

# Classification of [Name of Product] for young children as complementary (supplementary) drink

Compared to current Follow-up Formula (6-36 months)<sup>a</sup>,

Follow-up Formula for older infants (6-12 months)<sup>b</sup> and [Name of Product] for young children (12-36 months)<sup>c</sup> will be completely different products

Role

Follow-up Formula (6-36 months)

Liquid part of progressively diversifying diet

Follow-up Formula for Older Infants (6-12 months)

Liquid part of progressively diversifying diet

[Name of Product] for Young Children (12-36 months)

Complementary (supplementary) liquid nutrition

CANNOT BE SOLE SOURCE OF NUTRITION

#### **ESSENTIAL COMPOSITION IN CODEX TEXTS**



#### **KEY MESSAGES**

ISDI recalls that the eWG in 2018 concluded that these products should not be classified as Breast Milk Substitutes given the diversified dietary pattern of young children.

Considering the reasons presented in this document, ISDI is of the opinion that [Name of Product] for Young Children should be categorized as a liquid part of the complementary diet. ISDI also concurs with the recommendation of the eWG that [Name of Product] for Young Children should not be categorized as Breast Milk Substitutes.

#### **ISDI CALLS FOR:**

- A CLEAR DEFINITION THAT IDENTIFIES THAT [NAME OF PRODUCT] FOR YOUNG CHILDREN IS NOT A BREAST MILK SUBSTITUTE.
- A CLEAR STATEMENT ON THE LABEL THAT "THIS PRODUCT IS NOT FORMULATED AS A SUBSTITUTE FOR BREAST MILK AND IS NOT TO BE USED AS A SOLE SOURCE OF NUTRITION".

## Follow-up formula means a food intended for use as a liquid part of the weaning diet for the infant from the 6<sup>th</sup> month on and

for young children

Main source of nutrition while introducing a diversified diet

#### **PRODUCT DEFINITION**

Follow-up formula for older infants means a product, manufactured for use as a Breast Milk Substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced

Main source of nutrition while introducing a diversified diet

[Name of Product] for Young Children means a product manufactured for use as a liquid part of the diversified diet of young children in order to contribute to their nutritional needs

Complementary (supplementary) nutrition

CANNOT BE SOLE SOURCE OF NUTRITION

#### WHAT IS NEW FOR LABELLING?

#### SPECIFIC LABELLING REQUIREMENTS

- Follow-up formula shall not be introduced before the 6<sup>th</sup> month of life
- Shall receive other foods in addition to the Follow-up formula
- The products covered by this standard are not Breast Milk Substitutes and shall not be presented as such

## 6 ADDITIONAL SPECIFIC LABELLING REQUIREMENTS

- Shall not be introduced before 6 months of age
- Not to be used as a sole source of nutrition
- "Important notice"
- "Breast-milk is the best food for your baby"
- The product should only be used on advice of a health worker as to the need for its use and the proper method of use
- The use of this product should not lead to cessation of continued breastfeeding

#### **3 KEY PRINCIPLES**

- No pictures of infants, young children and women nor any other picture, text, or representation that might:
  - idealize the use of Follow-up formula for older infants
  - suggest use for infants under the age of 6 months (including references to milestones and stages)
  - recommend or promote bottle feeding
  - · undermine or discourage breastfeeding
  - convey an endorsement by a professional or any other body
- The terms "humanized", "maternalized" or other similar terms shall not be used
- Products shall be distinctly labelled in such a way as to avoid any risk of confusion, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them

### 3 SPECIFIC LABELLING REQUIREMENTS

- The product shall not be introduced before 12 months of age
- And should be used as part of a [diversified] diet
- "This product is not formulated as a substitute for breast milk and is not to be used as a sole source of nutrition"

#### **3 KEY PRINCIPLES**

- No image, text or representation [including pictures of feeding bottles,] that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children
- The terms 'humanized', 'maternalized' or other similar terms must not be used on the label
- Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, Follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them



### **KEY POINTS**

#### **HEALTH AND SAFETY**

The primary purpose of food regulations is to protect the health and safety of consumers by ensuring safe food supply and food labelling which provides adequate instructions and information regarding the safe use of foods.

[Name of Product] for Young Children are not safe to be used by either infants or young children as a sole source of nutrition. Categorising these products as Breast Milk Substitutes would increase the risk of these products being used as a sole source of nutrition.

This would be detrimental from a health and safety perspective as such misuse would result in serious health consequences for these vulnerable age groups.

#### **ROLE OF [NAME OF PRODUCT] FOR YOUNG CHILDREN**

- At least half of children worldwide aged 6 months to 5 years suffer from one or more micronutrient deficiencies, despite the fact that almost half of young children continue to be breastfed at two years of age¹.
- The intake of essential nutrients such as iron, zinc, vitamin A is often lacking<sup>2</sup>.
- Young Children (12-36 months) have very specific nutritional requirements as they transition to a family diet with a wider range of foods<sup>3</sup>.
- Scientific Experts recognize that [Name of Product] for Young Children cannot be considered as a
  necessity, however, these products support the nutritional needs of young children and address
  nutritional inadequacies that are widely prevalent in the diet of young children<sup>4</sup>.
- It is difficult to ensure nutritional adequacy of young children unless products such as [Name of the product] for Young Children are introduced in their diets<sup>5</sup>.
- These products ([Name of the product] for young children) are designed to contribute to balanced nutrition intake levels.

#### **USE OF [NAME OF PRODUCT] FOR YOUNG CHILDREN**

- Not intended to be used as a sole source of nutrition or to replace breast milk.
- Can be used in conjunction with continued breastfeeding similarly to complementary (supplementary) foods.
- Often used as a partial or complete replacement for cow's milk.
- Helps to reduce and possibly eliminate dependence on inappropriate beverages like sugar sweetened beverages.

#### **CODEX PRINCIPLES**

It would be factually incorrect to define [Name of Product] for Young Children as a 'Breast Milk Substitute'.

- ▲ In fact, such terminology would contravene the general principles of labelling:
  - "Prepackaged food 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."<sup>6</sup>
  - "Prepackaged food 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."
- ▲ Considering the Codex definition of claims<sup>8</sup> a claim is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality defining [Name of Product] for Young Children as a 'Breast Milk Substitute' would contravene the general principles of claims:
  - "The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect." 9
  - "The following claims should be prohibited:
    - Claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which a Codex standard regulates such claims as admissible claims or where appropriate authorities have accepted the product to be an adequate source of all essential nutrients.
    - Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.
    - Claims which cannot be substantiated."10
- a CXS 156-1987
- b Under revision at Codex Alimentarius
- <sup>c</sup> Under revision at Codex Alimentarius
- Black R et al. Maternal and child undernutrition: global and regional exposures and health consequences. Lancet 2008;371:243–260
- <sup>2</sup> Butte NF, Fox MK, Briefel RR, et al. Nutrient intakes of US infants, toddlers, and preschoolers meet or exceed dietary reference intakes. J Am Diet Assoc. 2010 Dec;110(12 Suppl):527–37. Cheng Chen, Liya Denney, Yingdong Zheng, et al. Nutrient intakes of infants and toddlers from maternal and child care centres in urban areas of China, based on one 24-hour dietary recall. BMC Nutrition 2015; 1:23.
- <sup>3</sup> Akkermans MD, Eussen SR, van der Horst-Graat JM, et al. A micronutrient-fortified young-child formula improves the iron and vitamin D status of healthy young European children: a randomized, double-blind controlled trial. Am J Clin Nutr. 2017; 105(2):391-399.
- 4 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific opinion on nutrient requirements and dietary intakes in infants and young children in the European Union. EFSA. 2013;11(10):3408.
- 5 Vieux F, Brouzes CM, Maillot M et al. Role of Young Child Formulae and Supplements to Ensure Nutritional Adequacy in U.K. Young Children. Nutrients. 2016;8(9):E539.
- <sup>6</sup> Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods.
- $^{\rm 7}$  Ref: Section 3.2 CODEX STAN 1–1985; Labelling of Prepackaged Foods.
- $^{8}$  Ref: Section 2 CODEX STAN 1-1985; Labelling of Prepackaged Foods.
- 9 Ref: Section 1.2 CODEX CAC/GL 1-1979; General Guidelines on Claims.
- <sup>10</sup> Ref: Section 3.1, 3.2, 3.3 CODEX CAC/GL 1–1979; General Guidelines on Claims.