CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 8 **CX/NFSDU 14/36/9**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-sixth Session

Bali, Indonesia

24-28th November 2014

PROPOSED DRAFT REVISION OF THE LIST OF FOOD ADDITIVES IN CODEX STAN 72-1981

(Prepared by Electronic Working Group led by Switzerland)

Introduction and scope of discussion

1. The 35th session of the CCNFSDU agreed to establish an electronic Working Group to discuss further the Draft Revision of the list of Food Additives of CODEX STAN 72-1981 (REP14/NFSDU, paragraph 115). The eWG[1] considered all comments which had been submitted in response to the draft list prepared by Switzerland (CX/NFSDU 13/35/8) for discussion at the 35th meeting: CX/NFSDU 13/35/8-Add.1, CX/NFSDU 13/35/8-Add.2, CRD 10, CRD 12, CRD 15.

2. The discussion of the eWG was only on those additives proposed for addition to the current subsections *4. Food Additives* of *Section A: Revised Standard for Infant Formula* and *Section B: Formula for Special Medical Purposes Intended for Infants* of the Codex Standard 72-1981. These proposed additives and their suggested conditions of use were listed in Appendix I of CX/NFSDU 13/35/8. The food additives already adopted in Section A and Section B were not subject of the discussions of the eWG.

3. Four substances had been scheduled for evaluation by the 79th meeting of JECFA in June 2014: Citric and fatty acid esters of glycerol (INS 472c), pectins (INS 440), carrageenan (INS 407), Starch sodium octenyl succinate (INS 1450). Those were not discussed initially with an understanding that discussions would continue as soon as the JECFA opinion was available. The summary report of the 79th JECFA meeting was published in July 2014[2].

Principles: eligibility of additives for infant formula

4. Food additives to be used in infant formula and formula for special medical purposes intended for infants, section A and section B of CODEX STAN 72-1981, respectively, shall be examined and discussed by the CCNSFDU and the CCFA following the same procedure as applied for any other food additives that are added to the GSFA and a commodity standard. Hence for the further discussion of these additives the guidance laid down in the Procedural Manual and the Preamble of the GSFA are the adequate starting points.

5. The 43rd Session Codex Committee on Food Additives agreed 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).

6. Additives in general are only eligible for addition to the GSFA and Codex commodity standards if

[1] Argentina, Australia, Brazil, Canada, China, Colombia, European Union, Finland, France, Ghana, Japan, Moldova, Peru, Republic of Korea, Russia, India, Indonesia, Mexico, Senegal, South Africa, Sweden, Thailand, Tunisia, USA, AIDGUM, CEFIC, ELC, FDE, IADSA, IDF, ILCA; ISDI, SNE

[2] http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/JECFA_79_Summary_Version_Final.pdf

a) JECFA performed a risk assessment resulting in an assignment of an ADI (or determination of the safety on the basis of other criteria such margin of exposure) and exposure assessment that took into account the proposed conditions of use;
b) The additive is of appropriate food grade quality which means specifications for the commercial material have been adopted by Codex (or in their absence: appropriate specifications developed by responsible national or international bodies);
c) Technological need has been demonstrated
d) The technological purposes cannot be achieved by other means that are economically and technologically practicable
e) The use of a food additive does not mislead the consumer.
f) An INS number has been assigned to the additive.

Additives for use in CODEX STAN 72 -1981 shall require also

g) an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age.

7. If an additive does not meet the criteria applicable to any Codex additive (criteria a. to e.) it may not be added to the GSFA (and therefore any Codex commodity standard) at all and should not be considered further. If an additive does not meet the criterion f (that it has been assessed by JECFA to be safe for infants below twelve weeks of age) it is not immediately eligible for inclusion into Section A or B of CODEX STAN 72-1981 and the corresponding GSFA food category.

8. There was a proposal by one member that the criterion of a JECFA evaluation for infants below 12 weeks should not be applied retroactively. However, it should be remembered that JECFA developed this principle during the 1970ies and published it in its first consolidated guidance document published by WHO in 1987 (Environmental Health Criteria 70). Applying the proposed split approach would result in a double standard where new substances would be scrutinized in detail and old substances would not. The decision whether for an “old” additive the available data are sufficiently robust remains with JECFA as risk assessment body and is not within the mandate of Codex committees.

9. With respect to the retrospective application of the criterion 6 g) it was proposed that the Committee may wish to consider scrutinizing the already adopted provisions of CODEX STAN 72-1981. Such work may be initiated by sending a recommendation to CCFA to consider a formal review of additives currently listed by JECFA whether they meet criterion 6 g).

10. As criterion 6 g) is not mentioned in the preamble to the GSFA the CCNFSDU may wish to propose to the CCFA to include in an appropriate section of the preamble to the GSFA the principle that an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age needs to be available when food additives are listed in categories in *13.1.1 Infant formulae* and *13.1.3 Formulae for special medical purposes for infants.*

Principles: nominating additives for CODEX STAN 72-1981

11. Should a member or observer continue to support the inclusion of an additive into Section A or B of CODEX STAN 72-1981 it is their responsibility to address possible data gaps which are in most cases missing evaluations by JECFA.

12. From a procedural point of view there is no difference between additives missing only criterion g) and those missing also the more basic five criteria a) to f).

13. A request for evaluation by JECFA should be presented to the CCFA (in response to the corresponding Circular Letter). Once a JECFA evaluation is finalized, and specifications have been adopted by Codex, the request for adding an additive to Section A or B of CODEX STAN 72-1981 will be discussed by CCNFSDU.

14. It should be noted that any member or observer shall propose evaluations by JECFA directly to CCFA; there is no need to involve or route such a request via CCNSFDU. It is not part of the mandate of CCNFSDU to discuss and request JECFA evaluations. Interested parties should do this at CCFA and seek close cooperation with the Codex Secretariat or the JECFA Secretariat in case of questions with respect to the procedure.

15. The very recent evaluation of four additives by the 79th meeting of JECFA is a good example of this approach (see also para 30 ff). Interested parties notified in this case to CCFA their request for an evaluation by JECFA and their commitment to make available the specific data needed; they responded to the call for data published in 2013 and submitted these data; JECFA assessed the

proposed uses which allows Codex Alimentarius Commission to consider the addition of these three additives to CODEX STAN 72-1981 or, if the CCFNSDU proceeds in accordance with the recommended procedure (see para 31), directly to the General Standard on Food Additives (GSFA).

16. Based on a different understanding of the Procedural Manual one member proposed that the CCNFSDU should continue to consider and discuss food additives used in infant formula as a continuous activity and apply a different procedure whereby candidate substances would be proposed by interested parties and discussed by the CCNFSDU whether they meet the relevant criteria including an assessment whether the data were adequate with respect to the safety. A key part of the proposed procedure would be that CCNFSDU would nominate on behalf of sponsors (i.e. industry) substances to the CCFA for evaluation by JECFA and thereby take over responsibility for completeness of available safety, efficacy and quality data. As this proposal was submitted late it was not discussed further by the eWG.

17. In view of the Chair of the eWG the establishment of such a formal approach would require a consultation with the Secretariat, the CCFA and possibly other Codex committees such as the Committee on General Principles or the Executive Committee. Beside an interpretation whether such a procedure would be compatible with words and spirit of the Procedural Manual and other Codex texts it should also be considered whether it is desirable with respect to the work load of committees involved. The eventual result of both procedures (paras 13 and 14 vs para 16), to include only safe additives into the categories 13.1.1 and 13.1.3 of the GSFA and to replace the additive listings in CODEX STAN 72-1981 would not be different.

Fate of the list of proposed food additives

18. The proposed list currently under discussion by CCNFSDU (see Appendix 1) should be only a short and transitory document; it should not be a permanent list of pending requests leaving the impression that compounds are real candidates for inclusion in the near future. During the discussion all positive and negative aspects of using an additive in infant formulae should be taken into account. Maintaining the list for a too long period may leave the wrong impression that the discussion itself already means that substances are somehow accepted by Codex. It should be noted that food additives listed in discussion documents are not endorsed by the Commission or its Committees any use under consideration.

Other comments

19. The response from members was generally favourable to the principle to restrict the number of additives used in foods for infants and young children. The analysis of the members' and observers' comments, as far as not discussed already above, focuses therefore not on opinions supporting deletions but the requests to keep additives on the list or requests for a JECFA evaluation.

20. The members of the eWG reiterated the understanding that all additives listed in subsection 4 of Section A of CODEX STAN 72-1981 are by default accepted with the same conditions of use in Section B. Provided that a specific technological use is justified for Section B formula only and the additive is found to be safe for this use by JECFA, additives may be listed under Section B only. No such additives have been adopted for Section B only until now. This understanding applies to current and to newly proposed listings.

21. All proposed substances where re-checked for compliance of their status with the principles for food additives to be added to the GSFA as explained above. Substances without an adequate status (as a minimum: an existing JECFA evaluation, adopted Codex specifications) are proposed for immediate deletion. In Appendix I those substances are specifically identified.

22. Some members defended the continued listing of additives such as E 308 / E 309 in a CCNFSDU list of proposed additives although these additives do not meet these general safety criteria for Codex food additives. Other members were of the opinion that food additives proposed for adoption in sub-sections 4 of Section A/B of CODEX STAN 72-1981 should meet all the requirements for a "normal" Codex food additive and be assessed in addition by JECFA to be safe for infants below twelve weeks of age.

23. Some members suggested that current listing of such additives in national legislation was providing sufficient evidence of history of safe use. It should however be noted that such safe use was not documented during the discussion and that the concept of "history of safe use" in itself does not waive the need for a full risk assessment in accordance with current scientific principles. The Committee may wish to consider whether it supports the connotation that it applies less stringent

requirements for food additives to be used in infant formula than Codex applies to these additives when used in other foods.

24. With respect to food additives to be removed from the CCNFSDU draft list interested parties are invited to consider that they may at any time submit to CCFA a request for evaluation by JECFA. One comment proposed that substances should stay on the list while interested parties assess whether they would initiate generating the required data. As stated above such a solution would allow the interpretation that CCNFSDU considers the use of additives in infant formula as acceptable or possible although the substances do not qualify as Codex food additives at all.

25. As the prioritization of proposals for food additives evaluations by JECFA is the prerogative of CCFA, it would not be appropriate for CCNFSDU to maintain a list of candidates for a future JECFA evaluation. Such proposals should be presented to the CCFA and its JECFA priorities working group where the request for evaluations, the availability of data and the deadline for their submission as presented by interested parties are recorded and updated annually. It would be a duplication of efforts outside of the mandate of CCNFSDU if the Committee would maintain a separate list.

26. Positive comments that a substance is used, that it enjoys already an ADI for the general population, and a commitment to support an evaluation by JECFA for infants below twelve weeks of age were considered by the eWG as sufficient support for addition of the additive to CODEX STAN 72-1981. They may stay therefore on the draft list for a limited time (in case the Committee maintains this list, otherwise the request may be channelled by interested parties via CCFA/JECFA as it is appropriate (see para *Recommendation II*).

27. Substances for which a JECFA evaluation is significantly supported by eWG members shall be presented to the CCFA and its working group of JECFA priorities at the next possible occasion, the 47th session in 2015. This approach is proposed in analogy to the four substances evaluated by the 79th meeting of JECFA in 2014.

28. Some members of the eWG stated that they were or would establish data required for JECFA. Such commitment is welcome, but as stated in other sections of this report, this should be presented to and discussed by the CCFA and its priority working group of JECFA.

29. It was mentioned in the eWG discussion that the Codex Alimentarius Commission has already decided that GSFA food categories and commodity standards shall be aligned with respect to the food additive provisions. Such an alignment would mean that section 4 of CODEX STAN 72-1981 refers generally to the GSFA and its provisions but that specific additives and their conditions of use would only be listed in the GSFA food categories *13.1.1 Infant formulae* and *13.1.3 Formulae for special medical purposes for infants* (cf. Procedural Manual, 22nd edition, page 44).

30. The eWG recognizes that this may be desirable but is not yet the case and that it will require more work in future. However, new additives could already be added first to the GFSA which is a more rapid procedure as maintenance of the GFSA does not require approval of new work by the Commission (cf. Procedural Manual, 22nd edition, page 28). As this approach would increase temporarily inconsistencies between CODEX STAN 72-1981 and the corresponding GSFA categories, adoption may be postponed until a revision of CODEX STAN 72-1981 has been initiated.

31. With respect to the collaboration between CCFA and commodity committees it was suggested by one member that it was the prerogative of the CCNFSDU alone to decide whether an additive meets the requirements for inclusion into the GSFA. The procedure as discussed by the CCFA and endorsed by the Commission in the Procedural Manual[3] is different: the CCFA may be described as the guard of Codex with respect the principles of adopting food additive provisions.

[3] "All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the 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 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.
All provisions in respect of food additives contained in commodity standards will require endorsement by the 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." (Proc. Manual, 22nd edition, p. 44)

32. The main responsibility of a commodity committee such as CCNFSDU is to assess the technological need and purpose in vertical standards whereas CCFA is tasked with providing assurance that safety and quality aspects of the additive as horizontal aspects across the whole Codex Alimentarius are respected.

JECFA Evaluation (79th meeting)

33. The 79th meeting of JECFA assessed four additives proposed for use in formulae described in CODEX STAN 72-1981. A summary of the recommendations was published in July 2014; the relevant conclusions for the discussion of the eWG are as follows:

Carrageenan (for use in infant formula and formula for special medical purposes intended for infants)	The Committee concluded that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern. The Committee recognized that there is variability in medical conditions among infants requiring formulas for special medical purposes that contain the higher levels of carrageenan, and the Committee noted that these infants would normally be under medical supervision.
Citric and fatty acid esters of glycerol (CITREM) (for use in infant formula and formula for special medical purposes intended for infants)	The Committee concluded that there are no toxicological concerns about the use of CITREM in infant formula and formula for special medical purposes at concentrations up to 9 g/L. At the higher use levels, there is a possibility of diarrhoea from free citric acid released from formula containing CITREM. Given the paucity of clinical data and the fact that exposure assumptions for citric acid have been maximized, it is difficult to estimate the risk of diarrhoea, but it is considered to be low.
Octenyl succinic acid (OSA)–modified starch (starch sodium octenyl succinate) (for use in infant formula and formula for special medical purposes intended for infants)	…the Committee concluded that the consumption of OSA-modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at use levels up to 20 g/L.
Pectin (for use in infant formula and formula for special medical purposes intended for infants)	…the Committee concluded that the use of pectin in infant formulas at the maximum proposed use level (0.5%) is of concern. JECFA requested additional data to support the safety evaluation of pectin in infant formula, including an explanation for the decreased feed intake and body weight gain in neonatal pigs.

34. As the detailed report of JECFA is not yet available, it may be considered premature to act on the JECFA summary already now. As these publications will become available before the next CCFA's session, the CCFNSDU may already consider its options:

35. First the Committee may wish to propose to the CCFA to add the three additives cleared by JECFA to the GSFA food categories 13.1.1 Infant formulae and 13.1.3 Formulae for special medical purposes for infants at the conditions of use as assessed by JECFA.

36. If the CCNFDSU decides to maintain a separate additive listing in CODEX STAN 72-1981, secondly, at a future revision of the Section A (and therefore Section B) of CODEX STAN 72-1981 these three additives would then be added to the text of the standard itself.

37. One additive (pectin) should be removed from the temporary CCNFSDU list as it safety at the proposed conditions of use has not been established by JECFA. Should interested parties decide to reply to JECFA's request for additional data they shall present their plans and commitment to CCFA (as discussed above).

38. For carrageenan the Committee may wish to ask CCFA in addition to endorse the previously proposed conditions of use of 0.03 g in regular milk-and soy-based liquid infant formula and 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only. As JECFA has concluded that concentrations up to 1000 mg/L are of no concern in both types of formula, it was proposed that these specific conditions of use may be replaced by a more general one, however, in that case it would probably be needed to discuss whether the criteria 6c) and 6d) technological need are met.

Recommendation I

39. Based on the discussion about principles to be applied, the feedback of eWG members, and the status of additives at JECFA/Codex the following decisions are proposed (more detailed arguments are presented in Appendix I):

Proposed decision	**Section A**	**Section B**
Initiate procedure for revision of the additives sections of CODEX STAN 72-1981	Carrageenan (INS 407) Citric and fatty acid esters of glycerol (INS 472c)	Starch sodium octenyl succinate (INS 1450)
Propose to the CCFA for inclusion into the GSFA (categories 13.1.1 and 13.1.3) or endorsement of existing provisions (INS 407 only)	Carrageenan (INS 407) Citric and fatty acid esters of glycerol (INS 472c)	Starch sodium octenyl succinate (INS 1450)
Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority list in 2015: remove from list.	Xanthan gum (INS 415) Sucrose esters of fatty acids (INS 473) Acetic and fatty acid esters of glycerol (INS 472a) Phosphoric acid (INS 338) Tartaric and fatty acid esters of glycerol (INS 472e)	Sodium alginate (INS 401) Carob bean gum (Locust bean gum) (INS 410) Guar gum (INS 412)
Remove from list as substance does meet food additive criteria for GSFA, was not recognized as safe by 79th JECFA, or is not significantly supported	Gum Arabic (acacia) (INS 414) *) Vitamin E concentrate (no INS) Gamma tocopherol (INS 308) Delta tocopherol (INS 309)	Propane 1,2-diol alginate (INS 405) Pectin (INS 440) Sodium carboxymethyl cellulose (INS 466) Mono- and diglycerides (INS 471)

*) This removal would not affect the adopted use of INS 414 as carrier for vitamins and other nutrients the *Advisory List of Food Additives for Special Nutrient Forms* (CAC/GL 10-1979).

Recommendation II

40. Based on the principles discussed above, the eWG recommends for future additives to be included into CODEX STAN 72-1981 or, as more appropriate, into the GSFA the following more structured approach which is based on the Procedural Manual and the preamble to the GSFA:

> Step 1: Proposal to be checked for status at JECFA and Codex re available evaluation, specifications, technological justification, and safety when used at proposed levels in infant formula. Any deficiency needs to be addressed by interested parties with CCFA and JECFA before further discussions at CCNFSDU.
>
> Step 2: Once all requirements are met, CCNFSDU will consider whether there is sufficient support based on technological needs that supports the use of the additive in Sections A or B of the standard.

Recommendation III

41. It was noted by some eWG members that the current subsection 4 of Section A and therefore B list additives that are not aligned with the GSFA. The CCNFSDU may wish to discuss how this contradiction between both Codex standard may be removed and provisions of food additives of CODEX STAN 72-1981 and the corresponding GSFA categories could be aligned.

Recommendation IV

42. The Committee may wish to agree to discontinue at latest at its next session the discussion of this list as interested parties should have submitted until then their requests for evaluation via CCFA to JECFA. Any follow up of possible data gaps identified by JECFA should be followed up by interested parties with JECFA and CCFA without future involvement of the CCNFSDU.

APPENDIX 1

Food Additives

Request for additional food additives for use in Infant Formula (Section A) and Infant Formula as Food for Special Medical Purposes (Section B)

Note: substances in shaded rows are proposed for immediate deletion from the list.

Section A (Infant Formula):

INS no.	Additive	Use level	Technological Justification	JECFA status	Comments	eWG Proposal
Thickeners						
407	Carrageenan	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only	Retains homogeneity	Use accepted by 79th meeting of JECFA (June 2014)	General support Section A	ask CCFA to endorse the previously proposed conditions of use of 0.03 g in regular milk-and soy-based liquid infant formula and 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only. Consider to propose to CCFA the inclusion of the additive to food categories 13.1.1 and 13.1.3 of the GSFA
415	Xanthan gum	GMP	Retains homogeneity	30th JECFA (1986): ADI NS; infants <12 weeks not mentioned Tox database: three-generation reproduction study adverse effects attributable to Xanthan gum were not found	General support for JECFA evaluation for use in Section A/B Sponsor for JECFA identified by ELC.	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
414	Gum Arabic (acacia)	GMP	Retains homogeneity	35th JECFA (1989): ADI NS No effects in teratogenicity	No strong support for compound, no commitment to support JECFA evaluation.	Remove from the list as substance is not supported significantly demonstrating limited technological need (listing in CAC GL 10-1979 no affected)
1450	Starch	2 g	Retains	Use for Section A and B	General support Section	Consider to propose to CCFA the

INS no.	Additive	Use level	Technological Justification	JECFA status	Comments	eWG Proposal
	sodium octenyl succinate		homogeneity.	accepted by 79th meeting of JECFA (June 2014)	A/B – was listed originally only for Section B	inclusion of the additive to food category 13.1.3 of the GSFA
Emulsifiers						
472c	Citric and fatty acid esters of glycerol*	0.75 g in powder formula[4] 0.9 g in liquid formula containing hydrolysed protein or amino acids [1]	Retains homogeneity	Use accepted by 79th meeting of JECFA (June 2014)	General support Section A/B	Consider to propose to CCFA the inclusion of the additive to food categories 13.1.1 and 13.1.3 of the GSFA
473	Sucrose esters of fatty acids*	12 mg in formula containing hydrolysed protein or amino acids [1]	Retains homogeneity	49th JECFA (1997) :ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned	General support for JECFA evaluation for use in Section A/B No sponsor for JECFA identified	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
472e	Tartaric and fatty acid esters of glycerol	GMP (China) 0.5 g	Retains homogeneity	61st JECFA (2003) ADI specified at 0-50 mg/kg bw (2003); infants <12 weeks not mentioned	General support for JECFA evaluation for use in Section A/B No sponsor for JECFA identified	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
472a	Acetic and fatty acid esters of glycerol	GMP (USA)		17th JECFA (1973): ADI NS (not limited); infants <12 weeks not mentioned	Limited support for JECFA evaluation for use in Section A/B No sponsor for JECFA identified	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.

[4] If more than one of the substances INS 472c, 473 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances.

INS no.	Additive	Use level	Technological Justification	JECFA status	Comments	eWG Proposal
Acidity Regulators						
338	Phosphoric acid	0.1 g expressed as P_2O_5 singly or in combination and within the limits for sodium, potassium and phosphorus in Section 3.1.3 (e) in all types of infant formula		15th JECFA (1971): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio MTDI: 70 mg/kg bw as P (combined for all P sources)	Limited support	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
Antioxidants						
306	Vitamin E concentrate	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Under this name and number not evaluated. 30th JECFA (1986) evaluated Tocopherol Concentrate, Mixed (INS 307b) – synonym: Vitamin E	Is equivalent to JECFA specification INS 307b INS 307b is already listed in Section A of CODEX STAN 72-1981. "INS 306" is not listed in the current INS list (CAC/GL 36-1989) INS number still used in national lists	Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA; in addition not recognized as a food additive (no INS)
308	Gamma tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Not evaluated by JECFA, no specifications available	Limited support by few members and ISDI INS 308 is in current INS list "Tocopherol, gamma-, synthetic"	Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA
309	Delta tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Not evaluated by JECFA, no specifications available	Limited support by few members and ISDI INS 309 is in current INS list "Tocopherol, delta-, synthetic"	Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA

Section B (Infant Formula as Food for Special Medical Purposes):

INS no.	Additive	Use level	Technological Justification	JECFA Status	Comments	eWG proposal
Thickeners						
401	Sodium alginate	100 mg	Retains homogeneity	39th JECFA (1992) , not specified, infants < 12 weeeksweare not discussed by JECFA	Limited support by few members and ISDI Request as carrier for nutrients not within the scope of the eWG.	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
405	Propane 1,2-diolalginate	20 mg	Retains homogeneity	41st JECFA (1993) , not specified	Not supported, no specific need for infant formula presented Need in specific formula for infants at ages > 12 months not to be discussed under this entry	Remove from the list, as the substance is not supported by any member/observer, no technological need.
410	Carob bean gum (Locust bean gum)	0.5 g	Retains homogeneity	25th JECFA (1981) , not specified	Supported by some members and observers	Listed at 0.1 g/100 ml in Section A. Maintain on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.
412	Guar gum	1 g	Retains homogeneity	19th JECFA (1975) , not specified	Supported by some members and observers	Listed at 0.1 g/100 ml in Section A. Maintain on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.
414	Gum Arabic (acacia)	GMP	Retains homogeneity	35th JECFA (1989) , not specified	No strong support for compound, no commitment to support JECFA evaluation. Carrier for fatsoluble vitamins not within the scope of eWG	Remove from the list as substance is not supported significantly demonstrating limited technological need

INS no.	Additive	Use level	Technological Justification	JECFA Status	Comments	eWG proposal
415	Xanthan gum	0.12 g	Retains homogeneity	30th JECFA (1986), not specified	General support for JECFA evaluation for use in Section A/B Sponsor for JECFA identified by ELC.	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
440	Pectins	1 g	Retains homogeneity	79th JECFA meeting did not establish safety of proposed conditions of use	General support Section A/B	Remove from the list, as the substances does not meet the essential criterion of being recognized as safe for infants below 12 weeks of age by JECFA
466	Sodium car-boxymethyl cellulose	1 g	Retains homogeneity	35th JECFA (1989) , not specified	No strong support for compound, no commitment to support JECFA evaluation.	Remove from the list as substance is not supported significantly demonstrating limited technological need
Emulsifiers[5]						
471	Mono- and diglycerides	0.5 g	Retains homogeneity	17th JECFA (1973), not specified	Supported by some members and observers	Listed already in Section A for 0.4 g: is an additional separate entry at 0.5 g necessary and justified? Remove from the list as no technological need
473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Retains homogeneity	71st JECFA (2009) :Group ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned, no studies with animals in weaning stage mentioned	Supported by some members and observers	Maintain on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.

[5] If emulsifiers are used in combination, the combined levels should be within the levels listed and be proportionately reduced, and with the minimum amount necessary to achieve the intended technical effect.