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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2a **CX/NFSDU 11/33/2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirty-third Session

Bad Soden am Taunus, Germany
14 – 18 November 2011

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

A. DECISIONS OF THE 34TH SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

STANDARDS CONSIDERED AT STEP 8

1. The Commission adopted the *Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population* as proposed by the Committee (Appendix III to REP11/CAC).

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

2. The Commission approved as new work the Inclusion of a New Part B for Underweight Children in the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981) (Appendix VI to REP11/CAC). This subject will be considered under **Agenda Item 7**.

B. MATTERS ARISING FROM OTHER CODEX COMMITTEES FOR INFORMATION

32nd Session of the Committee on Methods of Analysis and Sampling (CCMAS)

Endorsement of Methods of Analysis Provisions in Codex Standards[1]

3. The CCMAS recalled that its last session had endorsed the methods for the determination of dietary fibre as Type IV and asked the CCNFSDU to define the scope of the methods more precisely.

4. The CCMAS noted that the working group had discussed whether several Type I methods should be included in view of the possible overlap between these methods and had amended the type of some methods.

5. In the third group of methods, the two methods for insoluble and soluble dietary fibres were moved to the first group as these methods did not measure the lower molecular weight fraction and were retained as Type I. The Committee noted that the method for fructans (not applicable to highly depolymerised fructans) had a more limited scope and agreed to endorse it as Type III. The Committee also agreed to endorse the remaining methods in this group as Type II as they were rational methods.

[1] REP11/MAS, paras 28 – 32

6. The CCMAS briefly discussed the proposal to consider the use of a decision tree to facilitate the selection of adequate methods for the determination of dietary fibre. It was agreed that on the basis of the proposal put forward in CRD 8, an electronic working group, led by the United Kingdom and working in English, would consider the elaboration of a decision tree to facilitate the selection by analysts of available methods for dietary fibre, for consideration at the next session.

7. The CCMAS considered that at the present time, it was important for analysts to specify what method was used and for what purpose, as this would be especially relevant for enforcement and trade purposes.

39th Session of the Committee on Food Labelling (CCFL)

Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Non-communicable Diseases for the General Population[2]

8. The CCFL agreed to review the appropriate sections of the Guidelines after CCNFSDU had completed the general principles for establishing nutrient reference values for nutrients associated with non-communicable diseases and the list of NRVs.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES FOR ACTION

43rd Session of the Committee on Food Additives (CCFA)

Discussion Paper on Food Additive Provisions in the Standard for Infant Formulas and Formula for Special Medical Purposes (CODEX STAN 72-1981)[3]

9. The CCFA agreed with the two main recommendations of the discussion paper:

i. That the principle that was discussed and proposed by JECFA in 1971 and subsequently implemented by the Codex Alimentarius Commission when adopting standards for baby food remains valid: *"Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use."* (Annex 3 of TRS 488);

ii. Proposals for the inclusion of an additive in Codex standards for foods intended for infants below 12 weeks of age require a separate evaluation by JECFA since for additives used in foods for this population the toxicological investigations should be more extensive and include evidence of safety to young animals. Requests for evaluation should be presented to the CCFA. Such requests should be made using the agreed form, include an inventory of available studies and should state that the data meet the requirements for this age group by JECFA as laid down in the *Principles and methods for the risk assessment of chemicals in food* (EHC 240) and the *Principles for the safety assessment of food additives and contaminants in food* (EHC 70).

10. The CCFA reiterated that, as the substances had not been forwarded to it for endorsement, it could not take a position and encouraged the CCNFSDU to give consideration to the grouping of substances proposed in paras 14-18 of CX/FA 11/43/5, where the requested additives had been grouped in accordance with their needs for different levels of assessment (see Annex 1).

11. The CCFA thanked the Delegation of Switzerland for the useful document and agreed to forward it to the CCNFSDU for their consideration.

Discussion Paper on the Revision of Section 4 "Carry-over of Food Additives into Food" of the Preamble of the GSFA[4]

12. The CCFA agreed to request the CCNFSDU to clarify if carry-over of food additives from ingredients was inappropriate for the foods included in the standards falling under food categories 13.1 (Infant formulae, follow-up formulae, and formulae for special medical purposes for infants) and 13.2 (Complementary foods for infants and young children).

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[2] REP11/FL, para. 8
[3] REP11/FA, paras 43-45
[4] REP11/FA, para. 125

39th Session of the Committee on Food Labelling (CCFL)

Proposed Draft Definition of Nutrient Reference Values[5]

13. The CCFL noted that the draft definition (see Annex 2) would be referred to the CCNFSDU for comments, which would be taken into account at the next session when finalising the definition.

Proposal for New Work on Review of the Definition of Trans-Fatty Acids[6]

14. The Delegation of Malaysia proposed new work to review the definition of trans-fatty acids in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) taking into consideration the origin of transfatty acids to take into account natural trans-fatty acids from dairy products and new scientific data such as the outcome of the FAO/WHO expert consultation.

15. Some delegations and observers supported new work. Other delegations questioned the need for such revision at this stage as there was no clear scientific evidence to support it. Some delegations were of the view that CCNFSDU would be more appropriate to conduct this work.

16. Regarding the health effects of industrial trans-fatty acids and ruminant trans-fatty acids, the Representative of WHO informed the Committee that much of the evidence reviewed for the 2007 WHO Scientific Update on trans-fatty acids was based on the studies on partially hydrogenated vegetable oils as not many studies on ruminant trans-fatty acids existed. The 2008 joint FAO/WHO Expert Consultation on fats and fatty acids drew much of the evidence review from the 2007 WHO Scientific Update. The Representative also informed the Committee that WHO reviewed new scientific data periodically and WHO anticipates taking up the topic of trans-fatty acids this year.

17. The Committee recalled that with regard to the current definition, the 31st Session of the Committee (2003) had asked CCNFSDU to provide a definition of trans-fatty acids for the purpose of the Guidelines19 and the 34th Session of the Committee (2006) had considered the definition based on the draft definition provided by CCNFSDU. The Committee therefore agreed to invite CCNFSDU to give its opinion on revising the definition of trans-fatty acids.

[5] REP11/FL, para. 171
[6] REP11/FL, paras 188 – 191

Annex 1

Discussion Paper on Food Additive Provisions in the *Standard for Infant Formulas and Formula for Special Medical Purposes* (Codex Stan 72-1981) (CX/FA 11/43/5)

Paragraphs 11 to 18

Currently valid principles

11. The above mentioned principles were developed forty years ago based on the advice of an FAO/WHO meeting on additives in baby food held in 1971 and subsequent additional considerations by JECFA. The recently published FAO/WHO guidance on the *Principles and methods for the risk assessment of chemicals in food* reinforced them in the subchapter *Subpopulations at risk* on pages 7-17/7-18:

"Very young infants are a particularly sensitive subgroup because their metabolic capacities are not yet fully developed. It should be noted that health-based guidance values are not considered applicable to infants under the age of 12 weeks who might be at risk at lower levels of exposure. Accordingly, risk characterization of exposure of such infants to chemicals (e.g. in infant formula or occurring as contaminants) has to be considered on a case-by-case basis. This is in accordance with similar advice in EHC 70 (IPCS, 1987), where the scientific rationale for this conclusion was originally set out. EHC 237, which provides a systematic analysis of the scientific principles to be considered in assessing health risks in children from exposures to environmental agents during distinct stages of development, is a useful reference in this regard (IPCS, 2006)." [7]

12. The guidance provided by EHC 70 is worthwhile to be repeated because it outlines the expectations of experts towards a toxicological database that should be available if a food additive was to be used in foods for very young infants:

"[…] guidelines on toxicological testing include the following:

(a) Before a food additive is regarded as safe for use in food intended for infants up to 12 weeks of age, the toxicological studies should be extended to include animals in the corresponding period of life.

(b) It is difficult to recommend precise toxicological testing procedures until more basic research has been undertaken. There are also difficulties in selecting appropriate species. In these circumstances, short- term studies should be conducted in several species and should include the oral administration of the additive under test, at suitable dose levels, to newly born animals up to and including the end of the weaning period.

(d) When life-span studies and multi-generation studies are carried out, they should be extended to include oral administration of the food additive at suitable dose levels to a proportion of animals from the day of birth throughout the pre-weaning period.

The practical difficulties and cost of implementing these recommendations on a routine basis would be immense, involving, as it would, artificial feeding of litters of newborn laboratory animals. However, in situations in which young infants are a target population for an additive, it seems reasonable that studies such as these should be performed."

13. In short, the toxicological database for a food additive needs to provide data from studies where animals of a comparable life stage have been exposed to the chemical in question and such data need to provide reasonable evidence that the substance would cause no harm in infants below 12 weeks of age. The assessment of substances cannot be done using a schematic approach but rather case-by-case taking into account separately the data available for each substance.

[7] http://www.who.int/ipcs/food/principles/en/index1.html

Characterization of requested additives

14. Based on the summary provided in paragraphs 11-13 there is no simple answer to CCNFSDU. The requested additives (see Annex II) are a mixed bag of substances with different profiles. However, these additives were not forwarded to the CCFA for endorsement and therefore CCFA will not take any position whether their eventual use in infant formula is acceptable. The following considerations are offered in order to facilitate the discussion:

15. Some additives may be considered physiological body constituents such as the salts of citric or phosphoric acids which consist of ions such as calcium, sodium, citrate, phosphate that are part of additives already permitted by the standard or of minerals listed in the *Advisory List of Mineral Salts and Trace Elements for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979). Should the CCNFSDU propose those for inclusion in Section A of the standard, CCFA may consider endorsing their use provided that levels of potassium, sodium and phosphorus in the formula are compatible with the nutritional requirements of infants.

16. Other proposed additives are - in adults - physiological metabolites of compounds that occur also in food. Mono- and diglycerides e.g. may already be present in raw materials used in the manufacturing of formulae; however, an increase of their level may require an assessment whether such levels pose a hazard to the incompletely developed gastric tract of infants.

17. Several substances, among them specifically the proposed thickeners and emulsifiers are xenobiotics for which an assessment from JECFA is available but an adequate database would be required along the lines summarized above before they would be acceptable for use in infant formula.

18. The three proposed antioxidants (E306, E308, E309) are substances that have not yet been assessed by JECFA at all and a more comprehensive full assessment would be required before considering their use as food additives.

Annex 2

Proposed draft definition of nutrient reference values

(for inclusion in the guidelines on nutrition labeling (CAC/GL 2-1985)[8]

(Proposed by the 39th Session of the Committee on Food Labelling and adopted at Step 5 by the 34th Session of the Codex Alimentarius Commission)

"Nutrient Reference Values (NRVs) are a set of numerical values that are based on scientific data and established for purposes of nutrition labelling and relevant claims. NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related non-communicable diseases."

[8] REP11/FL, Appendix IV