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Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

November 2021

Welcome and Introduction



Why does the revision of the follow-up formula standard remain important and relevant?

Preparing for the Codex Committee on Nutrition and Special Dietary Uses 2021

Katherine Shats, Legal Specialist, Nutrition

November 2021

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What is Codex?

Codex Alimentarius Commission:

Intergovernmental body making food standards

- Joint program of WHO and FAO.
- 189 member-states
(Note: country delegations can have non-government participants).
- 240 'observers' currently (non-state actors, such as international organizations, civil-society and industry associations.
Vast majority represent the private sector).



What is Codex?

- **Codex Alimentarius:** The body of texts developed by the commission (e.g. standards, guidelines).
- Dual mandates:
 - Protect consumer health; and
 - Remove barriers to trade.
- Promotes international **harmonization**
- Works through committees – such as Committee on Nutrition and Special Dietary Uses (CCNFSDU) and the Committee on Food Labelling (CCFL).

WTO: a balance between rights and obligations

- WTO agreements are designed to establish a balance between **rights** (to regulate) and **obligations** (to facilitate trade).
- WTO members may implement measures and regulations so long as they are:
Non-discriminatory, not more **trade restrictive** than **necessary** ... to achieve a **legitimate objective** (e.g. protect human health).
- Some WTO agreements require (SPS) or strongly encourage (TBT) the use of **international standards** like Codex.
 - Under the TBT agreement, following international standards creates a rebuttable presumption that a measure does not create an unnecessary obstacle to international trade.



WTO and Codex: specific trade concerns



“The representative of Canada said that while supporting Thailand's public health objective of promoting breast feeding, his delegation supported the concerns expressed by the US, the EU and others related to the sole use of guidance from the WHO in developing technical regulations. In this context, Canada **reminded the Committee that the TBT Agreement strongly encouraged Members to base their measures on international standards. Canada encouraged Thailand to consider the standard on infant formula...**”

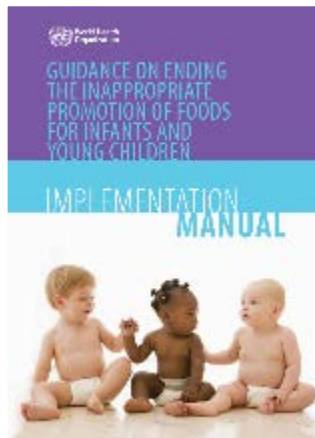
“As a **reliable supplier of high quality dairy products** to Thailand, Australia encouraged Thailand to implement the measure in a trade facilitating manner...”

“The representative of the European Union ... reminded Thailand of the need to ensure that the draft Milk Code **was aligned with relevant international standards** and, therefore, the **need to take into consideration the ongoing revision taking place within the Codex Alimentarius of the Standard on Follow-up Formula.**”

Follow-up formula

State Parties shall take appropriate measures “to **ensure that all segments of society**, in particular parents and children, **are informed**, have access to education and are supported in the use of basic knowledge of **... the advantages of breastfeeding ...**”

Convention on the Rights of the Child Art. 24



The WHO ‘Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children’ adopted as part of WHA Resolution 69.9 made it clear that:

FOLLOW-UP FORMULA ARE BREASTMILK SUBSTITUTES

“Products that function as breast-milk substitutes, including any milks or products that could be used to replace milk (in either liquid or powdered form, including follow-up formula and growing-up milks), marketed for feeding IYC up to the age of 36 months **should not be promoted.**”

Follow-up formula: the evidence

Breastfeeding declines substantially when follow-up formula is consumed by older infants and young children. The promotion of follow-up formula undermines continued breastfeeding.

Despite the WHO stating that follow-up formula is not necessary, the market for these products continues to grow.

- The market for follow-up formula and growing up milks is growing in LMICs, while declining in some HIC.
- Countries where stunting is high are experiencing some of the greatest market growth.

REVIEW OF THE CODEX STANDARD FOR FOLLOW-UP FORMULA

Policy Brief

CODEX ALIMENTARIUS MUST PUT SAVING CHILDREN'S LIVES FIRST

WHO/UNICEF INFORMATION NOTE

Cross-promotion of infant formula and toddler milks

The International Code of Marketing of Breast-milk Substitutes prohibits the promotion of breast-milk substitutes to the general public.¹ WHO has noted that breast-milk substitutes can sometimes be indirectly promoted through the promotion of related products that use similar colour schemes, designs, names, slogans, or mascots.² This common marketing practice, known as cross-promotion, puts the health of infants at risk because it discourages breastfeeding and creates confusion about the use of infant formula. This Information Note describes dangers inherent in the cross-promotion of infant formula and toddler milks.

What is cross-promotion?

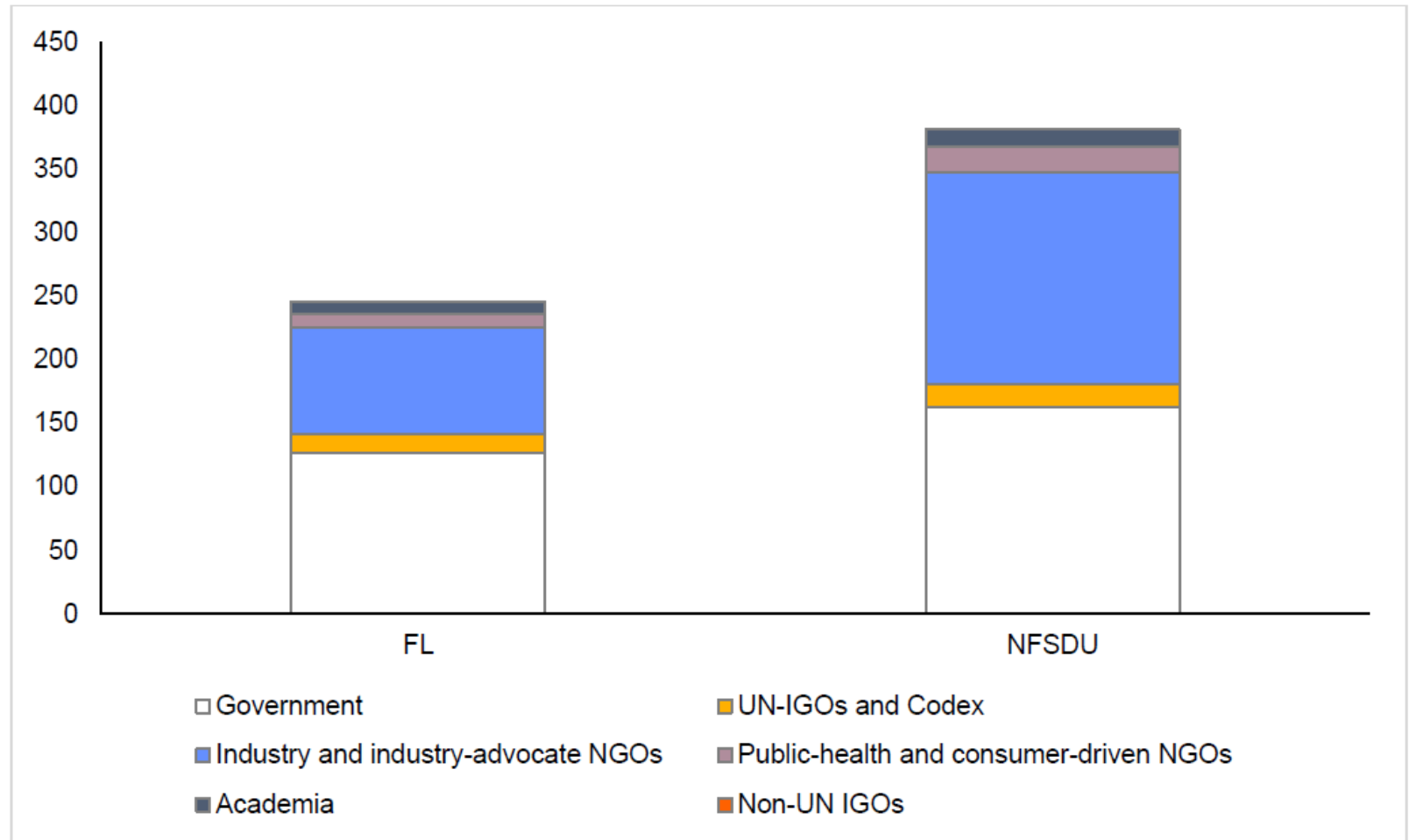
The Cambridge dictionary defines cross-promotion as advertising or advertising of its products by the WHO.

the stages are defined for infants and young children of specific ages. These products are

Infant formula	Follow-up formula	Toddler milk
		
		
		
		

Participation at Codex

- Member-States and Observers can join committees and working groups, such as the CCNFSDU and the Electronic Working Group on Review of the Follow-up Formula Standard.
- All Member-States have **National Codex Focal Points**, responsible for engaging in Codex activities, including collecting input from stakeholders to inform national positions.
- However, not all interests are represented equally...



Attendance in Codex Committees Reviewing FUF Standard in 2019
Russ et al., IJHPM, 2021. doi: 10.34172/ijhpm.2021.109

All member states can support the development of **evidence-based** Codex standards free from **conflicts of interest** that prioritize **child rights, protecting breastfeeding**, and child health.

Act now!

Member states and observer organizations from all countries can speak up at Codex and make a difference

1. **Attend and be prepared to SPEAK UP at CCNFSDU taking place virtually from 19-25 November and 1 December 2021.**

Civil society and NGOs who are not observers

1. **Identify your national Codex Focal Point** and encourage them to engage at CCNFSDU.
2. **Brief them and submit comments outlining the public health and child rights perspective:**
 - Many national Codex representatives don't have a public health background and may not be based in Ministries of Health.

**REACH OUT UNICEF AND HKI FOR SUPPORT
AT ANY STAGE IN THE PROCESS**

Thank you

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Review of the Standard for Follow-up Formula (CXS 156-1987)

What is the status and
what will be the key items
for discussion at the
upcoming meeting?

Jane Badham:
Consultant to the HKI ARCH Project

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP20/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-third Session

FAO Headquarters, Rome, Italy

6 - 11 July 2020

REPORT OF THE FORTY-FIRST SESSION OF THE
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

DÜSSELDORF, Germany

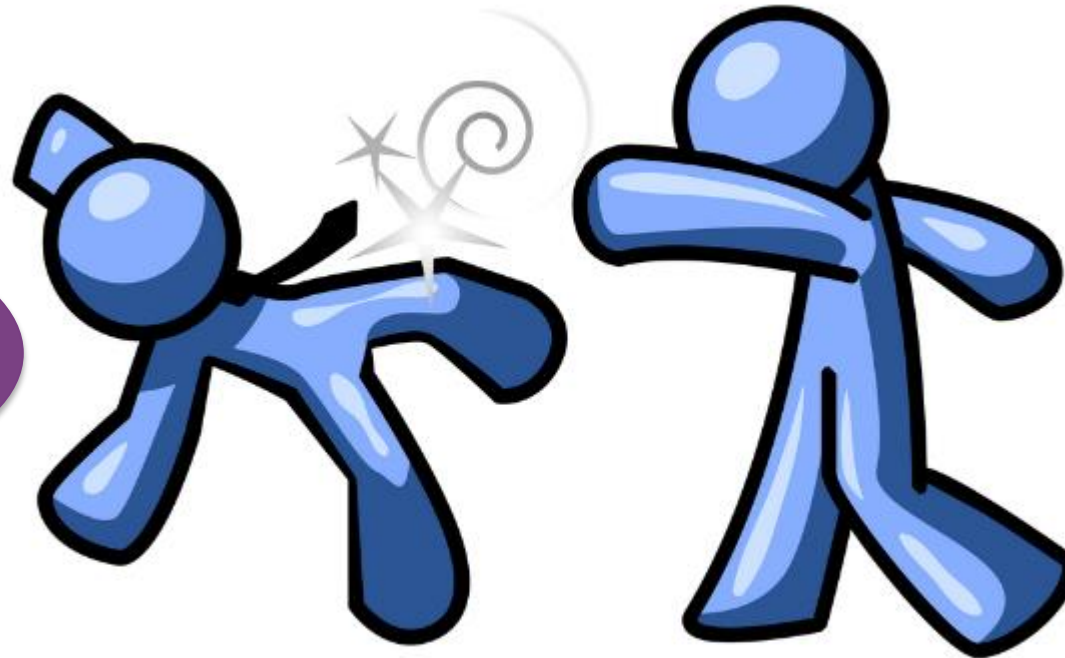
24 – 29 November 2019

REVIEW OF THE STANDARD FOR FOLLOW UP FORMULA:
SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

E

The BATTLE...

CONSUMER
HEALTH



TRADE

Process being followed for review of the Standard for Follow-up Formula

- **The standard has 2 parts:**
 - Part A: Follow-up Formula for older infants (6-12 months).
 - Part B: Drink/product for young children with added nutrients OR Drink for young children (12-36 months).
- **Each part had 2 elements:**
 - Essential composition requirements.
 - Scope / Description / Labelling.
- **Things are moving at different speeds and some text is already completed and other still being discussed.**

Process being followed for review of the Standard for Follow-up Formula

- **Matters already discussed and completed** held at Step 7 until the full text is completed and will then be joined and submitted to CAC.
- **Only matters not yet completed** are still on the agenda for discussion.
- **Incomplete matters** are being dealt with 'piece by piece'. Currently:
 - Matters referred back by Codex Committee on Food Labelling.
 - Remaining sections of both parts A / B.
 - Completion of scope, description and labelling for product for young children:
 - Definition
 - Nitrogen to protein conversion
- **Incomplete matters** to be dealt with when other sections completed (and unlikely at this meeting):
 - Structure.
 - Preamble.

**Labelling of product for
older infants
Section 9.6.5**

Agenda item 2



HISTORY:

- CCFL 2019 had not endorsed the use of the wording ‘cross promotion’ and so returned the text for further consideration by CCNFSDU.
- CCNFSDU 2019 had extensive debate and compromise was reached and the following text sent back to CCFL 2021:

OUTCOME:

9.6.5 The labelling of infant formula, Drink/Pre for young children, or infants, including num



r infants shall not refer to with added nutrients or Drink al purposes intended for mages of these products.

NOTE: Read 9.6.4 together with 9.6.5

**Labelling of product for
young children
as referred back by
CCFL 2021**

Agenda item 2
Will be raised here but probably
discussed under Agenda item 4



HISTORY:

- CCNFSDU 2019 had extensive debate, compromise was reached, and the labelling text was sent to CCFL 2021 for endorsement:

OUTCOME:

i. CCFL endorsed the labelling provisions



ii. Requests CCNFSDU to consider whether exclusion of the term product in the name 'drink for young children' was an omission

- Meeting only meant to discuss if the name, ‘Drink for young children’, omitted to read ‘Drink/**product** for young children’ to be aligned with the other name ‘Drink/product for young children with added nutrients’.
- Note many will want to try and re-open the discussion on both names as many do not like the first name due to the ‘added nutrients’ being perceived as a claim.
- What will the Chairs allow?



Remaining sections for
follow-up formula for
older infants
and drink/product for
young children with added
nutrients or
drink for young children

Agenda item 4.1 / 4a

Step 4



- **Recommendation 1:**
Dextrose equivalents.
- **Recommendation 2:**
Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product].
- **Recommendation 3a/b:**
Purity requirements.
- **Recommendation 4a/b:**
Vitamin compounds and mineral salts.
- **Recommendation 5a/b:**
Consistency and particle size.
- **Recommendation 6a/b:**
Specific prohibitions.
- **Recommendation 7a/b:**
Food additives (excluding flavourings).
- **Recommendation 8a/b:**
Food additives (excluding flavourings).
- **Recommendation 9a/b:**
Carry-over food additives and nutrient carriers.
HKI supports option 1.



Remaining sections

- **Recommendation 10a/b:** Flavourings. 

HKI believes NO flavourings should be permitted in these products as:

- They replace the liquid part of the diet and are considered breast-milk substitutes and not complementary foods.
- Flavourings can contribute to developing sweet taste preferences which is not recommended and can have a negative impact on food choices and health outcomes throughout the child's life and into adulthood.

Indicators for assessing infant and young child feeding practices

Definitions and measurement methods



'Technical Scientific Report:
Healthy Beverage
Consumption in Early
Childhood –
Recommendations from Key
National Health and Nutrition
Organisations'

- **Recommendation 11a/b:**
Contaminants.
- **Recommendation 12a/b:**
Hygiene.
- **Recommendation 13a/b:**
Packaging.
- **Recommendation 14a/b:**
Fill of the container.
- **Recommendation 15a/b:**
Methods of analysis and sampling.



Draft scope, description and labelling for product for young children

Definition

Nitrogen to protein conversion

Agenda item 4.2 / 4b

Step 7



Definition:

Current text:

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

- Only text in [] is open for discussion.
- The US will propose new text for the definition as they do not think it is sufficiently descriptive to characterise the basic nature of the product.



Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

Our view and justification:

Text in [] should be DELETED.

REASON 1:

It fulfils the requirements of the Codex Procedural Manual covering all requirements in the various parts of the sections of text.

REASON 2:

WHA has declared these products as UNNECESSARY and the text in [] gives the impression that they have a role to play in young children's diets This is false.

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

REASON 3:

- Mandating certain nutrients to be included / specifying the inclusion or exclusion of certain ingredients / specifying levels in the composition of these products is stated in the compositional requirements NOT in the definition, nor does it mean that the product offers specific benefits.
- Precedent is set with the definition of follow-up formula for older infants “*means a product, manufactured for use as a breastmilk substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.*”
Part A and Part B should be aligned and consistent.

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

REASON 4:

- Mandating certain nutrients to be included / specifying levels of certain nutrients DOES NOT make the products necessary. Member States have agreed they are unnecessary no matter their composition.
- The benefits of these products over and above continued breastfeeding has not been demonstrated while there is evidence of the benefits of continued breastfeeding.
- Evidence exists that these products replace breastmilk which is contrary to what has been agreed this text should do.
- Other optional ingredients can be added that could change the overall profile of the products making the text in [] untrue and misleading.

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

REASON 5:

- Any contribution of these products to the diets of young children does not apply equally across all countries and the text is misleading.
- The products may interfere with continued breastfeeding and there are concerns around some of the ingredients and that they are ultra-processed.
- The text in [] is outside the mandate of Codex – Codex should not be setting a universal principle as to the nutritional needs of young children, that is the responsibility of Member States.

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹

¹ In some countries these products are regulated as breast-milk substitutes.

REASON 6:

- The request to have the text include (not as a footnote) that these products function as a breast-milk substitute was refused on the grounds that ‘this was not the case in all countries.’
To reach consensus it was decided “*Codex remain silent on the issue of whether the product was or was not to be described as a breast-milk substitute.*”
- The same principle should be applied here – the definition should remain silent on whether or not this product may or may not contribute to the nutritional needs of young children.

Text as we would like to see it in order to protect, promote and support breastfeeding:

Drink/product for young children with added nutrients or
Drink/product for young children means a product manufactured for use as a liquid part of the diversified diet of young children¹

¹ In some countries these products are regulated as breast-milk substitutes.

Scope, description, labelling for older infants

Agenda item 4.3 / 4c



Completed and held at Step 7 until all text is completed

Essential composition requirements for follow-up formula for older infants and drink/product for young children with added nutrients or drink for young children

Agenda item 4.4 / 4d



Completed and held at Step 7 until all text is completed

**Other relevant
CCNFSDU
agenda items**

Update on RUTF Codex Guideline

Alison Fleet

4th October 2021

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The RUTF Codex guideline, is at **step 6** with just three areas of work to complete for CCNFSDU 2021.

2020-2021: Codex CCNFSDU Webinar and Informal discussion group.

Areas to finalize at the November 2021 meeting are:

- EFA levels
- Magnesium levels
- Preamble.

Recommendation 2

Based on the scientific evidence for specific requirements of SAM children, the CCNFSDU propose to change the linoleic acid and alpha-linolenic values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential fatty acid values

Linoleic Acid = 2.5-7.2% of total energy

[The level of linoleic acid should not be less than 280 mg per 100 kcal]

Alpha-linolenic acid = 1.0-2.5% of total

[The level of alpha-linolenic acid should not be less than 110 mg per 100 kcal]

Current Spec:

3-10% n-6

0.3-2.5% n-3

The American Journal of Clinical Nutrition
Low linoleic acid foods with added DHA given to
Malawian children with severe acute malnutrition
improves cognition: a randomized, triple blinded,
controlled clinical trial

Treatment of uncomplicated SAM with DHA-HO-RUTF resulted in an improved 60 MDAT score, conferring a cognitive benefit six months after completing diet therapy. This treatment should be explored in operational settings.

How much will it cost to change the EFAs in RUTF?

Table 3: Cost summary of amending n-3 and n-6 of RUTF composition as reported by RUTF supplier base.

Percent reported cost change estimate	\$US cost change/sachet
0.5%	\$0.001
1%	\$0.05
5%	\$0.003
20%	\$0.01
Mean: 6.6%	Mean: \$0.02
Median: 3%	Median: \$0.01

Table 5: Mean and median cost estimates in percentage and USD value based on 72mg and 104mg /100g in RUTF.

Percent cost change adding 72mg DHA	\$US cost change/sachet adding 72mg DHA	Percent cost change adding 104mg DHA	\$US cost change/sachet adding 104mg DHA
Mean: 0.04%	Mean: \$0.02	Mean: 0.06%	Mean: \$0.03
Median: 0.05%	Median: \$0.02	Median: 0.06%	Median: \$0.03

Magnesium levels

Ongoing work to review if there is any clinical evidence that increasing magnesium has shown benefit to SAM children.

Codex RUTF Guideline Informal discussion group

- The report on EFAs in RUTF and Magnesium will be shared with Codex members in the informal discussion ongoing online – this information on how to register is on the CCNSFDU webpage.

<http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFS&session=42>

Thank You

General Principles for the establishment of NRVs-R for persons aged 6-36 months

Alissa Pries

HKI – Alissa Pries, Senior Research Advisor, ARCH Project



- **Codex definition of nutrient reference values (NRVs)**
 - “Set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims.”
 - NRVs-R: based on levels of nutrients associated with nutrient requirements
 - NRVs-NCD: based on levels of nutrients associated with reduction in risk of diet-related non-communicable disease, not nutrient deficiency
- **CCNFSDU41 agreed to continue work to develop NRVs-R for older infants and young children**
 - Protein and 23 vitamins and minerals (22 listed in Guidelines for Formulated Complementary Foods + sodium)
 - Request for scientific advice derivation of these NRVs-R → scientific report
 - Chairs drafted principles aligned with CXG2 Annex: General Principles for Establishing NRVs for the General Population

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per 2/3 cup	
Calories	230
% DV*	
12%	Total Fat 8g
5%	Saturated Fat 1g
	<i>Trans Fat</i> 0g
0%	Cholesterol 0mg
7%	Sodium 160mg
12%	Total Carbs 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	Vitamin D 2mcg
20%	Calcium 260mg
45%	Iron 8mg
5%	Potassium 235mg

* Footnote on Daily Values (DV) and calories reference to be inserted here.

Example of three nutrients in metric units and as a percentage of their respective NRVs-R in servings of food

Nutrient	Amount/100 g	NRV-R	% NRV/100 g serving	% NRV/150 g serving
Protein	10 g	50 g	20	30
Vitamin C	15 mg	100 mg	15	23
Zinc	2 mg	11 mg	18	27

Recommendation 1 - Approaches to derive DIRVs from WHO/FAO and 6 RASBs:

The Chairs recommend that a three-category ranking is used in the General Principles and that NRVs should be based on DIRVs derived using the most rigorous scientific methods. These methods, ranked in order of overall scientific rigor, are as follows:

1. Using physiological evidence for the target age group
2. Extrapolating up or down from DIRVs of other age groups
3. Estimates of nutrient intake of the target group; or interpolation



Recommendation 2 - Establishing General Principles as a separate Annex :

A separate Annex has been drafted by the eWG Chairs for consideration by the Committee (see Appendix II). The Chairs recommend that the Committee considers this draft text on General Principles for NRVs-R for persons aged 6 to 36 months and that it also considers whether the information contained should be integrated into Annex 1 or remain as a **separate text**.



Recommendation 3 - The application of different sets of NRVs for persons aged

6 to 36 months: The Chairs recommend referral to CCFL for their input on:

1. what criteria should be used to choose the most appropriate set of NRVs for a food
2. where in the main text of CXG 2-1985 (Guidelines on Nutrition Labelling) should such criteria be placed

Foods specifically labelled for older infants	Foods specifically labelled for young children	Foods specifically labelled for both older infants and young children
NRVs-R for older infants	NRVs-R for young children	NRVs-R for older infants and young children combined

As NRVs may differ for different age groups (i.e. iron) careful consideration is needed for the selection of a combined NRV that optimizes health and safety of older infants and young children. Discussion is needed on how to combine different NRVs, and these methods should be noted in the General Principles.






Recommendation 4 – Purpose of NRVs-R for persons aged 6 to 36 months:

The Chairs recommend that the NRVs-R established for labelling should also apply as reference criteria for vitamin and mineral composition, but not protein, in the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991).



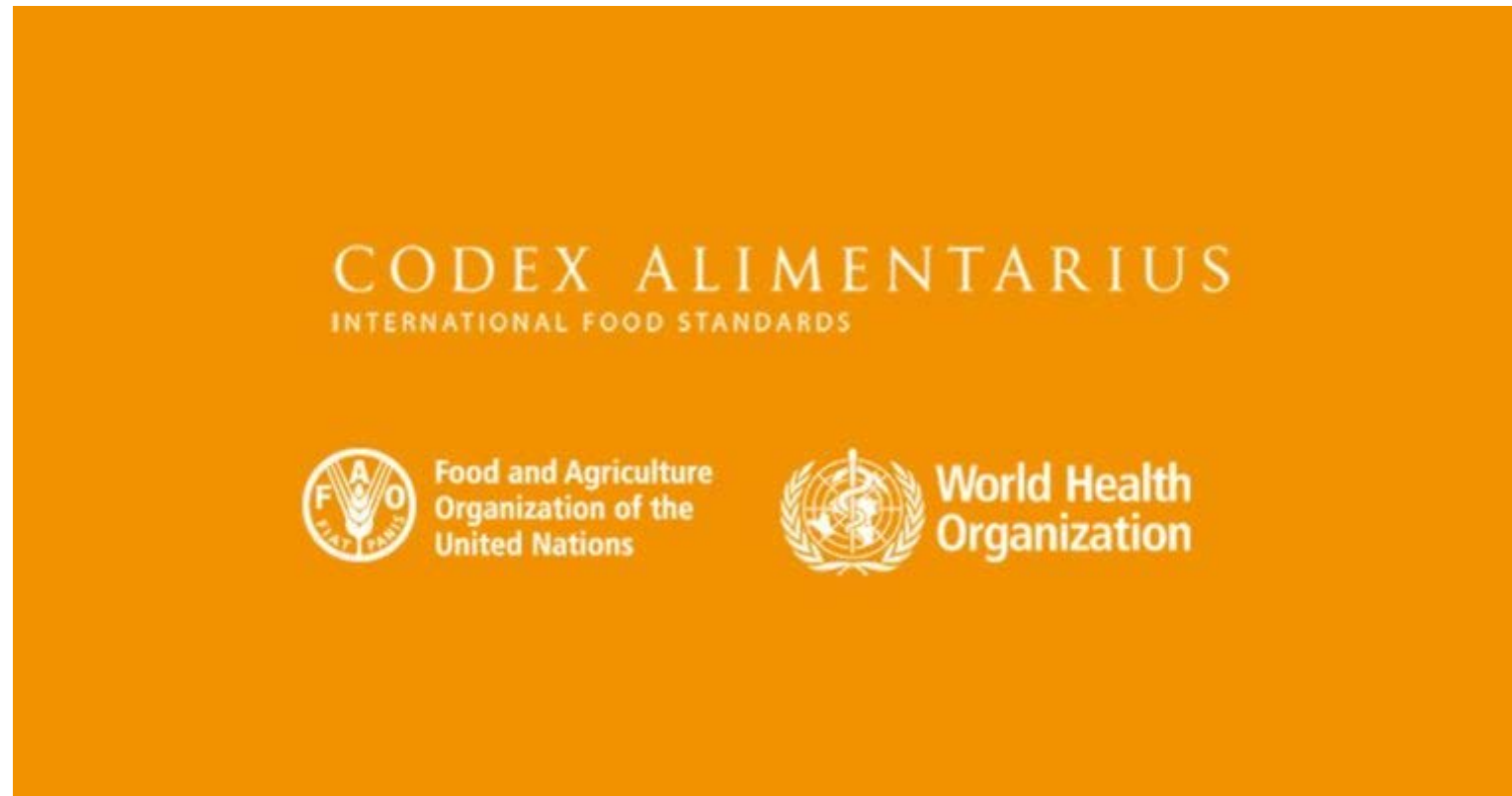
Recommendation 5 – Issues relevant to General Principles but outside current TORs:

The Chairs recommend that the Committee consider issues relevant to the General Principles but that are outside the current ToRs:

1. Inclusion of sodium 
2. The type of NRV (NRV-NCD or an NRV-R) for sodium and potassium 
3. NRVs-R should be limited to labelling purposes in FSDU texts other than the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991). 

Thank You

Tips and etiquette for attending Codex virtually



Tips for virtual Codex meetings

- **Be as well prepared as ever or even more prepared.**
 - Know your national position.
 - Know which items you want to speak on.
 - Have all the relevant documents printed out / in front of you.
- **Make sure your microphone and camera work.**
 - You are asked to turn your camera on when you are asked to speak.
- **Rename yourself when you join:**
 - Country – First name / Surname.
 - Country (HD) – First name / Surname.
- **Only head of delegation permitted to raise their hand.**
 - Head of delegation can inform Chair that they hand over to someone else from the delegation to speak.

Tips for virtual Codex meetings

- **Making an intervention:**

- Turn on camera (to assist translators) and unmute when called on by Chair.
- Shorter meeting means the Chairs ask for clear/focussed interventions.
- Shorter meeting means the Chairs will try and limit interventions per delegation so know where you want to speak and prioritise your interventions.
- Interventions can only be 2 minutes and there is a countdown timer.
- Consider pre-writing what you want to say – 250-280 words = 2 minutes spoken.
- Make it clear what wording changes you propose and read it out carefully, clearly and slowly. If it does not appear on the screen perhaps ask for it to be written on the screen.

- **Technical issues when making an intervention.**

- If the internet gives problems and you cannot be heard, the Chairs may ask you to submit your proposed wording in the chat box so have it ready.

Tips for virtual Codex meetings

- **Chat box:**

- Only to be used when the Chair requests a delegation to enter proposed text.
- Interventions must NOT be written in the chat – only spoken interventions are considered
- Direct messaging to others is enabled – good option for ‘talking’ to other delegations.

- **Silence is agreement:**

- The Chair may state that delegations are asked to remain silent if they are in agreement with text on the screen – this helps save some time.

- **CRD's:**

- The final deadline is likely to be midnight CET on the first day of the meeting but you can submit now.
- If your country cannot attend the meeting, submission of a CRD is important to ensure your views are recognised (let us know, so we can ensure your CRD is recognised).

Questions & Discussion

The way forward towards CCNFSDU



The Way Forward

- **HKI / UNICEF technical support:**

- We will be available to assist you with any technical support you might need leading up to the meeting.

- **Communication during the meeting:**

- We will set up 2 WhatsApp groups (English / French) as always.
- You can WhatsApp me directly +27 825627755 or email me jane@jbconsultancy.co.za at any time leading up to / during the meeting.
- You can use the direct messaging function in Zoom as this is enabled in the meeting.
- I will coordinate with the experts and get back to you.

Closing

Elizabeth Zehner
HKI, Director, ARCH Project

