

CCNFSDU45

Overview ISDI Positions

Item 2 - Matters referred by the Codex Alimentarius Commission and other subsidiary bodies

Item 2.1. Precautionary Allergen Labelling

Completion of the guideline on the use of PAL, consider new work to ensure consistency between PAL and CXS 118-1979.

ISDI welcomes the completion of the Guidelines on the Use of Precautionary Allergen Labelling (PAL), which provide practical, science-based recommendations to support consistent allergen risk management and communication to consumers at the international level. These guidelines represent an important step towards greater harmonization in the use of PAL and improved protection of consumers with food allergies and coeliac disease.

ISDI supports the review of the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CXS 118-1979) following the completion of the Guidelines on the use of PAL and their incorporation as an annex to the General Standard for the Labelling of Prepackaged Foods. Given the integration of gluten-related provisions within the PAL guidelines, a revision of CXS 118-1979 would help ensure consistency and alignment across relevant Codex texts. Such a review would provide an opportunity to appropriately reflect the outcomes of the PAL guidelines in the standard and facilitate coherent implementation by regulators and industry.

Item 2.3. Revocation of Batch 2 Additives in Infant Formula

ISDI supports the conclusion of CCFA56 to revoke the provisions for Acetylated Distarch Phosphate (INS 1414), Distarch Phosphate (INS 1412), Guar Gum (INS 412), Hydroxypropyl Starch (INS 1440) and Phosphated Distarch Phosphate (INS 1413) in Categories 13.1.1 and 13.1.3. This recommendation is also in line with the conclusion of CCNFSDU44 on the technological justification and use of these additives in infant formula and formula for special medical purposes intended for infants. ISDI notes that four of these substances fall within a similar class (modified starches), and it is possible that more technologically advanced alternatives exist today.

ISDI fully endorses the widely agreed principle that the use of food additives in infant formula should be restricted and limited to where there is demonstrated technological need and established safety for the sensitive populations consuming these products. Consistent with this principle, ISDI has played an active role in the review of additives in infant formula and has strongly supported the revocation of Batch 2 additives through the provision of industry expertise and technical input.

CCNFSDU45

Overview ISDI Positions

However, the successful removal of unnecessary additives should not be interpreted as evidence that all additive use can be eliminated from infant formula. Certain additives continue to serve essential technological functions that are necessary to ensure the safety, quality, stability and nutritional integrity of these products. Industry therefore remains committed to maintaining additive use and resulting exposures at the lowest levels reasonably achievable, consistent with the General Principles for the Use of Food Additives in the GSFA, while ensuring the highest level of consumer protection.

Item 3 - Matters of interest from FAO and WHO

Item 4 - NRVs-R for persons aged 6-36 months (at Step 4)

General position

ISDI would like to express its sincere appreciation to the Chair, Co-Chairs and all delegates who have contributed to this work over the past several years. The development of NRVs-R for older infants and young children has involved extensive scientific review, consultation and discussion, and represents a significant achievement for CCNFSDU. ISDI acknowledges the considerable time, expertise and commitment invested in advancing this work towards completion and particularly appreciates the careful consideration and integration of comments received throughout the consultation process.

ISDI recognises the significance of establishing NRVs-R for older infants and young children and is strongly supportive of CCNFSDU45 completing and adopting the proposed values. ISDI is generally supportive of the proposed NRVs-R, including in instances where the final values deviate from the previously agreed stepwise approach, as the values remain within nutritionally safe and appropriate ranges, are supported by robust scientific foundation, and provide a suitable basis for international reference values for older infants and young children. The proposed values represent a pragmatic and balanced outcome that supports the successful finalization of this important work.

At the same time, ISDI acknowledges that the adoption of these NRVs-R may have important implications for food regulation, product development and labelling approaches. Given the significance of this work and its potential impact on the global market, careful consideration should be given to the interpretation, implementation and application of the values once adopted. ISDI notes the importance of harmonised implementation by Member countries in order to avoid unnecessary discrepancies and regulatory divergence. ISDI therefore recommends that clear guidance and a coordinated approach be promoted, including consideration of an appropriate transition period once the full set of values has been finalised.

CCNFSDU45

Overview ISDI Positions

Deviation of the Stepwise Process and Scientific Justification

ISDI would like to thank the Chair and Co-Chairs for the additional explanations provided in the Circular Letter regarding instances where the proposed values deviated from the agreed Stepwise Process. ISDI had previously highlighted the importance of clearly articulating the scientific rationale underpinning such deviations, and appreciates the efforts made to provide this clarification.

The transparency demonstrated throughout this process has facilitated an informed assessment of the proposed values and contributed to maintaining confidence in both the outcomes of this work and the integrity of the Stepwise Process itself.

Vitamin B12

ISDI supports the proposed NRV-R of 0.9 µg for vitamin B12 for older infants.

While the use of the mean value represents a departure from the Stepwise Process, ISDI supports the compromise proposed by the Chair in the interest of facilitating completion of this important work. Furthermore, the proposed value remains physiologically reasonable, especially when considered alongside the corresponding value established for young children.

ISDI acknowledges the lack of physiological data in this age group, particularly the lack of age-specific reference values for biomarkers of vitamin B12 deficiency. However, ISDI notes that a recent and extensive analysis of breastmilk vitamin B12 concentrations, including 2,767 samples from well-nourished mothers, reported a pooled median concentration of 0.302 µg/L (Allen et al., 2025). Based on an assumed breastmilk intake of 0.78 L/day and extrapolation to older infants, these data are consistent with the previous AI of 0.5 µg/day established by the US/Canada IOM and Australia/New Zealand and therefore provide support for a lower reference value.

Nevertheless, ISDI considers that the proposed value of 0.9 µg provides an appropriate and scientifically sound basis for the NRVs-R. However, ISDI does not support a further increase above 0.9 µg, as this would move the NRV-R beyond the compromise reached by the Chair, bring it close to the value established for young children, and result in a value that is substantially higher than several of the underlying DIRVs considered during the process, without a sufficiently compelling scientific rationale.

Iron

ISDI supports the proposed NRVs-R for iron for older infants and young children based on 10% bioavailability.

ISDI agrees with the application of the Stepwise Process and notes that the proposed values are supported by the available DIRVs from FAO/WHO as well as more recent DIRVs from NIHN, NCM and EFSA. The proposed NRVs-R represent a scientifically sound basis for international reference values.

At the same time, ISDI notes that iron bioavailability is highly dependent on the diet and complementary feeding practices. Iron from animal-source foods is generally more readily absorbed than iron from plant-based foods, which may contain inhibitors of

CCNFSDU45

Overview ISDI Positions

absorption. Consequently, iron bioavailability can differ considerably between populations depending on the nature of complementary foods and overall dietary practices. Reference values based on either 10% or 15% bioavailability may therefore be appropriate in different contexts.

ISDI therefore welcomes the Committee's recognition throughout this work that both 10% and 15% bioavailability assumptions can be relevant in different contexts. While ISDI supports the proposed NRVs-R based on 10% bioavailability, it is important that the basis for these values remains clearly identified and that Member countries retain the flexibility to consider alternative iron bioavailability assumptions where justified by local dietary patterns and nutritional circumstances.

To enhance clarity and facilitate implementation, ISDI recommends the inclusion of an explanatory footnote to indicate that the adopted NRVs-R are based on a 10% iron bioavailability assumption.

"The NRVs-R for iron are based on an assumed iron bioavailability of 10%. Governments may consider other bioavailability assumptions, as appropriate taking into account local complementary feeding practices, dietary patterns and other relevant nutritional considerations"

Manganese

ISDI supports the NRV-R of 1.0 mg for manganese for young children, which is derived through application of the agreed Stepwise Process and remains well below the upper intake levels or safe levels established by recognized scientific bodies.

In previous consultations, ISDI supported the Chair's compromise proposal of 0.83 mg as a pragmatic adjustment to facilitate consensus and advance the work. However, ISDI does not support a further reduction to 0.5 mg. ISDI is surprised by the proposed reduction, as the feedback received during the third consultation round did not appear to indicate support for moving to a lower value. Rather, a number of comments supported retention of 0.83 mg, while others supported the Stepwise Process outcome of 1.0 mg. Against this background, ISDI finds it difficult to understand the rationale for the proposed reduction to 0.5 mg.

In our view, the proposed value of 0.83 mg already represented a substantial departure from the outcome derived through the Stepwise Process while remaining within a nutritionally appropriate range.

ISDI therefore encourages the Committee to retain the previous value of 0.83 mg, which represents a reasonable and balanced outcome that takes account of both the agreed methodology and the discussions held throughout the consultation process.

CCNFSDU45

Overview ISDI Positions

Item 5 - Draft standard for foods for older infants and young children (at Step 4)

Role of FFOIYC

Foods for older infants and young children (FFOIYC) form part of the normal and diversified diet of older infants and young children. They are not intended to constitute the sole source of nutrition, but to contribute to the diversified diet of older infants and young children during the progressive adaptation to ordinary food. They provide parents and caregivers with nutritionally appropriate options specifically designed for the intended age group, in contrast to general foods, which may not always be suitable for older infants and young children in terms of their nutritional composition or overall suitability.

At the same time, Foods for older infants and young children (FFOIYC) are recognized as foods for special dietary uses¹ and therefore should remain clearly differentiated from foods for the general population. They are specifically formulated to meet the particular nutritional needs of a defined population group. While such foods may contribute to addressing specific nutrient gaps, this should not be presented as their sole or primary purpose, as their role is broader and nutrient gaps may not exist in every individual or dietary context.

ISDI therefore considers that these two aspects are complementary rather than mutually exclusive. FFOIYC are foods for special dietary uses formulated for the particular needs of older infants and young children, while also forming part of their diversified diet.

ISDI also notes that the role and use of FFOIYC vary considerably across regions and dietary contexts. In some settings, such products may be used primarily for convenience, while in others they can make a more meaningful contribution to the diet, including through products such as cereal-based foods that have traditionally played an important role in complementary feeding in developing regions.

ISDI considers that the Standard should describe the role of FFOIYC in broad and flexible terms, without establishing rigid distinctions between their role for older infants and for young children, or introducing specific age limits linked to different stages of dietary transition.

The transition from human milk or formula to complementary foods, and subsequently to a diversified diet and family foods, is a gradual and highly individualized process. It depends on the child's developmental stage and individual needs, such as oral-motor skills development, the ability to manage progressively more varied textures, including chewing where developmentally appropriate, as well as cultural practices, geographical context, family circumstances and the wider feeding environment. This is consistent with paediatric guidance such as ESPGHAN, which recommends the progressive

¹ General Standard on Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (Codex Standard 146-1985)

CCNFSDU45

Overview ISDI Positions

introduction of complementary foods and textures according to developmental readiness, rather than relying solely on rigid age-based distinctions². The role and relative importance of FFOIYC may therefore differ considerably between children, families and regions

Against this background, ISDI would not support an overly prescriptive age-description based on specific textures, stages of development or defined transition points. Such an approach may not adequately reflect the diversity of complementary feeding practices worldwide.

ISDI therefore supports a general description consistent with the approach currently reflected in the Standard for Canned Baby Foods CXS 73-1981: FFOIYC are “foods intended primarily for use during the normal infant’s weaning period and for the progressive adaptation of infants and young children to ordinary food.”

This general formulation is sufficiently flexible to encompass different individual developmental stages, feeding practices and cultural realities

Nutritional Profile

Calories and Macronutrients

ISDI notes that recommendations for energy and macronutrient intakes for older infants and young children have been developed by a number of scientific and governmental bodies in different regions. Relevant examples include FAO/WHO energy requirement reports, EFSA dietary reference values, and national dietary reference intake frameworks such as those developed by the National Academies of Sciences and Medicine.

At the same time, ISDI observes that recommended intakes can vary considerably between authorities due to differences in methodologies, reference populations, dietary patterns, and underlying policy objectives. For this reason, identifying a single set of globally applicable values or average macronutrient distribution ranges may be challenging. and may not be the most appropriate basis for Codex compositional requirements.

In this context, ISDI is of the opinion that the approach already used in the 2 existing standards remains valid and applicable in order to establish a Codex standard. Establishing nutritional profiles to guide the future standard is complicated and may potentially miss the purpose of such standard which is there to serve the Codex’ mandate: to protect consumer health and ensure fair practices in food trade.

² Fewtrell M. et al. Complementary Feeding: A Position Paper by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 2017;64(1):119–132

CCNFSDU45

Overview ISDI Positions

ISDI therefore supports retaining the approach already established in the Standard for Canned Baby Foods CXS 73-1981, while recognising the need to update the existing standards to reflect current science and product diversity.

Vitamins and Minerals

ISDI considers that the Nutrient Reference Values for older infants and young children currently under discussion in CCNFSDU provide the most appropriate basis for establishing vitamin and mineral reference values within this work. The ongoing CCNFSDU process represents the most comprehensive and internationally relevant effort to establish globally applicable reference values for this population group.

Regarding additional nutrients, such as fibre, essential fatty acids, or saturated fat, ISDI acknowledges their nutritional relevance. However, establishing globally applicable reference values for such nutrients may present significant scientific and practical challenges, particularly where regional recommendations, methodologies and approaches differ substantially, as mentioned in our response to b(i).

ISDI therefore considers that any proposal to introduce additional reference values should be supported by a clear scientific rationale and a demonstrated need for globally applicable recommendations.

To be noted that ISDI's position on sodium could be found in our answer for CP2.

Essential composition and product categories

As stated in ISDI's response to CP2, ISDI believes that the essential composition should differ according to product category.

Different categories of foods serve different purposes within the diets of older infants and young children and may contribute nutrients in different ways. For example, a fruit puree, a vegetable puree, a meat/fish-containing puree, a dairy-based product ... naturally have different compositions and different nutritional roles. In addition, the ingredients used across product categories can vary substantially in their nutritional composition. Applying a single nutrient profile across all categories does not appropriately reflect the recipe of these foods. could limit the availability of nutritionally appropriate products that contribute to varied dietary patterns and feeding practices across different regions and populations.

ISDI therefore supports an approach whereby compositional requirements are developed in a manner that takes account of the characteristics and intended role of the relevant product category. Further information is provided in ISDI's response to Question C.

CCNFSDU45

Overview ISDI Positions

ISDI further notes that category differentiation may need to apply not only to the numerical criteria, but also to the basis on which criteria are expressed, for example per 100 g or per 100 kcal, depending on the product category.

In addition, as indicated previously, the principles already used in the 2 existing standards remains valid and applicable in order to establish a Codex standard.

Product Composition

ISDI supports a category nutrient-based approach (second option but based on categories) for establishing the essential composition of foods for older infants and young children, while recognising the important role that food groups can play in identifying the relevant product categories and nutrients that are expected to contribute meaningfully to the diet within each category.

In ISDI's view, the objective should be to ensure that products make a meaningful nutritional contribution to the diets of older infants and young children, while maintaining sufficient flexibility to accommodate the diversity of products, ingredients, dietary practices and cultural contexts covered by the Standard. For this reason, ISDI considers that nutrient requirements should form the foundation of the compositional framework, with food groups helping to identify the key nutrients that are expected from different categories of foods.

For example, certain food groups may be recognised as important sources of specific nutrients, such as calcium from dairy-based ingredients or protein, iron and other micronutrients (such as Vit B12) from animal-source ingredients.

However, ISDI does not consider that the nutritional contribution of a product should necessarily be limited to nutrients naturally present in those ingredients. Key nutrients could be provided either inherently through the food ingredients used or through the addition of nutrients, provided that the final product delivers the intended nutritional benefit.

ISDI also considers that the compositional framework should remain practical and proportionate. Attempting to establish an extensive set of requirements for all nutrients across all product categories could result in an unnecessarily complex approach that may be difficult to implement and could limit product diversity and innovation. Instead, consideration could be given to identifying a limited number of nutritionally relevant nutrients associated with particular food groups or categories and establishing criteria around those nutrients.

At the same time, ISDI recognizes that a number of important questions would need to be addressed if such an approach were pursued, including:

- which food groups or product categories should be used as the basis for the framework;
- which nutrients should be considered key contributors within each food groups or categories;
- what level of contribution should be expected from those nutrients; and

CCNFSDU45

Overview ISDI Positions

- how mixed or composite products should be addressed

ISDI therefore supports further work to explore a nutrient-based framework informed by food groups and product categories, with the objective of ensuring nutritional relevance while preserving flexibility and applicability across the wide range of products and feeding contexts covered by the Standard. Any compositional criteria should be scientifically justified, internationally validated, nutritionally relevant, technologically feasible and implementable across the diversity of products covered by the Standard.

Reports to consider for establishing product composition and product categories

ISDI does not support using the identified reports as the primary basis for establishing compositional requirements for foods for older infants and young children. Moreover it does not necessarily reflect the diversity of these foods and dietary patterns at a global level.

ISDI does not consider that guidance reports are the most appropriate starting point for the development of Codex compositional requirements. Product composition should instead be informed by existing national and convergent regional regulatory frameworks that have been established following scientific evaluation by competent authorities and risk assessment bodies and that have accumulated practical implementation experience over many years.

ISDI therefore encourages the Committee to undertake a review of existing regulatory approaches for foods intended for older infants and young children in different jurisdictions. Such an exercise would provide a more robust and globally relevant basis for identifying areas of convergence and developing internationally applicable requirements.

While these publications may provide useful background information within their regional context, they were developed for specific regional purposes and therefore do not necessarily reflect the diversity of dietary patterns, nutritional needs, product categories and regulatory approaches that exist globally.

In particular, the UNICEF Southeast Asia guide, the WHO Europe Nutrient and Promotion Profile Model and the First Foods West Africa recommendations were developed to address regional priorities and cannot readily be considered representative of the broader international context that Codex standards are intended to serve.

ISDI acknowledges that the WHO Guideline for complementary feeding of infants and young children 6-36 months of age (2023) may be helpful to advance conversations on the composition. ISDI notes that recommendation 4 (dietary diversity) of the WHO Guidelines may be helpful in this context.

However, ISDI invites the PWG to consider the multi-society response to the WHO 2023 complementary feeding guideline, published in the Journal of Pediatric Gastroenterology and Nutrition, which welcomed

CCNFSDU45

Overview ISDI Positions

several WHO recommendations while raising concerns on selected aspects of the guideline and proposing modified approaches based on paediatric clinical and scientific expertise³.

To conclude, while the reports identified by the Chairs may be considered as supplementary sources of information, ISDI does not believe they provide a sufficiently uniform or internationally representative basis on which to establish Codex compositional requirements.

Dietary Modelling

ISDI notes that dietary modelling is complicated to address at international level.

ISDI does not consider that dietary modelling should be a prerequisite for establishing compositional requirements for foods for older infants and young children.

While dietary modelling may provide useful insights in certain contexts, its outputs are highly dependent on the assumptions made, the dietary patterns considered and the population on which the model is based.

Given the considerable variation in dietary practices, food availability, cultural habits and feeding patterns across regions, it may be challenging to develop a dietary modelling approach that is sufficiently representative and globally applicable for Codex purposes.

ISDI considers that compositional requirements should primarily be guided by the nutritional needs of older infants and young children and by the intended role of the relevant product categories in the diet. In this regard, internationally agreed reference values, such as the NRVs-R under development in CCNFSDU, together with relevant dietary recommendations and feeding guidelines, may provide a more appropriate basis for this work.

ISDI therefore encourages the Committee to focus on ensuring that foods covered by the Standard can make a meaningful contribution to meeting the nutritional and development requirements of older infants and young children, rather than developing composition requirements based on specific dietary modelling exercises

Structure of the Standard

ISDI continues to support the two-part structure proposed in previous consultations:

- Part A: Foods for Older Infants and Young Children (update of the Standard for Canned Baby Foods)
- Part B: Cereal-based Foods (update of the Standard for Processed Cereal-based Foods)

³ See: World Health Organization (WHO) guideline on the complementary feeding of infants and young children aged 6–23 months 2023: A multisociety response ([link](#))

CCNFSDU45

Overview ISDI Positions

ISDI considers this approach to be the most appropriate and practical for several reasons:

1. it is consistent with the existing Codex framework and builds upon the current standards already established for these product categories. It also aligns with the categorization reflected in other Codex texts, including the GSFA, where cereal-based foods are distinguished from other foods intended for older infants and young children;
2. cereal-based foods represent a distinct product category with specific characteristics, formulations and nutritional considerations. Maintaining a dedicated section for these products would provide the necessary flexibility to address their particular role and composition without creating unnecessary complexity for other categories of foods.

In contrast, ISDI does not support structuring the Standard around separate sections for foods intended for older infants and foods intended for young children. As noted in our responses to questions a(ii) to a(iv), the transition from infancy to a diversified diet is gradual and highly individualized. Feeding practices, developmental readiness, dietary patterns and cultural approaches vary considerably between children, families and regions.

A structure based on age categories could therefore create practical challenges and artificial distinctions between products. In particular, many products may be suitable for both older infants and young children, resulting in overlaps between categories and uncertainty regarding classification and applicable requirements. Such an approach may also fail to reflect the reality that feeding practices are driven not only by age, but also by individual developmental stages and local cultural contexts.

ISDI therefore considers that distinguishing between cereal-based foods and other foods for older infants and young children provides a more practical, scientifically justified and internationally applicable framework than introducing separate categories based on age groups. This approach would maintain consistency with existing Codex texts while accommodating the diversity of products and feeding practices encountered globally. Maintaining a separate section for cereal-based foods also supports continuity with current Codex food categorisation, including GSFA-related classifications, and reduces the risk of unintended consequences for authorised technological functions.

As a conclusion, while ISDI recognises that the two existing standards are outdated and require revision, including with respect to essential composition and other relevant provisions, ISDI considers that the current distinction between cereal-based foods and other foods for older infants and young children remains valid.

Preamble

ISDI does not consider a preamble necessary, as the purpose, scope and requirements of the Standard are already clearly described in the operative text. If retained, the preamble must remain brief, factual and limited to contextual information, without introducing additional concepts or requirements.

CCNFSDU45

Overview ISDI Positions

Draft Standard

Scope

- “Healthy”: ISDI supported the addition of the term "healthy" as a means of clarifying that the Standard applies to the general population of older infants and young children and does not cover foods for special medical purposes. While ISDI continues to consider this clarification useful, we note that support for the addition appeared limited during previous consultations. ISDI would therefore be willing to accept its removal, provided that the scope of the Standard clearly excludes FSMPs and that no ambiguity is created regarding the products covered.
- Beverages: ISDI supports the inclusion of “beverages” in the scope of the Standard. Products consumed in liquid and semi-liquid formats by infants and young children regardless of whether they are included within the Standard. Indeed, in some regions, products such as fruits juices or liquid cereals are part of dietary habits, and caregivers recommendation. Excluding beverages would therefore create a regulatory uncertainty and gap, leaving an entire category of foods intended for this population without internationally recognised compositional requirements. In ISDI's view, foods intended for older infants and young children should not be excluded solely based on their format. Including beverages within the scope of the Standard would ensure that they are subject to appropriate compositional provisions and contribute meaningfully to the nutritional needs of the target population. However, a reference to beverages as such is not required: ISDI refers to section 1.4 of the Procedural Manual “Definitions for the purposes of the Codex Alimentarius” which defines foods. The definition does not refer to beverages but to drinks⁴ as included in the definition of foods. Therefore, it is redundant and more relevant to get a section 1.2 which provides clarity on those foods covered by this standard.
- Codex Standards: ISDI welcomes the fact that the exclusions are framed through references to existing Codex standards, as this provides legal certainty and clarity regarding the products covered and excluded. In our view, reliance on existing Codex texts represents the most appropriate approach.
- Breastmilk substitutes: ISDI does not understand the need for an additional exclusion stating that products considered to be breastmilk substitutes are out of scope. The draft text already excludes products covered by the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981) and the Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987). As these Codex texts cover the categories of products recognized by Codex as breastmilk substitutes, ISDI considers that the proposed exclusion is

⁴ Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

CCNFSDU45

Overview ISDI Positions

already adequately addressed through the references included at the beginning of Section 1.2, and does not understand the need for duplication.

- "Intended", "presented as suitable for" or "marketed to": ISDI prefers the term "intended". In ISDI's view, "intended" provides the clearest and most neutral basis for determining whether a product falls within the scope of the Standard. It is consistent with terminology commonly used in Codex texts and focuses on the purpose for which the product is designed, rather than marketing practices or presentation, which may vary across jurisdictions. ISDI therefore supports the use of "intended" as the most objective and internationally applicable formulation.
- Section 1.3: ISDI supports maintaining both sentences, as they are complementary and together reinforce the principle that foods for older infants and young children are a distinct category of foods specifically developed for the nutritional needs of the target population and should therefore be differentiated from general foods. ISDI also supports retaining the reference to "presented as suitable foods". This wording is consistent with Sections A.1.3 and B.1.3 of the Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987) and reflects established Codex terminology. Furthermore, ISDI notes that Section 1.3 of the Codex Procedural Manual states that Codex standards and related texts contain requirements for food aimed at ensuring consumers receive safe and wholesome products that are correctly labelled and presented. Similarly, the scope of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) refers to the labelling of foods and to aspects relating to their presentation. ISDI therefore considers that the concept of presentation is well established within the Codex framework and remains relevant when determining whether a product is positioned as suitable for older infants and young children. Retaining the reference would provide an additional and useful criterion for distinguishing products specifically intended for this population from general foods.

Definitions

- Description: ISDI notes that the term "Description" is consistent with the "Format for Codex Commodity Standards" set out in Section 2.6 of the Codex Procedural Manual. For this reason, ISDI would support retaining "Description" unless there is a clear justification for deviating from the established Codex format.

CCNFSDU45

Overview ISDI Positions

- FFOIYC: ISDI considers that the term “foods” includes the concept of beverages. Therefore, ISDI does not support any reference to ‘beverages’ and refers to section 1.4 of the Procedural Manual “Definitions for the purposes of the Codex Alimentarius” which defines foods. The definition does not refer to beverages but to drinks⁵ and include them in foods. Therefore, it is redundant and more relevant to get a section 1.2 which provides clarity on those foods covered by this standard
- OI and YC: ISDI considers that the term “foods” includes the concept of beverages. Therefore, ISDI does not support any reference to ‘beverages’ and refers to section 1.4 of the Procedural Manual “Definitions for the purposes of the Codex Alimentarius” which defines foods. The definition does not refer to beverages but to drinks⁶ and include them in foods. Therefore, it is redundant and more relevant to get a section 1.2 which provides clarity on those foods covered by this standard.
- Marketed as suitable: ISDI does not support the inclusion of a definition for "marketed as suitable". As noted in our comments on Section 1, ISDI does not support the use of the term "marketed as suitable" and has instead expressed a preference for the term "presented as suitable", which is more consistent with existing Codex terminology and texts. Given this preference, ISDI does not see a need to develop a definition for "marketed as suitable".
- Food groups: ISDI is not yet convinced of the need for a specific definition of "food groups" within the Standard. At this stage, the added value of introducing such a definition is unclear, particularly as the role of food groups within the overall compositional framework remains under discussion. ISDI considers the proposed definition of "food groups" to be self explanatory and does not see value in defining it specifically in this standard. It may also have repercussions beyond this standard which are not evaluated. ISDI would therefore welcome further clarification from the Chairs regarding the intended use of this definition and how it is expected to support the development of compositional requirements by categories. In particular, ISDI would be interested to understand whether the Chairs envisage the future development of definitions for individual food groups once these have been identified. Should the work ultimately be based on food groups, additional clarity may be needed regarding the scope, categorisation and criteria associated with each group in order to ensure consistent interpretation and implementation of the Standard. If food groups are retained as part of the compositional framework, ISDI considers that they should primarily be used to support product categorisation and identification of relevant nutrients, rather than as stand-alone quantitative compositional thresholds unless scientifically justified.

⁵ Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

⁶ Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

CCNFSDU45

Overview ISDI Positions

Item 6- Technological justification of several food additives

ISDI supports confirmation of the technological justification for the use of lactic acid (INS 270), lecithins (INS 322(i)), citric acid (INS 330), citrates (INS 331(i), 331(iii), 332(i), 332(ii)) and mono- and diglycerides of fatty acids (INS 471) in products conforming to CXS 72-1981 and supports retention of the existing GSFA provisions.

ISDI considers that the available evidence demonstrates that these additives continue to perform important technological functions in infant formula and/or formulas for special medical purposes intended for infants.

ISDI notes that comprehensive technological justification has already been provided during the EWG consultations through the CCNFSDU appraisal framework. ISDI further notes that actual use levels of these additives vary according to formulation characteristics and technological requirements. The existence of lower commercial use levels in some products should not be interpreted as evidence that existing GSFA provisions are unnecessary. The GSFA maximum levels and GMP provisions provide flexibility across a broad range of product matrices, manufacturing processes and nutritional compositions while ensuring that additives are used only at the level necessary to achieve the intended technological function.

Therefore, ISDI recommends that CCNFSDU45:

- confirms the technological justification of Batch 3 additives;
- retains the existing GSFA provisions for these additives;
- and progresses the additives through the agreed CCNFSDU/CCFA/JECFA process for safety evaluation where applicable.

CCNFSDU45

Overview ISDI Positions

Item 7 - Review of the methods of analysis in CXS 234-1999 for standards falling under CCNFSDU's remit

ISDI supports the conclusions of the EWG, and the recommendations included in CX/NFSDU 26/45/7. ISDI supports the advancement of the proposed methods to CCMAS for endorsement and inclusion in CXS 234-1999, noting that these methods are validated, fit for purpose and relevant for verifying compliance with provisions contained in standards under the remit of CCNFSDU. This approach supports consistency and harmonization in the application of analytical methods across foods for special dietary uses and contributes to maintaining an up-to-date and scientifically robust framework within CXS 234-1999.

ISDI continues to support the Codex method-typing framework and the use of reference methods that have been demonstrated to be fit for purpose for the relevant product matrices. For complex FSDU products, method selection should take into account matrix-specific validation, analytical performance characteristics and suitability for regulatory verification. ISDI considers that maintaining clear, endorsed reference methods in CXS 234-1999 remains important for regulatory consistency, international trade and dispute resolution, while recognizing that laboratories may use alternative methods where appropriate.

Overall, ISDI supports the recommendations of the EWG and encourages CCNFSDU to continue supporting a science-based process that prioritizes consistency with established Codex principles for methods of analysis.

CCNFSDU45

Overview ISDI Positions

Item 8- Proposal for new work/emerging issues

Item 8.1. Proposal to review the Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)

ISDI notes the proposal to review the Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005). ISDI further notes that the Guidelines have not been reviewed since their adoption and that developments have occurred in both the regulatory and market landscape. In this context, discussions could provide an opportunity to consider whether any updates may be warranted and how the Guidelines interact with relevant horizontal Codex texts, such as the General Standard for Food Additives (CXS 192-1995) and the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), with a view to maintaining consistency and coherence across the Codex framework.

Should CCNFSDU decide to undertake this work, it will be important to clearly define its scope, maintain consistency with relevant Codex texts, and ensure that any revisions remain science-based and proportionate.

Item 8.2. Proposal for the development of International Prebiotic Guidelines for Use in Foods and Dietary Supplements

ISDI notes the proposal to develop international guidance on prebiotics. While ISDI recognizes the objective of promoting greater consistency in the evaluation and use of prebiotics across jurisdictions, it would welcome further clarification on the specific need that a dedicated Codex text is intended to address and the added value it would provide.

ISDI notes that clear definitions and science-based criteria are important considerations in any regulatory framework. From an FSDU perspective, existing Codex standards already provide a sufficient framework for the development, assessment, composition and labelling of products containing prebiotics. For example, ingredients with prebiotic properties, such as fructo-oligosaccharides, are already permitted under Codex standards for certain FSDU categories, including as an optional ingredient in the Standard for Infant Formula and Formulas for special medical purposes intended for Infants (CXS 72-1981). Should this work proceed, it will be important to clearly define its scope and objectives and to ensure consistency with existing Codex texts and product-specific standards.

ISDI further considers that any future guidance should remain science-based and focused on areas where there is a demonstrated need for international harmonization.

Item 8.3. Proposal on Guidance on Risk Analyses Approaches for Diet Related Non-Communicable Diseases

CCNFSDU45

Overview ISDI Positions

ISDI recognizes the increasing interest among governments and public health authorities in food-based approaches to addressing diet-related non-communicable diseases (DRNCDs). In this context, ISDI sees merit in exploring whether existing Codex risk analysis principles could provide a science-based framework for evaluating the relationship between foods, dietary patterns and health outcomes.

ISDI notes that, in the absence of internationally harmonized approaches, some initiatives have increasingly focused on food classification systems based on factors such as processing. While these initiatives continue to evolve, questions remain regarding their scientific basis, consistency and application across jurisdictions. ISDI also notes that processing can play an important role in the development of Foods for Special Dietary Uses (FSDU), where it is often necessary to achieve the nutritional, safety and functional characteristics required to meet the needs of specific population groups. In this context, a Codex approach grounded in established risk-analysis principles could therefore contribute to a more robust and internationally harmonized framework.

At the same time, any future work should recognize that Foods for Special Dietary Uses (FSDU), as specified in the Codex definition, are specifically formulated to meet the nutritional requirements of particular population groups and are designed to deliver specific nutritional benefits. As such, considerations relating to dietary patterns, food categories or composition may need to be interpreted differently for FSDU products than for foods intended for the general population.

ISDI therefore considers that any future work should remain science-based, carefully scoped, and include specific consideration of the role and purpose of FSDU products within the diet.

Item 9 - Other business