

CODEX ALIMENTARIUS COMMISSION



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Organization of the
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Agenda Item 9b

NFSDU/41 CRD 40

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-first Session

Düsseldorf, Germany

24 - 29 November 2019

ALIGNMENT OF FOOD ADDITIVE PROVISIONS IN CCNFSDU STANDARDS WITH THE GSFA

Comments by ISDI

ISDI would like to first thank Germany for the preparation of CX/NFSDU 19/41/9 "Alignment of Food Additive Provisions in CCNFSDU Standards with the GSFA"

Overall ISDI is supportive of the vast majority of comments and recommendations. We have additional points for consideration as included in the relevant sections throughout the document.

ISDI supports forwarding the CCNFSDU work on alignment to CCFA at the earliest opportunity. In addition, if the Alignment document from Germany were endorsed by the Committee, we would fully support this ISDI CRD be forwarded to the CCFA to be taken into further consideration by that Committee. Finally, ISDI would like to offer our participation in the CCFA electronic working group on Alignment to further discuss all additive provisions relating to CCNFSDU standards in the respective GSFA Food Categories.

Several overall comments/questions for consideration in relation to alignment of CCNFSDU standards are as follows:

1. **Change in units to mg/L:** ISDI proposes an additional edit to all of the provisions in Food Categories 13.1.1, 13.1.2, and 13.1.3 in the GSFA to ensure complete alignment between the commodity standards and the GSFA. The commodity standards that correspond with Food Categories 13.1.1, 13.1.2, and 13.1.3 all express their additive provisions "as-fed" with units of **g/100 mL**.

While the GSFA currently expresses all provisions in the unit "mg/kg", ISDI believe that for these Food Categories, it would be more harmonized to express the maximum use levels with the unit "mg/L". This is harmonized with the current provisions, since they all have a Note¹ defining the maximum use levels on the "as-consumed" or "ready-to-eat" basis. ISDI believes this change in unit would be highly beneficial in ensuring aligned interpretations of the provisions.

2. **Moving additives to parent category FC 13.1:** As described in the Preamble to the GSFA under 5a), the food category system is hierarchical such that when an additive is recognized for use in a general category, it is also recognized for use in all its subcategories. In the case of CXS 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, and CXS 56-1987 Follow Up Formula for example, this would be taken to mean that additive provisions under FC 13.1 would also be recognized for use in FC13.1.1, FC 13.1.2, and FC 13.1.3.

We note that there are a number of cases in those 3 FCs with identical provisions (INS, maximum use level, and notes) that could potentially be listed under the general category 13.1. This could lead to a more compact list of provisions; we note that this approach has been taken in the case of some other food categories. If appropriate, ISDI welcomes further consideration of this approach.

3. During the current work on Alignment, we noted examples where certain additive provisions in the commodity standards may require revision in order to be accurately and precisely reflected in the standard. Acknowledging that the aim of the current Alignment work is to ensure accuracy of additive provisions in the GSFA, we would like to seek clarification from the Committee on whether work may proceed to amend the commodity standards where needed. As an example, would the changes as proposed in paragraph 1 of parts A, B, C and D not actually be implemented into the commodity

¹ GSFA Note 72: "on the ready-to-eat basis"

GSFA Note 381: "as consumed"

standard. Indeed, the additive provisions will be deleted in the commodity standard, and the INS and names are already correct in the GSFA.

Part A

Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)

1. According to box A of the decision tree on the alignment developed by the CCFA the following amendments should be made regarding the food additive provisions of the commodity standard:

INS 410	Carob bean gum (Locust bean gum)
INS 322 (i)	Lecithin
INS 471	Mono- and diglycerides of fatty acids
INS 270	Lactic acid, L(+)-L-, D-, and DL-
INS 332	Potassium citrate
INS 332 (i)	Potassium dihydrogen citrate
INS 332 (ii)	Tripotassium citrate
INS 307 b	Mixed-t Tocopherols concentrate, mixed

ISDI comments: ISDI supports the proposed changes

2. The functional classes of the authorized food additives are as follows according to CXG 36-1986 (listed in the order as authorized in CXS 72-1981):

INS 412	Emulsifier, Stabilizer, Thickener
INS 410	Emulsifier, Stabilizer, Thickener
INS 1412	Emulsifier, Stabilizer, Thickener
INS 1414	Emulsifier, Stabilizer, Thickener
INS 1413	Emulsifier, Stabilizer, Thickener
INS 1440	Emulsifier, Stabilizer, Thickener
INS 1450	Emulsifier, Stabilizer, Thickener
INS 407	Emulsifier, Stabilizer, Thickener, Bulking agent, Carrier, Gelling agent, Glazing agent, Humectant

The food additives listed above have been authorized as thickeners in CXS 72-1981.

ISDI comments: ISDI considers that INS 410, 412, 1412, 1413, 1414, 1440, 1450, 407 should be listed as both thickeners and stabilizers.

INS 322 (i)	Antioxidant, Emulsifier
INS 471	Antifoaming agent, Emulsifier, Stabilizer
INS 472c	Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer

The food additives listed above have been authorized as emulsifiers in CXS 72-1981.

INS 524	Acidity regulator
INS 500 (ii)	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener
INS 500 (i)	Acidity regulator, Anticaking agent, Emulsifying salt, Raising agent, Stabilizer, Thickener
INS 525	Acidity regulator
INS 501 (ii)	Acidity regulator, Stabilizer, Raising agent
INS 501 (i)	Acidity regulator, Stabilizer
INS 526	Acidity regulator, Firming agent
INS 270	Acidity regulator
INS 330	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant
INS 331 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 331 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer

INS 332 (i)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 332 (ii)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 339 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 339 (ii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener
INS 339 (iii)	Acidity regulator, Emulsifier, Humectant, Preservative, Sequestrant, Stabilizer, Thickener
INS 340 (i)	Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340 (ii)	Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener

The food additives listed above have been authorized as acidity regulators in CXS 72-1981.

ISDI comments: ISDI agrees with this assessment

INS 307 b	Antioxidant
INS 304	Antioxidant

The food additives listed above have been authorized as antioxidants in CXS 72-1981.

ISDI comments: ISDI agrees with this assessment

In addition, ISDI notes that since only one ascorbyl ester (304) and only one tocopherol (307b) are authorized for this product category, the note "1 mg in all types of infant formula singly or in combination" currently in 72-1981 may be deleted from this standard since, as proposed by the German delegation, it is not being carried over into the GSFA

INS 290	Carbonating agent, Foaming agent, Packaging gas, Preservative, Propellant
INS 941	Foaming agent, Packaging gas, Propellant

The food additives listed above have been authorized as packaging gases in CXS 72-1981.

ISDI comments: ISDI agrees with this assessment

3. Whereas the food additive provisions of CXS 72-1981 are related to the food categories 13.1, 13.1.1 and 13.1.3 of the GSFA, the answer to the question in box B of the decision tree on the alignment developed by the CCFA is "NO".

ISDI comments: ISDI agrees with this assessment

4. The food additive provisions are contained in the food categories 13.1, 13.1.1 and 13.1.3. The commodity standard rules that the provisions in food category 13.1.1 should be the same as in 13.1.3. The answer to the question in box D of the decision tree on the alignment developed by the CCFA is "YES" for all the provisions except for the provision for starch sodium octenyl succinate (INS 1450) which is not listed in food category 13.1.1 and thus needs to be included in the GSFA food category according to box J. In addition, phosphates should be authorized in food categories 13.1.1 and 13.1.3 with restrictions as governed by CXS 72-1981 according to box G.

The following changes of the GSFA seem to be necessary for the full alignment:

Food categories 13.1.1.and 13.1.3:

Adding a provision as follows:

Phosphates	339(i)-(iii); 340(i)-(iii)	450 mg/kg	33, 230 & New note (a): Sodium dihydrogen phosphate (INS 339 (i)), Disodium hydrogen phosphate (INS 339 (ii)), Trisodium phosphate (INS 339 (iii)), Potassium dihydrogen phosphate (INS 340 (i), Dipotassium hydrogen phosphate (INS 340 (ii)) and Tripotassium phosphate (INS 340 (iii)) only, singly or in combination & New note (b): Within the limits for sodium,
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potassium and phosphorus specified in the Standard for Infant Formula and Formula for Special Dietary Purposes Intended for Infants (CXS 72-1981)

ISDI comments: ISDI agrees with this proposal (addition to 13.1.1 and 13.1.3 as well as the new notes (a) and (b)).

Food category 13.1.1:

Adding a provision as follows:

<u>Starch sodium octenyl succinate</u>	<u>1450</u>	<u>20000 mg/kg</u>	<u>376 & 381</u>
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ISDI comments: ISDI agrees with the proposal to add this additive provision in 13.1.1 along with footnote 72 (replacing footnote 381), and footnote 376

5. According to the advice in box E of the decision tree on the alignment developed by the CCFA the food additive provisions in the GSFA are considered to be in line with the provisions of the commodity standard CXS 72-1981 to a large extent. CXS 72-1981 authorizes inter alia “322 Lecithins”. According to CXG 36-1986 the following Lecithins exist: Lecithin (INS 322 (i)), Lecithin, partially hydrolysed (INS 322 (ii)) and Lecithin, hydroxylated (INS 322 (iii)). For Lecithin, hydroxylated (INS 322 (iii)) no specifications exist and it can therefore not be authorized. For Lecithin, partially hydrolysed (INS 322 (ii)) there are no provisions in the GSFA. It is therefore suggested that the authorization of “322 Lecithins” in CXS 72-1981 be interpreted as authorization of Lecithin INS 322 (i)). The following changes of the GSFA seem to be necessary for the full alignment:

Food category 13.1.1:

Amending the provision for Carrageenan as follows:

Carrageenan	407	300 mg/kg	378 & 381 <u>& New note: for use in liquid infant formula except for use in hydrolyzed protein and/or amino acid based liquid infant formula at 1000 mg/kg</u>
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ISDI comments: ISDI supports the proposal to modify footnote in 13.1.1 and to eliminate Note 378 and to add the New Note.

ISDI also supports replacing Note 381 with Note 72

Adding a new note to the provisions for Lecithin and Mono- and diglycerides of fatty acids as follows:

If Lecithin (INS 322 (i)) is used in combination with Mono- and diglycerides of fatty acids (INS 471) the maximum level for each of the substances is lowered with the relative part as present of the other substance.

ISDI comments: As for the wording of the new Note, ISDI would rather suggest the following in order to aid in consistent interpretation of this Note:

“If Lecithin (INS 322 (i)) is used in combination with Mono- and diglycerides of fatty acids (INS 471) the sum of the proportions of these substances in the food must not be more than 1. The sum of the proportions is calculated as: Sum of proportions = (Concentration of INS 322(i) / Maximum Permitted Level of INS 322(i)) + (Concentration of INS 471 / Maximum Permitted Level of INS 471)”

Food category 13.1.3:

Amending the notes to Acetylated distarch phosphate (INS 1414) as follows:

72, 150, ~~284~~ & 292

ISDI comments: ISDI supports Germany proposal to add Note 284 to create the singly or in combination limitation

Amending the provision for Carrageenan as follows:

Carrageenan	407	300 mg/kg 4000 mg/kg	379 & 381 <u>& New note: for use in liquid infant formula except for use in hydrolyzed protein and/or amino acid based liquid infant formula at 1000 mg/kg</u>
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ISDI comments: ISDI supports the proposal to modify footnotes in 13.1.3 and to eliminate Note 379 and to add the New Note.

ISDI supports German proposal to modify Max Level in 13.1.3 to 300 mg/kg, as long as New Note is adopted.

ISDI also supports replacing Note 381 with Note 72

Amending the notes to distarch phosphate (INS 1412) as follows:

72, 150, ~~284~~ & 292

ISDI comments: ISDI supports Germany proposal to add Note 284 to create the singly or in combination limitation

Amending the footnotes to hydroxypropyl starch (INS 1440) as follows:

72, 150, ~~284~~ & 292

ISDI comments: ISDI supports Germany proposal to add Note 284 to create the singly or in combination limitation

Adding a new note to the provisions for Lecithin and Mono- and diglycerides of fatty acids as follows:

If Lecithin (INS 322 (i)) is used in combination with Mono- and diglycerides of fatty acids (INS 471) the maximum level for each of the substances is lowered with the relative part as present of the other substance.

ISDI comments: As for the wording of the new Note, ISDI would rather suggest the following in order to aid in consistent interpretation of this Note:

“If Lecithin (INS 322 (i)) is used in combination with Mono- and diglycerides of fatty acids (INS 471) the sum of the proportions of these substances in the food must not be more than 1. The sum of the proportions is calculated as: $\text{Sum of proportions} = (\text{Concentration of INS 322(i)} / \text{Maximum Permitted Level of INS 322(i)}) + (\text{Concentration of INS 471} / \text{Maximum Permitted Level of INS 471})$ ”

Amending the footnotes to Phosphated distarch phosphate (INS 1413) as follows:

72, 150, ~~284~~ & 292

ISDI comments: ISDI supports Germany proposal to add Note 284 to create the singly or in combination limitation

Additional remark:

For the sake of consistency the footnote 381 “As consumed” when used in the food categories 13.1, 13.1.1 and 13.1.3 might be replaced by the footnote 72 “On the ready-to-eat basis”.

ISDI comments: ISDI supports replacing Note 381 with Note 72

6. Section 7.1 of CXS 72-1981 (Packaging) contains the following provision: “Nitrogen and carbon dioxide may be used as packing media.” It is suggested that this provision be interpreted as the use of Nitrogen (INS 941) and Carbon dioxide (INS 290) which are already authorized according to section 4 as packaging gases. It is suggested that the provision in section 7.1 be removed as it may lead to confusion.

ISDI comments: ISDI support Germany proposal to remove the provisions from Section 7.1 of 72-1981, and keep the provisions for carbon dioxide and nitrogen as packaging gases in Section 4 of 72-1981 and the GSFA

Part B**Standard for Canned Baby Food (CXS 73-1981)**

1. According to box A of the decision tree on the alignment developed by the CCFA the following amendments should be made regarding the food additive provisions of the commodity standard:

<u>INS 410</u>	<u>Carob</u> locust bean gum
<u>INS 412</u>	Guar gum
<u>INS 1412</u>	Distarch phosphate
<u>INS 1414</u>	Acetylated distarch phosphate
<u>INS 1413</u>	Phosphated distarch phosphate
<u>INS 1440</u>	Hydroxypropyl starch
<u>INS 1422</u>	Acetylated distarch adipate
<u>INS 1411</u>	Distarch glycerol
	Acetylated distarch glycerol
<u>INS 440</u>	Pectins
<u>INS 322 (i)</u>	Lecithin
<u>INS 471</u>	Mono- and Diglycerides <u>of fatty acids</u>
<u>INS 500 (ii)</u>	Sodium hydrogen carbonate
<u>INS 500 (i)</u>	Sodium carbonate
<u>INS 501 (ii)</u>	Potassium hydrogen carbonate
<u>INS 170 (i)</u>	Calcium carbonate
<u>INS 330</u>	Citric acid
<u>INS 331 (i)</u>	<u>Sodium dihydrogen citrate</u>
<u>INS 331 (iii)</u>	<u>Trisodium citrate</u>
<u>INS 270</u>	Lactic acid, <u>L(+), D-, and DL-</u>
<u>INS 260</u>	Acetic acid, <u>glacial</u>
<u>INS 307 b</u>	Mixed-t Tocopherols concentrate, <u>mixed</u>
<u>INS 307 a</u>	<u>Tocopherol, d-alpha</u>
<u>INS 307 c</u>	Tocopherol, <u>dl-alpha</u>
<u>INS 304</u>	L-Ascorbyl palmitate
<u>INS 300</u>	L-Ascorbic acid, <u>L-</u> and its Na, Ca salts
<u>INS 301</u>	<u>Sodium ascorbate</u>
<u>INS 303</u>	<u>Potassium ascorbate</u>

ISDI comments: ISDI supports the proposed changes with one exception:

As lecithin authorization does not seem to be specific in the commodity standard, clarification is needed to understand if both additives 322i and 322ii are currently used in foods characterized under this standard. ISDI could come back with clarification at next CCFA or CCNFSDU

2. The functional classes of the authorized food additives are as follows according to CXG 36-1986 (listed in the order as authorized in CXS 72-1981):

INS 410	Emulsifier, Stabilizer, Thickener
INS 412	Emulsifier, Stabilizer, Thickener
INS 1412	Emulsifier, Stabilizer, Thickener
INS 1414	Emulsifier, Stabilizer, Thickener
INS 1413	Emulsifier, Stabilizer, Thickener

INS 1440	Emulsifier, Stabilizer, Thickener
INS 1422	Emulsifier, Stabilizer, Thickener
INS 1411	Emulsifier, Stabilizer, Thickener
INS 440	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener

The food additives listed above have been authorized as “Thickening Agents” according to CXS 73-1981. It is suggested that this authorization be interpreted as authorization of thickeners.

ISDI comments: ISDI supports the proposal

INS 322 (i)	Antioxidant, Emulsifier
INS 471	Antifoaming agent, Emulsifier, Stabilizer

The food additives listed above have been authorized as emulsifiers according to CXS 73-1981.

INS 500 (ii)	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener
INS 500 (i)	Acidity regulator, Anticaking agent, Emulsifying salt, Raising agent, Stabilizer, Thickener
INS 501 (ii)	Acidity regulator, Stabilizer, Raising agent
INS 501 (i)	Acidity regulator, Stabilizer
INS 170 (i)	Acidity regulator, Anticaking agent, Colour retention agent, Sequestrant
INS 330	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant
INS 331 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 331 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 270	Acidity regulator
INS 260	Acidity regulator, Preservative

The food additives listed above have been authorized as “pH Adjusting Agents” according to CXS 73-1981. “pH Adjusting Agent” is not a functional class of a food additive but one of the technological purposes of the functional class “Acidity regulator”. It is therefore suggested that the authorization be interpreted as authorization of acidity regulators.

ISDI comments: ISDI supports the proposal with one exception: calcium carbonate INS 170 (i) as different function class as per the latest amendment of the GSFA (2019). See excerpt below:

CALCIUM CARBONATE

INS 170(i)	Calcium carbonate	Functional Class: Acidity regulator, Anticaking agent, Colour, Firming agent, Flour treatment agent, Stabilizer
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INS 307 b	Antioxidant
INS 307 a	Antioxidant
INS 307 c	Antioxidant
INS 304	Antioxidant
INS 300	Acidity regulator, Antioxidant, Flour treatment agent, Sequestrant
INS 301	Antioxidant
INS 303	Antioxidant

The food additives listed above have been authorized as antioxidants according to CXS 73-1981.

INS 290	Carbonating agent, Foaming agent, Packaging gas, Preservative, Propellant
INS 941	Foaming agent, Packaging gas, Propellant

The food additives listed above have not been authorized as food additives in section 4 of CXS 73-1981 but as packing media in section 7 (Packaging) as follows: “Nitrogen and carbon dioxide may be used as packing media”. It is suggested that this provision be interpreted as the use of Nitrogen (INS 941) and Carbon dioxide (INS 290) as packaging gases. This would ensure consistency with CXS 72-1981 and CXS 74-1981. It is suggested that the provision in section 7 be removed as it may lead to confusion.

(CXS 73-1981) for foods corresponding to that standard: singly or in combination with other sodium containing additives.”

ISDI comment: we agree with the proposal to drop Note 240 whenever Note 319 is used in association

It is proposed to consider dropping note 319 wherever it is used together with note 239, as note 319 is related to CXS 73-1981, while note 239 excludes products conforming to CXS 73-1981. This is the case with the provisions for Sodium acetate (INS 262 (i)), Sodium hydroxide (INS 524) and Sodium lactate (INS 325).

ISDI comment: we agree with the proposal to drop Note 319 whenever Note 239 is used in association

On the possible replacement of note 239 by note XS73 see paragraph 3 above.

ISDI comment: in order to complete the full alignment, ISDI as identified several remaining issues needing CCNSFDU attention:

INS	Additives	ISDI proposal
330	Citric acid	A note will have to be added for citric acid and sodium salt to limit within the sodium levels. E.g. Note 240 "The use level is within the limit for sodium listed in the Standard for Canned Baby Foods (CODEX STAN 73-1981)."
331i, 331ii, 331iii	Monosodium citrate (INS 331i), Disodium monohydrogen citrate (INS 331ii), Trisodium citrate (INS 331iii),	Any sodium citrate should be considered as they are sodium salts of citric acid. The group should be approved and supported. CXS 73 just states "citric acid and sodium salt" are permitted, without specifying the INS. Therefore, ISDI considers that further evaluation is needed on the current use of that additive in foods covered by this specific commodity standard and we should come with a conclusion either at coming CCFA or next CCNFSDU
300	L-Ascorbic acid	CXS 73 limits the use within the limit for sodium. Addition of Note 240 "The use level is within the limit for sodium listed in the Standard for Canned Baby Foods (CODEX STAN 73-1981)." is needed
307a, b, c	Tocopherols	CXS 73 states 300mg/kg fat, singly or in combination with tocopherols. Therefore, Note 168 should be added for products falling under CXS73
151	Silicon dioxide, amorphous	There is currently a Note 318 "In dry cereal only". We consider that Note XS73 should be added to exclude the provision from canned baby foods

Part C
Standard for Processed Cereal-based Food for Infants and Young Children
(CXS 74-1981)

1. According to box A of the decision tree on the alignment developed by the CCFA the following amendments should be made regarding the food additive provisions of the commodity standard:

INS 322 (i)	Lecithine
INS 471	Mono- and diglycerides of fatty acids
INS 270	L(+) Lactic acid, L-, D-, and DL-
INS 260	Acetic acid, glacial
INS 261 (i)	Potassium acetates
INS 296	Malic acid, DL-L(+) form only
INS 325	Sodium lactate (solution) — L(+) form only
INS 326	Potassium lactate (solution) — L(+) form only
INS 327	Calcium lactate — L(+) form only
INS 331 (i)	Monos Sodium dihydrogen citrate
INS 331 (iii)	Trisodium citrate
INS 332 (i)	Monop Potassium dihydrogen citrate
INS 333 (iii)	Tri Calcium citrate
INS 334	L(+)- Tartaric acid, L(+) form only
INS 335 (ii)	Dis Sodium L(+) -tartrate
INS 337	Potassium sodium L(+)-tartrate L(+) form only
INS 339 (i)	Monos Sodium dihydrogen orth phosphate
INS 339 (ii)	Disodium hydrogen orth phosphate
INS 339 (iii)	Trisodium orth phosphate
INS 340 (i)	Monop Potassium dihydrogen orth phosphate
INS 340 (ii)	Dipotassium hydrogen orth phosphate
INS 340 (iii)	Tripotassium orth phosphate
INS 341 (i)	Monos Calcium dihydrogen orth phosphate
INS 341 (ii)	Dis Calcium hydrogen orth phosphate
INS 341 (iii)	Tricalcium orth phosphate
INS 307 b	Mixed-t Tocopherols concentrate, mixed
INS 307 a	Alpha-t Tocopherol, d-alpha
INS 307 c	Tocopherol, dl-alpha
INS 304, 305	L- Ascorbyl palmitate esters
INS 300	L- Ascorbic acid, L-
INS 414	Gum Arabic (Acacia gum)
INS 440	Pectins (Amidated and Non-Amidated)
INS 1420	Starch acetate esterified with acetic anhydride

ISDI comments: ISDI supports the proposed changes with one exception:

As lecithin authorization does not seem to be specific in the commodity standard, clarification is needed to understand if both additives 322i and 322ii are currently used in foods characterized under this standard. ISDI could come back with clarification at next CCFA or CCNFSDU.

2. The functional classes of the authorized food additives are as follows according to CXG 36-1986 (listed in the order as authorized in CXS 74-1981):

INS 322 (i)	Antioxidant, Emulsifier
INS 471	Antifoaming agent, Emulsifier, Stabilizer
INS 472 a	Emulsifier, Sequestrant, Stabilizer
INS 472 b	Emulsifier, Sequestrant, Stabilizer
INS 472 c	Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer
The food additives listed above have been authorized as emulsifiers according to CXS 74-1981.	
INS 500 (ii)	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener
INS 501 (ii)	Acidity regulator, Stabilizer, Raising agent
INS 170 (i)	Acidity regulator, anticaking agent, Colour retention agent, Sequestrant
INS 270	Acidity regulator
INS 330	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant
INS 260	Acidity regulator, Preservative
INS 261 (i)	Acidity regulator, Preservative
INS 262 (i)	Acidity regulator, Preservative, Sequestrant
INS 263	Acidity regulator, Preservative, Stabilizer
INS 296	Acidity regulator
INS 325	Acidity regulator, Antioxidant, Bulking agent, Emulsifier, Emulsifying salt, Humectant, Thickener
INS 326	Acidity regulator, Antioxidant, Emulsifier, Humectant
INS 327	Acidity regulator, Emulsifying salt, Firming agent, flour treatment agent, Thickener
INS 331 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 331 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 332 (i)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 332 (ii)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 333 (iii)	Acidity regulator, Firming agent, Emulsifying salt, Sequestrant, Stabilizer
INS 507	Acidity regulator
INS 524	Acidity regulator
INS 525	Acidity regulator
INS 526	Acidity regulator, Firming agent
INS 575	Acidity regulator, Raising agent Sequestrant
INS 334	Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant
INS 335 (ii)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 337	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 338	Acidity regulator, Antioxidant, Sequestrant
INS 339 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 339 (ii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener
INS 339 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Preservative, Sequestrant, Stabilizer, Thickener
INS 340 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener

INS 340 (ii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener
INS 340 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Humectant, Sequestrant, Stabilizer, Thickener
INS 341 (i)	Acidity regulator, Anticaking agent, Emulsifying salt, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener, Firming agent, Flour treatment agent
INS 341 (ii)	Acidity regulator, Anticaking agent, Emulsifying salt, Humectant, Raising agent, Stabilizer, Thickener, Firming agent, Flour treatment agent
INS 341 (iii)	Acidity regulator, Anticaking agent, Emulsifier, Emulsifying salt, Humectant, Raising agent, Stabilizer, Thickener, Firming agent, Flour treatment agent

The food additives listed above have been authorized as acidity regulators according to CXS 74-1981.

INS 307 b	Antioxidant
INS 307 a	Antioxidant
INS 307 c	Antioxidant
INS 304, 305	Antioxidant
INS 300	Acidity regulator, Antioxidant, Flour treatment agent, Sequestrant
INS 301	Antioxidant
INS 302	Antioxidant
INS 303	Antioxidant

The food additives listed above have been authorized as antioxidants according to CXS 74-1981.

INS 503 (i)	Acidity regulator, Raising agent
INS 503 (ii)	Acidity regulator, Raising agent
INS 500 (i)	Acidity regulator, Anticaking agent, Emulsifying salt, Raising agent, Stabilizer, Thickener
INS 500 (ii)	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener

The food additives listed above have been authorized as raising agents according to CXS 74-1981.

INS 410	Emulsifier, Stabilizer, Thickener
INS 412	Emulsifier, Stabilizer, Thickener
INS 415	Emulsifier, Foaming agent, Stabilizer, Thickener
INS 440	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener
INS 1404	Emulsifier, Stabilizer, Thickener
INS 1410	Emulsifier, Stabilizer, Thickener
INS 1412	Emulsifier, Stabilizer, Thickener
INS 1413	Emulsifier, Stabilizer, Thickener
INS 1414	Emulsifier, Stabilizer, Thickener
INS 1422	Emulsifier, Stabilizer, Thickener
INS 1420	Emulsifier, Stabilizer, Thickener
INS 1450	Emulsifier, Stabilizer, Thickener
INS 1451	Emulsifier, Stabilizer, Thickener

The food additives listed above have been authorized as thickeners according to CXS 74-1981.

INS 551	Anticaking agent, Carrier, Antifoaming agent
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The food additive listed above has been authorized as anticaking agent according to CXS 74-1981.

INS 290	Carbonating agent, Foaming agent, Packaging gas, Preservative, Propellant
INS 941	Foaming agent, Packaging gas, Propellant

The food additives listed above have been authorized as packaging gases according to CXS 74-1981.

3. The answer to the question in box B of the decision tree on the alignment developed by the CCFA is “YES”.

The food additive provisions are contained in the food category 13.2.

The food additive provision for Hydroxypropyl starch (INS 1440) in food category 13.2 is correctly associated with the note 237 “Excluding products conforming to the *Standard for Processed Cereal-based Baby Foods for Infants and Young Children* (CXS 74-1981)”.

In the interest of consistency with other XS-notes and in the interest of ease of understanding, it is proposed to consider replacing note 237 by note XS74.

ISDI comment: [we agree with the proposal to replace Note 237 with Note XS74](#)

The food additive provisions in food category 13.2 for Phosphates go beyond those in CXS 74-1981 and include additionally Phosphates with the INS numbers 342 (i)-(ii), 343 (i)-(iii), 450 (i)-(iii), (v)-(vii), (ix), 451 (i)-(ii), 452 (i)-(v) and 542. Taking into account that (a) the Phosphates listed in food category 13.2 share a group ADI and (b) their use is restricted to that of an acidity regulator by note 230 the provision for Phosphates in food category 13.2 may be considered as conforming to the related provisions in CXS 74-1981.

ISDI comment: [we agree with the proposal](#)

4. According to box C of the decision tree on the alignment developed by the CCFA note XS73 should be added to the following draft and proposed draft food additive provisions in food category 13.2:

Isomalt	INS 953
Lactitol	INS 966
Maltitol	INS 965 (i)
Maltitol syrup	INS 965 (ii)
Sorbitol	INS 420 (i)
Sorbitol syrup	INS 420 (ii)
Thaumatococin	INS 957
Xylitol	INS 967

ISDI comment: [we note that there may be a mistake whereby “note XS73” is written rather than “note XS74”.](#)

[In addition, we are confused with the presence of those additives in the alignment work. These are sweeteners which are not yet in either CXS73 nor CXS74. We would appreciate clarification on the reason of their presence in this document.](#)

5. The answer to the question in box D of the decision tree on the alignment developed by the CCFA is “YES” except for Potassium ascorbate (INS 303). The food additive provisions are contained in the food category 13.2.

ISDI comment: [in addition to Potassium ascorbate \(INS 303\), the following additives are also permitted in CXS 74 but missing in FC 13.2:](#)

[Monocalcium citrate INS 333\(i\)](#)

[Dicalcium citrate INS 333\(iii\)](#)

[In CXS 74, the group “Calcium Citrate INS 333” is permitted but only Tricalcium Citrate INS 333\(iii\) is currently permitted in FC 13.2.](#)

6. The answer to the question in box F of the decision tree on the alignment developed by the CCFA is “NO” for Potassium ascorbate (INS 303).

ISDI comment: [The answer is “NO” for Monocalcium citrate \(INS 333\(i\)\) and dicalcium citrate \(INS 333\(ii\)\) as well.](#)

7. For Potassium ascorbate (INS 303) there are no specifications established for this food additive (see [List of Codex Specifications for Food Additives \(CXM 6-2019\)](#)). According to the advice in box G of the decision tree on the alignment developed by the CCFA the food additive provision for Potassium ascorbate (INS 303) should be removed from the commodity standard in view of the consideration above and the fact that other food additives of the same functional class (Antioxidant) are authorized as alternative.

ISDI comment: we question the removal of potassium ascorbate. It is currently present in standard 74-1981. We consider that further evaluation is needed on the current of that additive in foods covered by this specific commodity standard.

For monocalcium citrate (INS 333(i)) and dicalcium citrate (INS 333(ii)), there are no specifications established for these food additives, only for tricalcium citrate (INS 333(iii)). However, given that the group is currently permitted in CXS 74, we believe the group should be permitted in FC 13.2.

8. According to the advice in box E of the decision tree on the alignment developed by the CCFA the food additive provisions in food category 13.2 of the GSFA are considered to be in line with the provisions of the commodity standard CXS 74-1981 (except for those food additives specifically dealt with above).

ISDI comment: in order to complete the alignment, ISDI has identified some remaining issues requesting the attention of the CCNFSDU:

INS	Additives	ISDI proposal
322	Lecithin	Changing name to INS322(i) may limit use of 322(ii).
500ii	Sodium hydrogen carbonate	The note 320 is not as such present from commodity standard 74-1981
262i	Sodium acetates	The note 320 is not as such present from commodity standard 74-1981
325	Sodium lactate (solution) - L(+) form only	The note 320 is not as such present from commodity standard 74-1981
331i	Monosodium citrate	The note 320 is not as such present from commodity standard 74-1981
331ii	Trisodium citrate	The note 320 is not as such present from commodity standard 74-1981
524	Sodium hydroxide	The note 320 is not as such present from commodity standard 74-1981
334	L(+)-Tartaric acid - L(+) form only	Suggestion to remove note 45 as not in CXS 74, need note 83 Note 45 "as tartaric acid" Note 83 "L(+)-form only"
335ii	Disodium tartrate	Suggestion to remove note 45 as not in CXS 74 Note 45 "as tartaric acid"
337	Potassium sodium L(+) tartrate L(+) form only	Suggestion to remove note 45 as not in CXS 74, need note 83 and note 320 Note 45 "as tartaric acid" Note 83 "L(+)-form only" Note 320 "Within the limit for sodium listed in the Codex Standard"

		for Processed Cereal-based Foods for Infants and Young Children (CODEX STAN 74-1981) for foods corresponding to that standard : singly or in combination with other sodium containing additives.”
307a, b, c	Tocopherols	CXS 74 states 300mg/kg fat, singly or in combination with tocopherols. Therefore, Note 168 should be added for products falling under CXS74.
301	Sodium ascorbate	The note 320 is not as such present from commodity standard 74-1981
500i	Sodium carbonate	The note 320 is not as such present from commodity standard 74-1981
500ii	Sodium hydrogen carbonate	The note 320 is not as such present from commodity standard 74-1981
551	Silicon dioxide (amorphous)	No limitation as carry-over, Note 65 should be removed

Part D

Standard for Follow-up Formula (CXS 156-1987)

1. According to box A of the decision tree on the alignment developed by the CCFA the following amendments should be made regarding the food additive provisions of the commodity standard:

<u>INS 412</u>	Guar gum
<u>INS 410</u>	<u>Carob</u> locust bean gum
<u>INS 1412</u>	Distarch phosphate
<u>INS 1414</u>	Acetylated distarch phosphate
<u>INS 1413</u>	Phosphated distarch phosphate
<u>INS 1422</u>	Acetylated distarch adipate
<u>INS 407</u>	Carrageenan
<u>INS 440</u>	Pectins
<u>INS 322 (i)</u>	Lecithin
<u>INS 471</u>	Mono- and Diglycerides <u>of fatty acids</u>
<u>INS 500 (ii)</u>	Sodium hydrogen carbonate
<u>INS 500 (i)</u>	Sodium carbonate
<u>INS 331 (III)</u>	Tris Sodium citrate
<u>INS 331 (i)</u>	<u>Sodium dihydrogen citrate</u>
<u>INS 501 (ii)</u>	Potassium hydrogen carbonate
<u>INS 501 (i)</u>	Potassium carbonate
<u>INS 332(i)</u>	<u>Potassium dihydrogen citrate</u>
<u>INS 332 (ii)</u>	Tri Potassium citrate
<u>INS 524</u>	Sodium hydroxide
<u>INS 525</u>	Potassium hydroxide
<u>INS 526</u>	Calcium hydroxide

<u>INS 270</u>	L(+) Lactic acid, <u>L-, D-, and DL-</u> L(+) Lactic acid producing cultures
<u>INS 330</u>	Citric acid
<u>INS 307 b</u>	Mixed-t Tocopherols concentrate, <u>mixed</u>
<u>INS 307 a</u>	Alpha -Tocopherol, <u>d-alpha</u>
<u>INS 307 c</u>	Tocopherol, <u>dl-alpha</u>
<u>INS 304</u>	L -Ascorbyl palmitate
<u>INS 300</u>	L -Ascorbic acid, <u>L-</u> and its Na, Ca salts
<u>INS 301</u>	<u>Sodium ascorbate</u>
<u>INS 302</u>	<u>Calcium ascorbate</u>

ISDI comments: ISDI agrees with the proposed modifications

2. The functional classes of the authorized food additives are as follows according to CXG 36-1986 (listed in the order as authorized in CXS 72-1981):

INS 412	Emulsifier, Stabilizer, Thickener
INS 410	Emulsifier, Stabilizer, Thickener
INS 1412	Emulsifier, Stabilizer, Thickener
INS 1414	Emulsifier, Stabilizer, Thickener
INS 1413	Emulsifier, Stabilizer, Thickener
INS 1422	Emulsifier, Stabilizer, Thickener
INS 407	Emulsifier, Stabilizer, Thickener, Bulking agent, Carrier, Gelling agent, Glazing agent, Humectant
INS 440	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener

The food additives listed above have been authorized as „Thickening agents“ according to CXS 156-1987. It is suggested that this authorization be interpreted as authorization of thickeners.

ISDI comments: ISDI agrees with this assessment

INS 322 (i)	Antioxidant, Emulsifier
INS 471	Antifoaming agent, Emulsifier, Stabilizer

The food additives listed above have been authorized as emulsifiers according to CXS 156-1981.

ISDI comments: ISDI agrees with this assessment

INS 500 (ii)	Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener
INS 500 (i)	Acidity regulator, Anticaking agent, Emulsifying salt, Raising agent, Stabilizer, Thickener
INS 331 (i)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 331 (iii)	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer
INS 501 (ii)	Acidity regulator, Stabilizer, Raising agent
INS 501 (i)	Acidity regulator, Stabilizer
INS 332 (i)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 332 (ii)	Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer
INS 524	Acidity regulator
INS 525	Acidity regulator
INS 526	Acidity regulator, Firming agent
INS 270	Acidity regulator
INS 330	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant

The food additives listed above have been authorized as “pH Adjusting Agents” according to CXS 156-1987. “pH Adjusting Agent” is not a functional class of a food additive but one of the technological purposes of the functional class “Acidity regulator”. It is therefore suggested that the authorization be interpreted as authorization of acidity regulators.

ISDI comments: ISDI agrees with this assessment

INS 307 b	Antioxidant
INS 307 a	Antioxidant
INS 307 c	Antioxidant
INS 304	Antioxidant
INS 300	Acidity regulator, Antioxidant, Flour treatment agent, Sequestrant
INS 301	Antioxidant
INS 302	Antioxidant

The food additives listed above have been authorized as antioxidants according to CXS 156-1987.

ISDI comments: ISDI agrees with this assessment

INS 290	Carbonating agent, Foaming agent, Packaging gas, Preservative, Propellant
INS 941	Foaming agent, Packaging gas, Propellant

The food additives listed above have not been authorized as food additives in section 4 of CXS 73-1981 but as packing media in section 7.1 (Packaging) as follows: “Nitrogen and carbon dioxide may be used as packing media”. It is suggested that this provision be interpreted as the use of Nitrogen (INS 941) and Carbon dioxide (INS 290) as packaging gases. This would ensure consistency with CXS 72-1981 and CXS 74-1981. It is suggested that the provision in section 7 be removed as it may lead to confusion.

ISDI comments: ISDI support Germany proposal to remove the provisions from Section 7, and provided that the provisions for carbon dioxide and nitrogen as packaging gases are added into the GSFA for FC 13.1.2 at GMP with Note 59.

3. Whereas the food additive provisions of CXS 156-1987 are related to the food categories 13.1 and 13.1.2 of the GSFA the answer to the question in box B of the decision tree on the alignment developed by the CCFA is “YES”. The provision for Citric and fatty acid esters of glycerol (INS 472 c) in food category 13.1 is not listed in the commodity standard. It shall not be applicable to the subcategory 13.1.2, but only to the subcategories 13.1.1 and 13.1.3. Therefore this provision should be removed in food category 13.1 and introduced in the subcategories 13.1.1 and 13.1.3.

The subcategory 13.1.2 does not contain food additive provisions which are not listed in the commodity standard.

ISDI comments: ISDI support Germany proposal to include the provision in subcategories 13.1.1 and 13.1.3

4. The answer to the question in box D of the decision tree on the alignment developed by the CCFA is “YES” except for Carbon dioxide (INS 290) and Nitrogen (INS 941). The food additive provisions are contained in the food category 13.1.2.

ISDI comments: ISDI agrees with this assessment

5. According to the advice in box E of the decision tree on the alignment developed by the CCFA the food additive provisions in food category 13.1.2 of the GSFA are considered to be in line with the provisions of the commodity standard CXS 156-1987 except for Carbon dioxide (INS 290) and Nitrogen (INS 941).

ISDI comments: ISDI agrees with this assessment

For full alignment according to box J of the decision tree on the alignment developed by the CCFA it is suggested that provisions for Carbon dioxide (INS 290) and Nitrogen (INS 941) be introduced in food category 13.1.2, both at GMP with note 59 associated.

ISDI comments: ISDI agrees with this proposal

For full alignment, ISDI would nonetheless have additional proposed changes to FC 13.1.2 in the GSFA:

INS	Additive name	ML	Footnotes	ISDI proposal
304, 305	Ascorbyl esters	50 mg/kg	72 on the ready to eat basis	New Note needed to reflect the note in CXS

			<p>187 Ascorbyl palmitate (INS 304) only</p> <p>315 Singly or in combination: ascorbic acid (INS300), sodium ascorbate (INS301), calcium ascorbate (INS 302), and ascorbyl palmitate (INS304)</p>	<p>156-1987 "as ascorbic acid"</p> <p>e.g. Note 70 ("As the acid")</p>
307a, b, c	Tocopherols	30mg/kg	72 on the ready to eat basis	<p>Need new Note for singly or in combination e.g. Note 168 "Singly or in combination: d-alpha-tocopherol (INS 307a), tocopherol concentrate, mixed (INS 307b) and dl-alpha-tocopherol (INS 307c)."</p>