adopted** the draft standard as proposed.

Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979)[2]

4. The Commission noted that, in the listing of purity criteria, the references to the body abbreviated as "FSANZ" in Part A2, A4 and C1 should be deleted and that the reference to "FP" in Part C for 1.22 L-Arginine L-Aspartame should be changed to "Ph EUR" in the English version. With these amendments the Commission **adopted** the Advisory Lists as proposed.

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1 ALINORM 08/31/26, Appendix III.
2 ALINORM 08/31/26, Appendix IV.

STANDARDS CONSIDERED AT STEP 5

Establishment and Application of Risk Analysis Principles by the Codex Committee on Nutrition and Foods for Special Dietary Uses[3]

5. The Commission, noting that, after finalization, this document on risk analysis would constitute a part of the Codex Alimentarius Procedural Manual, **adopted** the draft text at Step 5 and advanced it to Step 6, and referred technical comments submitted to the 31st Session of the Commission for consideration by the next session of the Committee on Nutrition and Foods for Special Dietary Uses. The Commission noted that the input from FAO and WHO would be important to define risk analysis policy and procedures in this area.

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

6. The Commission **approved** the elaboration of new standards and related texts as summarized in Appendix X to ALINORM 08/31/REP, including the Revision of Nutrient Reference Values of Vitamins and Minerals in the Guidelines for Nutrition Labelling (CAC/GL 2-1985); Job number N06-2008. This matter will be considered by the Committee under Agenda Item 7.

REVIEW OF THE CODEX COMMITTEE STRUCTURE AND MANDATES OF CODEX COMMITTEES AND TASK FORCES (Agenda Item 11)

PROPOSAL 10 (TASKS RELATED TO NUTRITION)

60th Session of the Executive Committee of the Codex Alimentarius Commission (ALINORM 08/31/3, paras 27-38)

7. The Committee noted that the comments submitted generally recognised the importance of work on nutrition in Codex, currently undertaken by the Committees on Nutrition and Foods for Special Dietary Uses and on Food Labelling.

8. Some members expressed the view that it might be beneficial for FAO/WHO Coordinating Committees to discuss nutrition-related matters of regional interest, particularly in relation to the WHO Global Strategy on Diet, Physical Activity and Health.

9. In this regard, the Representative of WHO stated that the WHO Global Strategy should be followed and supported worldwide and be addressed in appropriate international fora. The Representative cautioned the Committee against the risk of a global momentum being lost if the Global Strategy was taken down to the regional level.

10. The Committee noted that, from the procedural point of view, it was open for Coordinating Committees to discuss any matter of regional interest, in accordance with their terms of reference and the recommendation of the 28th Session of the Commission to encourage Coordinating Committees to consider any particular items of regional interest within the terms of reference of the Committees.

11. In relation to the mechanism to ensure adequate provision of scientific advice to the Committee on Nutrition and Foods for Special Dietary Uses, the Representative of WHO informed the Committee that currently discussion was ongoing between WHO and FAO with a view to establishing a joint expert body on nutrition.

31st Session of the Codex Alimentarius Commission (ALINORM 08/31/REP, paras 162-163).

12. The Commission **agreed** that the tasks related to nutrition were adequately addressed in the current structure of Codex through the Committee on Nutrition and Foods for Special Dietary Uses and, where appropriate, the Committee on Food Labelling, and that there was no need for another subsidiary body such as a Task Force.

13. The Representatives of FAO and WHO, referring to the discussions held at the 60th Session of the Executive Committee, indicated that FAO and WHO were ready to provide scientific advice in nutrition in order to reflect the high importance of nutrition issues, that the mechanism to be used was under consideration and that the parent organisations would ensure that it was flexible enough to address the requests to be formulated by Codex in this area.

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[3] ALINORM 08/31/26, Appendix VI.

OTHER DECISIONS THAT HAVE IMPACT ON THE WORK OF CCNFSDU

Amendments to Codex Standards and related texts (Agenda Item 7)

14. The Commission had adopted the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at Step 5/8 (ALINORM 08/31/REP, para. 45) and while doing so it revoked the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) (ALINORM 08/31/REP, para.75 and Appendix IX).

15. The Commission had also discussed the issue of amendments to Codex standards and related texts in order to address inconsistencies discovered in adopted Codex texts (ALINORM 08/31/REP, paras 76-91).

16. In Section on Food Hygiene of the Guidelines on Formulated Supplementary Foods for Infants and Young Children (CAC/GL 08-1991) there was a reference to the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979). This revoked Code contained end-product microbiological specifications of advisory nature for dried biscuit type product (plain and coated), dried and instant products, dried products requiring heating before consumption and thermally processed products packaged in hermetically sealed containers. The revoked Section VIII of the above Code is attached to this document as Appendix for ease of reference.

17. The Committee is invited to consider on how to deal with this inconsistency (and others that might have arisen from previous revocations or amendments) and decide on course of action(s), if required.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Draft Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (ALINORM 08/31/23, paras 55-56)

18. The Committee noted the replies by the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and agreed to delete methods for dietary fibre and PER. While agreeing to the request from CCNFSDU to delete the methods for dietary fibre, the Committee noted that a method for dietary fibre was necessary to calculate total energy and agreed to request the CCNFSDU to reconsider inclusion of methods for dietary fibre.

19. The Committee endorsed the ISO and IDF method for sodium and potassium as Type II and the AOAC 984.27 method as Type III and agreed to replace the current method for crude protein with AOAC 991.20 or ISO 8968-1/2:2001|IDF 20-1/2:2001 with a footnote on the use of the appropriate conversion factors as proposed by the CCNFSDU.

20. The Committee is therefore invited to reply to the CCMAS regarding the inclusion of method for dietary fibre in the Standard for Infant Formulae and Formulas for Special Medical Purposes (CODEX STAN 72-1981, Rev.1-2007). The Committee is also invited to consider the recommendations prepared by an Electronic Working Group led by New Zealand regarding methods of analysis regarding the finalization of the list of methods applicable to infant formula (see CX/NFSDU 08/30/2-Add.1).

CODEX COMMITTEE ON FOOD ADDITIVES

Carrageenan (INS 407) and Processed Eucheuma seaweed (PES) (INS 407a))(ALINORM 08/31/12, para.27)

21. The Committee was informed of JECFA's view that based on the information available it was inadvisable to use carrageenan or PES in infant formulas. The JECFA Secretariat clarified that it was not the existence of data raising any specific concerns, but rather the lack of data on the potential impact on the immature gastrointestinal and immune systems which led to the conservative conclusion. As a general principle, JECFA considered that the ADI was not applicable to infants under the age of 12 weeks, in the absence of specific data to demonstrate the safety of these substances for this age group.

22. Several delegations pointed out that carrageenan and PES have been used in liquid infant formulas since the 1950's without notable adverse effects, and that any action taken by this Committee would have broad implications on international trade. In response the JECFA Secretariat pointed out that adverse effects could only be identified if they were specifically looked for and that this had not been the case in relation to these particular substances. Post-market surveillance studies had been made available to JECFA, however they did not include the most appropriate endpoints.

23. The Delegation of the Philippines indicated that Southeast Asia was the largest producer of carrageenan and PES and proposed that further work be undertaken to provide relevant information that would address the question for infants, and that the draft provisions in the GSFA be held at step 7 until data could be provided to JECFA for further evaluation. This proposal was supported by several delegations. Several observers indicated their willingness to provide relevant data in future.

24. The Committee noted that no provisions (either adopted or in the Step procedure) for foods intended for children under 12 weeks were currently included in the GSFA and that Table 1 of the GSFA only included provisions for carrageenan and PES in food categories 13.1.2 "Follow-up formula" and 13.2 "Complementary foods for infants and young children", which were currently at Step 7. It further noted that no provisions for carrageenan and PES (either adopted or in the Step procedure) were associated with food categories 13.1.1 "Infant formulae". The JECFA Secretariat further clarified that concern was raised by JECFA for infants below 12 weeks of age but data was also insufficient to establish the safety for infants up to 12 months. The JECFA Secretariat further indicated that data were necessary to address all questions for infants of 12 months and younger; and that details could be found in the toxicological monograph from the 68th JECFA meeting.

25. The Committee agreed to hold current provisions for carrageenan and PES in food categories 13.1.2 and 13.2 of the GSFA, at step 7, pending the submission of further data for evaluation by JECFA. It noted that the Delegation of the Philippines would coordinate the collection of these data. It further agreed to refer the above discussion and the report of the 68th JECFA evaluation of carrageenan and PES to the 30th Session of the CCNFSDU.

26. The Committee is invited to note the report of the 68th JECFA and the above discussion and take any action(s) on this matter, if it assumes appropriate.

Applicability of ADIs to Infants and Young Children (ALINORM 08/31/12, Appendix XIV))

27. The Committee noted that the question of the applicability of ADIs to infants and young children had been considered by its last session but the full reply had not been forwarded back to the CCNFSDU. The Committee agreed with the recommendation of the in-session Working Group to forward a reply to the CCNFSDU as contained in Appendix XV of its report. The reply is reproduced as Appendix II to this document for ease of reference.

28. The Committee is invited to consider this reply and take any action(s) on this matter, if it assumes appropriate.

CODEX COMMITTEE ON FOOD LABELLING

Draft Revised Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (ALINORM 08/31/22, para. 51)

29. The Committee endorsed the labelling provisions as proposed.

The WHO Global Strategy on Diet, Physical Activity and Health (ALINORM 08/31/22, paras18-46)

30. The Committee on Food Labelling had extensively considered the implementation of the WHO Global Strategy at its 36th Session. For details of consideration see paras 18-46 of ALINORM 08/31/22, which is available from:

http://www.codexalimentarius.net

31. The Committee on Food Labelling had agreed to undertake new work on proposed amendments to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) regarding the list of nutrients and the legibility and readability of information, as presented in the project document (see Appendix IX of ALINORM 08/31/22). This work had been approved as new work by the Commission (N16-2008).

32. The Committee is invited to take into consideration the work of the CCFL on this matter while discussing the outcome of the CCNFSDU physical working group on matters related the WHO Global Strategy on Diet, Physical Acitivity and Health.

Appendix I

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN (CAC/RCP 21-1979)

8. SECTION VIII - END-PRODUCT SPECIFICATIONS

8.1 General

The food for infants and/or children should be free from foreign and other objectionable matter to the extent possible in good manufacturing practice, as well as free from toxic substances in a concentration believed to constitute a health hazard for infants and children.

8.2 Pesticide Residues and Food Additives

The food for infants and/or children should comply with the requirements for pesticide residues and food additives laid down by the Codex Alimentarius Commission.

8.3 Microbiological Specifications

The following microbiological specifications are of an advisory nature in accordance with the General Principles for the Establishment and Application of Microbiological Criteria for Foods adopted by the Codex Alimentarius Commission. The specifications are intended to increase assurance that the provisions of hygienic significance have been met but should not be regarded as mandatory.							
Product	Test	Case	Class / Plan	n	c	Limit per g m	Limit per g M
8.3.1 Dried biscuit type product [a]							
8.3.1.1 plain	none	-	-	-	-	-	-
8.3.1.2 coated	Coliforms	5	3	5	2	<3 [d]	20
	Salmonellae [b c]	11	2	10	0	0	-
8.3.2 Dried and instant products [e f]	Mesophilic aerobic bacteria [g]	6	3	5	2	10^3	10^4
	Coliforms	6	3	5	1	<3 [d]	20
	Salmonellae [c]	12	2	60	0	0	-
8.3.3 Dried products requiring heating before consumption [f h]	Mesophilic aerobic bacteria	4	3	5	3	10^4	10^5
	Coliforms	4	3	5	2	10	100
	Salmonellae [c]	10	2	5	0	0	-
8.3.4 Thermally processed products packaged in hermetically sealed containers[a]	These products: a) shall be free of microorganisms capable of growth in the product under normal non						

[a] Dry shelf-stable products.

[b] Applies only to products containing one or more *Salmonella* sensitive ingredients, e.g. chocolate coatings.

[c] For the examination of such foods for the presence of *Salmonella*, 25 g samples shall be used and these may be pooled.

[d] <3 means no positive tube in the standard-3-tube MPN method.

[e] Products intended for consumption after addition of liquid; includes dried infant formulae, instant infant cereals, etc.; microbial limits apply to dry product.

[f] Includes supplementary products, e.g. sweetening agents, starches, texturizers and similar products, singly or in combination.

[g] Not applicable to products which are produced by a microbial fermentation process.

[h] Products intended for consumption after addition of liquid and which are specified to be heated to boiling before consumption; microbial limits apply to dry product.

	refrigerated conditions of storage and distribution; b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and c) if they have a pH above 4.6 shall have received a processing treatment which renders the products free of viable forms of microorganisms having public health significance.

[a]Includes aseptically canned products and liquid infant formulae; assumes these products are manufactured in accordance with the respective Codes of Good Manufacturing Practice.

8.4 Methods for Microbiological Analysis for Foods for Infants and Children (Up to Three Years)

8.4.1 Mesophilic aerobic bacteria

Draft International Standard ISO/DIS 4833. Refer to ICMSF (1974), Chapter 7, pages 83-91 for collection and preparation of samples for analysis; in all instances 25 g shall constitute a sample unit (analytical unit); incubation of agar plates shall be at 30°C.

8.4.2 Coliform count

Draft International Standard ISO/DIS 4831. Collection and preparation of samples, sample unit and incubation as in viable colony count above.

8.4.3 Salmonellae

According to the "Report of the 13th Session of the Codex Committee on Food Hygiene, Rome, 10-13 May 1976, Appendix VI, para. 9".

Collection and preparation of samples, sample unit and incubation as in viable colony count above.

8.4.4 Labour and cost of testing may be reduced by testing pooled sample units (analytical units). Studies have shown [4] that salmonellae may be detected with equal accuracy, and that there is no significant difference in sensitivity when testing a large sample versus multiple subsamples. Therefore, 25 g sample units may be composited to a quantity not to exceed 400 g. Analysis may then proceed as for a 25 g unit with appropriate change in equipment, media volume, etc.

[4] American Public Health Association, 1976. Compendium of Methods for the Microbiological Examination of Foods, M.L. Speck (Ed.), Chapter 25, page 313. American Health Association, 1015 18th St., N.W., Washington D.C. 20036, USA.

Appendix II

CCFA RESPONSE TO THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES ON THE APPLICABILITY OF ADIS TO INFANTS AND YOUNG CHILDREN

In response to the following request by CCNFSDU, the JECFA Secretariat would like to provide the following response:

To what extent does an ADI established by JECFA, whether numerical or not specified, apply to young infants below 12 weeks; what scientific principles should apply to the evaluation of additives intended for this group of population? Is the establishment of an ADI in itself sufficient or do other issues need to be addressed?

JECFA has considered this specific question on several occasions. In particular at its twenty-first meeting, and a detailed consideration of this issue is published in the report[5]. The Committee at that time concluded that for most food additives the ADIs allocated are applicable only to children older than 12 weeks. The Committee also pointed out that food additives should not generally be used in foods for infants and very young children. JECFA is continuing to maintain this general position to date.

More detailed guidance on this matter is contained in EHC 70: Principles for the safety assessment of food additives and contaminants in food, published in 1987[6]. These principles are based on the advice of an FAO/WHO meeting on additives in baby food held in 1971 and additional considerations by JECFA subsequently. Since the usual protocols for toxicological studies do not directly cover the developmental period in question, specific guidance for toxicological testing for substances likely to be used in infant foods is given.

Certain food additives have been evaluated for safety of use in infant formula on a case-by-case basis. Specific data to demonstrate safety for this age group are required, and this depends on the toxicological profile and potential concern for the compound. Consequently, the existence or establishment of an ADI based on standard toxicological data packages is not sufficient.

These basic principles are still valid to date, however in light of advancing science it may be appropriate to perform a detailed scientific review and give further guidance on this matter. A recent WHO publication[7] details some biological and scientific principles on the susceptibility of children and may serve as a starting point for the development of further applied guidance on the applicability of health-based guidance values, like ADIs and TDIs, to infants and young children, including data requirements for safety assessment for these age-groups. Initial discussions to elaborate such an activity have commenced at WHO, but no time-lines have been set.

[5] WHO Technical Report Series 617: Evaluation of certain food additives, WHO Geneva 1978.

[6] Environmental Health Criteria 70: Principles for the safety assessment of food additives and contaminants in food. WHO, Geneva 1987.

[7] Environmental Health Criteria 237: Principles for evaluating health risks in children associated with exposure to chemicals. WHO, Geneva 2006.