COMMIT

Consortium for Improving Complementary Foods in Southeast Asia

Consortium for Improving Complementary Foods in Southeast Asia (COMMIT)

Compendium of international standards and guidelines for the improved composition and labelling of commercially produced complementary foods in Southeast Asia

Acknowledgements

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The Consortium for Improving Complementary Foods in Southeast Asia (COMMIT) Initiative, made up of UN agencies and civil society organizations, was formed to assess the consumer, product, and policy landscapes for commercially produced complementary foods (CPCF) across seven Southeast Asian countries. Results of the COMMIT Initiative assessment indicated that the diets of children aged 6–23 months are suboptimal and deficient in micronutrients and that many CPCF sold in the region contained added sugar/sweeteners, had a high total sugar and/or high sodium content, and no CPCF products adhered to internationally recommended labelling practices. Further, national legal binding measures relevant to CPCF in the Southeast Asian region do not fully align with available global guidance. Urgent actions are necessary to strengthen national regulations addressing CPCF nutrient composition and labelling practices in order to mitigate the marketing and use of inappropriate CPCF for infant and young child feeding. The COMMIT Initiative recognizes that one of the most effective ways to transform the food system and food environment is by supporting governments to establish regulatory environments that enable access to healthy food, adequately regulate unhealthy products and protect consumers from inappropriate marketing practices.

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Contents

List of tables:

1 Introduction

Foreword

Commercially Produced Complementary Foods (CPCF) are manufactured foods, distinct from breast-milk substitutes, specifically marketed for feeding older infants and young children up to three years of age. In Southeast Asia, the market for CPCF is rapidly evolving despite many CPCF sold in the region presenting an undesirable nutrient profile and/or inappropriate labelling practices[1,2,3]. As these products become increasingly available, concerns on CPCF quality and labelling have emerged. While some Southeast Asian countries have taken steps to regulate these products, none have established comprehensive policies (standards) regulating the nutrient composition, labelling and production requirements of CPCF[4]. The creation or improvement of national standards for CPCF are a critical first step to safeguard young child diets.

To guide development of national standards for food products, several global guidance documents exist that cover CPCF nutrient composition, labelling and production requirements. Available global guidance includes guidelines and standards from Codex Alimentarius (Codex), the World Health Organization (WHO) and the Commission of the European Communities (European Commission). However, a single reference document that contains all nutrient composition, labelling and production requirements for all categories of CPCF is not available. This gap hiders countries from aligning their national standards with relevant global guidance. As such, a comprehensive unified reference document drawing from relevant Codex, WHO and European Commission standards and guidelines is needed.

The *Compendium of International Standards and Guidelines for the Improved Composition and Labelling of Commercially Produced Complementary Foods in Southeast Asia* (Compendium) has been developed to address this need. The Compendium is a single resource document merging key requirements from fourteen relevant Codex standards and guidelines, the WHO Europe Nutrient and Promotion Profile Model for CPCF (2022)[5], the European Commission Directive 2006/125/EC[6] and recommendations from the COMMIT Initiative. Written in a format consistent with Codex, the Compendium sets minimum standards, laying the groundwork for Southeast Asian countries to strengthen their national policies on CPCF. Countries are further encouraged to make their national standards and regulations more specific and stringent than the Compendium's requirements, based on national requirements.

This Compendium aims to serve as a comprehensive resource supporting governments to establish robust regulatory environments that ensure CPCF sold as suitable for older infants and young children are

[1] Bassetti, E., Blankenship, J., White, J. M., Sweet, L., Threapleton, D., Pries, A. M. (2023). Benchmarking the nutrient composition and labelling practices of dry or instant cereals for older infants and young children across seven Southeast Asian countries. Maternal & Child Nutrition, under review.
[2] Bassetti, E., Blankenship, J., White, J. M., Mulder, A., Threapleton, D., Pries, A. M. (2023). Benchmarking the nutrient composition and labelling practices of commercially produced ready-to-eat purées and meals for older infants and young children across seven Southeast Asian countries. Maternal & Child Nutrition, under review.
[3] Pries, A. M., Bassetti, E., White, J. M., Mulder, A., Threapleton, D., Blankenship, J. (2023). Benchmarking the nutrient composition and labelling practices of finger foods and snacks for infants and young children across seven Southeast Asian countries. Maternal & Child Nutrition, under review.
[4] Blankenship, J., Nguyen, T., White, J., Badham, J., Cashin, J., Zambrano, P., Vu, D., Nguyen, H., Kupka, R. (2023). Over promoted and under regulated: National binding legal measures related to commercially produced complementary foods in seven Southeast Asian countries are not fully aligned with available guidance. Maternal & Child Nutrition, under review.
[5] Nutrient and promotion profile model: supporting appropriate promotion of food products for infants and young children 6–36 months in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO.
[6] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006L0125

nutritionally adequate and labelled in a responsible manner that does not mislead caregivers. Through this Compendium, the COMMIT Initiative aims to catalyse positive change in regulation of CPCF ensuring that CPCF products marketed and consumed in Southeast Asia contribute to healthy diets for older infants and young children and are appropriately labelled.

Methodology

The following steps were undertaken in the development of this Compendium:

1. Identification of relevant global guidance documents: Relevant global guidance documents that were either specific or generally related to CPCF were first identified. The Compendium is grounded in 17 key reference documents related to nutrient composition, labelling practices, and production requirements for CPCF. These include:

    - Fourteen Codex standards and guidelines, pertaining specifically or generally to CPCF.
    - The European Commission Directive 2006/125/EC.
    - The WHO Europe Nutrient and Promotion Profile Model for CPCF.
    - The COMMIT Initiative recommendations, which represent the most up-to-date global international guidelines and standards relevant to public health priorities in Southeast Asia region.

    The complete list of these documents can be found in Table 1.

2. Content Mapping: The content from each reference document was systematically mapped to the twelve CPCF product categories, based on those outlined in the WHO Europe Nutrient and Promotion Profile Model for CPCF.

3. Codex Standards and Guidelines Integration:

    - The foundational content of the Compendium was sourced from three CPCF-specific Codex standards: Codex STAN 74-1981, Codex STAN 73-1981, and CAC/GL 8-1991.
    - Eleven additional Codex standards and guidelines were incorporated, where they were referenced in the three primary CPCF-specific Codex standards/guidelines. Four Codex standards/guidelines (STAN 1-1985, CAC/GL 2-1985, CAC/GL 23-1997, and CAC/GL 10-1979) were directly incorporated without changes. Another set of four Codex standards/guidelines (STAN 192-1995, CAC/RCP 66-2008, STAN 72-1981, and STAN 234-1999) were included verbatim for specific sections relevant to CPCF. Finally, three Codex standards/guidelines (CAC/RCP 1-1969, CAC/GL 21 – 1997, and CAC/GL 9-1987) were referred in the Compendium, but their content was not incorporated as they were more general and not specifically related to CPCF.

4. Integration of Additional References: Two other guidance documents, the WHO Europe Nutrient and Promotion Profile Model for CPCF (2022) and the European Commission Directive 2006/125/EC, were integrated. Furthermore, other recent global guidances were applied to the Compendium alongside evidence addressing public health priorities specific to the Southeast Asia region. This information is presented as the 'COMMIT Initiative recommendations'.

5. Review and recommendations from the COMMIT Initiative: Upon review of the compiled global guidance, additional recommendations from the COMMIT Initiative were applied to the relevant sections of the Compendium.

6. Conflict Resolution: In instances where Codex guidance documents had conflicting requirements, the most recent or the strictest requirement was integrated. Likewise, recent global guidance and

standards (summarized as 'COMMIT Initiative recommendations') were used instead of Codex documents, as those guidance and standards are deemed to have a more rigorous public health focus than available Codex documents. In the Compendium, the blue text differentiates COMMIT Initiative recommendations and other non-Codex references from Codex references.

7. **Compendium Compilation**: The Compendium combines components from all 17 reference documents into a singular document following Codex documentation style. Content from Codex reference documents was included verbatim. However, in select cases, Codex sections were paraphrased to ensure clarity while preserving accuracy.

Table 1: List of international guidelines and standards used as reference documents in the Compendium

Publishing Body	Title
CODEX	Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981.
CODEX	Standard for Canned Baby Foods, CODEX STAN 73-1981.
CODEX	Guidelines on Formulated Complementary Foods for Older Infants and Young Children, CAC/GL 8-1991.
CODEX	General Standard for The Labelling of Pre-packaged Foods, CODEX STAN 1-1985.
CODEX	Guidelines on Nutrition Labelling, CAC/GL 2-1985.
CODEX	Guidelines for Use of Nutrition and Health Claims, CAC/GL 23-1997.
CODEX	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Children, CAC/GL 10-1979.
CODEX	General Standard for Food Additives Codex, STAN 192-1995.
CODEX	General Principles of Food Hygiene, CAC/RCP 1-1969.
CODEX	Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, CAC/RCP 66-2008.
CODEX	Principles for the establishment and application of microbiological criteria for foods, CAC/GL 21-1997.
CODEX	General principles for the addition of essential nutrients to foods, CAC/GL 9-1987.
CODEX	Standard for infant formula and formulas for special medical purposes intended for infants, Codex STAN 72-1981.
CODEX	Recommended methods of analysis and sampling, CODEX STAN 234-1999.
Commission of the European Communities	European Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children.
WHO Regional Office for Europe	Nutrient and promotion profile model: supporting appropriate promotion of food products for infants and young children 6–36 months in the WHO European Region.
COMMIT Initiative	COMMIT Initiative Recommendations for Nutrient Composition and Labelling Practice Requirements of commercially produced complementary foods.

Before you use this compendium

Prior to using this Compendium, it is recommended to review the information below to optimize understanding and use of its content:

Definitions	• **Specific Definitions**: Within each section of the Compendium, definitions pertinent to that particular section are provided. • **General Definitions**: At the end of the document, a 3 Full list of definitions section is provided, including the comprehensive list of definitions relevant to the entire Compendium.
Product Categorization	The categorization of products in this compendium aligns with the twelve categories of the WHO Europe Nutrient and Promotion Profile Model (2022).
Compendium Sections (A-D)	The Compendium is structured in four sections: • **Section A** pertains to all commercially produced complementary foods for older infants and young children. • **Sections B to D** pertain specifically to the twelve categories of commercially produced complementary foods for older infants and young children covered by this Compendium.
Placeholders for national legislation	In the Compendium, any reference to existing national legislation or the inclusion of national languages is written in italics. This makes it easier for users to identify and refer to their national regulations where applicable.
Text Colour Differentiation	• **Codex Standards and Guidelines**: Content derived from Codex is presented in **black**. This ensures that users can easily differentiate between Codex standards and other guidance documents. • **Non-Codex Content**: Any text that is not from Codex, including content from the WHO Europe Nutrient and Promotion Profile Model for CPCF, European Commission Directive 2006/125/EC, and the 4 COMMIT Initiative Recommendations for Nutrient Composition and Labelling Practice Requirements of Commercially Produced Complementary Foods, is written in **blue**.
Annexes	The annexes are provided in a separate, stand-alone document. They offer supplementary information and details that support the main content of the compendium.

General disclaimers

It's worth noting that, while the Compendium compiles all available global guidance documents for CPCF, it does not hold the same authority as Codex standards.

The Compendium sets minimum standards tailored for the Southeast Asian context. However, national legislations play a crucial role in adapting these standards to their specific contexts and needs. Countries are therefore encouraged to implement national standards and regulations that are more stringent and detailed than the Compendium's recommendations and tailored to the national needs.

Finally, all reasonable precautions have been taken by the authors to verify the information contained in this publication. However, the published material is distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall UNICEF EAPRO or COMMIT partners be liable for damages arising from the use of this Compendium.

Limitations

The Compendium has certain limitations that users should acknowledge. Firstly, the Compendium incorporates Codex standards and guidelines, that were formulated through consultations with various stakeholders, including industry representatives. As such, Codex standards may not always optimally represent public health considerations. Moreover, the field of nutrition and food standards is ever-evolving driven by ongoing research, changing consumer habits and advancements in food technology. Therefore, the global standards and guidelines referenced in the Compendium are subject to periodic updates. As such, over time, some of its content may become outdated, and users are encouraged to verify any changes in the referenced documents to ensure they're implementing the most recent and accurate CPCF standard recommendations.

2 Compendium of international standards and guidelines for the improved composition and labelling of commercially produced complementary foods in Southeast Asia

PREAMBLE

This Standard is divided into four sections. Section A refers to all commercially produced complementary foods for older infants and young children, and Section B to Section D refers specifically to the twelve categories of commercially produced complementary foods for older infants and young children covered by this Standard.

SECTION A: ALL COMMERCIALLY PRODUCED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

1. SCOPE

1.1 The provisions of this Standard apply to commercially produced complementary foods for older infants and young children (as defined in Section 2.1 below) intended for feeding older infants as a complementary food from the age of 6 months onwards, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

1.2 Products not marketed for children under 3 years of age, vitamin and mineral supplements and products that function as breast-milk substitutes are not considered to be commercially produced complementary food for older infants and young children and are not covered by this Standard. Confectionary and drinks are not considered appropriate for older infants and young children and do not qualify as commercially produced complementary food for older infants and young children.

1.3 The Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for commercially produced complementary foods for older infants and young children.

1.4 Only products that comply with the criteria laid down in the provisions of this Standard shall be presented as commercially produced complementary foods for older infants and young children. No person shall import, manufacture, advertise for sale or sell commercially produced complementary foods for older infants and young children that are classified as confectionary or drinks to be promoted for older infants and young children.

2. DESCRIPTION

2.1 Product Definition

2.1.1 Commercially produced complementary food for older infants and young children is a manufactured food or drink, other than a breast-milk substitute, which is marketed as suitable for feeding older infants and young children during the complementary feeding period.

Commercially produced complementary foods for older infants and young children are considered to be marketed as being suitable for this age group if they:

a) are labelled with the words 'baby', 'infant', 'toddler' or 'young child';

b) are recommended for introduction at an age of less than 3 years;

c) have a label with an image of a child who appears to be younger than 3 years of age or who is feeding with a bottle; or

d) are in any other way presented as being suitable for children under the age of 3 years.

Twelve categories of commercially produced complementary foods for older infants and young children are covered by this Standard:

2.1.1.1 The category *Dry Cereals and Starches* means:

a) Dry or powdered cereals or starches without added high protein food to be eaten or cooked with milk (or equivalent non-sweet liquid); or

b) Dry or powdered cereals or starches with added high protein food to be eaten or cooked with water (or protein-free liquid).

Dry or powdered cereals include but are not limited to instant porridge, porridge that requires cooking, muesli and dry cereal to be eaten without cooking.

c) Rice, dry pasta and plain fresh pasta to be cooked in water prior to being served.

2.1.1.2 The category *Dairy Foods* means products where the largest ingredient is dairy, and fruit may constitute up to 5% of the product on a wet weight basis. They include but are not limited to porridge, rice pudding, yogurt, fromage frais, and custard.

2.1.1.3 The category *Fruit-containing Foods* means products, excluding Dry cereals and Starches and Snacks and Finger Foods, where fruit constitutes more than 5% of the product on a wet weight basis. These products are typically soft or pureed in texture. They include but are not limited to fruit purees/smoothies, fruit and yogurt, fruit custard, fruit porridge and other fruit desserts.

2.1.1.4 The category *Vegetable Only Foods* means products containing single or mixed vegetables and/or legumes only. They include but are not limited to pureed or mashed vegetables and/or legumes.

2.1.1.5 The category *Food with No Protein Named* means savoury meals or meal components without protein or cheese included in the name of the food. They contain vegetables and/or legumes and/or cereals and/or starches and may contain traditional proteins, dairy or fats.

2.1.1.6 The category *Food with Cheese Named* means savoury meals or meal components with cheese and no other protein included in the name of the food. They contain cheese, vegetables and/or legumes and/or cereals and/or starches and may contain traditional proteins, dairy or fats.

2.1.1.7 The category *Food with Protein Named* means savoury meals or meal components with the protein source not named first in the name of the food but included later in the name of the food. They contain traditional protein, vegetables and/or legumes and/or cereals and/or starches and may contain dairy or fats.

2.1.1.8 The category *Food with Protein Named First* means savoury meals or meal components with the protein source named first in the name of the food. They contain traditional protein, vegetables and/or legumes and/or cereals and/or starches and may contain dairy or fats.

2.1.1.9 The category *Food with Only Protein Named* means a savoury meal component where the protein source is the only food named in the name of the food. They are pureed cooked meat products that may contain small quantities of grain or starch that are not included in the product name.

2.1.1.10 The category *Fruit* means products comprised only of fresh fruit, whole dry fruit or pieces of dried fruit.

2.1.1.11 The category *Snacks and Finger Foods* means any dry or semi-dry grain, starch, pulse or root vegetable snack. They include but are not limited to breads, pastries, cakes and pancakes, as well as rusks, crackers and biscuits recommended to be eaten dry or pulverized with liquid.

2.1.1.12 The category *Ingredients* means products for use during cooking or adding to food in small quantities. They include but are not limited to oils, stock cubes, seasonings and sauces.

2.2 Other Definitions

2.2.1 **Breast-milk substitute** means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose. A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either the liquid or powdered form, that are specifically marketed for feeding infants, older infants and young children up to the age of 3 years.

2.2.2 **Complementary feeding period** is the period from 6 months of age when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating the family diet[7].

2.2.3 **Composition statements** refers to factual statements related to: 1) common allergens (for example "containing" or being "free from [gluten, dairy/lactose, nuts] etc.); 2) religious or cultural requirements (for example "meat free", "vegetarian" "contains meat" "Kosher", "Halal" etc.); 3) factual descriptive words within the ingredients list (for example "organic carrots" and "wholegrain wheat flour" etc.)

2.2.4 **Confectionary** means chocolate confectionery (includes white chocolate confectionery. Excludes cakes and pastries and other baked goods flavoured with or covered in chocolate and chocolate flavoured breakfast cereals) and sugar confectionery (includes jellies and boiled sweets; chewing gum and bubble gum; caramels; liquorice sweets; marzipan sweets; fruit

[7] According to the WHO, 2002, Complementary Feeding, Report of the Global Consultation appropriate complementary feedings should start from the age of six months with continued breast feeding up to two years or beyond; refer also to WHO 2003 Guiding Principles for Complementary feeding of the breastfed child, WHO 2005 Guiding principles for feeding non-breastfed children 6-24 months of age.

chews made from fruit juice or pulped and dehydrated or dried fruit such as fruit gums, bars or fruit strips, leathers or roll-ups).

2.2.5 Drinks means fruit juice and other sweetened or flavoured drinks (includes any drinkable product containing crushed, blended, pulped or puréed fruit and/or vegetable, fruit and/or vegetable juice and/or water, with or without added free sugar or sweetening agents; 100% juices; reconstituted juice from concentrate; smoothies with added juice or water; drinks made from cordials; energy drinks, ices and soft drinks).

2.2.6 Fruit for the purpose of this standard excludes tomatoes, avocadoes and coconut. Fruit means, unsweetened whole or chopped fruits, dry whole or chopped 100% fruits, blended, pulped, puréed or powdered 100% fruits (i.e. not juice) including puréed/powdered dried fruit.

2.2.7 Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

2.2.7.1 Nutrient function claims – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.
Examples: "Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

2.2.7.2 Other function claims –These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.
Examples: "Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

2.2.7.3 Reduction of disease risk claims – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.
Examples: "A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A." "A healthful diet rich in nutrient or substance A may reduce the risk of disease D". "Food X is high in nutrient or substance A."

2.2.8 Marketing means product promotion, distribution, selling, advertising, product public relations and information services.

2.2.9 Non-addition claim means any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food.

2.2.10 Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food.

Examples: "source of iron"; "low in saturated fat".

2.2.11 **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods.
Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".

2.2.12 **Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:
(a) the mention of substances in the list of ingredients;
(b) the mention of nutrients as a mandatory part of nutrition labelling;
(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by *national legislation*.

2.2.13 **Older infants** means persons from the age of 6 months and not more than 12 months of age.

2.2.14 **Traditional protein** means any meat, offal, poultry or fish.

2.2.15 **Young children** means persons from the age of more than 12 months up to the age of three years (36 months).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Refer to Annex I for Codex Alimentarius general guidance on composition and processing of commercially produced complementary foods for older infants and young children.

The following raw materials, most of which are locally available, are suitable ingredients for the production of commercially produced complementary foods for older infants and young children under the specified conditions given below:

3.1 All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content, when necessary, and to decrease and, if possible, to eliminate antinutrients such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption. The use of appropriate enzymes may be considered to decrease fibre and anti-nutrients, if needed.

3.2 Field beans or fava beans (Viciafaba L.) should not be used in commercially produced complementary foods for older infants and young children because of the danger of favism. Heat treatment does not completely inactivate the toxic components (vicine and co-vicine).

3.3 Legumes and pulses such as chickpeas, lentils, peas, cowpeas, mungo beans, green gram, kidney beans and soya beans, containing at least 20% protein on a dry weight basis.

3.4 Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors.

3.5 When phytoestrogen containing legumes and pulses such as soya are added as an ingredient in commercially produced complementary foods for older infants and young children, products with low levels of phytoestrogens should be used.

3.6 Partially hydrogenated fats and oils and industrially produced trans-fatty acids should not be used in commercially produced complementary foods for older infants and young children.

3.7 Added sugars and/or sweeteners should not be used in commercially produced complementary foods for older infants and young children.

3.8 Vitamins and Minerals

3.8.1 Vitamins and/or minerals added should be selected from the Codex Alimentarius Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Commercially Produced Complementary Foods (Annex II) or *national legislation*.

3.8.2 These lists include vitamin and mineral compounds, which may be used for nutritional purposes in commercially produced complementary foods for older infants and young children in accordance with the criteria and conditions of use identified in this standard. As noted in Sections B, C and D of this standard, the use of vitamin and mineral compounds may either be essential or optional.

3.8.3 *Setting level for the addition of vitamins and minerals*

3.8.3.1 The decision to add vitamins and minerals to commercially produced complementary foods for older infants and young children should take into account local conditions including the nutrient contribution to the diet from local foods, vitamins and minerals provided by national programs, food processing technologies applied and the nutritional status of the target population as well as the requirements stipulated by [*national legislation*] and the Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).

3.8.3.2 If the dietary intake data for the target population are available, they can be used to determine appropriate levels for the addition of vitamins and/or minerals to ensure a low prevalence of either inadequate or excessive nutrient intakes using available assessment or monitoring tools.

3.8.3.3 If the dietary intake data for the target population is not available, the vitamin and mineral reference values listed in Codex Alimentarius Guidelines on Formulated Complementary Food for Older Infants and Young Children - CAC/GL 8-1991 (Annex III) can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to commercially produced complementary foods for older infants and young children.

3.9 The total micronutrient intake from the commercially produced complementary foods for older infants and young children, local diet (including breastmilk and/or breastmilk substitutes) and other sources do not regularly exceed recommended upper levels of micronutrient intake for older infants and young children.

3.9.1 *Selecting vitamins and/or mineral for nutrient addition*

3.9.1.1 When establishing the specifications for the premix of vitamin compounds and mineral salts, the vitamin and mineral content and presence of antinutritive substances in the other ingredients used in the formulation of the food should be taken into account.

3.9.1.2 Vitamins and/or minerals should be selected from the Codex Alimentarius Advisory Lists of Nutrient Compounds for Use in Commercially Produced Complementary Foods for Older Infants and Young Children (Annex II) or *national legislation*.

3.9.1.3 The choice of a vitamin and/or mineral compound should take into account its relative bioavailability within the food vehicle, the effect on the sensory properties of the food vehicle

and its stability in the packaged food vehicle under normal storage conditions. The Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) provides specific guidelines in this area.

4. FOOD ADDITIVES AND FLAVOURINGS

4.1 Carry Over of Food Additives into Foods

4.1.1 *Conditions applying to carry-over of food additives from ingredients and raw materials into foods*

Only the food additives listed in the respective product category sections of this Standard or in the Codex Alimentarius Advisory List of Vitamin Compounds for Use in Commercially Produced Complementary Food for Older Infants and Young Children (Annex II) may be present in the product, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice (GMP), consistent with the provisions on carry-over of this Standard.

4.1.2 *Special conditions applying to the use of food additives not directly authorised in food ingredients and raw materials*

An additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this Standard, including that any maximum level applying to the food is not exceeded.

4.1.3 *Foods for which the carry-over of food additives is unacceptable*

Carry-over of a food additive from a raw material or ingredient is unacceptable for commercially produced complementary food unless a food additive provision in the specified category is listed in Tables 1 and 2 of the Codex Alimentarius General Standard for Food Additives (STAN 192-1995).

4.1.4 The following additives are permitted in the preparation of the commercially produced complementary food for older infants and young children (in 100g of product, ready-to-eat prepared following manufacturer's instructions unless otherwise indicated).

INS no.		Maximum level
Emulsifiers		
322	Lecithins	1500 mg
471	Mono- and diglycerides	500 mg Singly or in combination
472a	Acetic and fatty acid esters of glycerol	
472b	Lactic and fatty acid esters of glycerol	
472c	Citric and fatty acid esters of glycerol	
Acidity Regulators		
500 ii	Sodium hydrogen carbonate	GMP
501 ii	Potassium hydrogen carbonate	GMP
170 i	Calcium carbonate	GMP
270	L(+) Lactic acid	GMP
330	Citric acid	GMP
260	Acetic acid	GMP
261	Potassium acetates	
262 i	Sodium acetate	
263	Calcium acetate	
296	Malic acid (DL) – L(+)-form only	
325	Sodium lactate (solution) – L(+)-form only	
326	Potassium lactate (solution) – L(+)- form only	
327	Calcium lactate – L(+)-form only	
331 i	Monosodium citrate	
331 ii	Trisodium citrate	
332 i	Monopotassium citrate	
332 ii	Tripotassium citrate	
333	Calcium citrate	
507	Hydrochloric acid	
524	Sodium hydroxide	
525	Potassium hydroxide	
526	Calcium hydroxide	
575	Glucono delta-lactone	GMP
334	L(+)-Tartaric acid – L(+)form only	500 mg Singly or in combination Tartrates as residue in biscuits and rusks
335 ix	Monosodiumtartrate	
335 ii	Disodium tartrate	
336 i	Monopotassium tartrate –L(+)form only	
336 ii	Dipotassium tartrate – L(+)form only	
337	Potassium sodium L(+)tartrate L(+)form only	
338	Orthophosphoric acid	

339 i	Monosodium orthophosphate	Only for pH adjustment 440 mg Singly or in combination as phosphorous
339 ii	Disodium orthophosphate	
339 iii	Trisodium orthophosphate	
340 i	Monopotassium orthophosphate	
340 ii	Dipotassium orthophosphate	
340 iii	Tripotassium orthophosphate	
341 i	Monocalcium orthophosphate	
341 ii	Dicalcium orthophosphate	
341 iii	Tricalcium orthophosphate	
Antioxidants		
306	Mixed tocopherols concentrate	300 mg/kg fat or oil basis, Singly or in combination
307	Alpha-tocopherol	
304	L-Ascorbyl palmitate	200 mg/kg fat
300	L-Ascorbic acid	50 mg, expressed as ascorbic acid
301	Sodium ascorbate	
303	Potassium ascorbate	
302	Calcium ascorbate	20 mg, expressed as ascorbic acid
Raising Agents		
503 i	Ammonium carbonate	Limited by GMP
503 ii	Ammonium hydrogen carbonate	
500 i	Sodium carbonate	
500 ii	Sodium hydrogen carbonate	
Thickeners		
410	Carob bean gum	1000 mg singly or in combination 2000 mg in gluten-free cereal-based foods
412	Guar gum	
414	Gum arabic	
415	Xanthan gum	
440	Pectins (Amidated and Non-Amidated)	
1404	Oxidized starch	5000 mg Singly or in combination
1410	Monostarch phosphate	
1412	Distarch phosphate	
1413	Phosphated distarch phosphate	
1414	Acetylated distarch phosphate	
1422	Acetylated distarch adipate	
1420	Starch acetate esterified with acetic anhydride	

1450	Starch sodium octenyl succinate	
1451	Acetylated oxidized starch	
Anticaking Agents		
551	Silicon dioxide (amorphous)	200 mg for dry cereals only
Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

5. CONTAMINANTS

5.1 Pesticide Residues

Commercially produced complementary foods for older infants and young children shall be prepared according to GMP in order that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

5.2 Other Contaminants

Commercially produced complementary foods for older infants and young children shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 It is recommended that the products, and their ingredients, covered by the provisions of this Standard be prepared, handled, packaged and held under sanitary conditions in accordance with the appropriate sections of the Codex Alimentarius General Principles of Food Hygiene (CXC 1-1969) and other relevant Codex Alimentarius texts such as Codes of Hygienic Practice [for example, the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004); Code of Practice for the Reduction of Acrylamide in Foods (CAC/RCP 67-2009); Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004); Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)].

6.2 The product should comply with any microbiological criteria established in accordance with the Codex Alimentarius Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997).

7. PACKAGING

7.1 Commercially produced complementary foods for older infants and young children shall be packed in containers which will safeguard the hygienic and other qualities of the food.

7.2 The containers of commercially produced complementary foods for older infants and young children, including packaging material, shall be made only of substances which are safe and suitable for their intended use.

7.3 Where [*national legislation* or the Codex Alimentarius Commission] has established a standard for any such substance used as packaging material, that standard shall apply.

8. LABELLING

8.1 General Principles

8.1.1 The requirements of the Codex Alimentarius General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to this Standard. With specific reference to Section 7 of the Codex Alimentarius General Standard for the Labelling of Prepackaged Foods national jurisdictions may further restrict the use of pictorial devices.

8.1.2 Commercially produced complementary food for older infants and young children shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

8.1.3 Commercially produced complementary food for older infants and young children shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

8.2 Mandatory Labelling of Commercially Produced Complementary Foods for Older Infants and Young Children

The following information shall appear on the label of commercially produced complementary foods for older infants and young children as applicable to the food being labelled, except to the extent otherwise expressly provided in Sections B to D of this Standard:

8.2.1 *The name of the food*

8.2.1.1 The name shall indicate the true nature of the food and normally be specific and not generic.

8.2.1.1.1 Where a name or names have been established for a food in the product category sections of this Standard, at least one of these names shall be used.

8.2.1.1.2 In other cases, the name prescribed by [*national legislation*] shall be used.

8.2.1.1.3 In the absence of any such name, either a common or usual name existing by common usage as an appropriate descriptive term which was not misleading or confusing to the consumer shall be used.

8.2.1.1.4 A "coined", "fanciful", "brand" name or "trade mark" may be used provided it accompanies one of the names provided in Subsections 8.2.1.1.1 to 8.2.1.1.3.

8.2.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packing medium, style, and the condition or type of treatment it has undergone; for example: pureed, ready-to-eat, dried.

8.2.1.3 The name of the product must clearly name the largest ingredient added by proportional content, except when the largest ingredient is implied in the name (such as milk in porridge or rice in risotto).

8.2.1.4 The name of the food to be declared on the label shall indicate that the food is a commercially produced complementary food for older infants and young children. The appropriate designation indicating the true nature of the food should be in accordance with [*national legislation*]. The major sources of protein and the age from which the product is recommended for use shall appear in close proximity to the name of the food.

8.2.2 *List of ingredients*

8.2.2.1 Except for single ingredient foods, a list of ingredients shall be declared on the label.

8.2.2.2 The list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term 'ingredient'.

8.2.2.3 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these may be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.2.2.4 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in [*Refer to relevant national legislation or Codex Alimentarius standards*] constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

8.2.2.5 The ingredient list must clearly indicate the proportion (%) of:

a) The largest single ingredient (including water/stock, except when used for rehydration of legumes/grains etc.);

b) The amount of added water/stock (except when used for rehydration of legumes/grains etc.);

c) The total or individual proportions of fresh or dried fruit;

d) The amount of fish, poultry, meat, or other traditional source of protein.

8.2.2.6 The following foods and ingredients are known to cause hypersensitivity and shall always be declared:

a) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

b) Crustacea and products of these;

c) Eggs and egg products;

d) Fish and fish products;

e) Peanuts, soybeans and products of these;

f) Milk and milk products (lactose included);

g) Tree nuts and nut products; and

h) Sulphite in concentrations of 10 mg/kg or more.

8.2.2.7 Added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared.

8.2.2.8 As an alternative to the general provisions of this section, dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as "ingredients of the product when prepared in accordance with the directions on the label" is included.

8.2.2.9 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 8.2.2.6 shall be declared.

8.2.2.10 When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

8.2.2.11 A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 8.2.1 (Name of the Food) except that:

8.2.2.11.1 Except for those ingredients listed in Section 8.2.2.6, and unless a general class name would be more informative, the following class names may be used:

Name of Classes	Class Names
Refined oils other than olive	'Oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or' partially hydrogenated', as appropriate
Refined fats	'Fat' together with either, the term 'vegetable' or 'animal', as appropriate
Starches, other than chemically modified starches	'Starch'
All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish	'Fish'
All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not refer to a specific type of poultry meat	'Poultry meat'
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese	'Cheese'
All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food	'Spice', 'spices', or 'mixed spices', as appropriate
All herbs or parts of herbs not exceeding 2% by weight either singly or in combination in the food	'Herbs' or 'mixed herbs', as appropriate
All types of gum preparations used in the manufacture of gum base for chewing gum	'Gum base'
All types of sucrose	'Sugar'
Anhydrous dextrose and dextrose monohydrate'	'Dextrose' or 'glucose'
All types of caseinates	'Caseinates'
Milk products containing a minimum of 50% of milk protein (m/m) in dry matter *	'Milk Protein'
Press, expeller or refined cocoa butter	'Cocoa butter'
All crystallized fruit not exceeding 10% of the weight of the food	'Crystallized fruit'
*Calculation of milk protein content: Kjeldahl nitrogen × 6.38	

8.2.2.12 Notwithstanding the provision set out in Section 8.2.2.11.1, pork fat, lard and beef fat shall always be declared by their specific names.

8.2.2.13 For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods, the following functional classes shall be used together with the specific name or recognized numerical identification such as the Codex guidance Class Names and the International Numbering System for Food Additives (CXG 36-1989) or as required by *national legislation*.

a) Acidity Regulator

b) Flour Treatment Agent

c) Anticaking Agent

d) Foaming Agent

e) Antifoaming Agent

f) Gelling Agent

g) Antioxidant

h) Glazing Agent

i) Bleaching Agent

j) Humectant

k) Bulking Agent

l) Preservative

m) Carbonating Agent

n) Propellant

o) Colour

p) Raising Agent

q) Colour Retention Agent

r) Sequestrant

s) Emulsifier

t) Stabilizer

u) Emulsifying Salt

v) Sweetener

w) Firming Agent

x) Thickener

y) Flavour Enhancer.

8.2.2.14 The following class titles may be used for food additives falling in the respective classes and appearing in lists of food additives permitted generally for use in foods:

a) Flavour (s) and Flavouring(s)

b) Modified Starch(es).

The expression "flavours" may be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate.

8.2.2.15 Processing aids and carry-over of food additives:

8.2.2.15.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

8.2.2.15.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in Section 8.2.2.6

8.2.3 Net contents and drained weight:

8.2.3.1 The net contents shall be declared in the metric system ("Système International" units). The declaration of net contents represents the quantity at the time of packaging and is subject to enforcement by reference to an average system of quantity control.

8.2.3.2 The net contents shall be declared in the following manner:

a) For liquid foods, by volume;

b) For solid foods, by weight;

c) For semi-solid or viscous foods, either by weight or volume.

8.2.3.3 In addition to the declaration of net contents, a food packed in a liquid medium shall carry a declaration in the metric system of the drained weight of the food. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices in canned fruits and vegetables only, or vinegar, either singly or in combination (The declaration of drained weight is subject to enforcement by reference to an average system of quantity control).

8.2.4 Name and address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

8.2.5 Country of origin

8.2.5.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.

8.2.5.2 When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

8.2.6 Lot identification

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot.

8.2.7 Date marking and storage instructions

8.2.7.1 The following date marking shall apply, unless clause 8.2.7.1 (vii) applies:

(i) When a food must be consumed before a certain date to ensure its safety and quality the "Use–by Date" or "Expiration Date" shall be declared.

(ii) Where a "Use-by Date" or "Expiration Date" is not required, the "Best-Before Date" or "Best Quality Before Date" shall be declared.

(iii) The date marking should be as follows:

- On products with a durability of not more than three months; the day and month shall be declared and in addition, the year when competent authorities consider consumers could be misled.
- On products with a durability of more than three months at least the month and year shall be declared.

(iv) The date shall be introduced by the words:

- "Use-by <insert date>" or "Expiration Date <insert date>" or Best before <insert date>" or "Best Quality Before <insert date>" as applicable where the day is indicated; or
- "Use-by end <insert date>" or "Expiration date end <insert date>" or "Best before end <insert date>" or "Best Quality Before end <insert date>" as applicable in other cases.

(v) The words referred to in paragraph (iv) shall be accompanied by:

- Either the date itself; or
- A reference to where the date is given.

(vi) The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).

(vii) Provided that food safety is not compromised, the provision in 8.2.7.1 (i) or 8.2.7.1 (ii) is not required for a food if one or more of the following criteria apply:

1. Where safety is not compromised and quality does not deteriorate because the nature of the food is such that it cannot support microbial growth (e.g. alcohol, salt, acidity, low water activity under intended or stated storage conditions;

2. Where deterioration is clearly evident by physical examination at the point of purchase, such as raw fresh produce that has not been subject to processing and presented in a manner that is visible to the consumer;

3. Where the key/organoleptic quality aspects of the food are not lost;

4. Where the food by its nature is normally consumed within 24 hours of its manufacture, such as some bakers' or pastry-cooks' wares.

   For example, foods such as (this is an illustrative list):

   - Fresh fruit and vegetables, including tubers, which have not been peeled, cut or similarly treated;

- Bakers' or pastry-cooks' wares, which given the nature of their content, are normally consumed within 24 hours of their manufacture;
- Vinegar;
- Non-iodized food grade salt.

In such cases, the "Date of Manufacture" or the "Date of Packaging" may be provided.

(viii) A "Date of Manufacture" or a "Date of Packaging" may be used in combination with 8.2.7.1 (i) or (ii). It shall be introduced with the words "Date of Manufacture" or "Date of Packaging", as appropriate, and use the format provided in clause 8.2.7.1 (vi).

8.2.7.2 Any special conditions for the storage of the food shall be declared on the label where they are required to support the integrity of the food and, where a date mark is used, the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.

8.2.8 Information for use

8.2.8.1 The label shall indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.

8.2.8.2 Directions as to the preparation and use of the food, and its storage and keeping before and after the container has been opened, shall appear on the label and may also appear on the accompanying leaflet.

8.2.8.3 Instructions for use, including reconstitution, where applicable, shall be included on the label, as necessary, to ensure correct utilization of the food.

8.2.8.4 The suggested number of feedings per day should be indicated.

8.2.8.5 In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:

a) Where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;

b) Where the food contains heat-processed basic ingredients:

i. the food requires boiling, or

ii. can be mixed with boiled water that has been cooled.

8.2.8.6 For commercially produced complementary foods for older infants and young children to which fats, sugars or other digestible carbohydrates should be added during preparation, the instructions for use shall identify appropriate sources and indicate the amounts of the ingredients to be added. In such situations, fats and oils with an appropriate essential fatty acid ratio should be recommended.

8.2.8.7 Directions for use shall include a statement that only an amount of food sufficient for one feeding occasion should be prepared at one time. Foods not consumed during the feeding

occasion should be discarded, unless consumed within a period as recommended by the manufacturer under the instructions for use.

8.2.8.8 The label should also include a statement that commercially produced complementary food for older infants and young children are to be consumed to complement family foods and breastmilk/breast-milk substitutes. Example, "This product should only be included as part of the 6 month and older child's diet together with family foods and breastmilk"

8.2.9 Declaration of nutritional information

8.2.9.1 *Application of nutrient declaration*

8.2.9.1.1 Nutrient declaration should be mandatory for all commercially produced complementary foods for infants and young children.

8.2.9.1.2 Nutrient declaration may be exempted where national circumstances do not support such declarations. Certain foods may be exempted for example, on the basis of nutritional or dietary insignificance or small packaging. *National legislation should specify the circumstances where nutrient declaration is not mandatory.*

8.2.10 *Listing of Nutrients*

8.2.10.1 Where nutrient declaration is applied, the declaration of the following should be mandatory:

8.2.10.2 The declaration of nutrition information shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ) and the number of grammes of protein, available carbohydrate, fibre, total sugar, total fat, saturated fat, cholesterol and the number of milligrams of sodium per 100 grammes or per 100 millilitres of the food as sold as well as per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

b) The amount of any other nutrient for which nutrient content claim is made; and

c) The amount of any other nutrient considered to be relevant for maintaining a good nutritional status, as required by national legislation or national dietary guidelines. (*Countries where the level of intake of trans-fatty acids is a public health concern should consider the declaration of trans-fatty acids in nutrition labelling.*)]

8.2.10.3 Where a specific nutrient content claim is applied, then the declaration of the amount of any other nutrient considered relevant for maintaining a good nutritional status as required by national legislation or national dietary guidelines should be mandatory.

8.2.10.4 Where a claim is made regarding the amount and/or the type of carbohydrate, the amount of total sugars should be listed in addition to the requirements in Section 8.2.10.2. The amounts of starch and/or other carbohydrate constituent(s) may also be listed. Where a claim is made regarding the dietary fibre content, the amount of dietary fibre should be declared.

8.2.10.5 Where a claim is made regarding the amount and/or type of fatty acids or the amount of cholesterol, the amounts of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids and cholesterol should be declared, and the amount of trans fatty acid may be required according to national legislation, in addition to the requirements of Section 8.2.10.2 and in accordance with Section 8.2.11.

8.2.10.6 In addition to the mandatory declaration under 8.2.10.4, 8.2.10.5 and 8.2.10.6 vitamins and minerals may be listed in accordance with the following criteria:

Only vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared.

When nutrient declaration is applied, vitamins and minerals which are present in amounts less than 5% of the Nutrient Reference Value or of the officially recognized guidelines of the competent authority per 100 g or 100 ml or per serving as quantified on the label should not be declared.

8.2.10.7 In the case where a product is subject to labelling requirements of *national legislation* or Codex Alimentarius standard, the provisions for nutrient declaration set out in that standard should take precedence over but not conflict with the provisions of Sections 8.2.10.2 to 8.2.10.7 of this Standard.

8.2.11 *Calculation of Nutrients*

8.2.11.1 Calculation of energy

The amount of energy to be listed should be calculated by using the following conversion factors:

Carbohydrates: 4 kcal/g – 17 kJ

Protein: 4 kcal/g – 17 kJ

Fat: 9 kcal/g – 37 kJ

Alcohol (Ethanol): 7 kcal/g – 29 kJ

Organic acid: 3 kcal/g – 13 kJ

8.2.11.2 Calculation of protein

The amount of protein to be listed should be calculated using the formula:

Protein = Total Kjeldahl Nitrogen x 6.25

unless a different factor is given in a Codex Alimentarius standard or in the Codex Alimentarius method of analysis for that food.

8.2.12 *Presentation of Nutrient Content*

8.2.12.1 The declaration of nutrient content should be numerical. However, the use of additional means of presentation should not be excluded.

8.2.12.2 Information on energy value should be expressed in kJ and kcal per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

8.2.12.3 Information on the amounts of protein, carbohydrate and fat in the food should be expressed in g per 100 g or per 100 ml or per package if the package contains only a single portion. In addition,

this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

8.2.12.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the NRV per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

In addition, information on protein and additional nutrients may also be expressed as percentages of the NRV where an NRV has been established.

8.2.12.5 In countries where serving sizes are normally used, the information required by Sections 8.2.12.2 to 8.2.12.4 may be given per serving only as quantified on the label or per portion provided that the number of portions contained in the package is stated.

8.2.12.6 The presence of available carbohydrates should be declared on the label as "carbohydrates". Where the type of carbohydrate is declared, this declaration should follow immediately the declaration of the total carbohydrate content in the following format:

Carbohydrate ... g, of which sugars ... g".

This may be followed by the following: "x" ...g

where "x" represents the specific name of any other carbohydrate constituent.

8.2.12.7 Where the amount and/or type of fatty acids or the amount of cholesterol is declared, this declaration should follow immediately the declaration of the total fat in accordance with Section 8.2.12.3.

The following format should be used:

Total Fat ... g

of which

saturated fatty acids ... g

trans fatty acids ... g

monounsaturated fatty acids ... g

polyunsaturated fatty acids ... g

Cholesterol ... mg

8.2.13 *Tolerances and compliance*

8.2.13.1 Tolerance limits should be set in relation to public health concerns, shelf-life, accuracy of analysis, processing variability and inherent liability and variability of the nutrient in the product, and, according to whether the nutrient has been added or is naturally occurring in the product.

8.2.13.2 The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.

8.2.13.3 Where national tolerance limits have not been set, the tolerance limits provided for macronutrients and micronutrients in European Union (EU) Directive 2002/46/EC and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods should be used.

8.2.14 *Principles and criteria for legibility of nutrition labelling*

8.2.14.1 Specific features of presentation

8.2.14.2 The recommendations related to specific features of presentation are intended to enhance the legibility of nutrition labelling.

8.2.14.3 Format – Nutrient content should be declared in a numerical, tabular format. Where there is insufficient space for a tabular format, nutrient declaration may be presented in a linear format.

8.2.14.4 Nutrients should be declared in a specific order developed by competent authorities and should be consistent across food products.

8.2.14.5 Font –The font type, style and a minimum font size as well as the use of upper- and lower-case letters should be considered by competent authorities to ensure legibility of nutrition labelling.

8.2.14.6 Contrast – A significant contrast should be maintained between the text and background so as to be that the nutrition information is clearly legible.

8.2.14.7 Numerical Presentation – The numerical presentation of nutrient content should be in accordance with the provisions of Section 8.2.12.

8.2.15 *Supplementary nutrition information*

8.2.15.1 Supplementary nutrition information is intended to increase the consumer's understanding of the nutritional value of their food and to assist in interpreting the nutrient declaration (Guidelines on front-of-pack nutrition labelling are provided in Annex 2 of the Codex Alimentarius Guidelines on Nutrition Labelling - CAC/GL 2-1985). There are a number of ways of presenting such information that may be suitable for use on food labels.

8.2.15.2 The use of supplementary nutrition information on food labels should be optional and should only be given in addition to, and not in place of, the nutrient declaration, except for target populations who have a high illiteracy rate and/or comparatively little knowledge of nutrition. For these, food group symbols or other pictorial or colour presentations may be used without the nutrient declaration.

8.2.15.3 Supplementary nutrition information on labels should be accompanied by consumer education programmes to increase consumer understanding and use of the information.

8.2.15.4 Nutrition and health claims shall not be permitted for foods for infants and young children except for specific nutrient content claims of nutrients stated in section 9.

8.3 Additional Mandatory Requirements

8.3.1 *Quantitative ingredients declaration*

8.3.1.1 The ingoing percentage of an ingredient (including compound ingredients or categories of ingredients), by weight or volume as appropriate, at the time of manufacture, shall be disclosed for foods sold as a mixture or combination where the ingredient:

a) Is emphasised as present on the label through words or pictures or graphics; or

b) Is not within the name of the food, is essential to characterise the food and is expected to be present in the food by consumers in the country where the food is sold if the omission of the quantitative ingredient declaration would mislead or deceive the consumer.

Such disclosure is not required:

a) Where the ingredient is used in small quantities for the purpose of flavouring; or

b) Where commodity specific standards of Codex Alimentarius conflict with the requirements described here.

With respect to 8.3.1.1(a):

A reference in the name of the food to an ingredient or category of ingredients shall not of itself require quantitative ingredient declaration if:

that reference would not mislead or deceive or would not be likely to create an erroneous impression to the consumer regarding the character of the food in the country of marketing because the variation in quantity of the ingredient(s) between products is not necessary to characterise the food or distinguish it from similar foods.

8.3.1.2 The information required in Section 8.3.1.1 shall be declared on the product label as a numerical percentage. The ingoing percentage, by weight or volume as appropriate, of each such ingredient shall be given on the label in close proximity to the words or pictures or graphics emphasising the particular ingredient, or beside the name of the food, or adjacent to each appropriate ingredient listed in the ingredient list as a minimum percentage where emphasis is on the presence of the ingredient and a maximum percentage where emphasis is on the low level of the ingredient. For foodstuffs which have lost moisture following heat or other treatment, the percentage (by weight or by volume) shall correspond to the quantity of the ingredient(s) used, related to the finished product. When the quantity of an ingredient or the total quantity of all ingredients expressed on the labelling exceeds 100%, the percentage may be replaced by the declaration of the weight of the ingredient(s) used to prepare 100g of finished product.

8.4 Exemption from Mandatory Labelling

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm^2, may be exempted from the requirements of paragraphs in 8.2.2 and 8.2.7 to 8.2.9.

8.5 Optional Labelling

8.5.1 Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 8.1.

8.5.2 If grade designations are used, they shall be readily understandable and not be misleading or deceptive in any way.

8.6 Presentation of mandatory Information

8.6.1 *General*

8.6.1.1 Labels in commercially produced complementary foods for older infants and young children shall be applied in such a manner that they will not become separated from the container.

8.6.1.2 Statements required to appear on the label by virtue of this standard or any *other national legislation*/Codex Alimentarius standards shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.

8.6.1.3 Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper or not obscured by it.

8.6.1.4 The name and net contents of the food shall appear in a prominent position and in the same field of vision.

8.6.2 *Language*

8.6.3 The information required in this Standard shall be provided in [*national language*].

8.6.4 In the case of imported products, a sticker(s) with the information in [*national language*] may be placed over the foreign language.

8.7 Additional Labelling Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

8.7.1 The following statement must be included on the label of commercially produced complementary foods for older infants and young children: "For optimal baby health, breastfeeding should continue up to 2 years of age and beyond together with complementary feeding."

8.7.2 All images of bottles and the recommended use of bottles in the instructions for use are prohibited on labels of commercially produced complementary foods for older infants and young children.

9. CLAIMS

9.1 Nutrient Content Claims

The only nutrition and health claims permitted on the labels of commercially produced complementary foods for older infants and young children are specific nutrient content claims, all other nutrition and health claims including nutrient function claims, disease risk reduction claims, and endorsements are prohibited.

9.1.1 Any food for which a nutrient content claim is made should be labelled with a nutrient declaration in accordance with Section 9.2.10 of this Standard.

9.1.2 Nutrient content claims are only permitted for specific nutrients included in the Table of Permitted Nutrient Content Claims.

9.1.3 When a nutrient content claim that is listed in the Table of permitted nutrient content claims is made, the conditions specified in the Table for that claim should apply.

9.1.4 A claim to the effect that a food is free of salt can be made, provided the food meets the conditions for free of sodium listed in the Table of Permitted Nutrient Content Claims.

9.1.5 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".

9.1.6 Products from the category Dry Cereals and Starches mentioned in points 2.1.1.1a and 2.1.1.1b shall be fortified with calcium, iron and zinc, as specified in Section B.

Table of Permitted Nutrient Content Claims		
Component	**Permitted claim**	**Condition (not more than)**
Fat	Low	≤ 3 g per 100 g (solids) or ≤ 1.5 g per 100 ml (liquids).
	Free from	≤ 0.5 g per 100 g (solids) or 100 ml (liquids).
Saturated fat	Low	≤ 1.5 g per 100 g (solids), ≤0.75 g per 100 ml (liquids) and 10% of energy from saturated fat.
	Free from	≤ 0.1 g per 100 g (solids) or ≤ 0.1 g per 100 ml (liquids).
Cholesterol	Low	≤ 0.02 g per 100 g (solids) or ≤ 0.01 g per 100 ml (liquids).
	Free from	≤ 0.005 g per 100 g (solids) or 0.005 g per 100 ml (liquids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 ml (liquids), and 10% of energy from saturated fat.
Sugars	Free from	≤ 0.5 g per 100 g (solids), ≤ 0.5 g per 100 ml (liquids).
Sodium	Low	≤ 0.12 g per 100 g
	Very Low	≤ 0.04 g per 100 g
	Free from	≤ 0.005 g per 100 g
Component	**Claim**	**Condition (not less than)**
Protein	Source of	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	the content of protein is two times the values for "source"
Vitamins and minerals	Source of	≥ 15% INL 98 per 100 g (solids), 7.5% INL 98 per 100 ml (liquids) Or 5% INL 98 per 100 kcal Or 15% INL 98 per serving

	High in	30% INL 98 per 100 g (solids) 15% INL 98 per 100 ml (liquids) Or 10% INL 98 per 100 kcal Or 30% INL 98 per serving
Dietary fibre	Source of	3 g per 100 g or 1.5 g per 100 kcal or 10 % of daily reference value per serving
	High	6 g per 100 g or 3 g per 100 kcal or 20 % of daily reference value per serving

9.2 Composition Statements

The following composition statements are permitted on the labels of commercially produced complementary foods for older infants and young children:

a) statements relating to common allergens (such as containing or being "free from… [gluten, dairy/lactose, nuts])";

b) statements relating to religious or cultural requirements (such as "meat free", "vegetarian", "contains meat", "Kosher", "Halal");

c) Descriptive words may be used within the ingredient list (such as "organic carrots" and "wholegrain wheat flour").

10. METHODS OF ANALYSIS AND SAMPLING

10.1 For checking the compliance with this Standard, the methods of analysis contained in Annex V of this Standard, shall be used.

10.2 Methods of analysis by commodity categories and names are reported in Annex V.

SECTION B: THE CATEGORIES DRY CEREALS AND STARCHES AND SNACKS AND FINGER FOODS

1. SCOPE

1.1 This section of the Standard applies to the Commercially Produced Complementary Food categories Dry Cereals and Starches and Snacks and Finger Foods (as defined in 2.1 and 2.2 below) intended for feeding older infants as a complementary food from the age of 6 months onwards, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Dry Cereals and Starches and Snacks and Finger Foods.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as Dry Cereals and Starches and Snacks and Finger Foods for older infants and young children.

2. DESCRIPTION

2.1 The category *Dry Cereals and Starches* means:

2.1.1 Dry or powdered cereals or starches without added high protein food to be eaten or cooked with milk (or equivalent non-sweet liquid); or

2.1.2 Dry or powdered cereals or starches with added high protein food to be eaten or cooked with water (or protein-free liquid).

Dry or powdered cereals include but are not limited to instant porridge, porridge that requires cooking, muesli and dry cereal to be eaten without cooking.

2.1.3 Rice, dry pasta and plain fresh pasta to be cooked in water prior to being served.

2.2 The category *Snacks and Finger Foods* means any dry or semi-dry grain, starch, pulse or root vegetable snack. They include but are not limited to breads, pastries, cakes and pancakes, as well as rusks, crackers and biscuits recommended to be eaten dry or pulverized with liquid.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 Refer to section A.3.

3.1.2 The requirements concerning energy and nutrients refer to the product ready-to-eat as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

3.2 Energy density

For products mentioned in points 2.1 and 2.2, the energy density shall not be less than 3.3 kJ/g (0.8 kcal/g), or 16.7 kJ/g (4 kcal/g) on a dry weight basis.

3.3 Protein

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

3.3.2 For products mentioned in points 2.1.2 and 2.2, the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal).

3.3.3 For products mentioned in point 2.1.2, the added protein content shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

3.3.4 For rusks and biscuits mentioned in point 2.2 made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5 g/ 100 kcal).

3.4 Carbohydrates

3.4.1 For products referred to in points 2.1.1 and 2.2, the total sugar content shall not exceed 0.9g/100 kJ (3.75g /100 kcal).

3.4.2 For products referred to in point 2.1.2, the total sugar content shall not exceed 1.2g/100 kJ (5g/100 kcal).

3.5 Lipids

3.5.1 For products mentioned in point 2.1.2 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal). If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

a) the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal);

b) the amount of lauric acid shall not exceed 15% of the total lipid content;

c) the amount of myristic acid shall not exceed 15% of the total lipid content.

3.5.2 Products mentioned in points 2.1.1 and 2.2 shall not exceed the maximum lipid content of 0.8 g /100 kJ (3.3 g/100 kcal).

3.5.3 For products mentioned in point 2.2 with added milk, the lipid content shall not exceed 1.1g/100 kJ (4.5g/100kcal).

3.6 Minerals

3.6.1 Refer to Section A 3.8.

3.6.2 Sodium

For products mentioned in point 2.1. and 2.2, the sodium content shall not exceed 12 mg/100 kJ (50 mg/100kcal).

3.6.3 Calcium

3.6.3.1 For products mentioned in point 2.1.1 and 2.1.2 the calcium content shall not be less than 375 mg/100g and 250 mg/daily ration[8].

3.6.3.2 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.2 manufactured with the addition of milk and presented as such. .

3.6.4 Iron (10% bioavailability)

For products mentioned in point 2.1.1 and 2.1.2, the iron content shall not be less than 4.35 mg/100g and 2.9 mg/daily ration[8].

3.6.5 Zinc (10% bioavailability)

For products mentioned in points 2.1.1 and 2.1.2, the zinc content shall not be less than 3.075 mg/100g and 2.05 mg/daily ration[8].

3.7 Vitamins

3.7.1 Refer to section A 3.8.

3.7.2 Vitamin B_1 (Thiamine)

For products mentioned in points 2.1 and 2.2, the amount of vitamin B_1 (thiamine) shall not be less than 12.5µg/100 kJ (50µg/100 kcal).

3.7.3 Vitamin A and Vitamin D

3.7.3.1 For products mentioned in 2.1.2, the amount of vitamin A and vitamin D shall be within the following limits:

	µg/100kJ	µg/100kcal
Vitamin A (µg retinol equivalents)	14 - 43	60 - 180
Vitamin D	0.25 - 0.75	1 - 3

These limits are also applicable to the products mentioned in points 2.1.1, 2.1.3 and 2.2 when vitamin A or D are added.

3.7.3.2 Reductions of the maximum amounts for vitamin A and Vitamin D referred to in 3.7.3.1 and the addition of vitamins and minerals for which specifications are not set above shall be in conformity with [*Refer to national legislation*].

3.8 Optional Ingredients

3.8.1 In addition to the ingredients listed in Section A.3, other ingredients suitable for older infants and young children can be used.

3.8.2 Only L(+) lactic acid producing cultures may be used.

[8] Daily ration is the equivalent of two servings of the product.

3.9 Quality factors

3.9.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.

3.9.2 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

3.10 Consistency and particle size

When prepared according to the label directions for use, the products mentioned in points 2.1 and 2.2 should have a texture appropriate for the spoon feeding of older infants or young children of the age for which the product is intended.

3.11 Specific prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES AND FLAVOURINGS

4.1 Refer to Section A.4.

4.2 The following flavourings may be used:

a) Natural fruit extracts and vanilla extract: GMP.

b) Ethyl vanillin and vanillin: 7mg/100 g of the ready-to-eat product.

5. CONTAMINANTS

Refer to Section A.5.

6. HYGIENE

Refer to Section A.6.

7. PACKAGING

Refer to Section A.7.

8. LABELLING

8.1 Refer to Section A.8.

8.2 In addition to Section A.8.3, the name of the food shall be "Dry cereal for children from 6 months", "Rusks for older infants (and/or young children)" or "Biscuits (or "Milk biscuits") for older Infants (and/or young children)" or "Pasta for older infants (and/or young children)", or any

appropriate designation indicating the true nature of the food, in accordance with [*Refer to national legislation*].

8.2.1 In addition to Section A 8.10, for products referred to in point 2.1.1, directions on the label shall state "Milk or formula but no water shall be used for dilution or mixing" or an equivalent statement.

8.2.2 When the product is composed of gluten-free ingredients and food additives, the label may show the statement "gluten-free".

8.2.3 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of Section A 8.2.10.7 expressed in numerical form per 100g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

9. CLAIMS

Refer to Section A.9

10. METHODS OF ANALYSIS AND SAMPLING

Refer to Section A.10.

SECTION C: THE CATEGORIES DAIRY FOODS, FRUIT AND VEGETABLE FOODS AND SAVOURY MEALS/MEAL COMPONENTS

1. SCOPE

1.1 This section of the Standard applies to the commercially produced complementary food categories Dairy Foods, Fruit and Vegetable Foods and Savoury Meals/Meal Components (as defined in 2.1, 2.2 to 2.3 and 2.4 to 2.8 respectively below) intended for feeding older infants as a complementary food from the age of 6 months onwards, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

1.2 Dairy Foods, Fruit and Vegetable Foods and Savoury Meals/Meal Components in ready-to-eat form are processed by heat before or after being sealed in their containers.

1.3 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Dairy Foods, Fruit and Vegetable Foods and Savoury Meals/Meal Components.

1.4 Only products that comply with the criteria laid down in the provisions of this section would be accepted for marketing as Dairy Foods, Fruit and Vegetable Foods and Savoury Meals/Meal Components for older infants and young children.

2. DESCRIPTION

2.1 The category *Dairy Foods* mean products where the largest ingredient is dairy, and fruit may constitute up to 5% of the product on a wet weight basis. They include but are not limited to porridge, rice pudding, yogurt, fromage frais, and custard.

2.2 The category *Fruit-containing Foods* means products, excluding Dry cereals and Starches and Snacks and Finger Foods, where fruit constitutes more than 5% of the product on a wet weight basis. They include but are not limited to fruit purees/smoothies, fruit and yogurt, fruit custard, fruit porridge and other fruit desserts.

2.3 The category *Vegetable Only Foods* means products containing single or mixed vegetables and/or legumes only. They include but are not limited to pureed or mashed vegetables and/or legumes.

2.4 The category *Food with No Protein Named* means savoury meals or meal components without protein or cheese included in the name of the food. They contain vegetables and/or legumes and/or cereals and/or starches and may contain traditional proteins, dairy or fats.

2.5 The category *Food with Cheese Named* means savoury meals or meal components with cheese and no other protein included in name of the food. They contain cheese, vegetables and/or legumes and/or cereals and/or starches and may contain traditional proteins, dairy or fats.

2.6 The category *Food with Protein Named* means savoury meals or meal components with the protein source not named first in the name of the food but included later in the name of the

food. They contain traditional protein, vegetables and/or legumes and/or cereals and/or starches and may contain dairy or fats.

2.7 The category *Food with Protein Named First* means savoury meals or meal components with the protein source named first in the name of the food. They contain traditional protein, vegetables and/or legumes and/or cereals and/or starches and may contain dairy or fats.

2.8 The category *Food with Only Protein Named* means a savoury meal component where the protein source is the only food named in the name of the food. They are pureed cooked meat products that may contain small quantities of grain or starch that are not included in the product name.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 Refer to Section A.3.

3.1.2 The categories listed in points 2.1 to 2.8 may be prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food, including spices.

3.1.3 The addition of salt (NaCl) to products mentioned in point 2.2 is not permitted.

3.2 Protein

3.2.1 For products mentioned in point 2.1, the protein content shall not be less than 0.5g/100kJ (2.2g/100kcal).

3.2.2 For products mentioned in points 2.4 to 2.6, the protein content shall not be less than 0.7g/100kJ (3g /100kcal).

3.2.3 For products mentioned in point 2.7, the protein content shall not be less than 0.9g/100kJ (4g/100kcal).

3.2.4 For products mentioned in point 2.8, the protein content shall not be less than 1.7g/100kJ (7g/100kcal).

3.3 Total sugar

3.3.1 For products mentioned in point 2.1, the total sugar content shall not exceed 1.2g/100 kJ (5g /100kcal).

3.3.2 For products mentioned in point 2.2 that do not contain vegetables, the total sugar content shall not exceed 20g/100g. For products referred to in 2.2 that contain vegetables, the total sugar content shall not exceed 15g/100g.

3.3.3 For products mentioned in point 2.3, the total sugar content shall not exceed 10g/100g.

3.3.4 For products mentioned in points 2.4 to 2.8, the total sugar content shall not exceed 0.9g/100 kJ (3.75g /100 kcal).

3.4 Lipids

3.4.1 For products mentioned in points 2.1 to 2.4 and 2.6, the total fat content shall not exceed 1.1g/100kJ (4.5 g/100kcal).

3.4.2 For products mentioned in points 2.5, 2.7 and 2.8, the total fat content shall not exceed 1.4g/100kJ (6.0g/100kcal).

3.5 Minerals

3.5.1 Refer to Section A 3.8.

3.5.2 Sodium

3.5.2.1 For products mentioned in points 2.1 to 2.4 and 2.6 to 2.8, the sodium content shall not exceed 11.9 mg/100 kJ (50 mg/100 kcal). If products referred to in 2.1, 2.6 or 2.7 include cheese in the product name, the sodium content shall not exceed 23.9 mg/100 kJ (100 mg/100 kcal).

3.5.2.2 For products mentioned in point 2.5, the sodium content shall not exceed 23.9 mg/100 kJ (100 mg/100 kcal).

3.6 Vitamins

3.6.1 Refer to Section A 3.8.

3.7 Consistency and Particle size

Ready-to-eat products are homogeneous or comminuted in the following forms:

(a) strained: food of a fairly uniform, small particle size which does not require and does not encourage chewing before being swallowed;

(b) junior: food that ordinarily contains particles of a size to encourage chewing by older infants and young children.

3.8 Purity Requirements

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with excessive fibre removed where necessary. Fish, meat and poultry ingredients shall be practically free of pieces of bones.

3.9 Specific Prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES AND FLAVOURINGS

4.1 Refer to Section A.4.

4.2 The following additives are permitted in the preparation of the products comminuted in 2.1 to 2.8 with the restrictions stated below.

Maximum level in 100g of the ready-to-eat product (unless otherwise indicated):

INS no.		Maximum level in 100 g of the ready-to-eat product (unless otherwise indicated)
Thickening agents		
410	Locust bean gum[9]	0.2g
412	Guar gum	0.2g
1412	Distarch phosphate	6g, singly or in combination
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1440	Hydroxypropyl starch	
1422	Acetylated distarch adipate	
1411	Distarch glycerol	
1423	Acetylated distarch glycerol	
440	Non-amidated pectin	1g in products mentioned in 2.2 only
Emulsifiers		
322	Lecithin	0.5 g
471	Mono- and diglycerides	0.15 g
pH Adjusting Agents		
500(ii)	Sodium hydrogen carbonate	Limited by good manufacturing practice and within the limit for sodium in Section 3.5.2.1 and Section 3.5.2.2 and Section 3.5.2.3
500(i)	Sodium carbonate	
501(ii)	Potassium hydrogen carbonate	Limited by good manufacturing practice
170(i)	Calcium carbonate	
330 and 331	Citric acid and sodium salt	0.5 g and within the limit for sodium in Section 3.5.2.1 and Section 3.5.2.2 and Section 3.5.2.3
270	L(+) Lactic acid	0.2 g
260	Acetic acid	0.5 g
Antioxidants		
307a	Mixed tocopherols concentrate	300 mg/kg fat, singly or in combination
307b	A-Tocopherol	
304	L-Ascorbyl palmitate	200 mg/kg fat
300,301, and 303	L-Ascorbic acid and its sodium and potassium salts	0.5 g/kg, expressed as ascorbic acid and within the limit for sodium in Section 3.5.2.1 and Section 3.5.2.2 and Section 3.5.2.3

[9] Temporarily endorsed.

4.3 The following flavourings may be used:

a) Vanilla extract: Limited by good manufacturing practice.

b) Ethyl vanillin and vanillin: ≤7 mg/100 g of the ready-to-eat product.

5. CONTAMINANTS

Refer to Section A.5.

6. HYGIENE

Refer to Section A.6.

7. PACKAGING

7.1 Refer to Section A.7.

7.2 The product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

8. FILL OF CONTAINER

The fill of container shall be:

a) Not less than 80% v/v for products weighing less than 150 g (5½ oz.);

b) Not less than 85% v/v for products in the weight range 150-250 g (9 oz.); and

c) Not less than 90% v/v for products weighing more than 250 g (9 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

9. LABELLING

9.1 Refer to Section A.8.

9.2 In addition to Section A 8.3, the name of the product shall be that of the major or characterizing ingredient(s) accompanied by words suitable to indicate the consistency or intended use.

10. CLAIMS

Refer to Section A.9.

11. METHOD OF ANALYSIS AND SAMPLING

Refer to section A.10.

SECTION D: THE CATEGORIES FRUIT AND INGREDIENTS

1. SCOPE

1.1 This section of the Standard applies to the Commercially Produced Complementary Food categories Fruit and Ingredients (as defined in 2.1 and 2.2 below) intended for feeding older infants as a complementary food from the age of 6 months onwards, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Fruit and Ingredients.

1.3 Only products that comply with the criteria laid down in the provisions of this section would be accepted for marketing as Fruit and Ingredients for older infants and young children.

2. DESCRIPTION

2.1 The category *Fruit* means products comprised of fresh fruit, whole dry fruit or pieces of dried fruit.

2.2 The category *Ingredients* means products for use during cooking or adding to food in small quantities. They include but are not limited to oils, stock cubes, seasonings and sauces.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

Refer to Section A.3.

3.2 Lipids

For products referred to in 2.1, the total fat content shall not exceed 1.08g/100kJ (4.5 g/100 kcal).

3.3 Minerals

Refer to Section A.3.8.

3.3.1 Sodium

For products referred to in points 2.1 and 2.2, the sodium content shall not exceed 11.96mg/100kJ (50mg/100kcal).

4. FOOD ADDITIVES AND FLAVOURINGS

Refer to Section A.4.

5. CONTAMINANTS

Refer to Section A.5.

6. HYGIENE

Refer to Section A.6.

7. PACKAGING

Refer to Section A.7.

8. LABELLING

Refer to Section A.8.

9. CLAIMS

Refer to Section A.9.

10. METHODS OF ANALYSIS AND SAMPLING

Refer to Section A.10.

3 Full list of definitions

Added sugar and/or sweeteners means all:

- all monosaccharides and disaccharides (including sugars derived from fruits, sugarcane, palms or root vegetables, etc.);
- all syrups, nectars and honey (including molasses, agave, maple, blossom nectar, malted barley syrup, brown rice syrup, etc.);
- fruit juices or concentrated/powdered fruit juice, excluding lemon or lime juice (e.g. pear juice, concentrated apple juice or powdered mango juice);
- non-sugar sweeteners (such as saccharin, acesulfame, aspartame, sucralose or stevia etc.);

added to foods and beverages by the manufacturer, cook or consumer during processing or preparation.

Best Before Date or Best Quality Before Date means the date which signifies the end of the period, under any stated storage conditions, during which the unopened product will remain fully marketable and will retain any specific qualities for which implied or express claims have been made. However, beyond the date the food may still be acceptable for consumption.

Calorie means a kilocalorie or "large calorie" (1 kilojoule is equivalent to 0.239 kilocalories).

Claim means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality.

Complementary feeding period is the period when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating the family diet. Appropriate complementary feeding should start from the age of six months.

Consumer means persons and families purchasing and receiving food in order to meet their personal needs.

Container means any packaging of food for delivery as a single item, whether by completely or partially enclosing the food and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

Date of manufacture means the date on which the food becomes the product as described. This is not an indication of the durability of the product.

Date of packaging is the date on which the food is placed in the immediate container in which it will be ultimately sold. This is not an indication of the durability of the product.

Dietary fibre means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

a) Edible carbohydrate polymers naturally occurring in the food as consumed,

b) carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,

c) synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, 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.

Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

Free sugars and sweeteners means:

a) all mono- and disaccharides (including sugars derived from fruits, sugarcane, palms or root vegetables, etc.);

b) all syrups, nectars and honey (including molasses, agave, maple, blossom nectar, malted barley syrup and brown rice syrup, etc.);

c) fruit juices or concentrated/powdered fruit juice, excluding lemon or lime juice (e.g. pear juice, concentrated apple juice or powdered mango juice);

d) non-sugar sweeteners (such as saccharin, acesulfame, aspartame, sucralose or stevia etc.);

Fruit juice means fruit that is prepared with the edible pulp removed.

Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

a) Nutrient function claims – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

   Example:

   "Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

b) Other function claims – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples:

"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

c) Reduction of disease risk claims – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition.

Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

"A healthful diet low in nutrient or substance A may reduce the risk of disease D.

Food X is low in nutrient or substance A."

"A healthful diet rich in nutrient or substance A may reduce the risk of disease D.

Food X is high in nutrient or substance A."

Good Manufacturing Practices (GMP) means all food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following: a) The quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect; b) The quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and, c) The additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

Ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

Labelling includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

Lot means a definitive quantity of a commodity produced essentially under the same conditions.

Marketing includes product promotion, distribution, selling, advertising, product public relations and information services.

Maximum use level of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.

The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

Non-addition claim means any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food.

Nutrient means any substance normally consumed as a constituent of food:

a) which provides energy; or

b) which is needed for growth, development and maintenance of life; or

c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: "source of calcium"; "high in fibre and low in fat".)

Nutrient declaration means a standardized statement or listing of the nutrient content of a food.

Nutrient Reference Values (NRVs) are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims.

Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:

a) the mention of substances in the list of ingredients

b) the mention of nutrients as a mandatory part of nutrition labelling

c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

Nutrition labelling is a description intended to inform the consumer of nutritional properties of a food. Nutrition labelling consists of two components:

a) nutrient declaration;

b) supplementary nutrition information.

Older infants are persons from the age of 6 months and not more than 12 months of age.

Polyunsaturated Fatty Acids means fatty acids with cis-cis methylene interrupted double bonds.

Prepackaged means packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes.

Processing aid means a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the nonintentional but unavoidable presence of residues or derivatives in the final product.

Promotion includes the communication of messages that are designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. Messages may be communicated in a variety of settings and via packaging, branding, and labelling.

Ready to Use (RTU) means that a product is prepared and packaged to be consumed directly without the necessity of further comher preparation

Total sugar means any intrinsic sugars contained within plant cells walls, liberated sugars (released from plant cell walls), free sugars and sugars naturally present in milk (largely lactose).

Trans Fatty Acids means all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration.

Use-by Date or Expiration Date means the date which signifies the end of the period under any stated storage conditions, after which the product should not be sold or consumed due to safety and quality reasons.

Young children means persons from the age of more than 12 months up to the age of three years (36 months).

4 COMMIT Initiative Recommendations for Nutrient Composition and Labelling Practice Requirements of Commercially Produced Complementary Foods

The following section presents two tables outlining the COMMIT Initiative's recommendations on nutrient composition and labelling practices for commercially produced complementary foods. Details on the recommendations (including the evidence used) are available in footnotes.

Table 2: COMMIT Initiative recommendation for nutrient composition requirements of commercially produced complementary foods

<table>
<tr><th rowspan="3">Product name</th><th rowspan="3">Product description</th><th colspan="8">Nutrient content requirements</th></tr>
<tr><th rowspan="2">Energy Density (kcal/100g)</th><th rowspan="2">Sodium (mg/ 100kcal)</th><th rowspan="2">Total sugar (g/100kcal, %)</th><th rowspan="2">Added sugar or sweetener</th><th rowspan="2">Total protein (g/100kcal)</th><th rowspan="2">Total fat (g/100kcal)</th><th colspan="4">Micronutrients</th></tr>
<tr><th></th><th>Calcium (mg)</th><th>Iron (mg)[1]</th><th>Zinc (mg)[1]</th></tr>
<tr><td rowspan="6">Dry cereals and starches</td><td rowspan="2">Dry or powdered cereals or starches without added high protein food</td><td rowspan="5">≥80 kcal/ 100 g as eaten[2] or at least 400kcal/100 g on a dry weight basis[3]</td><td rowspan="5">≤50 mg/ 100kcal[4]</td><td rowspan="2">≤3.75 g /100kcal [5,6]</td><td rowspan="5">No added sugar or sweeteners. This include all sugars derived from fruits, sugar-cane, palms or root vegetables, all syrups, nectars and honey, fruit juices or concentrated/powdered fruit juice excluding lemon or lime juice, and non-sugar sweeteners such as saccharin, acesulfame, aspartame, sucralose, or stevia[7]</td><td rowspan="2">/</td><td rowspan="2">≤3.3 g/ 100kcal[8]</td><td>Per daily ration[9]</td><td>≥250 mg</td><td>≥2.9 mg</td><td>≥2.05 mg</td></tr>
<tr><td>Per 100 g</td><td>≥375 mg</td><td>≥4.35 mg</td><td>≥3.075 mg</td></tr>
<tr><td rowspan="2">Dry or powdered cereals or starches with added high protein food</td><td rowspan="2">5 g/100kcal [5,10]</td><td rowspan="2">≥2 g/ 100kcal and ≤5.5 g/100kcal[11]</td><td rowspan="2">≤4.5 g/ 100kcal[8]</td><td>Per daily ration[10]</td><td>≥250 mg</td><td>≥2.9 mg</td><td>≥2.05 mg</td></tr>
<tr><td>Per 100 g</td><td>≥375 mg</td><td>≥4.35 mg</td><td>≥3.075 mg</td></tr>
<tr><td>Rice, dry pasta and plain fresh pasta and like products</td><td>/</td><td>/</td><td>≤3.3 g/ 100kcal[8]</td><td colspan="4" rowspan="2">/</td></tr>
<tr><td>Dairy foods</td><td>Products where the largest ingredient is dairy, and fruit may constitute up to 5% of the product on a wet weight basis</td><td>/[12]</td><td>≤50 mg/ 100kcal or ≤100 mg/ 100kcal if name includes cheese[4]</td><td>≤5 g /100kcal [5,10 13]</td><td>≥2.2 g 100kcal[14]</td><td>≤4.5 g/ 100kcal[15]</td></tr>
</table>

Product name	Product description	Nutrient content requirements								
		Energy Density (kcal/100g)	Sodium (mg/ 100kcal)	Total sugar (g/100kcal, %)	Added sugar or sweetener	Total protein (g/100kcal)	Total fat (g/100kcal)	Micronutrients		
									Calcium (mg)	Iron (mg)[1]	Zinc (mg)[1]
Fruit-containing Foods	Products, excluding Dry cereals and Starches and Snacks and Finger Foods, where fruit constitutes more than 5% of the product on a wet weight basis	/	≤50 mg/ 100kcal[4]	20 g/100 g for fruit and 15 g/ 100 g for fruit and vegetable mixes[16],[17]	No added sugar or sweeteners. This include all sugars derived from fruits, sugar-cane, palms or root vegetables, all syrups, nectars and honey, fruit juices or concentrated/powdered fruit juice excluding lemon or lime juice, and non-sugar sweeteners such as saccharin, acesulfame, aspartame, sucralose, or stevia[7]	/	≤4.5 g/ 100kcal[15]	/			
Vegetable Only Foods	Products containing single or mixed vegetables and/or legumes only	/	≤50 mg/ 100kcal[4]	10 g/100 g for vegetable only[18]		/	≤4.5 g/ 100kcal[15]				
Food with No Protein Named	Savoury meals or meal components without protein or cheese included in the name of the food	/	≤50 mg/ 100kcal[4]	≤15% of total energy[19]		≥3 g/ 100kcal [20,21]	≤4.5 g/ 100kcal[15]				
Food with Cheese Named	Savoury meals or meal components with cheese and no other protein included in the name of the food	/	≤100 mg/ 100kcal[4]	≤15% of total energy[19]		≥3 g/ 100kcal[22]	≤6 g/ 100kcal[23]				

Product name	Product description	Nutrient content requirements								
		Energy Density (kcal/100g)	Sodium (mg/ 100kcal)	Total sugar (g/100kcal, %)	Added sugar or sweetener	Total protein (g/100kcal)	Total fat (g/100kcal)	Micronutrients		
									Calcium (mg)	Iron (mg)[1]	Zinc (mg)[1]
Food with Protein Named	Savoury meals or meal components with the protein source not named first in the name of the food but included later in the name of the food	/	≤50 mg/ 100kcal or ≤100 mg/ 100kcal if name includes cheese[4]	≤15% of total energy[19]	No added sugar or sweeteners. This include all sugars derived from fruits, sugar-cane, palms or root vegetables, all syrups, nectars and honey, fruit juices or concentrated/powdered fruit juice excluding lemon or lime juice, and non-sugar sweeteners such as saccharin, acesulfame, aspartame, sucralose, or stevia[7]	≥3 g/ 100kcal[24]	≤4.5 g/ 100kcal[15]	/		
Food with Protein Named First	Savoury meals or meal components with the protein source named first in the name of the food	/	≤50 mg/ 100kcal or ≤100 mg/ 100kcal if name includes cheese[4]	≤15% of total energy[19]		≥4 g/ 100kcal[25]	≤6 g/ 100kcal[23]			
Food with Only Protein Named	Savoury meal component where the protein source is the only food named in the name of the food	/	≤50 mg/ 100kcal[4]	≤15% of total energy[19]		≥7 g/ 100kcal[26]	≤6 g/ 100kcal[23]			
Fruit	Products comprised only of fresh fruit, whole dry fruit or pieces of dried fruit	/	≤50 mg/ 100kcal[4]	/		/	≤4.5 g/ 100kcal[15]			

Product name	Product description	Nutrient content requirements								
		Energy Density (kcal/100g)	Sodium (mg/ 100kcal)	Total sugar (g/100kcal, %)	Added sugar or sweetener	Total protein (g/100kcal)	Total fat (g/100kcal)	Micronutrients		
									Calcium (mg)	Iron (mg)[1]	Zinc (mg)[1]
Snacks and Finger Foods	Dry or semi-dry grain, starch, pulse or root vegetable snack	≥80 as eaten[2]	≤50 mg/ 100kcal[4]	≤15% of total energy or ≤3.75g /100kcal [5,6]	No added sugar or sweeteners. This include all sugars derived from fruits, sugar-cane, palms or root vegetables, all syrups, nectars and honey, fruit juices or concentrated/powdered fruit juice excluding lemon or lime juice, and non-sugar sweeteners such as saccharin, acesulfame, aspartame, sucralose, or stevia[7]	≥1.5 g/ 100kcal and ≤5.5 g/ 100kcal[27]	≤4.5 g/ 100kcal[15]	/		
							≤3.3 g/ 100kcal[8, 28]			
Ingredients	Products for use during cooking or adding to food in small quantities	/	≤50 mg/ 100kcal[4]	/		/	/			
Confectionery	Confectionery	Not appropriate for promotion to children under 3 years								
Drinks	Drinks	Not appropriate for promotion to children under 3 years								

[1] Considering 10% availability

[2] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.2: Energy Density: The energy density of cereal-based foods should not be less than 3.3 kJ/g (0.8kcal/g)

[3] Based on Guidelines on Formulated Complementary Foods for Older Infants and Young Children, CAC/GL 8-1991, section 6.2.3: The energy density of the Formulated Complementary Food should be at least 4 kcal per gram on dry weight basis

[4] A lower threshold of maximum sodium content for all CPCF is proposed in view of increased risk of cardiometabolic disease in children (Fewtrell, 2017). CODEX STAN 74-1981 thresholds is ≤100 mg /100kcal European Commission Directive 2006/125/EC threshold is ≤200mg/100kcal or 300mg/100kcal if cheese is the only ingredient mentioned in the name of the product and CODEX STAN 73-1981 maximum threshold is ≤200mg /100g.

[5] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.4.1. Moreover, WHO guidelines on sugar states not more than 10% of energy should come from free sugars (2.5g/100kcal). CODEX STAN 74-1981 sets a higher threshold for added fructose for dry cereal based CPCF that do not include milk (3.75g/100kcal) and for dry cereal based CPCF that do include milk (2.5g/100kcal). The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) and the American Heart Association recommends avoiding added sugars with a desirable goal of less than 5% energy intake from free sugars. The threshold of ≤3.75g/100kcal (15%) was developed to account for naturally occurring sugars in the CPCF food categories e.g., 100% contribution of calories from total sugar in products comprised of 100% fruit purees or fresh/dried fruit pieces.

[6] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.4.1: the amount of added carbohydrates from these sources (sucrose, fructose, glucose, glucose syrup or honey) shall not exceed 3.75g/100kcal.

[7] Codex and European Commission Directive 2006/125/EC both provide maximum thresholds for the addition of specific sugars (sucrose, fructose, glucose, glucose syrup or honey). However, the evidence base for the elimination of added sugars and limitation of total sugars in the diets of older infants and young children is robust, including WHO Guideline, the American Heart Association, a Position Paper of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition, and an explanation of the Scientific Advisory Committee on Nutrition's recommendations about sugars and health.

[8] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.5.1: For products with added milk the lipid content shall not excel 4.5g/100kcal; and section 3.5.2: Product categories 2.1.1 (dry cereal without added milk) shall not exceed a maximum lipid content of 3.3g/100kcal.

[9] Based on Guidelines on Formulated Complementary Foods for Older Infants and Young Children, CAC/GL 8-1991Annex Table (Page 10): Reference INL_{98} values for 22 micronutrients. The suggested total quantity of each of these vitamins and minerals contained in a daily ration of the Formulated Complementary food is at least 50% of the INL_{98}. COMMIT Comprehensive Nutrient Gap Assessment (CONGA) identified calcium, iron and zinc as micronutrients of concern. A daily ration was determined as 33g based on analysis of median daily ration size for dry cereal based CPCF in seven COMMIT countries. A daily ration is determined as two servings of the CPCF cereal.

[10] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.4.2: The amount of added carbohydrates from these sources (sucrose, fructose, glucose, glucose syrup or honey) shall not exceed 5g/100kcal

[11] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section3.3.2: For dry cereals containing milk the added protein should be ≥2g/100kcal and ≤5.5g/100kcal

[12] Available reference standards do not provide energy density thresholds for CPCF that are not cereal based.

[13] No threshold for dairy products is provided for total sugar. European Commission Directive 2006/125/EC provides guidance on total carbohydrates for desserts and puddings (25g/100g). In light of global recommendation mentioned in footnote 8, advocating for a reduction of total sugar consumption to less than 5% for children under 5 years of age, the threshold for CPCF cereals with milk added has been applied here.

[14] Based on European Commission Directive 2006/125/EC, Annex II. 1.1.7: Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2.2 g dairy protein/100kcal. WHO South-East Asia Region Office decided in expert consultation to remove dairy protein from the threshold as this was difficult to measure with current nutrition labelling guidance. The recommended threshold applies to total protein.

[15] Based on European Commission Directive 2006/125/EC, Annex II. 3.1.2: For all other products, the total fat in the product from all sources shall not exceed 4.5g/100kcal.

[16] Based on European Commission Directive 2006/125/EC, Annex II Article 2: The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit only dishes and desserts or puddings shall not exceed: 10g/100ml for vegetable juices and drinks, 20g/100g for fruit only dishes, 25g/100g for desserts and puddings. The threshold of 20g of total sugar per 100g product was selected to be consistent with European Commission Directive 2006/125/EC although it is noted that the directive refers to total carbohydrates. For fruit and vegetable mixes, the average of the thresholds for fruit only and vegetable only was provided to ensure that a small amount of vegetable was not added for labelling purposes.

[17] The threshold for fruit and vegetable mixes was determined by the mean of fruit only (20g/100g) and vegetable only (10g/10g) baby foods from article 2 of the European Commission Directive 2006/125/EC. The lower threshold compared to fruit only baby foods is to recognize that mixed purees frequently have a high percentage of fruit compared to vegetables however place the name of the vegetable prominently on the label.

[18] European Commission Directive 2006/125/EC sets the total sugar content for vegetable juices at 10g/100g

[19] No total sugar or carbohydrate threshold for these food categories in the Codex standards/guidelines or the European Commission Directive 2006/125/EC. To reduce the masking of savoury flavours with the addition of fruit purees and sweet tasting vegetables, the threshold for cereal based CPCF without milk was applied here from the CODEX STAN 74-1981, section 3.4.1: The amount of added carbohydrates from these sources (sucrose, fructose, glucose, glucose syrup or honey) shall not exceed 3.75g/100kcal).

[20] Based on Guidelines on Formulated Complementary Foods for Older Infants and Young Children, CAC/GL 8-1991,section 6.3.5: Taking into account the preceding considerations, the energy from protein should not be less than 6% of the total energy from the product and typically should not exceed 15%.

[21] Based on European Commission Directive 2006/125/EC, Annex II, section 1.5: If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, the total protein in the product from all sources shall not be less than 3g/100kcal.

[22] Based on European Commission Directive 2006/125/EC, Annex II, section 1.4: If cheese is mentioned together with other ingredients in the name of a savory product, whether or not the product is presented as a meal then: the total protein in the product from all sources shall not be less than 3g/10kcal.

[23] Based on European Commission Directive 2006/125/EC, Annex II, section 3.1: If meat or cheese are the only ingredients or are mentioned first in the name of a product, the total fat in the product from all sources shall not exceed 6g/100kcal

[24] Based on European Commission Directive 2006/125/EC, Annex II section 1.3: If meat, poultry, fish offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal then the total protein in the product from all sources shall not be less than 3g/100kcal.

[25] Based on European Commission Directive 2006/125/EC, Annex II, section 1.2: If meat, poultry fish, offal or other traditional source of protein, singularly or in combination are mentioned first in the name of the product, whether or not the product is presented as a meal, then: the protein from the named sources shall be ≥4g/100kcal.

[26] Based on European Commission Directive 2006/125/EC, Annex II, section 1.1: If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product then the total protein from the named sources shall be ≥7g/100kcal.

[27] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981, section 3.3.2: For dry cereals containing milk the added protein should be ≥2g/100kcal and ≤5.5g/100kcal.

[28] Based on Standard for Processed Cereal-based Foods for Infants and Young Children, CODEX STAN 74-1981CXS, section 3.5.2: Product categories 2.1.4 (dry snacks and finger foods) shall not exceed a maximum lipid content of 3.3g/100kcal.

Table 3: COMMIT Initiative recommendations for labelling requirements of commercially produced complementary foods

Claims	This mandatory standard does explicitly prohibit nutrient content claims for sugar, sodium, or 22 micronutrients if specific conditions are met.	
	All other claims including non-permitted compositional claims, non-permitted nutrient claims, nutrient function claims, disease risk reduction claims, and endorsement claims are prohibited.	Note the following composition statements are permitted:
		1. statements relating to common allergens (such as containing or being "free from… [gluten, dairy/lactose, nuts] etc.
		2. statements relating to religious or cultural requirements (such as "meat free", "vegetarian" "contains meat" "Kosher", "Halal" etc.;
		3. Descriptive words may be used within the ingredient list (such as "organic carrots" and "wholegrain wheat flour"
Product name clarity	The front of pack product name and legal product name must:	1. Clearly represent or name the main or largest ingredients by proportional content, where appropriate, except when the largest ingredient is implied in the name (such as milk in porridge or rice in risotto)
		2. List ingredients in an appropriate order (to indicate decreasing proportional content)
Ingredient list clarity	The ingredient list must clearly indicate the proportion (%) of:	1. the largest single ingredient (including water/stock, except when used for rehydration of legumes/grains etc.)
		2. the amount of added water/stock (except when used for rehydration of legumes/grains etc.)
		3. the total or individual proportions of fresh or dried fruit
		4. the amount of fish, poultry, meat, or other traditional source of protein
Protection and Promotion of Breastfeeding	Inclusion of statement on continued breastfeeding to 2 years or beyond: "For optimal baby health, breastfeeding should continue up to 2 years of age and beyond along with complementary feeding."	
	All images of bottles and the recommended use of bottles in the instructions for use are prohibited for labelling	
	Inclusion of the minimum recommended age of introduction starting from 6 months. I.e., Explicit statement on the label of "6+"	

Language	Any indication required in the labelling should be made in the appropriate language of the country in which the product is sold[29]. The following indications are specified: product name, product description, age recommendation, instructions for preparation, feeding and storage instructions, net weight or volume, ingredients list and nutrition information table. If product is imported, sticker(s) may be placed over the foreign language.	
Prohibition of Food Categories	No person shall import, manufacture, advertise for sale or sell CPCF that are classified as confectionary[30] or drinks[31] to be promoted for children 6-35.9 months of age.	

[29] Codex STAN 074-1981, REV. 1-2006

[30] Chocolates, sweets, liquorice, marzipan, fruit chews and similar products

[31] Fruit juice and other sweetened or flavoured drinks. Excludes 100% fruit/vegetable puree, breastmilk substitutes or unsweetened milk/milk alternatives

ANNEXES

ANNEX 1

GUIDELINES FOR THE COMPOSITION OF COMMERCIALLY PRODUCED FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

(Taken from the Codex Alimentarius GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991)

1.1 COMPOSITION: BASIC RAW MATERIALS AND INGREDIENTS

The following raw materials, most of which are locally available, are suitable ingredients for the production of Commercially Produced Complementary Foods under the specified conditions given below:

1.1.1 *Cereals*

1.1.1.1 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%) but are limiting in the amino acid lysine. Combining cereals with legumes and/or pulses, which are higher in lysine, can compensate for the limiting level in cereals.

1.1.2 *Legumes and Pulses*

1.1.2.1 On the whole, legumes and pulses are deficient in L-methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine may be desirable in order to improve the nutritional value of the product.

1.1.2.2 Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors. When phytoestrogen containing legumes and pulses such as soya are added as an ingredient, products with low levels of phytoestrogens should be used.

a) Lectins can be reduced by moist heat treatment;

b) Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling.

c) Phytate can be reduced enzymatically or by soaking or fermentation.

d) Phytoestrogens can be reduced by fermentation.

1.1.3 *Oil seed flours and oil seed protein products*

1.1.3.1 Flours, protein concentrates and protein isolates of oil seeds are acceptable if manufactured to appropriate global/Codex specifications which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. The decision to add oil seeds flour to a commercially produced complementary food should take into account local conditions and requirements. Such oil seeds may include:

a) Soya beans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate

b) Groundnuts: paste, protein isolate

c) Sesame seed: whole ground and defatted flour

d) Cottonseed: defatted flour

e) Sunflower seed: defatted flour, full fat

f) Low erucic acid rapeseed: full fat flour.

1.1.3.2 Defatted oil seed flours and protein isolates, if produced and appropriately processed for human consumption, can be good sources of protein (50-95%).

1.1.4 *Animal Source Foods*

Animal source foods such as meat, fish, poultry, eggs, milk and milk products are nutrient dense and good sources of high-quality proteins and micronutrients and incorporation of these foods or their derived protein concentrates in commercially produced complementary food as technologically feasible is encouraged.

1.1.5 *Fats and Oils*

1.1.5.1 Fats and oils can be incorporated in adequate quantities as technologically feasible for the purpose of increasing the energy density of the product. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Such care is important for fat-containing ingredients (e.g., oil seed flours and oil seed protein products, fish meals, and fish protein concentrates) as well as fats and oils.

1.1.5.2 Partially hydrogenated fats (and oil) should not be used in Commercially Produced Complementary Foods.

1.1.6 *Fruits and Vegetables*

Fruits and vegetables may be good sources of micronutrients and can be added to Commercially Produced Complementary Food, when technologically feasible.

1.1.7 *Other Ingredients*

Other ingredients, including those listed in Codex CAC/GL 8-1991 may be used to improve the nutritional quality and/or acceptability of the commercially produced complementary food provided that they are readily available and have been proven to be suitable and safe for their intended purpose.

1.1.7.1 *Digestible carbohydrates*

Energy density of commercially produced complementary food can be increased by the addition of appropriate digestible carbohydrates.

1.2 COMPOSITION: TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

1.2.1 Preliminary Treatment of Raw Materials

Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to:

1.2.1.1 Cleaning or washing: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.

1.2.1.2 Dehulling: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption.

1.2.1.3 Degermination: where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

1.2.2 Milling

1.2.2.1 Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.

1.2.2.2 Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.

1.2.2.3 Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in legumes and pulses. Boiling improves the digestibility and absorption of nutrients.

1.2.2.4 The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food.

1.2.3 Toasting

1.2.3.1 Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.

1.2.3.2 Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.

1.2.3.3 Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.

1.2.3.4 Toasted raw materials can be milled or ground for use as ingredients.

1.2.4 Sprouting, Malting and Fermentation

1.2.4.1 Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.

1.2.4.2 During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

1.2.5 Other Processing Technologies

1.2.5.1 *Extrusion Cooking*

1.2.5.1.1 The mix of milled or ground basic ingredients (cereals, pulses, oilseed flours) may be further processed by extrusion cooking. Extrusion cooking may decrease available L-lysine, sulphur-containing amino acids, L-arginine, L-tryptophan and vitamins. The process should therefore be carefully controlled. The extruded product, after drying if necessary, is milled or ground to the desired particle size.

The effects of this technology are:

a) gelatinization of the starchy portion of the mixture with minimal quantities of water;
b) inactivation of lectins and reduction of trypsin inhibitor activity;
c) a reduction in the quantities of water needed for preparation of the food;

d) flavour development.

1.2.5.2 *Enzymatic Predigestion*

1.2.5.2.1 With this process the milled or ground basic ingredients (cereals, pulses, and oilseed flours) can be processed in the presence of water and appropriate enzymes under continuous stirring until the mixture acquires the desired fluidity. In the case of the use of amylase, starch molecules are split into dextrins and reducing sugars. After raising the temperature to inactivate the enzyme, the slurry is dried and comminuted to flour or to small flakes to allow for greater nutrient density.

1.2.5.2.2 The predigested product may have improved organoleptic characteristics, higher digestibility, good solubility, requires less water for the preparation of the food, and hence higher nutrient density.

1.3 COMPOSITION: NUTRITIONAL

1.3.1 All processing should be carried out in a manner that maintains protein quality and minimizes loss of micronutrients and maintains overall nutritive value.

ANNEX 2

ABBREVIATIONS, ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS; VITAMIN COMPOUNDS; AND AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR OLDER INFANTS AND YOUNG CHILDREN

(Taken from the Codex Alimentarius Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children - CAC/GL 10-1979)

Abbreviations	
BP	British Pharmacopoeia
BPC	British Pharmaceutical Codex
DAB	Deutsches Arzneibuch
DAC	Deutscher Arzneimittel-Codex
DVFA	Danish Veterinary and Food Administration
FCC	Food Chemicals Codex
BPC	British Pharmaceutical Codex
DAB	Deutsches Arzneibuch
DAC	Deutscher Arzneimittel-Codex
FCC	Food Chemicals Codex
FSANZ	Food Standards Australia New Zealand
FU	Farmacopoea Ufficiale della Republica Italiana
JP	The Pharmacopeia of Japan
Jap Food Stan	Japanese Food Standard
MI	Merck Index
MP	Martindale Pharmacopoeia
ÖAB	Österreichisches Arzneibuch
Ph Eur	Pharmacopoeia Europaea
Ph Franç	Pharmacopée Française
Ph Helv	Pharmacopoeia Helvetica
USP	The United States Pharmacopoeia

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Source of Calcium (Ca)								
1.1 Calcium carbonate	✓(1981)	JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
1.2 Calcium chloride	✓ (1979)	JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB	✓	✓	✓	✓	✓	✓
1.3 Tricalcium dicitrate (Calcium citrate)	✓ (1979)	JECFA (1975), FCC, USP, DAC	✓	✓	✓	✓	✓	✓
1.4 Calcium gluconate	✓ (1999)	JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
1.5 Calcium glycerophosphate		FCC, Ph Eur, Ph Franc	✓	✓	✓	✓	✓	✓
1.6 Calcium L-lactate	✓ (1978)	JECFA (1974), FCC, USP, Ph Eur (tri- and penta-hydrate), BP, DAB	✓	✓	✓	✓	✓	✓
1.7 Calcium hydroxide	✓ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP	✓	✓	✓	✓	✓	✓
1.8 Calcium oxide	✓ (1979)	JECFA (1975), FCC, DAC	-	✓	-	✓	✓	✓
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	✓ (1977)	JECFA (1996), Ph Int, FCC	✓	✓	✓	✓	✓	✓
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	✓ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	✓	✓	✓	✓	✓	✓
1.12 Calcium sulphate	✓ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB	-	✓	-	-	-	✓

[1] CAC = Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Food for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
2. Source of Iron (Fe)								
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	✓	-	✓	✓	✓
2.2 Ferrous fumarate		Ph Int, FCC, USP, Ph Eur, BP	✓	✓	✓	✓	✓	✓
2.3 Ferrous gluconate	✓ (2001)	JECFA (1999), FCC, USP, Ph Eur, DAB, BP	✓	✓	✓	✓	✓	✓
2.4 Ferrous lactate	✓ (1991)	JECFA (1989), FCC, NF	✓	✓	✓	✓	✓	✓
2.5 Ferrous sulphate	✓ (2001)	JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
2.6 Ferric ammonium citrate	✓ (1987)	JECFA (1984), FCC, DAC	✓	✓	✓	✓	✓	✓
2.7 Ferric citrate		FCC	✓	✓	✓	✓	✓	✓
2.8 Ferric diphosphate (pyrophosphate)		FCC	✓	✓	✓	✓	✓	✓
2.9 Hydrogen reduced iron		FCC, DAB	-	✓	-	✓	✓	✓
2.10 Electrolytic iron		FCC	-	✓	-	✓	✓	✓
2.11 Carbonyl iron		FCC	-	✓	-	✓	✓	✓
2.12 Ferric saccharate		Ph Helv, DAB, ÖAB	-	✓	-	✓	✓	✓
2.13 Sodium ferric diphosphate		FCC	-	✓	-	✓	✓	✓
2.14 Ferrous citrate		FCC	✓	✓	✓	✓	✓	✓
2.15 Ferrous succinate		MP, MI	✓	✓	✓	✓	✓	✓
2.16 Ferrous bisglycinate		JECFA (2003)	✓	✓	✓	✓	✓	✓
2.17 Ferric orthophosphate		FCC	-	-	-	✓	-	-
3. Source of Magnesium (Mg)								
3.1 Magnesium hydroxide carbonate		JECFA (1979), USP, BP, DAB	✓	✓	✓	✓	✓	✓
3.2 Magnesium chloride	✓ (1979)	JECFA (1979), FCC, USP, Ph Eur (-4,5-hydrate), BP, DAB	✓	✓	✓	✓	✓	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
3.3 Magnesium gluconate	✓ (2001)	JECFA (1998), FCC, DAC	✓	✓	✓	✓	✓	✓
3.4 Magnesium glycero-phosphate		Ph Eur, BPC	-	✓	-	✓	✓	✓
3.5 Magnesium hydroxide	✓ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
3.6 Magnesium lactate	✓ (1987)	JECFA (1983) (Mg-DL-Lactate, Mg-L-Lactate)	-	✓	-	✓	✓	✓
3.7 Magnesium oxide		JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
3.8 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic)	✓ (1985)	JECFA (1982), FCC, DAB	✓	✓	✓	✓	✓	✓
3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic)	✓ (1981)	JECFA (1982), FCC	✓	✓	✓	✓	✓	✓
3.10 Magnesium sulphate		Ph Eur (heptahydrate), FCC, USP, JP, BP, DAB, DAC	✓	✓	✓	✓	✓	✓
3.11 Magnesium acetate		Ph Eur, DAC	-	✓	-	-	-	✓
3.12 Magnesium salts of citric acid		USP, DAC	✓	✓	✓	✓	✓	✓
3.13 Magnesium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
4. Source of Sodium (Na)								
4.1 Sodium carbonate	✓ (1979)	JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	✓ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓
4.3 Sodium chloride		Ph Int, FCC, USP, Ph Eur, JP, BP, DAB	✓	✓	✓	-	-	✓
4.4 Trisodium citrate (Sodium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
4.5 Sodium gluconate	✓ (1999)	JECFA (1998), FCC, USP, DAC	✓	✓	✓	-	-	✓
4.6 Sodium L-lactate	✓ (1978)	JECFA (1974), FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓
4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	✓ (1995)	JECFA (1963), FCC, USP, Ph Eur (dihydrate)	✓	✓	✓	-	-	✓
4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)		JECFA (1975), Ph Int, FCC, USP, BP	✓	✓	✓	-	-	✓
4.9 Trisodium phosphate (Sodium phosphate, tribasic)		JECFA (1975), FCC, DAC	✓	✓	✓	-	-	✓
4.10 Sodium hydroxide	✓ (1979)	JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB	✓	✓	✓	-	-	✓
4.11 Sodium sulphate		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓
5. Source of Potassium (K)								
5.1 Potassium carbonate	✓ (1979)	JECFA (1975), FCC, USP, Ph Eur, DAC	✓	✓	✓	-	-	✓
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	✓ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓
5.3 Potassium chloride	✓ (1983)	JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
5.4 Tripotassium citrate (Potassium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
5.5 Potassium gluconate	✓ (1999)	JECFA (1998), FCC, USP, DAC	✓	✓	✓	✓	✓	✓
5.6 Potassium glycero-phosphate		FCC	-	✓	-	✓	✓	✓
5.7 Potassium L- lactate	✓ (1978)	JECFA (1974), FCC, DAB	✓	✓	✓	✓	✓	✓
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	✓ (1979)	JECFA (1982), FCC, NF, Ph Eur, BP, DAB	✓	✓	✓	-	-	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	✓ (1979)	JECFA (1982), FCC, BP	✓	✓	✓	-	-	✓
5.10 Potassium phosphate, tribasic	✓ (1979)	JECFA (1982)	✓	✓	✓	-	-	✓
5.11 Potassium hydroxide	✓ (1979)	JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC	✓	✓	✓	-	-	✓
6. Source of Copper (Cu)								
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	✓	✓	✓	✓	✓	✓
6.2 Cupric sulphate (Copper sulphate)	✓ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	✓	✓	✓	✓	✓	✓
6.3 Cupric carbonate		MI	✓	✓	✓	✓	✓	✓
6.4 Cupric citrate		FCC, USP	✓	✓	✓	✓	✓	✓
7. Source of Iodine (I)								
7.1 Potassium iodide		Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
7.2 Sodium iodide		Ph Eur, USP, BP, DAB	✓	✓	✓	✓	✓	✓
7.3 Potassium iodate	✓ (1991)	JECFA (1988), FCC	✓	✓	✓	✓	✓	✓
7.4 Sodium iodate		FCC	-	✓	-	✓	✓	✓
8. Source of Zinc (Zn)								
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	✓	✓	✓	✓	✓	✓
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	✓	✓	✓	✓	✓	✓
8.3 Zinc gluconate		FCC, USP, DAC	✓	✓	✓	✓	✓	✓
8.4 Zinc lactate		FCC	✓	✓	✓	✓	✓	✓
8.5 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
8.6 Zinc sulphate		FCC, USP, Ph Eur, BP	✓	✓	✓	✓	✓	✓
8.7 Zinc carbonate		USP, BP (hydroxide carbonate)	-	✓	-	-	-	✓
8.8 Zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)		USP	✓	✓	✓	✓	✓	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
9. Source of Manganese (Mn)								
9.1 Manganese(II) chloride		FCC	✓	✓	✓	✓	✓	✓
9.2 Manganese(II) citrate		FCC	✓	✓	✓	✓	✓	✓
9.3 Manganese(II) glycero-phosphate		FCC	-	✓	-	✓	✓	✓
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	✓	✓	✓	✓	✓	✓
9.5 Manganese(II) gluconate		FCC	✓	✓	✓	✓	✓	✓
9.6 Manganese(II) carbonate		MI	✓	✓	✓	✓	✓	✓
10. Source of Selenium (Se)								
10.1 Sodium selenate		MI	✓	✓	✓	✓	-	✓
10.2 Sodium selenite		Ph Eur, USP, MP, MI	✓	✓	✓	✓	-	✓
10.3 Sodium hydrogen selenite		DVFA	-	✓	-	-	-	✓
11. Chromium (Cr III)								
11.1 Chromium (III) sulphate		USP, MI	-	✓	-	-	-	✓
11.2 Chromium (III) chloride		USP, MI	-	✓	-	-	-	✓
12. Molybdenum (Mo VI)								
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	-	✓	-	-	-	✓
12.2 Ammonium molybdate		FCC, USP	-	✓	-	-	-	✓
13. Fluoride (F)								
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	✓	-	-	-	✓
13.2 Potassium fluoride		FCC, DAB	-	✓	-	-	-	✓
13.3 Calcium fluoride		DAB	-	✓	-	-	-	✓

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Vitamin A								
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	✓	✓	✓	✓	✓	✓
1.2 Retinyl acetate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	✓	✓	✓	✓	✓	✓
1.3 Retinyl palmitate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	✓	✓	✓	✓	✓	✓
2. Provitamin A								
2.1 Beta-Carotene	✓ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	✓	✓	✓	✓	✓	✓
3. Vitamin D								
3.1 Vitamin D_2 = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
3.2 Vitamin D_3 = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
4. Vitamin E								
4.1 D-alpha-Tocopherol	✓ (2001)	JECFA (2000), FCC, USP, NF, Ph Eur	✓	✓	✓	✓	✓	✓
4.2 DL-alpha-Tocopherol	✓ (1989)	JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan	✓	✓	✓	✓	✓	✓
4.3 D-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur	✓	✓	✓	✓	✓	✓
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	✓	✓	✓	✓	✓	✓
4.5 D-alpha-Tocopheryl acid succinate		FCC, USP, Ph Eur	-	✓	-	-	-	✓

1 CAC = Codex Alimentarius Commission
2 IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
3 IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
4 FUF = Follow-up Formula
5 PCBF = Processed Cereal Based Foods for Infants and Young Children
6 CBF = Canned Baby Food
7 FSMP = Food for Special Medical Purposes other than Infant Formula

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USP, Ph Eur	-	✓	-	-	-	✓
4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate		FCC, USP	-	✓	-	-	-	✓
5. Vitamin C								
5.1 L-Ascorbic acid	✓ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
5.2 Calcium-L-ascorbate	✓ (1983)	JECFA (1981), FCC, USP, Ph Eur	✓	✓	✓	✓	✓	✓
5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)		JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	✓	✓	✓	✓	✓	✓
5.5 Potassium-L-ascorbate		FCC	✓	✓	✓	✓	✓	✓
6. Vitamin B_1								
6.1 Thiaminchloride hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
6.2 Thiamin mononitrate		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
7. Vitamin B_2								
7.1 Riboflavin	✓ (1991)	JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
7.2 Riboflavin-5'-phosphate sodium	✓ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
8. Niacin								
8.1 Nicotinic acid amide (Nicotinamide)		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓
8.2 Nicotinic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	✓	✓	✓	✓	✓	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
9. Vitamin B_6								
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
9.2 Pyridoxal 5-phosphate		MI, FCC, USP	✓	✓	✓	✓	✓	✓
10. Folic acid								
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	✓	✓	✓	✓	✓	✓
10.2 Calcium-L-methyl-folate		JECFA (2005)	-	✓	-	-	-	✓
11. Pantothenic acid								
11.1 Calcium-D-pantothenate		FCC, USP, Ph Eur, Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	✓	✓	✓	✓	✓	✓
11.3 D-Panthenol/		FCC, USP, Ph Eur	✓	✓	✓	✓	✓	✓
11.4 DL-Panthenol		FCC, USP, Ph Eur	✓	✓	✓	✓	✓	✓
12. Vitamin B_{12}								
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	✓	✓	✓	✓	✓	✓
12.2 Hydroxo-cobalamin		Ph Int, USP, NF, Ph Eur (hydro-chloride)	✓	✓	✓	✓	✓	✓
13. Vitamin K_1								
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone/ Phytonadione)		Ph Int, FCC (vitamin K), USP, Ph Eur, BP	✓	✓	✓	✓	✓	✓
14. Biotin								
14.1 D-Biotin		FCC, USP, Ph Eur	✓	✓	✓	✓	✓	✓

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children				
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Amino acids[8]								
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	Only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	✓	Only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			✓
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB		✓				✓
1.3 L-Cystine		FCC, USP, Ph Eur		✓				✓
1.4 L-Cystine dihydrochloride		MI		✓				✓
1.5 L-Cysteine		DAB		✓				✓
1.6 L-Cysteine hydrochloride		FCC, Ph Eur		✓				✓
1.7 L- Histidine		FCC, USP, Ph Eur, DAB		✓				✓
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB		✓				✓
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB		✓				✓
1.10 L-Isoleucine hydrochloride		FCC, USP		✓				✓
1.11 L-Leucine		FCC, USP, Ph Eur, DAB		✓				✓
1.12 L-Leucine hydrochloride		MI, FCC, USP		✓				✓
1.13 L-Lysine		USP		✓				✓
1.14 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB		✓				✓
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB		✓				✓
1.16 L-Phenylalanine		FCC, USP, Ph Eur		✓				✓
1.17 L-Threonine		FCC, USP, Ph Eur, DAB		✓				✓
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB		✓				✓
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB		✓				✓

[1] CAC= Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Foods for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula
[8] As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
			IF					
	CAC[1]	International and/or national bodies	Sec. A[2]	Sec. B[3]	FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
1.20 L-Valine		FCC, USP, Ph Eur, DAB	Only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	✓	Only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			✓
1.21 L-Alanine		FCC, USP, Ph Eur, DAB	-	✓	-	-	-	✓
1.22 L-Arginine-L-aspartate		Ph Eur	-	✓	-	-	-	✓
1.23 L-Aspartic acid		FCC, USP, Ph Eur	-	✓	-	-	-	✓
1.24 L-Citrulline		USP, DAC	-	✓	-	-	-	✓
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	-	✓	-	-	-	✓
1.26 L-Glutamine		FCC, USP, DAB	-	✓	-	-	-	✓
1.27 Glycine		FCC, USP, Ph Eur	-	✓	-	-	-	✓
1.28 L-Ornithine		MI, FCC	-	✓	-	-	-	✓
1.29 L-Ornithine monohydrochloride		DAB	-	✓	-	-	-	✓
1.30 L-Proline		FCC, USP, Ph Eur, DAB	-	✓	-	-	-	✓
1.31 L-Serine		USP, Ph Eur, DAB	-	✓	-	-	-	✓
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-	✓	-	-	-	✓
1.33 N-Acetyl-L-methionine		FCC	-	✓	-	-	-	✓ Not for infants
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	-	✓	-	-	-	✓
1.35 L-Lysine L-Aspartate		Jap Food Stan	-	✓	-	-	-	✓
1.36 L-Lysine L-glutamate dihydrate		Jap Food Stan	-	✓	-	-	-	✓
1.37 Magnesium L- aspartate		Ph Eur	-	✓	-	-	-	✓
1.38 Calcium L-glutamate	✓ 1991	JECFA, FCC, Jap Food Stan	-	✓	-	-	-	✓
1.39 Potassium L- glutamate		JECFA, FCC, Jap Food Stan	-	✓	-	-	-	✓

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
2. Carnitine								
2.1 L-Carnitine		FCC, USP, Ph Eur	✓	✓	✓	✓	✓	✓
2.2 L-Carnitine hydrochloride		FCC	✓	✓	✓	✓	✓	✓
2.3 L-Carnitine tartrate		FCC, Ph Eur	✓	✓	✓	-	-	✓
3. Taurine								
3.1 Taurine		USP, JP	✓	✓	✓	-	-	✓
4. Choline								
4.1 Choline		FCC, USP	✓	✓	✓	✓	✓	✓
4.2 Choline chloride		FCC, DAC, DAB	✓	✓	✓	✓	✓	✓
4.3 Choline citrate		NF	✓	✓	✓	✓	✓	✓
4.4 Choline hydrogen tartrate		DAB	✓	✓	✓	✓	✓	✓
4.5 Choline bitartrate		FCC, NF, DAB	✓	✓	✓	✓	✓	✓
5. Inositols								
5.1 Myo-Inositol (=meso-Inositol)		FCC, DAC	✓	✓	✓	✓	✓	✓
6. Nucleotides								
6.1 Adenosine 5-mono-phosphate (AMP)		FSANZ	✓	✓	✓	-	-	✓
6.2 Cytidine 5-mono-phosphate (CMP)		FSANZ, Jap Food Stan	✓	✓	✓	-	-	✓
6.3 Guanosine 5-mono-phosphate (GMP)		JECFA (1985)	✓	✓	✓	-	-	✓
6.4 Inosine 5-monophos-phate (IMP)		JECFA (1974)	✓	✓	✓	-	-	✓
6.5 Disodium Uridine 5-monophosphate salt		FSANZ, Jap Food Stan	✓	✓	✓	-	-	✓
6.6 Disodium Guanosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	✓	✓	✓	-	-	✓
6.7 Disodium Inosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	✓	✓	✓	-	-	✓

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers:

INS n.º	Additive/ Carrier	Maximum Level in Ready-to-use Food for infants and young children (mg/kg)
414	Gum Arabic (gum acacia)	10
551	Silicon dioxide	10
421	Mannitol (for vitamin B_{12} dry rubbing, 0,1% only)	10
1450	Starch sodium octenyl succinate	100
301	Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	75

ANNEX 3

VITAMIN AND MINERAL NUTRIENT REFERENCE VALUES

(Taken from the Codex Alimentarius GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN - CAC/GL 8-1991)

The reference INL98 values listed in the Table provide a guide for selection and amounts of vitamins and minerals to be added to a Formulated Complementary Food. The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the commercially produced complementary food is at least 50% of INL98.

Vitamins and minerals	Reference nutrient intake or individual nutrient levels98 (inl98)
Vitamin A µg retinol equivalent	400
Vitamin D µg	5
Vitamin E mg (α-Tocopherol)	5
Vitamin C mg	30
Thiamine mg	0.5
Riboflavin mg	0.5
Niacin mg NE	6
Vitamin B_6 mg	0.5
Folate µg DFE	150
Vitamin B_{12} µg	0.9
Biotin µg	8
Pantothenic acid mg	2
Vitamin K µg	15
Calcium mg	500
Iron mg	11.6, 5.8, 3.9
Zinc mg	8.3, 4.1, 2.4
Iodine µg	90
Copper mg	0.34
Selenium µg	17
Magnesium mg	60
Manganese mg	1.2
Phosphorus mg	460

ANNEX 4

GENERAL CLASS NAMES

(Taken from the Codex Alimentarius GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS - CXS 1-1985)

Name of classes	Class names
Refined oils other than olive	'Oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or' partially hydrogenated', as appropriate
Refined fats	'Fat' together with either, the term 'vegetable' or 'animal', as appropriate
Starches, other than chemically modified starches	'Starch'
All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish	'Fish'
All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not refer to a specific type of poultry meat	'Poultry meat
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese	'Cheese'
All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food	'Spice', 'spices', or 'mixed spices', as appropriate
All herbs or parts of herbs not exceeding 2% by weight either singly or in combination in the food	'Herbs' or 'mixed herbs', as appropriate
All types of gum preparations used in the manufacture of gum base for chewing gum	'Gum base
All types of sucrose	'Sugar
Anhydrous dextrose and dextrose monohydrate'	'Dextrose' or 'glucose'
All types of caseinates	'Caseinates'
ilk products containing a minimum of 50% of milk protein (m/m) in dry matter *	'Milk Protein'
Press, expeller or refined cocoa butter	'Cocoa butter'
All crystallized fruit not exceeding 10% of the weight of the food	'Crystallized fruit'
*Calculation of milk protein content: Kjeldahl nitrogen × 6.38	

ANNEX 5

METHODS OF ANALYSIS BY COMMODITY CATEGORIES AND NAMES

(Taken from the Codex Alimentarius RECOMMENDED METHODS OF ANALYSIS AND SAMPLING- CXS 234-1999)

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
All foods	Acesulfame K, Aspartame	EN 12856	High performance liquid chromatography	II
All foods	Cyclamate	EN 12857	High performance liquid chromatography	II
All foods	Cyclamate	NMKL 123	Spectrophotometry	III
All foods	Saccharin	EN 12856	High performance liquid chromatography	III
All foods (see also meat products)	Nitrates and/or Nitrites	EN 12014-1	Part 1- General considerations	N/A
Individual foods2	Sulphites	EN 1988-1AOAC 990.28	Part 1: Optimized Monier-Williams method	III
Individual foods3	Sulphites	EN 1988-2NMKL 135	Part 2: Enzymatic method	III
Special foods	Ash	AOAC 942.05	Gravimetry	I
Special foods	Calcium	AOAC 984.27	ICP emission spectrometry	III
Special foods	Calories by calculation	Method described in CAC/VOL IX-Ed.1, Part III	Calculation method	III
Special foods	Carbohydrates	Method described in CAC/VOL IX-Ed.1, Part III	Calculation	III
Special foods	Chloride	AOAC 971.27 (Codex general method)	Potentiometry	II
Special foods	Dietary fibre, total	AOAC 985.29	Gravimetry (enzymatic digestion)	I
Special foods	Fat	CAC/RM 55	Gravimetry (extraction)	I
Special foods	Fat in foods not containing starch, meat or vegetable products	CAC/RM 1, B-2	Gravimetry	I
Special foods	Fill of containers	CAC/RM 46	Weighing	I

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Special foods	Folic acid	AOAC 944.12	Microbioassay	II
Special foods	Linoleate (in the form of glycerides)	AOAC 922.06; 969.33; 963.22	Acid hydrolysis, preparation of methyl esters and gas chromatography	II
Special foods	Linoleate (in the form of glycerides)	AOAC 922.06; 979.19	Acid hydrolysis and spectrophotometry	III
Special foods	Loss on drying (milk-based)	AOAC 925.23ISO 6731|IDF 21	Gravimetry	I
Special foods	Nicotinamide for foods not based on milk	AOAC 961.14	Colorimetry	II
Special foods	Nicotinamide for milk-based foods	AOAC 944.13	Microbioassay	II
Special foods	Pantothenic acid/enriched foods	AOAC 945.74	Microbioassay	II
Special foods	Pantothenic acid/non-enriched foods	*The Analyst* 89 (1964):1, 3-6, ibid. 232 US Dept Agr., *Agr. Handbook* 97 (1965)	Microbioassay	IV
Special foods	Phosphorous	AOAC 986.24	Colorimetry (molybdovanadate)	II
Special foods	Protein efficiency ratio (PER)	AOAC 960.48	Rat bioassay	I
Special foods	Protein, crude	Method described in CAC/VOL IX-Ed. 1, Part III	Titrimetry, Kjeldahl digestion	I
Special foods	Riboflavin	AOAC 970.65	Fluorometry	II
Special foods	Sodium and Potassium	ISO 8070|IDF 119	Flame atomic absorption spectrometry	II
Special foods	Sodium and potassium	AOAC 984.27	ICP emission spectrometry	III
Special foods	Vitamin A	AOAC 974.29	Colorimetry	IV
Special foods	Vitamin A in foods in which carotenes have been added as a source of vitamin A	AOAC 941.15	Spectrophotometry	III
Special foods	Vitamin B12	AOAC 952.20	Microbioassay	II
Special foods	Vitamin B6	AOAC 961.15	Microbioassay	II
Special foods	Vitamin C	AOAC 967.22	Microfluorometry	II
Special foods	Vitamin C	AOAC 967.21	Colorimetry (dichloroindophenol)	III
Special foods	Vitamin D (D3, milk based infant formula)	AOAC 992.26	Liquid chromatography	II

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Special foods	Vitamin E	AOAC 971.30	Colorimetry	IV
Special foods	Vitamin E (milk-based infant formula)	AOAC 992.03	Liquid chromatography	II
Special foods	Sodium and potassium	ISO 8070|IDF 119	Flame atomic absorption spectrometry	II
Follow-up formula	Dietary fibre, total	AOAC 991.43	Gravimetry (enzymatic digestion)	I
Follow-up formula	Iodine (milk based formula)	AOAC 992.24	Ion-selective potentiometry	II
Follow-up formula	Pantothenic acid	AOAC 992.07Measures total pantothenate (free pantothenic acid + CoA- + ACP-bound) and measured as D-pantothenic acid (or calcium D-pantothenate)	Microbioassay	II
Follow-up formula	Vitamin A	AOAC 974.29	Colorimetry	IV
Follow-up formula	Vitamin A (retinol isomers)	AOAC 992.04	HPLC	II
Follow-up formula	Vitamin A (retinol) (above 500 IU/l milk after reconstitution)	AOAC 992.06	HPLC	III
Follow-up formula	Vitamin K	AOAC 2015.09 / ISO 21446	HPLC-FLD	II
Foods with low-sodium content (including salt substitutes)	Iodine	AOAC 925.56	Titrimetry	II
Foods with low-sodium content (including salt substitutes)	Silica (colloidal, calcium silicate)	AOAC 950.85N	Gravimetry	IV
Gluten-free foods	Gluten	Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method *Eur J Gastroenterol Hepatol* 2003; 15: 465-474	Immunoassay	I

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Biotin	AOAC 2016.02 / ISO 23305	HPLC-UV	II
Infant formula	Biotin	EN 15607 (d-biotin)(Measures total D-biotin (free + D-biocytin))	HPLC- FLD	III
Infant formula	Calories (by calculation)	Method described in CAC/Vol IX-Ed.1, Part III5	Calculation	I
Infant formula	Calcium	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Calcium	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Calcium	ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	III
Infant formula	Calcium	AOAC 985.35	Flame atomic absorption spectroscopy	III
Infant formula	Carnitine	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
Infant formula	Chloride	AOAC 986.26	Potentiometry	III
Infant formula	Chloride	AOAC 2016.03 / ISO 21422 | IDF 242	Potentiometry	II
Infant formula	Choline	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
Infant formula	Choline	AOAC 999.14	Enzymatic colorimetric method with limitations on applicability due to choline and ascorbate concentration.	III
Infant formula	Copper	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Copper	AOAC 985.35	Flame atomic absorption spectroscopy	III
Infant formula	Copper	AOAC 2011/14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Chromium (Section B of CXS 72-1981 only)	EN 14082	Graphite furnace atomic absorption after dry ashing	III
Infant formula	Chromium (Section B of CXS 72-1981 only)	EN 14083	Graphite furnace AAS after pressure digestion	III
Infant formula	Chromium (Section B of CXS 72-1981 only)	AOAC 2006.03	ICP emission spectroscopy	III
Infant formula	Chromium (Section B of CXS 72-1981 only)	AOAC 2011.19 / ISO 20649 |IDF 235	ICP-MS	II

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Crude protein6	ISO 8968-1 | IDF 20-1	Titrimetry (Kjeldahl)	I
Infant formula	Fatty acids (including trans fatty acid)	AOAC 996.06	Gas chromatography	III
Infant formula	Fatty acids (including trans fatty acid)	AOCS Ce 1i-07	Gas chromatography	III
Infant formula	Folic acid	AOAC 992.05(Measures free folic acid + free, unbound natural folates, aggregated and measured as folic acid)EN 14131(Total folate (free + bound), aggregated and measured as folic acid)	Microbioassay	III
Infant formula	Folic acid	AOAC 2011.06	LC-MS/MS	II
Infant formula	Iodine(for milk-based formula)	AOAC 2012.15 / ISO 20647 | IDF 234	ICP-MS	II
Infant formula	Iron	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Iron	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Iron7	AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant formula	Iron	AOAC 999.11 | NMKL139	AAS after dry ashing	II
Infant formula	Magnesium	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Magnesium	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Magnesium	ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	III
Infant formula	Magnesium	AOAC 985.35	Flame atomic absorption spectroscopy	III
Infant formula	Manganese	AOAC 2015.06 /ISO 21424 | 243	ICP-MS	II
Infant formula	Manganese	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Manganese	AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant formula	Melamine	ISO/TS 15495 | IDF/RM 230	LC-MS/MS	IV

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Molybdenum (Section B of CXS 72-1981 only)	EN 14083	Graphite furnace AAS after pressure digestion	III
Infant formula	Molybdenum (Section B of CXS 72-1981 only)	AOAC 2006.03	ICP emission spectroscopy	III
	Molybdenum (Section B of CXS 72-1981 only)	AOAC 2011.19 / ISO 20649 | IDF 235	ICP-MS	II
Infant formula	Myo-Inositol	AOAC 2011.18 / ISO 20637	LC-pulsed amperometry	II
Infant formula	Niacin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
Infant formula	Niacin	AOAC 985.34 (niacin (preformed) and nicotinamide)	Microbioassay and turbidimetry	III
Infant formula	Niacin	EN 15652(Free and bound and phosphorylated forms measured either as aggregate of nicotinic acid + nicotinamide, or as individual forms)	HPLC	III8
Infant formula	Pantothenic acid	AOAC 2012.16 ISO 20639	UHPLC-MS/MS	II
Infant formula	Phosphorus	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Phosphorus	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Phosphorus	AOAC 986.24	Spectrophotometry (molybdovanadate)	III
Infant formula	Riboflavin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
Infant formula	Riboflavin	AOAC 985.319	Fluorimetry	III
Infant formula	Riboflavin	EN 14152 (Measures natural and supplemental forms, free, bound and phosphorylated (FMN and FAD) aggregated and measured as riboflavin.)	HPLC	III
Infant formula	Selenium	AOAC 996.16 or AOAC 996.17	Continuous hydride generation Flame atomic absorption spectrometry (HGAAS)	III

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Selenium	EN 14627	Hydride generation atomic absorption spectrometry (HGAAS)	III
Infant formula	Selenium	AOAC 2006.03	ICP emission spectroscopy	III
Selenium	AOAC 2011.19 / ISO 20649 | IDF 235	ICP-MS	II	
Infant formula	Sodium and potassium	AOAC 2015.06 /ISO 21424 | 243	ICP-MS	II
Infant formula	Sodium and potassium	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Sodium and potassium	ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	III
Infant formula	Thiamine	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
Infant formula	Thiamine	AOAC 986.2710	Fluorimetry	III
Infant formula	Thiamine	EN 14122(Measures all vitamin B1 forms (natural and added free, bound and phosphorylated) following extraction and conversion to thiamine)	HPLC with pre-or post column derivatization to thiochrom	III
Infant formula	Total carbohydrates Moisture / total solids Ash	AOAC 986.25 AOAC 990.19 or AOAC 990.20 ISO 6731|IDF 21 AOAC 942.05	Determination by difference Gravimetry Gravimetry	I
Infant formula	Total fat	AOAC 989.05ISO 8381|IDF 123	Gravimetry (Röse-Gottlieb)	I
Infant formula	Total fat for milk-based infant formula (Products not completely soluble in ammonia)	ISO 8262-1 |IDF 124-1	Gravimetry (Weibull-Berntrop)	I
Infant formula	Total fatty acids	AOAC 996.06	Gas Chromatography	III
Infant formula	Total fatty acids	AOAC 2012.13 / ISO 16958 | IDF231	Gas Chromatography	II
Infant formula	Total nucleotides	AOAC 2011.20 ISO 20638	LC	II

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Total phospholipids	AOCS Ja7b-91	Gas chromatography with suitable extraction and preparation procedures	III
Infant formula	Vitamin A	EN 12823-1 (all-trans-retinol and 13-cisretinol)Vitamin A (both natural + supplemental ester forms) aggregated and quantified as individual retinol isomers (13 – cis and all trans)	HPLC	III
Infant formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate)	AOAC 2012.10 ISO 20633	HPLC	II
Infant formula	Vitamin C	AOAC 2012.22 / ISO/DIS 20635	HPLC-UV	II
Infant formula	Vitamin D	EN 12821(D2 and/or D3 measured as single components. Hydroxylated forms not measured.)NMKL 167	HPLC-UV	III
Infant formula	Vitamin D	AOAC 995.05 D2 and D3 measured	HPLC-UV	III
Infant formula	Vitamin D	AOAC 2016.05 / ISO 20636	LC-MS	II
Infant formula	Vitamin E	AOAC 992.03 Measures all rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as α-congeners	HPLC	III
Infant formula	Vitamin E	EN 12822 (Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).	HPLC	II
Infant formula	Vitamin E	AOAC 2012.10 / ISO 20633	HPLC	II

Methods of analysis by commodity categories and names				
Commodity	Provision	Method	Principle	Type
Infant formula	Vitamin B6	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
Infant formula	Vitamin B6	AOAC 985.32	Microbioassay	III
Infant formula	Vitamin B6	EN 14166 (Aggregates free and bound pyridoxal, pyridoxine and pyridoxamine and measures as pyridoxine)	Microbioassay	III
Infant formula	Vitamin B6	AOAC 2004.07EN 14164(Free and bound phosphorylated forms (pyridoxal, pyridoxine and pyridoxamine) converted and measured as pyridoxine)	HPLC	III
Infant formula	Vitamin B12	AOAC 986.23(Measures total vitamin B12 as cyanocobalamin)	Turbidimetric method	III
Infant formula	Vitamin B12	AOAC 2011.10 / ISO 20634	HPLC	II
Infant formula	Vitamin K	AOAC 2015.09 / ISO 21446	HPLC-FLD	II
Infant formula	Zinc	AOAC 2015.06 /ISO 21424 | IDF 243	ICP-MS	II
Infant formula	Zinc	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Infant formula	Zinc	AOAC 985.35	Flame atomic absorption spectroscopy	III

ANNEX 6

MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULAE AND FORMULAE FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN

(Taken from the Codex Alimentarius CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN - CAC/RCP 66 – 2008)

1

- Microbiological criteria should be established in the context of available risk management options and in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-97). Two sets of criteria are provided below, one for a pathogen and a second for process hygiene indicators.

2

- Where a Competent Authority assesses that there is scientific evidence of a risk in relation to E. sakazakii (Cronobacter spp.) from consumption of follow-up formulae in the national population, under current manufacturing conditions and control measures, it may consider strengthening the combination of available control measures, including consideration of an appropriate microbiological criterion.

Criteria for pathogenic microorganisms

Microorganisms	n	c	m	Class Plan
*Salmonella**	60	0	0/25 g	2

Where n = number of samples that must conform to the criterion: c = the maximum allowable number of defective sample units in a 2-class plan. m= a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

* The mean concentration detected is 1 cfu in 2034g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 577g ((if the assumed standard deviation is 0.5 and probability of detection is 99%)[23].

- This criterion is to be applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary package is opened.
- The method to be employed for Salmonella should be the most recent edition of ISO 6579 or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.
- The criterion above is applied with the underlying assumption that the history of the lot is unknown, and the criterion is being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g., the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible. The typical action to be taken when there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption; (2) recall the product if it has been released for human consumption and (3) determine and correct the root cause of the failure.

3 Criteria for process hygiene

- These criteria are to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of the verification.
- The safe production of these products is dependent on maintaining a high level of hygienic control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these tests are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs.

Microorganisms	n	c	m	M	Class Plan
Mesophilic Aerobic Bacteria*	5	2	500/g	5000/g	3
Enterobacteriaceae**	10	2[24]	0/10 g	Not Applicable	2

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots , or in a 3-class plan, separates acceptable lots from marginally acceptable lots; M = a microbiological limit which, in a 3-class plan, separates marginally acceptable lots from unacceptable lots.

* The proposed criteria for mesophilic aerobic bacteria are reflective of Good Manufacturing Practices and do not include microorganisms that may be intentionally added such as probiotics. Mesophilic aerobic bacteria counts provide useful indications on the hygienic status of wet processing steps. Increases beyond the recommended limits are indicative of the build-up of bacteria in equipment such as evaporators or contamination due to leaks in plate-heat exchangers (refer to Annex III).

** The mean concentration detected is 1 cfu in 16g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 10g (if the assumed standard deviation is 0.5 and probability of detection is 99%).

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[24] This 2- class plan is used because a 3- class plan with equivalent performance would not be practical analytically, given the low levels of Enterobacteriaceae (EB) typically occurring when stringent hygiene conditions are maintained.

It may seem that peak contaminations in up to 2 samples are tolerated in this microbiological criterion (MC). However, it is assumed that the product is sufficiently homogeneous that high level contaminations will fail the MC. It is further assumed that, in practice, under sufficiently strict hygienic operation, the manufacturer will normally not find positives and that if, occasionally, positives are found the manufacturer will take appropriate actions.

Finding 1 or 2 positives should indicate to the manufacturer a trend toward potential loss of process control and appropriate actions would include further microbial evaluation of the implicated end product (i.e. re-evaluation of the EB content; when EB MC fails, evaluation of product safety using the proposed MC for *Salmonella* before its release as well as evaluation of the hygiene programme to confirm it is suitable to maintain ongoing hygiene control or to amend the programme such that is suitable to do so).

Finding 3 or more positives should signal to the manufacturer loss of process control and appropriate actions should be the evaluation of product safety using the proposed MC for *Salmonella* before release of the implicated product as well as evaluation of the hygiene programme to amend the programme such that it is suitable to maintain high hygiene control on an ongoing basis before production is resumed.

The rationale for using 2- class plans for hygiene indicators in particular situations is explained in Book 7 of the International Commission on Microbiological Specifications for Foods, 2002. *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management,* Kluwer Academic/Plenum, Publishers NY. ISBN 0-306-47262-7.

- The methods to be employed for Mesophilic Aerobic Bacteria and Enterobacteriaceae (EB) should be the most recent editions of ISO 4833 and ISO 21528-1/21528-2, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc. The criteria above are intended to assist in verifying a facility's microbiological hygiene

	programs. Such indicator tests are most effective when the stringency of the criteria allows deviations to be detected and corrective actions to be taken before limits are exceeded. The typical action to be taken when there is a failure to meet the above criteria would be to determine and correct the root cause of the failure and, as appropriate, review monitoring procedures, including environmental monitoring (Annex III), and review prerequisite programs in particular the hygienic conditions from the drying step up to the packaging step (Enterobacteriaceae) and the process conditions during wet processing (mesophilic aerobic bacteria). Continued failures should be accompanied by increased sampling of the product for Salmonella and potential re-validation of the control measures. • While these tests were originally developed for lot-by-lot applications where the history of the lot was unknown, their usefulness is much greater when there is a full understanding of the product and the processes used in its manufacture, in which case this can provide a means of verifying correct implementation of specific hygiene measures. Such indicator tests are particularly amenable to alternative process control sampling plans and statistics.
4	<u>Labelling and Education</u> • Follow-up formulae should only be used for the target population for which they are intended. There should be increased emphasis on the education of caregivers and healthcare professionals as to the appropriate uses of follow-up formulae, in addition to the training and education on the safe preparation, handling and storage (as recommended in Section IX of this Code of Practice) and effective labelling (25 Guideline for the Validation of Food Safety Control Measures (CAC/GL 69-2008)) with respect to the intended consumer.

ANNEX 7

GUIDANCE FOR THE ESTABLISHMENT OF MONITORING PROGRAMS FOR SALMONELLA, ENTEROBACTER SAKAZAKII (CRONOBACTER SPECIES) AND OTHER ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS AND IN POWDERED FORMULA PREPARATION UNITS

(Taken from the Codex Alimentarius CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN - CAC/RCP 66 – 2008)

1. Guidance for the establishment of an environmental monitoring and process control program in high hygiene processing areas	
1	• Even under adequate hygienic conditions, low levels of Enterobacteriaceae (EB), including E. sakazakii (Cronobacter species), may be present in the processing plant environment. This could lead to the sporadic presence of low levels of EB in the finished product due to post-pasteurization contamination from the environment. Tracking the level of EB in the processing plant environment is a useful means of verifying effectiveness of the hygienic procedures applied and also allows undertaking corrective actions in a timely manner. Environmental monitoring of EB provides baseline levels and therefore allows the tracking of changes over time. Although it is recognized that there is no universally demonstrated correlation to date between counts of EB and E. sakazakii (Cronobacter species)/Salmonella, it has been demonstrated at the individual processing plant level that a reduction in the levels of the EB in the environment leading to lower levels of EB (including E. sakazakii (Cronobacter species) and Salmonella) in the finished product. • In view of the limitations of end product testing alone, it is important to have an environmental monitoring program for these products, particularly since contamination has led to several recognized outbreaks. • Such a monitoring program could be used to assess control of the processing plant environment in the high hygiene areas (dry areas) where contamination might take place, and, thus, would be an essential food safety management tool. • The monitoring program should be part of a food safety control system incorporating prerequisite programs such as good hygienic practices and a HACCP program.
2	In order to design an appropriate monitoring program, it is important to understand the ecology of Salmonella and E. sakazakii (Cronobacter species) as well as the ecology of EB (used as indicators of process hygiene). • Salmonella is rarely found in dry processing areas and monitoring should be designed to assess whether the control measures to prevent entry have been effective. It should also allow one to assess whether, in case of entry, establishment in harbourage sites and spread throughout the area could be prevented or has taken place. • E. sakazakii (Cronobacter species) is more frequently found than Salmonella in dry processing areas and is found regularly when using appropriate sampling and testing methods. The monitoring program should be designed to assess whether E. sakazakii (Cronobacter species) is increasing and whether the control measures are effective to prevent the growth of the organism.

	• Enterobacteriaceae are widespread and therefore part of the normal flora in dry processing areas. They are found regularly when using appropriate sampling and testing (quantitative) methods. EB have been used for decades as indicators of process hygiene to detect deviations in good hygienic practices.
3	**A number of factors (a – i)** should be considered when developing the sampling program to ensure its effectiveness:
	(a) <u>Type of product and process/operation</u> The need for and extent of the sampling program should be defined according to the characteristics of the products and in particular the age and health status of the consumer. While Salmonella is considered a pathogen for all categories of products included in this Code, E. sakazakii (Cronobacter species) may only be relevant for specific products. Monitoring activities should be focused in areas where contamination is likely to occur, i.e., in the dry processing areas located in the high hygiene zones. Particular attention should be given to interfaces between these areas and external areas of a lower hygiene level as well as areas close to processing line and to equipment where contamination is more likely to occur, e.g., due to the design of equipment, presence of openings such as hatches which may be opened occasionally for inspections. Known or likely harbourage sites should be given priority for monitoring. Sampling of areas far from the processing line or even external areas is of limited use.
	(b) <u>Types of samples</u> Two types of samples should be included in monitoring programs: (1) Environmental samples collected from non food contact surface areas such as external parts of equipment, floors surrounding the line, pipeline and platforms. In this case, the risk of contamination will depend on the location and design of the processing line and equipment as well as on the levels determined. (2) Samples (line samples) collected from food contact surfaces inside the equipment located after the dryer and prior to packaging and which present a higher risk of directly contaminating the product. Examples of such areas are sifter tailings where product lumps will accumulate and which may be indicative of moisture uptake. The presence of indicator microorganisms, E. sakazakii (Cronobacter species) or Salmonella on food contact surfaces represents a very high risk of directly contaminating the product.
	(c) <u>Types of organisms</u> While Salmonella and E. sakazakii (Cronobacter species) are the main target organisms, industry has found it advantageous to include EB as indicators of process hygiene. Their levels are good indicators of conditions supporting the potential presence of Salmonella and the potential for growth of Salmonella and E. sakazakii (Cronobacter species).

	(d) Sampling locations and number of samples The number of samples will vary with the complexity of the process and processing lines. Preferential locations for sampling should focus on areas where harbourage or entry leading to contamination is likely to occur. Information on appropriate locations can be found in the published literature and can be based on process experience and expertise, or on historical data gathered through plant surveys. Sampling locations should be reviewed on a regular basis and additional ones may need to be included in the program, depending on special situations such as major maintenance or construction activities or where there is any observed indication of poor hygiene. Care should be taken not to introduce a bias in the time samples are taken. This includes ensuring that there is adequate sampling of all manufacturing shifts and production periods within these shifts. Additional samples just prior to start-up are good indices of the effectiveness of cleaning operations.
	(e) Frequency of sampling The frequency of environmental sampling for the different parameters should be based primarily on factors outlined under (a). It should be defined based on existing data on the presence of relevant microorganisms in the areas submitted to such a monitoring program. In the absence of such information, sufficient suitable data should be generated to correctly define the appropriate frequency. Such data should be collected over sufficiently long periods of time so as to provide representative and reliable information on the prevalence and occurrence of Salmonella over time, and/or E. sakazakii (Cronobacter species), where appropriate. The frequency of the environmental monitoring program needs to be adjusted according to the findings and their significance in terms of risk of contamination. In particular, the detection of pathogens and/or increased levels of indicator organisms in the finished product should lead to increased environmental and investigational sampling to identify the contamination sources. The frequency also needs to be increased in situations where an increased risk of contamination can be expected, e.g., in case of maintenance or construction activities or following wet cleaning activities.
	(f) Sampling tools and techniques It is important to choose and adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example, scrapings of residues or residues from vacuum cleaners provide useful samples, and humidified sponges (or dry swabs) may be more appropriate for larger surfaces.
	(g) Analytical methods The analytical methods used to analyse environmental samples should be suitable for the detection of the target organisms. Considering the characteristics of environmental samples it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Under certain circumstances, it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample. Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed-field gel electrophoresis) can potentially provide very useful information about the source(s) of E. sakazakii (Cronobacter species) and pathway(s) that lead to contamination of PF.

	(h) Data management The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. A continual review of the data is important to revise and adjust monitoring programs. For EB and E. sakazakii (Cronobacter species), it can also reveal low level, intermittent contamination that may otherwise go unnoticed
	(i) Actions in case of positive results The purpose of the monitoring program is to find target organisms if present in the environment. Decision criteria and responses based on these monitoring programs should be articulated prior to the establishment of the program. The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of contamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices up to holding and testing of product. Generally manufacturers should expect to find EB and E. sakazakii (Cronobacter species) in the processing environment. Therefore an appropriate action plan should be designed and established to adequately respond where decision criteria are exceeded. A review of hygiene procedures and controls should be considered. The manufacturer should address each positive result of Salmonella and evaluate changes in the trends of E. sakazakii (Cronobacter species) and EB counts; the type of action will depend upon the likelihood of contaminating the product with Salmonella and E. sakazakii (Cronobacter species).
2. Microbiological monitoring in powdered formula preparation units	
1	• The extrinsic microbiological contamination of powdered formulae during preparation is a factor which needs to be taken into consideration in the design of preventive measures in health care and child care facilities. Such measures are based, as in the case of the manufacture of the powdered formulae, on the application of Good Hygienic Practices as relevant for any establishment handling foods (Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and on the application of HACCP or similar systems to address specific hazards. • Such extrinsic microbiological contamination can occur either from the preparation environment, from preparation surfaces, and/or from utensils used during preparation. It is therefore important to assess and verify that the implemented measures are effective. • Microbiological monitoring of powdered formula storage areas, preparation areas, and surfaces in direct contact with the product (e.g., utensils) represents an essential element of the quality assurance program. • Results from a properly designed monitoring program will assist in identifying potential sources of contamination and in demonstrating the efficacy of cleaning and disinfections procedures.
2	• As for section 1 of this annex, a number of factors should be considered when developing the sampling program to ensure its effectiveness, including the target organisms, types of samples, sampling locations, number of samples, frequency of sampling and tools and techniques, analytical methods, data management and actions to take in case of positive results.

	• A monitoring program of PF preparation units is best achieved through sampling and testing of environmental samples for relevant microorganisms such as Salmonella and E. sakazakii (Cronobacter species) or hygiene indicators such as EB. • It should include swabs from surfaces of preparation areas, sinks, equipment and utensils used as well as residues, for example from vacuum cleaners, collected in the area. It is important that the sampling be done using appropriate sampling tools and techniques, adapted to the type of surfaces and location, and from relevant sites which may, if contaminated, lead to (extrinsic) contamination of PF.
3	• The analytical methods used should be suitable for the detection of the target organisms. Considering the characteristics of samples, it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Under certain circumstances, it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample. Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed-field gel electrophoresis) can potentially provide very useful information about the source(s) of E. sakazakii (Cronobacter species) and pathway(s) that lead to contamination of PF. • It is important as well to document sampling activities and to include a system to record the data and their evaluation, e.g., performing trend analyses, and to use the data to initiate corrective actions where necessary. For this purpose, it is important to define targets to be achieved, e.g., in terms of acceptable levels of hygiene indicators or absence of pathogens. Such targets should be based on historical data or, if not available, on an initial survey that would permit one to define the normal microbiological status of the different sampling points. For EB and E. sakazakii (Cronobacter species), it can also reveal low level, intermittent contamination that may otherwise go unnoticed. • The purpose of the monitoring program is to find target organisms, if they are present. Generally, it is expected that EB and E. sakazakii (Cronobacter species) would be present in the preparation room environment. Decision criteria and responses based on the monitoring program should be articulated prior to the establishment of the program. The plan should define the specific action to be taken where decision criteria are exceeded and the rationale for such action. Each positive result for Salmonella and E. sakazakii (Cronobacter species) should be addressed and changes in the trends of EB counts should be evaluated. The type of action will depend upon the likelihood of contaminating the formulae with Salmonella and E. sakazakii (Cronobacter species). This could range from no action (no risk of contamination), to intensified cleaning, to source tracing, to the review of hygienic practices. • It is also important to review the monitoring program on a regular basis to take into account changes in the set-up, trends, etc.

Compendium of international standards and guidelines for the improved composition and labelling of commercially produced complementary foods in Southeast Asia

COMMIT

Consortium for Improving Complementary Foods in Southeast Asia