CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CRD 15**
Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-seventh Session
Bad Soden a.T. – Germany
23 – 27 November 2015

REVIEW OF THE STANDARDS FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

Comments of Thailand, ELC and IFT

THAILAND

General comments

We agree with the revision of the Standard for Follow-up Formula (CODEX STAN 156-1987) to establish separated compositional requirements for two age groups, including older infants aged 6-12 months and young children aged 12 to 36 months.

The revision aims to differentiate products for the two different age groups to avoid confusion of consumers, since the current standard applies to the products for infant and young children (age range of 6–36 months).

In this connection, we are pleased to present our study on "Composition of Follow-up Formula for Young Children Aged 12-36 Months" which is Recommendations of International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy" (as attached document) for consideration of Codex member countries in the future. From epidemiology information of the study, it appears that nutrition problems, including underweight, stunting and wasting still occur with the young children aged 12-36 months in global level. Consequently, international recommendations for the composition of follow-up formula for these young children should be established in order to be a part of healthy diet.

Specific comment

Our comments on specific sections are as follows.

APPENDIX 2: PROPOSED DRAFT REVISION TO THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) At Step 3

2. DESCRIPTION

• 2.1 Product Definition

2.1.1

It is agreed to separate the definitions for older infants and young children as follows:

"2.1.1 Follow-up formula means a food intended for use as ~~*a liquid part of the weaning diet for the infant from the 6th month on and for young children.*~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

2.1.2

In general, Codex documents do not explain information of domestic trade, so option 2 should be revised as follows:

"2.1.2 ~~***[Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold*]**~~.

~~**OR**~~

[Follow-up formula is so processed ~~*by physical means only*~~ and ~~*so*~~ packaged as to prevent spoilageand contamination under all normal conditions of handling, storage ~~*[,]and*~~ ***and*** distribution ~~*[and sale] in the country where the product is sold]*~~.**"**

• 2.2 Other Definitions

2.2.2

It is agreed to insert the definition of older infants as described below:

"2.2.2 Older infants mean persons from the age of 6 months and not more than 12 months of age."

2.2.3

To be consistent with existing Codex documents, the term "young child" should be replaced with "young children". So, this section should be read:

"2.2.3 The term ~~*young child*~~ ***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 (for older infants 6-12 months)

For the title of this section, to be clear that the section addresses essential composition and quality factors for older infants, a square bracket should be removed from "for older infant" ;meanwhile "6-12 month" should be deleted. So the title should be read as follow:

"**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS ~~*[*~~ for older infants ~~*6-12 months)]*~~**"**

• 3.1 Essential composition

3.1.1

From our opinion, option 1 should be amended, the words "young children" should be deleted; meanwhile "older infant" should be retained. And, option 2 should be removed. So, this section should be read as follows:

"3.1.1 Follow-up formula is a ~~*[food] OR [*~~ product~~*]*~~ ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~,~~*[*~~ based on ~~*] OR [consisting of]*~~ milk of cows o rother animals or a mixture thereof [,] and/or other ingredients which have been ~~*[proved] OR [*~~ proven ~~*]*~~ to be ~~*[*~~ safe and~~*]*~~ suitable ~~*[and*~~ nutritionally ~~*adequate] [*~~ to support growth and development]

r ~~*[the intended age range] OR [*~~ older infants ~~*and young children].*~~ ~~Infants from the 6th month on and foryoung children.~~

~~*[*~~The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated tosupportgrowth and development of older infants ~~*and young children.]*~~

~~*OR*~~

~~*[Consumption of the formula should appropriately contribute to normal growth and development of theintended age range].*~~*"*

• Recommendations

Recommendation 1-4

It is agreed with Recommendations 1-4 to revise essential compositions for follow-up formula for older infants, including conversion factors, protein and total fat.

Recommendation 5

It is agreed with Recommendations 5. And, to be clear, on page 43, section b: Lipid, "alpha-Linolenic acid" should be added" as follows:

"[Ratio linoleic acid ***/ alpha-Linolenic acid]"***

Recommendation 6

We agree the addition of DHA, ARA and EPA as optional additions to follow-up formula.

Recommendation 7

1) The proposed revision of the carbohydrate minimum and maximum level is agreed.

2) For footnote 9, it is proposed that texts in square bracket should be removed, since this standard is intended to apply for older infant, so the addition of sucrose and fructose should not be allowed. This is aligned with the standard for infant formula that does not allow the addition of these sugars . Then, Footnote 9 should be read:

"9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. [Only precooked and/or gelatinised starches gluten-free by nature may be added.]
~~***[If needed, sucrose, fructose may be added provided the sum of these does not exceed ≤20% of total carbohydrate.]***~~"

Recommendation 8-20

It is agreed with Recommendation 8-20 to revise minimum and/or maximum level for vitamin A, vitamin D, vitamin B6, folic acid, iron, calcium and phosphorous, manganese, iodine, selenium, copper, zinc, optional Ingredients, including Choline and Myo-inositol**.**

Recommendation 21

With regards to the section of optional ingredients of the Standard for Follow-up Formula for a product for older infants

1) From our point of view, L-Carnitine should not be included in the optional ingredients section of the Standard for Follow-up Formula for a product for older infants, because its minimum and maximum levels have not been established.

2) Meanwhile, in order to explain that other ingredients can be used, when it is allowed by a country when it can be proved that the addition of ingredients is safe and has no side effect, it is proposed to add texts "other ingredients can be used depending on national authorities" in this section. So, the proposed additional texts should be read:

~~***"L-Carnitine***~~

~~***Levels may need to be determined by national authorities.***~~

Other ingredients can be uses depending on national authorities"

Recommendation 22

Our comments on Recommendation 22 are as described below:

3.3.2 Optional Ingredients

3.3.2.1

To be clear, it is proposed that option 1 should be revised as the following texts. Meanwhile, option 2 should be deleted. So, this section should be read:

"3.3.2.1 In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients ~~***[or substances]***~~ may be added ~~when required~~ to ~~ensure that~~ the product ~~***[provided the product]***~~ is ~~***[safe and]***~~ suitable to form part of a ~~***[***~~ progressively diversified ~~***diet] OR [the complementary diet]***~~ intended for use ~~***[from 6th months on] OR [from the age of 6 months/from 6 months of age] OR [***~~ by older infants ~~***] .***~~

~~***OR***~~

~~***[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]***~~"

3.3.2.2

It is proposed that option 2 should be revised as the following texts. Meanwhile, option 1 should be deleted. So, this section should be read:

"3.3.2.2 ~~***The usefulness of these nutrients shall be scientifically shown. [The suitability for the particular nutritional uses [in products for] of [older] infants and the safety of these [ingredients and] substances shall be scientifically demonstrated. [When any of these ingredients or substances is added] the formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.]***~~

~~***OR [***~~ When any of these ingredients ~~***or substances***~~ is added the formula shall contain sufficient amounts to achieve the intended ~~***effect OR***~~ benefit, ~~***[taking into account levels in human milk].]***~~"

3.3.2.3
To be clear, texts in this section should be read as follows:

"3.3.2.3 ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children~~ ~~***[***~~ The following ~~***substances***~~ ***ingredients*** may be added in conformity with national legislation, in which case their content per 100kcal (100kJ) ~~***in the Follow-up Formula***~~ ***for older infant*** ready for consumption shall not exceed the levels listedbelow. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added ~~***].***~~"

ELC - Federation of European Specialty Food Ingredients Industries

CODEX RASBs suggest mandatory addition of DHA to FUF based on scientific and precautionary arguments

- FAO/WHO: *"(…)because of their critical role in normal retinal and brain development in the human, they [DHA and ARA] should be considered conditionally essential during early development. Similarly they might be considered conditionally essential for life long health…".* Page 65 FAO/WHO expert consultation on fats and Fatty Acids in Human Nutrition. FAO Food and Nutrition Paper, 2010;91
- *EFSA: "The Panel considers that DHA should be added to IF and* FOF---. *Considering all of these factors, it seems prudent to provide preformed DHA to formula fed infant in similar amounts as breast fed infants--- ". Page 27/28.* EFSA Journal 2014;12(7):3760

LCPUFA : The need for proper balance

- Breast milk always contains both DHA and ARA. Therefore an infant complying with the **WHO recommendation on breast feeding will provide a breast fed infant with 140-180 mg ARA and 90-118 mg DHA per day**. Based on WHO estimates of volume of breast milk from 1-12 month of age (WHO 2002).
- Intake data: FAOstat data[1] identifies that **low intakes of DHA and ARA are reported in large numbers of children, particularly in low and medium income countries**. For most of these populations the main supply of DHA and ARA is from breast milk with very low intakes from complementary foods. **Infants who are not breast fed have significantly lower intakes of both DHA and ARA**. This represents a large proportion of the global population who are already disadvantaged and who would obtain the greatest benefit from FUF with DHA and ARA.
- It is evident that these infants **need both DHA and ARA in IF and FUF as adequate levels cannot be achieved by endogenous synthesis[2]**.
- By achieving adequate intake of DHA and ARA the risk of metabolic imbalance is avoided.
- The **CODEX IF standard 72-1981 provides guidance** that could be used to direct the addition of LCPUFAs to FUF. *"If* ***docosahexaenoic acid (22:6 n-3) is added to IF, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of***

[1] Please refer to IFT presentation delivered on 21st Nov (lunch time) during the p-WG
[2] Brenna 2009; Pawlosky 2006 and Rett 2011

eicosapentaenoic acid (20:5 n-3), which can occur in sources of LCPUFA, should not exceed the content of docosahexaenoic acid. "

Reflections on implications of the Cochrane Review (Simmer 2011).
Reference has been made to a Cochrane review (Simmer 2011) and the following comments may be relevant. ELC recognize that Cochrane reviews can provide a useful synthesis of evidence, and ELC is fully supportive of systematic reviews and the reasons for doing them. However, we share leading academic experts' concerns that Cochrane reviews are of uncertain validity in evaluating diet and chronic disease due to review conduct and reporting deficiencies. .

- The final analysis was based on 15 studies all from high income countries. We have previously identified data from low and medium income countries. Cochrane did not include randomized controlled trials from these countries. Therefore, there are limitations of the Cochrane Review to global policy on DHA and ARA.
- The early studies were from 1995, at a time when the understanding of dosage requirements and assessment tools were very limited. **Increasingly, the benefits of ARA and DHA are being published, providing insights into more subtle aspects of cognitive behavior such as attention control, information processing and problem solving.**
- The report comments on many methodological issues, such as small numbers of participants, dose, duration, type and timing of assessment. In retrospect, these are significant weaknesses of these earlier studies.

Based on the above points, **CODEX should regulate DHA and ARA for the most vulnerable infants worldwide. This will be achieved by recommending mandatory DHA and ARA in FUF.**

IFT - Institute of Food Technologists

IFT would like to provide the following comments for consideration of agenda item 5 (in particular as regards recommendation 6 in the pWG report in CRD 2) as not all delegates were able to attend the physical working group luncheon presentations.

Breast milk, composition

- Gold standard for formulation, breast milk always contains arachidonic acid (ARA, 20:4, n6) and docosahexaenoic acid, (DHA, 22:6, n3) in addition to linoleic acid (LA, 18:2, n6) & linolenic (ALA, 18:3, n3).
- Global averages for breast milk are 0.47% of fatty acids for ARA and 0.32% of fatty acids for DHA in addition to possessing 11-24% fatty acids as LA and 0.5-2% fatty acids as ALA.
- This composition is stable in mature breast milk over the entire lactation.
- Breast milk has the most well documented history of safe use for older infants and young children.
- Based on this composition and using WHO reported volumes of breast milk consumed by breast fed infants during complementary feeding, breastmilk would provide 118-182 mg ARA per day and 68 – 118 mg DHA per day at 12 months of age. These amounts translate into 0.14 – 0.23% of energy for ARA and 0.08 – 0.14% of energy for DHA.
- **Breast milk provides 16 – 25 mg ARA/100 kcal and 9.3 – 16 mg DHA/100 kcal.**
- Notably, **cow's milk has virtually no ARA or DHA** indicative of the differing dietary needs of human infants and the calves of cows' similar to the difference know for the inappropriately high protein content of cows' milk for human infant needs. Cows' milk alone will not provide physiologically significant amounts of ARA or DHA.

Providing formulas that include only DHA in the absence of ARA could adversely impact infant health and development. In the long term, possible adverse effects of an imbalance in ratio of ARA to DHA may take years to recognize as outcomes such as learning disabilities, allergies or impaired innate immune function may not manifest until a later stage of development and may be attributed to other possible causes until more specific assessment methods are established. Indeed, one of the long-term consequences of insufficient DHA and ARA during complementary feeding may translate to increased risk of chronic disease. For example, DHA and ARA supplementation through infant formula during infancy has been found to

reduce incidence of allergy in children in two independent trials from separate research groups: Birch et al., J Pediatr. 2010 156(6):902-6, 906.e1. and Foiles et al. (in press) J. Ped Allergy and Immunology.

Precursor conversion

- There is a thought that inclusion of LA & ALA will provide adequate amounts of ARA & DHA through enzymatic conversion.
- LA & ALA compete for the same enzymes; leaving open the potential of unbalanced production.
- **DHA in the absence of ARA** (such as in DHA supplemented cows' milk formula) or when provided in amounts equivalent to (1:1 DHA:ARA) or in amounts greater than ARA available in the diet through complementary feeding **will suppress the conversion of LA to ARA.**
- **Enzymatic conversion declines over time**. For example, compared to conversion rates ("synthesis") at one month, ARA "synthesis" at 7 months is 56% lower, and DHA "synthesis" is 85% lower. At these conversion rates "synthesis" could only provide 53% of the amounts of ARA and only 16% of the amounts of DHA provided by breast milk consumption.

Notion that provision of nutritious complementary foods provides appropriate amounts of ARA & DHA.

- **A new compilation of ARA and DHA intakes provided through complementary foods was created by IFT members** and shared in the electronic working group using country specific food disappearance data provided in the FAOSTAT, Food Balance Sheets data base. This intake information was adjusted for energy intake from food rather than breast milk, in an age appropriate fashion using information from the FAO, 2001, Human Energy Requirements. **This work showed that only 45% of total ARA and 57% of total DHA consumed by weaning breastfed infants are provided by complementary foods**.
- Moreover, the new compilation showed that total **ARA and DHA intakes of weaning infants in the vast majority of the 130 countries in the developing world did not reach 0.1% of energy intake**, largely because breastfeeding was not sustained.
- These finding suggest that complementary foods cannot be relied upon to provide ARA and DHA in amounts needed to compensate for cessation of breast feeding when an option of unsupplemented formula use is selected.
- Per capita intakes of DHA and ARA the FAO STAT data indicates that both DHA and ARA intakes in the lowest quartiles represents a population of 2.5 billion.
- These finding further suggest that supplementation of formula with DHA in isolation would suppress ARA "synthesis" through enzymatic conversion of LA present in the formula as amounts of ARA in complementary foods are, relatively, lower than those of DHA.

In response to comments made following IFT's presentation:

- Failure to find significant differences in outcomes for supplemented and unsupplemented formula in some systematic reviews such as the 2011 Cochrane Review (Simmer, Cochrane Database Syst Rev. 2011 Dec 7;(12):CD000376) and Qawasmi et al., Pediatrics 129: 1141-1149, 2012 mentioned in an NGO´s remark in CRD 105, were used to rationalize the use of formulas lacking ARA and DHA.
- IMPORTANTLY, 9 of the15 studies in Simmer, and all 12 of the studies in Qawasmi et al. relied upon the Bayley Scales for Infant Development (BSID) for their assessments.
- Whilst the BSID is considered a good screening device for identifying children in need of early intervention it has poor predictive value, unless the scores are very low(http://www.healthofchildren.com/B/Bayley-Scales-of-Infant-Development.html). It is based on timing of developmental events rather than quality of the events that occur at an appropriate age. It sets a minimum bar rather than being able to assess whether an optimum has been achieved. As such it is an insensitive instrument for nutritional assessments in relation to LCPUFA supplementation for FUF.

Formula and breast milk intake are reduced drastically between 6 and 12 months; replacement foods in developing and even in the developed world are lower in essential and conditionally essential nutrients than breast milk. As a result overall nutrient intake declines as complementary food is introduced. These factors in addition to sound science support the **conclusion that older infants & young children are a vulnerable population for ARA & DHA insufficiency.** It is important that ARA provisions, similar to those in the IF

Standard, are added to the revised FUF Standard for both older infants and young children. In the current IF Standard DHA and ARA are *not* independent optional ingredients but rather required to be provided simultaneously. Specifically the IF Standard indicates, *"If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid*"

No scientific evidence to date has challenged the need to supply ARA whenever DHA is added.