ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 45th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Prepared to Support the Participation of Codex Communities of Practice Supported by GFoRSS

2-6 November 2026 • Nuremberg, Germany

Disclaimer and Disclosure of Interest

It is important to note that the proposed analysis and associated conclusions and recommendations stem from the work of regional expert working groups. The analysis and associated recommendations or positions are presented as mere suggestions and should not be considered as a direction or final recommendation to the competent authority empowered to develop and endorse Codex positions.

Disclosure of Interest: *Some experts involved in the development of this analysis contribute to various food safety and nutrition regulatory capacity building initiatives funded by other Governments, aid agencies, industry and international organizations.*

OBJECTIVES

This document offers an analysis of priority agenda items to support participation in the 45th **session of the Codex Committee on Nutrition and Foods for Special Dietary Uses**, taking place in Nuremberg, Germany, from the **2nd to** the **6th of November, 2026**.

This document is intended for potential use by the Codex communities of practice promoted by the Global Food Regulatory Science Society (GFoRSS), as part of its contribution to the Arab Codex Initiative. This capacity-building effort seeks to enhance awareness, strengthen technical preparedness, and support effective and informed participation of representatives from Arab and CCNE Member Countries and Observers in international standard-setting processes, including Codex meetings.

This document provides an analysis of selected priority agenda items, identified through a scoring methodology applied by Arab and CCNE Member Countries, with the objective of supporting the development of national and regional positions. The analysis is indicative in nature and is intended for informational purposes only; it does not constitute, nor should it be interpreted as, an official position of the partner organizations, their memberships, or their management.

The analysis presented in this document provides a factual review of key agenda items of CCNFSDU45, pertaining to:

A. **Agenda Item 4:** NRVs-R for persons aged 6–36 months
B. **Agenda Item 5:** Draft Standard for Foods for Older Infants and Young Children
C. **Agenda Item 6:** Technological Justification for Several Food Additives

A. Agenda item 4: NRVs-R for persons aged 6–36 months.

Document Number: **CX/NFSDU 26/45/4**, **Add.1 and Add.2**

Status in Codex Process: Step 4

Background

CCNFSDU44 completed the first part of this work. It agreed the General Principles for establishing NRVs-R for persons aged 6–36 months and NRVs-R for 14 nutrients (vitamins A, B6, D, E, thiamin, riboflavin, niacin, pantothenic acid; calcium, copper, iodine, potassium, zinc; and protein). CAC47 adopted these into the Guidelines on Nutrition Labelling (CXG 2-1985), with the General Principles as Annex 1, Part B and the values in section 3.4.4.2. The adopted text specifies that the NRVs-R apply to the labelling of foods for special dietary uses for older infants and young children for which Codex texts exist (CX/NFSDU 26/45/4, paras 1–6).

The Electronic Working Group (EWG), chaired by Ireland and co-chaired by Costa Rica and the USA, was re-established with two tasks: (i) apply the Stepwise Process to propose NRVs-R for 6–12 months (older infants), 12–36 months (young children) and 6–36 months (combined) for vitamins C, K, B12, folate and biotin, and for magnesium, iron, selenium, manganese and phosphorus; and (ii) update the dietary intake reference value (DIRV) tables with newer data from Japan's NIHN (2020) and the Nordic Council of Ministers (NCM 2023). The EWG has 44 members, including **Egypt** and **Saudi Arabia** from the region. It ran three consultation papers between April 2025 and June 2026 (paras 7–13; Add.1, Appendix IV).

CCNFSDU45 is invited to (i) consider the updated NIHN 2020 and NCM 2023 DIRVs; (ii) adopt the proposed NRVs-R for older infants and young children; and (iii) adopt the proposed NRVs-R for the combined 6–36-month group (para 152). A virtual working group (VWG) on **27 October 2026** will discuss the proposals before the session, and its report will be issued as a CRD.

Add.2 compiles the comments submitted in reply to CL 2026/46-NFSDU by 21 Codex Members, the European Union and three Observers (EFAD, FIA and ISDI), including five countries from the region: **Egypt, Lebanon, Morocco, Saudi Arabia and the UAE**. These comments were made after the EWG consultations and are distinct from the EWG proposals themselves. They show that differences remain on vitamin B12, magnesium, iron and manganese, and they raise further points on the phosphorus safety benchmark, the combined 6–36-month values and implementation.

Table 1. NRVs-R proposed by the EWG for the ten remaining nutrients, with EWG feedback and later comments (CX/NFSDU 26/45/4, Table 2; Add.1, Appendix III; Add.2)

Nutrient	6–12 mo	12–36 mo	6–36 mo	Lowest UL (6–36 mo)	General pop. NRV-R	EWG support and Add.2 comments
Vitamin C (mg)	30	30	30	400	100	Unanimous in EWG; no objections in Add.2
Vitamin K (µg)	10	13	12	–	60	Unanimous in EWG; Morocco and UK query NCM age averaging
Folate (µg DFE)	80	120	100	200[a]	400	Unanimous in EWG; no objections in Add.2
Vitamin B12 (µg)	0.90	1.2	1.1	–	2.4	**Divided:** EU and Norway favour 1.2 µg for older infants; UAE, Lebanon and ISDI support 0.90 µg
Biotin (µg)	6	14	10	–	30	Unanimous in EWG; no objections in Add.2
Magnesium (mg)	80	105	90	65[b]	310	**Divided:** EU favours 95 mg combined; Norway and Uruguay support 90 mg
Iron (mg)	11	7	9	20	14 (15%) / 22 (10%)	**Values supported;** views differ on stating the 10% absorption basis
Selenium (µg)	15	15	15	55	60	Unanimous in EWG; no objections in Add.2
Manganese (mg)	0.50	0.50	0.50	2	3	**Divided:** several Members and Observers, incl. UAE and Lebanon, supported 0.83 mg for young children in their Add.2 submissions.
Phosphorus (mg)	165	235	200	3000[c]	700	Values supported; EU, Colombia, Morocco and UK question the 3000 mg benchmark

[a] EFSA UL for supplemental folate only. [b] NHMRC/MOH and IOM UL for supplemental magnesium only (children 1–8 y). [c] As shown in Table 2 of CX/NFSDU 26/45/4; Step 6 in Add.1 instead uses the EFSA ADI for phosphates of 40 mg P/kg bw/day (≈344 mg for an 8.6 kg infant and ≈476 mg for an 11.9 kg child). Green = agreed; amber = points still under discussion.

Analysis

Six of the ten nutrients (vitamins C and K, folate, biotin, selenium and phosphorus) had unanimous support from all respondents in the EWG consultations, so the regional analysis concentrates on the four nutrients where views diverge (B12, magnesium, iron and manganese). It also covers cross-cutting methodological points and internal inconsistencies that should be corrected before the values are finalised, while also addressing subsequent comments in Add.2 concerning the phosphorus safety benchmark and the application of combined-age values.

I. Cross-cutting issues

- **No regional reference-setting body, but regional data exist.** The EWG declined requests to add DIRVs from scientific bodies beyond FAO/WHO and the six recognised authoritative scientific bodies (RASBs), so as to keep the same evidence base used for the 14 adopted nutrients and for the general-population NRVs (para 38). This consistency is methodologically sound, and none of the RASBs is located in the Eastern Mediterranean or Near East. The absence of a regional reference-setting body is not the same as an absence of regional data, however. National intake surveys and micronutrient status data could help assess how well the proposed values apply to regional diets, notably for iron and B12, and inform future reviews, without reopening the agreed evidence-selection framework.
- **Step 4 is applied case by case, and the choice of statistic varies.** Most of the deliberation took place at Step 4 (expert review of rigour, data quality and all available evidence). The statistic chosen differs between nutrients: the mean for B12 (older infants) and magnesium (young children), the median for manganese, and a value "midway" between extremes for biotin. Each choice is explained, but together they leave Step 4 open to the perception that it is applied ad hoc. In Add.2, the UK and Uruguay ask for stronger justification where values depart from the Stepwise Process, and the UAE and ISDI ask that such rationales be clearly articulated. Documenting the decision rules in the information document on the Stepwise Process would improve transparency for any future review.
- **Rounding of exact half-values is not consistent.** Under the agreed rounding rules (Rep24/NFSDU, para 50), biotin 5.5 µg was rounded up to 6 µg, B12 1.05 µg up to 1.1 µg and phosphorus 199.5 mg up to 200 mg. Magnesium 92.5 mg, however, was rounded down to 90 mg "to be consistent with rounding rules" (para 99). The rules do not specify how ties are broken. Indonesia (Add.2) also notes that the cited reference does not appear to contain the rule that values above 20 are rounded to the nearest 5, and asks for the correct source.
- **Application of the combined 6–36-month values.** Each combined value is the mean of the older-infant and young-children values. In Add.2, Peru considers it inappropriate to group 6–36 months because requirements differ between the two age groups, and Lebanon asks for clear labelling guidance on when the single combined values apply and when the age-specific values should be used. The UK suggests a footnote explaining how the combined values are derived and questions the averaging method where the young-children DIRV is itself an average of NCM values for ages 1, 2 and 3 years, a point also raised by Morocco.

- **The phosphorus safety benchmark needs correcting.** Table 2 of the main paper shows 3000 mg as the lowest UL for phosphorus, whereas Step 6 in Add.1 relies on the EFSA ADI for phosphates (≈344 mg for an 8.6 kg infant and ≈476 mg for an 11.9 kg child). The EU proposes replacing 3000 mg with 344 mg and amending the footnote; Colombia and Morocco ask for clarification of the 3000 mg figure; and the UK asks that the 476 mg value for young children be added. The proposed NRVs-R (165, 235 and 200 mg) remain below the ADI-based values.
- **NRVs-R are labelling references, not composition targets.** Several values sit close to, or above, upper levels that apply only to specific sources (folate and magnesium ULs for supplemental forms; the EFSA safe supplemental iron level of 5 mg for older infants; the phosphate ADI). The final text should make clear that NRVs-R are used for nutrition labelling (%NRV declarations) and do not set minimum or maximum content, which remains a matter for the commodity standards, including the draft standard under Agenda Item 5.

II. Vitamin B12: 0.90 µg proposed for older infants as a compromise

- **The DIRVs rest on different derivation methods.** EFSA and NCM (1.5 µg) derive their values by allometric extrapolation from an adult AI based on biomarkers of cobalamin status, with observed EU intakes used as supporting evidence. NIHN, IOM and NHMRC/MOH (0.5 µg) derive theirs from breast-milk intakes of young infants, scaled up. The median is 1.5 µg using recent data only and 0.5 µg using all data. The EWG proposes the mean of all Category 2 DIRVs (0.90 µg) as a compromise, which also keeps the older-infant value below the young-children value of 1.2 µg (Add.1, Table 4). Both approaches carry uncertainty: breast-milk B12 depends on maternal status and lactation stage, while cut-off values for biomarkers of insufficiency in infants are not well established.
- **Submitted positions remain divided (Add.2, pp. 9–10, 13, 15 and 18–19).** The EU and Norway support 1.2 µg for older infants; Norway argues that biomarker-based extrapolation is the more robust approach and points to uncertainty in using breast-milk concentrations. The UAE and Lebanon support 0.90 µg and oppose any further increase, as does ISDI, which cites a recent pooled analysis of breast-milk B12 from well-nourished mothers that is consistent with the lower 0.5 µg value. New Zealand would prefer 0.5 µg but accepts the compromise. The UK and Uruguay ask for a stronger justification for using the mean rather than the median. The 0.90 µg compromise remains defensible and biologically ordered.

III. Magnesium: rounding of the combined value and the scope of the UL

- **The young-children value is a blend of two approaches.** Balance-study DIRVs (70–80 mg) may underestimate requirements, while EU intake-based DIRVs (170 mg) may overestimate them. The EWG took the mean of all DIRVs (105 mg), which it describes as 28% of the way between the two. The older-infant value (80 mg) was unanimously supported, and 105 mg was supported by 10 of 11 Codex Members. The UK (Add.2) asks for a clearer justification, including why the older FAO/WHO 2004 value was included in the mean.
- **The combined value is 92.5 mg, rounded to 90 mg.** Nine of eleven Codex Members accepted 90 mg in the EWG. In Add.2, the EU supports 95 mg, while Norway and Uruguay support 90 mg. As noted above, rounding down departs from how other exact half-values were treated. The UL of 65 mg shown in Table 2 applies to

supplemental magnesium only, for ages 1–8 years, yet Appendix II states that no UL is available. Morocco asks for a clarifying comment because the table gives the impression that the NRV-R exceeds the UL, and the EU and EFAD note that the footnote reference is missing from the table.

IV. Iron: 11 mg (6–12 months), 7 mg (12–36 months), 9 mg (6–36 months), without stated absorption levels

- **The approach is conservative and fits the region.** The EWG used only Category 1 (factorial) DIRVs based on absorption of 10% or less, given the high risk of iron deficiency in this age group and the limited bioavailability data for 6–36-month-olds. This is relevant to the region, where complementary diets are often cereal-based. WHO estimates that around 40% of children aged 6–59 months worldwide are anaemic, and anaemia remains a significant public health problem in many Arab and CCNE countries. The values themselves are widely supported, including by Egypt, Saudi Arabia and the UAE.
- **Views differ on whether to state the absorption basis (Add.2).** The UAE, Malaysia and ISDI propose a footnote stating that the values assume 10% bioavailability and that governments may consider other assumptions where justified by local complementary feeding practices and dietary patterns. The EU asks that the 10% dietary absorption be reported next to the values, and Lebanon's submission asks that bioavailability assumptions be defined in footnotes. New Zealand and Norway support omitting absorption references, as the EWG concluded, and Uruguay prefers to omit them from the table while keeping them in the supporting documentation. New Zealand also notes that FAO/WHO scoping work on iron intake values for this age group may warrant a later review. The combined value of 9 mg is below the 11 mg older-infant value; this follows from the Step 5 averaging used for all nutrients, but it is most consequential for iron.
- **Several safety benchmarks appear alongside the values.** EFSA (2024) set a safe supplemental level of 5 mg/day for older infants (excluding formula) and a safe total intake of 10 mg/day for young children; the lowest UL is 20 mg. These benchmarks do not conflict with a labelling reference, but they reinforce that the NRVs-R are not fortification targets.

V. Manganese: 0.50 mg for all age groups

- **The final value was not consulted on.** In CP3, 10 of 11 Codex Members supported 0.83 mg for young children and 0.67 mg for the combined group. After feedback raised safety concerns, the Chair and co-Chairs lowered the young-children value to 0.50 mg, the median of NIHN (1.5 mg), NCM (0.5 mg) and EFSA (0.5 mg) (paras 129–132). Members were therefore not consulted on 0.50 mg for young children before it appeared in the agenda paper.
- **Submitted positions, including within the region, are divided (Add.2).** Egypt and Saudi Arabia support all proposed values, including 0.50 mg, as do Australia, the EU, Norway, the USA, Uruguay, EFAD and others. The UAE and Lebanon's Add.2 submission favour retaining 0.83 mg, as do Canada, Colombia, Costa Rica, Malaysia and FIA; ISDI prefers the Step 3 outcome of 1.0 mg and otherwise 0.83 mg. Indonesia accepts a conservative approach but asks why 0.50 mg was chosen over 0.83 mg when both are well below the EFSA safe level of 4 mg/day.

- **The regional expert group recommends 0.50 mg.** Lebanon's Add.2 submission supported the Step 3 outcome of 1.0 mg and encouraged retaining 0.83 mg. Having reviewed the full set of comments in Add.2, the regional expert group recommends 0.50 mg, in view of the limited evidence on requirements in this age group, the absence of a known deficiency syndrome, the alignment of 0.50 mg with the most recent EFSA and NCM values, and the broad support for 0.50 mg among Members, including Egypt and Saudi Arabia, which would help the Committee conclude this work.
- **The case for 0.50 mg.** No manganese deficiency syndrome has been described in humans, the body adapts to a wide range of intakes by adjusting absorption and biliary excretion, and rigorous requirement data for 6–36-month-olds are lacking (para 130). Under these conditions, the median of the Category 2 DIRVs (0.50 mg) is a defensible choice, and it keeps a wider margin below the IOM UL (2 mg) and the EFSA safe levels (2 mg for older infants and 4 mg for young children). This margin matters because complementary foods, particularly cereal-based products, can contribute substantial manganese.
- **Points to acknowledge in the record.** Supporters of 0.83 mg note that most RASBs set a higher value for young children than for older infants (NIHN 1.5 mg, IOM 1.2 mg and NHMRC/MOH 2 mg), so a single value for both age groups departs from the usual age-related increase, and that 0.83 mg is itself well below the safe levels. A lower NRV-R also produces higher %NRV declarations for the same manganese content. The report should therefore explain why 0.50 mg was chosen and acknowledge that it was not put to members in CP3.
- **The main paper contradicts itself.** Paragraphs 139–140 still describe Step 4 and Step 5 outcomes of 0.83 mg and 0.67 mg, which conflict with the 0.50 mg recommendation in paragraphs 131–134 and Table 2, and should be aligned with the final proposal. Add.1, Appendix III, by contrast, records the questions and responses from the consultations and should retain the values actually consulted on (0.83 mg and 0.67 mg). Appendix II also states that no UL is available at Step 6, whereas Table 2 lists a lowest UL of 2 mg.

VI. Editorial inconsistencies to correct before finalization

- Para 39: "12–26 months" should read **12–36 months** (also raised by Colombia and Uruguay).
- Para 70: the folate value of 120 µg DFE is attributed to "Older Infants"; it should read **Young Children**.
- Paras 139–140 (manganese): these give 0.83 mg and 0.67 mg and should be aligned with the final 0.50 mg proposal. Add.1, Appendix III should keep the values consulted on, as a record of the consultation.
- Add.1, Table 9, Step 4 (manganese): 0.83 mg is described as the "median"; it is the mean of 1.5, 0.5 and 0.5 mg (raised by Indonesia).
- Add.1, Table 6, Step 6 (magnesium) and Table 9, Step 6 (manganese) state that no UL is available, whereas Table 2 lists 65 mg and 2 mg respectively; the footnote marker for the magnesium UL is also missing from Table 2.
- Table 2 (phosphorus): the 3000 mg "lowest UL" is inconsistent with the ADI-based benchmark used at Step 6 (344 mg and 476 mg).
- Add.1, Table 10, Step 3b (phosphorus): 233.5 mg is shown rounded to 234 mg, whereas the agreed rounding rule and Table 2 give **235 mg**.

VII. Regional relevance

- **The NRVs-R are likely to be used widely in the region, subject to each national framework.** Many Arab and CCNE countries reference Codex texts in national and regional (e.g. GSO) labelling regulations, so these NRVs-R are likely to become the reference for %NRV declarations on complementary foods, cereal-based foods and products for young children, both locally produced and imported. How they are applied will depend on each country's regulatory framework. The UAE (Add.2), supported by ISDI, asks for clear implementation guidance and a coordinated approach, including an appropriate transition period once the full set of values is final, to avoid regulatory divergence. This is directly relevant to regional coordination. The NRVs-R will also be read with the draft standard for foods for older infants and young children (Agenda Item 5), and the expert recommendations for the two items should be consistent.
- **Regional data can inform applicability and future reviews.** National food consumption and nutrient intake surveys of children under five, and anaemia and micronutrient status data, exist in several countries. They are not inputs to the current Stepwise Process, but they can be used to check whether the proposed values are plausible for regional diets, notably for iron and B12, and to support a future review. The region's two EWG members (Egypt and Saudi Arabia) and the other regional countries that commented in Add.2 are well placed to raise these points at the VWG on 27 October.

Recommendations

The proposals below are offered for regional discussion. They do not imply regional agreement where submitted positions differ, notably on manganese. The suggested approach is to support completion of this work at CCNFSDU45, accept the values that had unanimous support, and focus interventions on magnesium rounding, the iron absorption basis, the phosphorus benchmark, the recorded rationale for manganese and the clarity of the supporting text. Final positions rest with the competent national authorities.

I. Updated DIRV tables

- ✓ Support noting the updated NIHN (2020) and NCM (2023) DIRVs, which completes the second part of the EWG's terms of reference.

II. Vitamins C, K, folate and biotin; selenium; phosphorus

- ✓ Support the values as proposed (Table 1).
- ✓ Request that footnotes clearly state that the folate UL applies to supplemental forms only.
- ✓ For phosphorus, support replacing the 3000 mg figure in Table 2 with the ADI-based benchmark used at Step 6 (≈344 mg for older infants and ≈476 mg for young children), with an amended footnote.

III. Vitamin B12

- ✓ Support the compromise values of 0.90 µg (6–12 months), 1.2 µg (12–36 months) and 1.1 µg (6–36 months), consistent with the positions submitted by the UAE and Lebanon in Add.2.

- ✓ Support the request by the UK and Uruguay for a stronger written justification of the Step 4 choice, and encourage members with regional data on maternal and infant B12 status to share them for future reviews.

IV. Magnesium

- ✓ Support 80 mg (6–12 months) and 105 mg (12–36 months).
- ✓ For the combined group, accept 90 mg provided the rounding of an exact half-value is justified in the report, or otherwise apply round-half-up consistently (95 mg). Ask the Committee to confirm the source of the rounding rules and how ties are handled.
- ✓ Support Morocco's request for a footnote, referenced in the table, stating that the 65 mg UL applies to supplemental magnesium only, and correct Appendix II accordingly.

V. Iron

- ✓ Support 11 mg (6–12 months), 7 mg (12–36 months) and 9 mg (6–36 months).
- ✓ Support a footnote identifying the 10% absorption basis, as proposed by the UAE and consistent with Lebanon's submission. Whether the footnote should also allow justified alternative national assumptions, as the UAE, Malaysia and ISDI propose, is for regional discussion, noting that New Zealand and Norway prefer no absorption reference.

VI. Manganese (proposed position for regional discussion)

- ✓ Propose support for 0.50 mg for older infants, young children and the combined 6–36-month group, as a conservative approach given the absence of a deficiency syndrome, human adaptation to a wide range of intakes, limited requirement data and safety considerations.
- ✓ Acknowledge that regional submissions differ: Egypt and Saudi Arabia support 0.50 mg, while the UAE and Lebanon's Add.2 submission favoured 0.83 mg. Having reviewed the comments and supporting rationale, the regional expert group recommends 0.50 mg for the reasons given above.
- ✓ Request that the report set out why the young-children value was lowered from 0.83 mg after CP3, since members were not consulted on 0.50 mg, and that paragraphs 139–140 and the Step 6 statement on the UL be clarified and corrected as appropriate, while Appendix III keeps the values consulted on.

VII. Combined values, implementation and process

- ✓ Request a footnote explaining how the combined 6–36-month values are derived, and clear guidance on when combined and age-specific values apply in labelling, as raised by Lebanon, Peru and the UK.
- ✓ Support the UAE's request for clear implementation guidance, a coordinated approach and an appropriate transition period once the full set of values is final.
- ✓ Ask the EWG Chair to correct the editorial inconsistencies listed above, and to document the Step 4 decision rules (mean versus median, rounding) in the information document on the Stepwise Process.

- ✓ Raise these points at the VWG on 27 October 2026 through the region's EWG members and other participating members, and ensure consistency with the expert recommendations under Agenda Item 5.

B. Agenda item 5: Draft Standard for Foods for Older Infants and Young Children

Document Number: **CX/ NFSDU 26/45/5**

Status in Codex Process: Step 4

Background

At CCNFSDU44 in October 2024, the United States proposed a new standard for foods for older infants and young children, intended to replace the Standard for Canned Baby Foods (CXS 73-1981) and the Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981). CAC47 approved the new work in November 2024. The Electronic Working Group (EWG) is chaired by the United States and co-chaired by the European Union, Kenya and Panama. (CX/NFSDU 26/45/5, paras 1–8.)

Two consultation rounds, CP1 in May 2025 and CP2 in June 2026, revealed differing views on the standard's structure and how essential composition should be defined. CP1 used a food-group-based approach and addressed the main elements of a commodity standard; CP2 focused on purpose, scope, structure, definitions, essential composition and quality factors. The draft is presented for discussion at CCNFSDU45. (CX/NFSDU 26/45/5, paras 9–16.)

Analysis

I. Purpose and compositional framework

The Committee needs to clarify whether the standard is primarily intended to protect nutritional quality, identify suitable foods and ingredients for older infants and young children, limit nutrients of concern, or pursue these aims together. Agreement on these principles is needed before detailed requirements can be justified consistently. (CX/NFSDU 26/45/5, para 12.)

Options include requirements based on product categories, food groups, nutrient profiles, nutrients to limit, or a combination. A food-group approach may accommodate dietary diversity and local ingredients, but "meaningful amounts" and characterizing nutrients would need clear criteria and practical compliance methods. The suitability of a product-category approach for local and traditional foods also warrants consideration. (CX/NFSDU 26/45/5, para 12 and Appendix 3.)

II. Evidence and regional relevance:

Proposed nutrient reference values and numerical limits require a transparent scientific rationale. Relevant national or regional dietary data and dietary modelling, where available, can help assess applicability to Arab and CCNE feeding patterns, commonly used ingredients, energy density, moisture content and preparation or reconstitution instructions. Requirements for sodium, sugars, protein, lipids and energy density should reflect differences among

product categories and distinguish naturally occurring nutrients from added ingredients where relevant. Nutritional impact and technical feasibility should be considered together. These are proposed regional considerations arising from the framework questions in the working paper. (CX/NFSDU 26/45/5, para 12.)

III. Scope and the term "healthy":

Section 1.1 retains "healthy" in square brackets. Some EWG participants favour the term to distinguish general foods from products for special medical purposes; others consider it an unnecessary restriction on foods ordinarily consumed by older infants and young children. One Member also proposed specifying "commercially produced" foods.

Retaining [healthy]	**Removing [healthy]**
From regulatory clarity, it clearly delineates the scope of application that the standard is formulated to cover average healthy older infant and young children's requirements. It prevents ambiguity by distinguishing general commercial products from FSMP which have distinct formulation and safety requirements. But authorities could interpret "healthy" as a legal condition of use.	Removing the term healthy broadens the applicability of the standard to cover foods (like cereals or baby foods) routinely consumed by the general population of older infants and young children regardless of health status, provided they are not on a prescribed medical diet. Foods for Special Medical Purposes (FSMP) are proposed for exclusion from this scope.

The practical question is whether "healthy" improves scope clarity or could be interpreted as a legal condition of use. Removing it would not establish suitability for every child or medical condition. (CX/NFSDU 26/45/5, Appendix 1, section 1; Appendix 3, scope discussion.)

IV. Products proposed for exclusion and humanitarian aid:

The bracketed scope provisions propose excluding products covered by CXS 72-1981 (infant formula and formulas for special medical purposes), CXS 156-1987 (follow-up formula and products for young children), CXG 95-2022 (ready-to-use therapeutic foods), CXG 8-1991 (formulated complementary foods), and CXG 55-2005 (vitamin and mineral food supplements). These exclusions remain proposals for consideration. Some Observers favour including foods supplied through humanitarian aid; their treatment needs to be clear and consistent with exclusions for specialized products. (CX/NFSDU 26/45/5, Appendix 1, section 1.2; Appendix 3.)

V. Scope terminology and suitability provisions

The draft considers "intended for," "presented as suitable for" and "marketed to" as ways to identify the products covered. "Intended" focuses on the purpose for which a food is designed; "presented as suitable" addresses its representation through labelling, packaging, images, advertising or other communications. The contribution favours "intended for or presented as suitable" and questions whether "marketed to" clearly identifies the regulated product category. These expressions should be distinguished from "marketed as suitable for," which can encompass explicit or implicit representations of suitability. (CX/NFSDU 26/45/5, Appendix 1, sections 1.2–1.3; Add.1, p. 146.)

Section 1.3 presents two alternatives:

Option 1	Option 2
• Affirmative and establishes a positive condition that foods must meet to be marketed as suitable for the target age groups. • It directly links compliance with the standard to the ability to make a suitability claim. • It is easier to interpret and consistent with a standards-based approach • Potential limitation: The word "only" may be interpreted broadly. The provision should clarify that it concerns marketing or presenting foods as suitable under this standard, rather than necessarily prohibiting the sale of every non-compliant food for other purposes.	• Explicitly prohibits and directly addresses the misleading presentation of foods that do not conform to the standard. It is potentially easier to apply to non-compliant products as it focuses on what manufacturers must not do. • Potential limitations: Negative framing as it defines the requirement by identifying what is prohibited rather than establishing a clear positive condition. It focuses on non-compliant foods, rather than clearly establishing the condition that must be met before a suitability claim can be made.

The contribution favours the positive condition in Option 1; its application should remain tied to the products within scope and avoid unintended restrictions on foods sold for other purposes. (CX/NFSDU 26/45/5, Appendix 1, section 1.3.)

VI. Breast milk substitutes

Views differ on whether references to existing formula standards sufficiently address the exclusion of breast-milk substitutes or whether explicit wording is needed.

Breast-milk substitutes (BMS) are not limited to infant formulas and follow-up formulas. According to the *WHO International Code of Marketing of Breast-milk Substitutes*, foods and beverages, including bottle-fed complementary foods, also fall under this category when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk.

The contribution therefore supports retaining an explicit exclusion rather than assuming that references to existing formula standards cover every relevant product. (CX/NFSDU 26/45/5, Appendix 1, section 1.2; Appendix 3; WHO, 1981, Article 2.)

VII. Beverages

The EWG consultations did not resolve whether beverages should be included and, if so, which categories. The Chairs proposed excluding beverages in CP2 to address uncertainty around breast-milk substitutes; some Members and Observers favoured inclusion of fruit and vegetable juices and other nutrient-rich beverages.

A wide variety of beverages are available for older infants and young children, and including nutrient-rich beverages is an option for the Committee's consideration. Omitting them **could leave a gap in the coverage of this standard**. Including beverages **could provide a framework for appropriate composition and nutritional requirements**. However, the categories and conditions would still need to be specified, as inclusion within a standard does not, by itself, establish nutritional suitability. (CX/NFSDU 26/45/5, para 14; Appendix 3, scope discussion.)

VIII. Description and definitions

"Description" is preferred to "Definitions" for consistency with the Codex commodity-standard format and CXS 156-1987. Several Members suggested this change, and the Chairs and Co-Chairs proposed that the section be revised accordingly.

The draft describes foods manufactured for use within diversified diets, processed by physical means and packaged to prevent spoilage and contamination under normal handling, storage and distribution conditions. A product-category placeholder remains to be developed in section 2.1.3, based on feedback from some Members and Observers. Although the general Codex definition of food includes drinks, this does not settle the policy choice concerning beverage coverage. (CX/NFSDU 26/45/5, Appendix 1, section 2; Appendix 3; Codex Procedural Manual.)

If "marketed as suitable for" is retained, Saudi Arabia proposes: "means represented, labelled, advertised, promoted or otherwise presented, through words, images or other means, as being appropriate for consumption by older infants and/or young children." (CX/NFSDU 26/45/5 Add.1, p. 146.)

An alternative formulation retained in the contributors' draft describes an explicit or implicit designation through packaging design, descriptors, graphics, nutritional or health claims, or distribution, representing a product as appropriate, safe or intended for a designated consumer group or dietary purpose. The two formulations are alternatives; a definition is needed only if the term remains in the standard.

The food-group definition should be considered once its role in the compositional framework is clearer. The Committee may consider additional definitions as needed. (CX/NFSDU 26/45/5, Appendix 1, sections 2.1.3–2.2.4; Appendix 3.)

Recommendations

The following recommendations are proposed for consideration by Arab and CCNE Member Countries and Observers; they are not an official Codex position.

I. General principles and compositional framework

- Support agreement on the standard's purpose, scope and general principles before detailed compositional requirements are finalized. This will help ensure that nutritional quality, suitability of foods and ingredients, and practical enforcement are considered coherently.

- Seek clarification on the choice between product-category, food-group or combined approaches. If food groups and characterizing nutrients are retained, request clear evidence for the criteria, a definition of "meaningful amounts," and a practical method for assessing compliance; consider the implications for local ingredients and traditional foods.
- Request a transparent scientific rationale for proposed nutrient reference values and thresholds, supported by dietary modelling where feasible. Encourage the use of relevant national or regional dietary data, where available, to test whether proposed requirements suit feeding patterns in Arab and CCNE countries.

II. Scope

➢ 1.1 "Healthy"

- Removing [healthy]—while keeping the explicit exclusion of special medical formulas—is generally considered better and more practical. The proposed exclusion of formulas for special medical purposes would make the term "healthy" in Section 1.1 unnecessary.
- Extending the scope of this standard to all older infants and young children, rather than limiting it to healthy children, does not mean that every product covered by the standard is suitable for every child or medical condition, which may still require tailored dietary management.

➢ 1.2 Scope terminology

- Term "Intended" aligns and is consistent with standard terminology used in Codex texts (CXS73, CXS74, CXS72) explicitly defining and focusing on the core purpose for which a product is designed. As well as term "presented" used in CXS156 and it addresses labeling, claims and commercial presentation.
- Request clear and consistent scope definitions and terminology, particularly for beverages, foods for humanitarian aid, breast-milk substitutes, and the phrase "healthy" older infants and young children.

➢ 1.2 Breast-milk substitutes

Retain [breast milk substitutes] because according to the WHO International Code of Marketing of Breast-milk Substitutes, Breast-milk substitutes (BMS) are not limited to infant formulas and follow-up formulas. foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk, also fall under this category when marketed as a substitute for breast milk.

➢ 1.2 Other beverages

A wide range of beverages, including nutrient-dense options, are marketed for older infants and young children. Omitting them could leave a gap in the coverage of this standard. Including beverages could provide a framework for

appropriate composition and nutritional requirements, subject to agreement on the categories covered and appropriate safeguards.

- **1.3 Option 1**

Option 1 is affirmative and establishes a positive condition that foods must meet to be marketed as suitable for the target age groups. It is easier to interpret and consistent with a standards-based approach.

III. **Description and definitions**

- **2 Description**

Several Members suggested that this section should be called 'Description' rather than 'Definitions' This would be consistent with the standard for Follow-up formula for Older Infants, and Product/Drink for Young Children (CXS 156-1987) as well as the term "Description" is consistent with the "Format for Codex Commodity Standards" set out in Section 2.6 of the Codex Procedural Manual.

- **2.1 Product Definition**

A specific mention of beverages is not required, since beverages already fall under the general definition of foods.

- **2.2.3 Marketed as suitable for**

Defining this term is only necessary if consensus is reached to include it in the text of the standard.

- **2.2.4 Food Groups**

It is preferable to wait to introduce that definition until certain key points in the standard are clarified.

IV. **Further work**

Support a focused intersessional work plan identifying the outstanding policy and technical questions, evidence needs, and opportunities for Member and Observer input before the next stage of drafting.

C. Agenda item 6: Technological Justification for Several Food Additives

Document Number: **CX/ NFSDU 26/45/6**

Status in Codex Process: The European Union–chaired Electronic Working Group (EWG) submitted six recommendations on the technological justification of food additives for consideration at CCNFSDU45 (2–6 November

2026). These recommendations do not constitute completed JECFA safety assessments for infants younger than 12 weeks (CX/NFSDU 26/45/6, paras 1, 19–35).

Background

CCNFSDU44 (2024) completed its assessment of batch-2 food additives for use in foods conforming to the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981). The Committee agreed to communicate its conclusions to the Codex Committee on Food Additives (CCFA) for appropriate action and to continue the assessment of additional additives under its established work plan. These decisions were taken in the context of inadequate JECFA risk assessments for infants younger than 12 weeks of age (CX/NFSDU 26/45/6).

The European Union–chaired Electronic Working Group (EWG) was tasked with (i) collecting information on uses, use levels, and commitments to provide infant safety data for batch-3 additives and basic methacrylate copolymer (INS 1205); and (ii) assessing their technological justification using the CCNFSDU framework, including the proposed uses of INS 1205 in other foods intended for infants and young children. CCNFSDU45 is invited to consider the EWG's six recommendations concerning the technological justification of these additives and the need for further discussion of INS 1205 (CX/NFSDU 26/45/6, paras 5–18, 19–35).

Additive / INS	Use and conditions	EWG outcome	Key issues requiring clarification
INS 270 — L(+)-lactic acid	Acidity regulator; GMP; L(+)-form only (GSFA Note 83).	Rec. 1: Technologically justified in CXS 72-1981.	Formulation-specific necessity; reported use up to 1,200 mg/kg as consumed; alternatives.
INS 322(i) — Lecithin	Emulsifier and antioxidant; maximum 5,000 mg/L as consumed; Note 585 when combined with INS 471.	Rec. 2: Technologically justified at 5,000 mg/L, subject to Note 585.	Justification of maximum; reported 500–5,000 mg/L range; combined-use restrictions.
INS 330, 331(i), 331(iii), 332(i), 332(ii) — Citric acid and citrates	Acidity regulators; GMP; Note 55 and mineral limits.	Rec. 3: Technologically justified in CXS 72-1981.	Reported 0.02–850 mg/L citric acid and 0.1–12,000 mg/L citrates; necessity and mineral contributions.
INS 471 — Mono- and diglycerides of fatty acids	Emulsifier; maximum 4,000 mg/L as consumed; Note 585 with INS 322(i).	Rec. 4: Technologically justified at 4,000 mg/L, subject to Note 585.	Reported use up to 6,000 mg/L exceeds existing maximum; lowest effective level and combined use.

INS 1205 — Basic methacrylate copolymer (infant formula)	Proposed in CXS 72-1981; no commitment to provide safety data for infants under 12 weeks.	Rec. 5: Not considered technologically justified in CXS 72-1981.	Lack of safety-data commitment prevented further assessment; not proof of absent technological function.
INS 1205 — Other infant and young-child foods	Proposed carrier/glazing agent for nutrient encapsulation under CXS 73-1981, CXS 74-1981, CXS 156-1987 and CXG 95-2022.	Rec. 6: Further discussion required.	Technological efficacy, vitamin A stability, use levels, exposure, safety and alternatives.

Analysis

The analysis focuses on the main outstanding issues concerning the technological justification of food additives, including the necessity of their intended uses, the appropriateness of reported use levels, compliance with applicable GSFA restrictions, and consideration of technological alternatives. These considerations remain distinct from the separate JECFA safety-assessment process for infants younger than 12 weeks (CX/NFSDU 26/45/6, paras 19–35).

I. Cross-cutting scientific and regulatory issues

1. **Technological justification does not establish safety for infants younger than 12 weeks.** The EWG considered the batch-3 additives technologically justified for use in foods conforming to CXS 72-1981. However, adequate JECFA safety assessments for infants younger than 12 weeks remain outstanding. Technological endorsement should therefore be distinguished from safety confirmation, with reported use levels informing future age-specific exposure assessments (paras 1, 16 and 19–30).

Additional scientific context**:** EFSA guidance for infants below 16 weeks recommends a case-by-case risk assessment using a high formula-consumption assumption of 260 mL/kg body weight/day for exposure estimation. This guidance is complementary and does not constitute a JECFA assessment or establish a Codex maximum use level (EFSA Scientific Committee, 2017, Ref. 6; WHO, 2016, Ref. 10).

2. The evidence base and regional participation remain limited. Participation in the four EWG consultation rounds was limited, with seven, two, seven and four submissions, respectively. The findings reflect the evidence and perspectives of respondents rather than universal agreement among Codex members. Although Saudi Arabia participated in the EWG, additional region-specific evidence on additive use, dietary exposure, formulation practices and product stability under local storage conditions would strengthen future assessments (paras 6–18; Annex 1).

3. Reported use levels and combined-use restrictions require clarification. Considerable variation was reported in additive concentrations, particularly for citrates (0.1–12,000 mg/L) and mono- and diglycerides of fatty acids (INS 471; 20–6,000 mg/L). The reported upper level for INS 471 exceeds the GSFA maximum of 4,000 mg/L and warrants clarification. Furthermore, GSFA Note 585 requires that the sum of the proportions of lecithin (INS 322(i)) and INS 471 relative to their respective maximum levels must not exceed one when used together (paras 22–30).

4. Distinction between technological functions and additional nutritional or health claims. The technological justification of additives should be based on their demonstrated functions, such as acidity regulation and emulsification, supported by formulation-specific evidence of necessity, consideration of available alternatives, and use at the lowest technologically effective concentration. Additional claims concerning improved digestibility, nutritional benefits, or microbial protection should be assessed separately and should not be inferred from established technological functions without appropriate scientific substantiation. In particular, pH regulation does not replace validated processing and microbiological safety controls (CX/NFSDU 26/45/6, paras 19–30; Annex 1).

5. INS 1205 requires a distinction between insufficient evidence and absence of technological functionality. The EWG recommended that basic methacrylate copolymer (INS 1205) should not be considered technologically justified in CXS 72-1981 because no commitment was made to provide the safety data required for infants younger than 12 weeks. This does not independently demonstrate an absence of technological function. Its proposed use in other infant and young-child foods remains under discussion because important questions concerning technological efficacy, use levels and safety remain unanswered (paras 31–35; Annexes 1 and 2).

II. L(+)-lactic acid (INS 270):

The technological need is recognized, but its application is formulation-specific. The EWG considered L(+)-lactic acid (INS 270) technologically justified as an acidity regulator in infant formula and formulas for special medical purposes intended for infants (CXS 72-1981). Its use is permitted under Good Manufacturing Practice (GMP), restricted to the L(+)-form only under GSFA Note 83. The applicant explained that lactic acid is particularly useful in acidified infant formulas, where pH adjustment contributes to product stability and desired formulation characteristics, including protein digestibility. However, several EWG members reported no use of lactic acid in their markets, relying instead on alternatives such as citric acid (INS 330), potassium carbonate (INS 501(i)) and calcium hydroxide (INS 526). This suggests that its technological necessity is specific to certain formulations rather than universal across infant formula products (paras 19–20; Annex 1).

III. Lecithin (INS 322(i)):

The technological need is well established, particularly for emulsion stability and nutrient distribution. The EWG considered lecithin (INS 322(i)) technologically justified as an emulsifier and antioxidant in infant formula and formulas for special medical purposes intended for infants (CXS 72-1981). Lecithin prevents phase separation during storage and after reconstitution, maintains uniform nutrient distribution, and contributes to emulsion stability during thermal processing. Applicants also highlighted its antioxidant properties and potential synergistic effects with other emulsifiers. Reported use levels ranged from 500 to 5,000 mg/L, supporting the existing GSFA maximum of 5,000 mg/L in the product as consumed (paras 22–24; Annex 1).

Lecithin use was reported at 500–5,000 mg/L, against a GSFA maximum of 5,000 mg/L as consumed. The wide range calls for formulation-specific justification. Where lecithin is combined with INS 471, GSFA Note 585 requires that the sum of their respective fractions of permitted maximum levels not exceed one. Claims of improved digestion or vitamin absorption should not be treated as established technological functions without independent supporting evidence (paras 22–24; Annex 1).

Additional scientific consideration: EFSA's 2017 re-evaluation and its 2020 infant-specific follow-up discuss lecithin exposure and choline-related considerations in infant formula. The earlier EFSA opinion referred to a 1 g/L infant-formula benchmark, which differs from the 5 g/L Codex provision considered here. The differing regulatory contexts and more recent infant-specific evaluation warrant examination rather than direct substitution of one limit for another (EFSA ANS Panel, 2017, Ref. 7; EFSA FAF Panel, 2020, Ref. 8).

IV. Citric acid and citrates:

The technological need is recognized, but the additives perform several overlapping functions. The EWG considered citric acid (INS 330), sodium citrates (INS 331(i) and 331(iii)), and potassium citrates (INS 332(i) and 332(ii)) technologically justified as acidity regulators in infant formula and formulas for special medical purposes intended for infants (CXS 72-1981). These additives contribute to pH stability and protection of pH-sensitive nutrients, while citrates additionally act as buffering agents, sequestrants and emulsion stabilizers, helping prevent protein coagulation and mineral precipitation. Their use is permitted under Good Manufacturing Practice (GMP), subject to GSFA Note 55, which requires that citrate use, individually or in combination with other salts, remains within the sodium, calcium and potassium limits established in CXS 72-1981 (paras 25–27; Annex 1).

Reported use ranges were 0.02–850 mg/L for citric acid and 0.1–12,000 mg/L for citrates. Higher concentrations warrant clarification and evidence of the lowest effective level. GSFA Note 55 requires compliance with the relevant mineral limits, but mineral-limit compliance alone does not establish technological necessity (paras 25–27; Annex 1).

V. Mono- and diglycerides of fatty acids (INS 471):

The technological need is recognized, particularly for emulsion stability and product homogeneity. The EWG considered mono- and diglycerides of fatty acids (INS 471) technologically justified as emulsifiers in infant formula and formulas for special medical purposes intended for infants (CXS 72-1981). These additives prevent phase separation, maintain uniform nutrient distribution and preserve product texture throughout shelf life. Their combination with lecithin (INS 322(i)) may provide synergistic emulsification effects. The EWG therefore proposed endorsing their use at a maximum of 4,000 mg/L in the product as consumed, subject to GSFA Note 585, which requires that the sum of the proportions of INS 471 and lecithin relative to their respective maximum permitted levels does not exceed one (paras 28–30; Annex 1).

Reported INS 471 use ranged from 20 to 6,000 mg/L, with the upper value exceeding the GSFA maximum of 4,000 mg/L as consumed. This discrepancy and the lowest effective emulsifier level require clarification. Combined use with lecithin must comply with the proportional-sum restriction in GSFA Note 585 (paras 28–30; Annex 1).

Additional scientific consideration: EFSA's re-evaluation of E 471 identified specification concerns involving trans fatty acids, glycidyl esters and 3-MCPD-related impurities. Its general-population conclusion does not itself establish safety for infants younger than 12 weeks. Regional authorities may therefore request specification and impurity-control evidence alongside clarification of reported use levels (EFSA ANS Panel, 2017, Ref. 9).

VI. Basic methacrylate copolymer (INS 1205):

For infant formula (CXS 72-1981), the EWG recommended non-endorsement of INS 1205 on the available evidence, particularly in the absence of a commitment to provide the required infant-specific safety data, without implying a lack of technological functionality. For other infant and young-child foods, further discussion was recommended pending evidence of technological efficacy, appropriate use levels, exposure, safety, and alternatives. Any potential regional benefit, particularly for vitamin A stability under challenging storage conditions, should remain conditional on demonstrated efficacy and safety (CX/NFSDU 26/45/6, paras 31–35; Annexes 1 and 2).

VII. Regional relevance: Arab countries and CCNE

Regulatory consistency across Lebanon, Arab countries, and the CCNE region requires harmonized application of Codex provisions, including GSFA maximum levels, GMP conditions, and Notes 55 and 585. Given the region's high ambient temperatures and potentially extended distribution periods, technological claims relating to product and nutrient stability should be supported by evidence obtained under representative local storage conditions, without replacing the need for age-specific safety assessment.

Recommendations

The following are suggestions for regional discussion, not adopted national or regional positions. Support Recommendations 1–4, with the clarification and additional evidence requests below as follow-up actions rather than conditions for support. Support Recommendation 5 on INS 1205 in infant formula, and keep Recommendation 6 open pending further evidence.

I. L(+)-Lactic Acid (INS 270)

- ✓ Support technological justification under Good Manufacturing Practice (GMP), maintaining the restriction to the L(+)-form (GSFA Note 83), particularly where pH adjustment is technologically necessary in acidified infant formulas.
- ✓ Request formulation-specific evidence demonstrating technological necessity and the lowest effective concentration, taking into account the reported use of up to 1,200 mg/kg as consumed. Clarify that this represents an industry-reported use level relevant to exposure assessment, **not a proposed Codex maximum use level**.
- ✓ Encourage comparison with permitted alternative acidity regulators when assessing the technological need for L(+)-lactic acid in the intended formulations.

- ✓ Maintain a clear distinction between technological justification and the separate infant-specific safety assessment by JECFA (CX/NFSDU 26/45/6, paras 19–21; Annex 1).

II. Lecithin (INS 322(i))

- ✓ Support technological justification at the existing maximum use level of 5,000 mg/L as consumed, subject to Note 585.
- ✓ Request formulation-specific justification of concentrations in light of reported use level of 500–5,000 mg/L.
- ✓ Ensure that when used with INS 471, the sum of the fractions of their respective maximum levels does not exceed one.
- ✓ Distinguish established technological functions from nutritional claims requiring independent evidence.

III. Citric Acid and Citrates

- ✓ Support technological justification under GMP, subject to Note 55 and relevant sodium, calcium and potassium limits.
- ✓ Clarify wide reported levels, including citrates up to 12,000 mg/L, and demonstrate formulation-specific necessity.
- ✓ Assess cumulative mineral contributions from citrate salts and other ingredients.
- ✓ Emphasize that mineral-limit compliance alone does not establish technological need.

IV. Mono- and Diglycerides of Fatty Acids (INS 471)

- ✓ Support technological justification at the existing maximum of 4,000 mg/L as consumed, subject to Note 585.
- ✓ Clarify reported concentrations up to 6,000 mg/L and whether these reflect actual use.
- ✓ Demonstrate the lowest effective concentration and compliance with combined-use restrictions with lecithin.
- ✓ Consider specifications and impurity controls in subsequent safety assessments.

V. INS 1205 in Infant Formula

- ✓ Support non-endorsement under CXS 72-1981 on the evidence currently available.
- ✓ Clarify that lack of commitment to provide infant safety data prevented further assessment and is not proof that INS 1205 lacks technological function.

VI. INS 1205 in Other Infant and Young-Child Foods

- ✓ Support further discussion without endorsement for CXS 73-1981, CXS 74-1981, CXS 156-1987 and CXG 95-2022.

- ✓ Request evidence of technological efficacy in nutrient encapsulation and vitamin A retention during processing and storage.
- ✓ Encourage testing under realistic regional storage temperatures and distribution conditions.
- ✓ Clarify use levels, exposure, age-appropriate safety and alternative encapsulation materials.

VII. Cross-Cutting Regulatory Considerations and Regional Coordination

- ✓ Maintain a clear distinction between technological justification and infant-specific safety assessment.
- ✓ Encourage regional evidence on use levels, composition, manufacturing practices and stability.
- ✓ Promote coordination among Lebanon, Arab countries and CCNE members, including Saudi Arabia as an EWG participant.
- ✓ Document outstanding technical questions in the CCNFSDU45 report and apply GSFA Notes 55, 83 and 585 consistently.

References:

Item 4	➢ CX/NFSDU 26/45/4. NRVs-R for persons aged 6–36 months (at Step 4). Prepared by the EWG chaired by Ireland and co-chaired by Costa Rica and the USA. August 2026 (paras 1–152; Tables 1–2). ➢ CX/NFSDU 26/45/4 Add.1. Appendices I–IV: updated NIHN 2020 and NCM 2023 DIRVs; DIRV tables and application of the Stepwise Process (Tables 1–10); EWG feedback to CP2 and CP3 (Table 11); list of participants. August 2026. ➢ CX/NFSDU 26/45/4 Add.2. Comments in reply to CL 2026/46-NFSDU. September 2026. ➢ CX/NFSDU 26/45/1. Provisional agenda, CCNFSDU45, Nuremberg, 2–6 November 2026. ➢ Guidelines on Nutrition Labelling (CXG 2-1985), section 3.4.4.2 and Annex 1, Part B. ➢ Arab–CCNE Codex Coordination: 1st Meeting of the CCNFSDU45 Regional Expert Working Group, 15 October 2026 (presentation). ➢ Stevens GA et al. National, regional, and global estimates of anaemia by severity in women and children for 2000–19. Lancet Global Health 2022;10:e627–e639.
Item 5	➢ Codex Alimentarius Commission. *CX/NFSDU 26/45/5 — Draft Standard for Foods for Older Infants and Young Children (at Step 4).* August 2026. Main report, paragraphs 1–16; Appendix 1, proposed draft standard; Appendix 3, summary of EWG consultations. ➢ Codex Alimentarius Commission. *CX/NFSDU 26/45/5 Add.1 — Comments in reply to CL 2026/47-NFSDU.* September 2026. Includes Saudi Arabia's proposed definition of "marketed as suitable for," p. 146. ➢ World Health Organization. *International Code of Marketing of Breast-milk Substitutes.* Geneva: WHO; 1981. Article 2. ➢ Codex Alimentarius Commission. *CXS 73-1981 — Standard for Canned Baby Foods.* ➢ Codex Alimentarius Commission. *CXS 74-1981 — Standard for Processed Cereal-Based Foods for Infants and Young Children.* ➢ Codex Alimentarius Commission. *CXS 72-1981 — Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.* ➢ Codex Alimentarius Commission. *CXS 156-1987 — Standard for Follow-up Formula for Older Infants and Product for Young Children.* ➢ Codex Alimentarius Commission. *CXG 95-2022 — Guidelines for Ready-to-Use Therapeutic Foods (RUTF).* ➢ Codex Alimentarius Commission. *CXG 8-1991 — Guidelines on Formulated Complementary Foods for Older Infants and Young Children.*

	➢ Codex Alimentarius Commission. *CXG 55-2005 — Guidelines for Vitamin and Mineral Food Supplements.* ➢ Codex Alimentarius Commission. *Procedural Manual.* Sections "Format for Codex Commodity Standards" and "Definitions for the Purposes of the Codex Alimentarius."
Item 6	➢ Codex Alimentarius. CX/NFSDU 26/45/6. Technological Justification for Several Food Additives. Agenda Item 6, CCNFSDU45, 2026; main paper, Annexes 1 and 2. ➢ Codex Alimentarius. REP24/NFSDU. Report of CCNFSDU44, 2024, especially paras 75, 80, 84–86 (as cited in CX/NFSDU 26/45/6). ➢ Codex Alimentarius. CXS 72-1981. Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. ➢ Codex Alimentarius. CXS 192-1995. General Standard for Food Additives (GSFA), including Preamble section 3.2 and Notes 55, 83, 381, 551 and 585. ➢ Codex Alimentarius. CXS 73-1981; CXS 74-1981; CXS 156-1987; CXG 95-2022 (product texts considered for INS 1205). ➢ EFSA Scientific Committee. (2017). Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA Journal, 15(5), 4849. https://doi.org/10.2903/j.efsa.2017.4849 ➢ EFSA ANS Panel. (2017). Re-evaluation of lecithins (E 322) as a food additive. EFSA Journal, 15(4), 4742. https://doi.org/10.2903/j.efsa.2017.4742 ➢ EFSA FAF Panel. (2020). Opinion on the re-evaluation of lecithins (E 322) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation for uses in foods for all population groups. EFSA Journal, 18(11), 6266. https://doi.org/10.2903/j.efsa.2020.6266 ➢ EFSA ANS Panel. (2017). Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Journal, 15(11), 5045. https://doi.org/10.2903/j.efsa.2017.5045 ➢ World Health Organization. (2016). Guidance document for WHO monographers and reviewers evaluating food additives (excluding enzyme preparations and flavouring agents), version 1.0. ISBN 9789241515795.