## CODEX ALIMENTARIUS COMMISSION





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Agenda Item 5

CX/CAC/41 CRD/3rev
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# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

41st Session

FAO Headquarters, Rome, Italy, 2 – 6 July 2018
COMMENTS ON ADOPTION OF CODEX TEXTS AT STEP 5

Comments of Philippines, Sierra Leone, Senegal, Gambia, Ghana, Ecuador, Thailand, European Union, Liberia

- Committee on Fresh Fruits and Vegetables
  - Comité sur les fruits et légumes frais
  - Comité sobre fruta y hortaliza frescas

Standard for Ware Potatoes (Proposed Draft) (REP18/FFV) (Para. 60 (ii), Appendix IV)

Comments of Philippines, Sierra Leone, Senegal, Gambia, Liberia, Ghana, European Union

## **PHILIPPINES**

## 2.1 MINIMUM REQUIREMENTS

The Philippines proposes to simplify the minimum requirements of the ware potatoes on the following:

- Firm, clean and free from any visible foreign matter.
- Free from visible rots, dead and living insects, mold and other contaminants.
- Sound, free from greening\* and have well-developed tubers.
- Tubers must have normal appearance which is similar characteristics of the variety.
- \* (Appearance of green color on the tuber indicates the presence of solanin, an anti-nutritional factor. Toxic dose is 20-25mg (http://www.accessdata,fda.gov)

## 2.1.2 Maturity Requirements

The term "sufficiently developed" must be replaced by physiologically matured, thus to read:

Ware potatoes must be **physiologically matured** and cured for skin formation, account being taken of the characteristics of the variety and/or commercial type and the area in which they are grown.

#### 3. PROVISIONS CONCERNING SIZING

The Philippines proposes the size classification of ware potatoes classified according to size based on diameter and weight shown in following table. (PNS/BAFPS 53:2007)\*

Size	Diameter (cm)	Weight (g)
Jumbo	> 9.0	> 350
Super	8.1 – 9.0	301 - 350
Extra Large	7.1 – 8.0	251 - 300
Large	6.1 – 7.0	201 – 250
Big	5.1 – 6.0	151 - 200
Medium	4.1 - 5.0	101 - 150
Small	3.0 – 4.0	50 - 100
Marble/very small	< 3.0	< 50

<sup>\*</sup>Philippine National Standard/Bureau of Agriculture and Fisheries Product Standards (PNS/BAFPS)

#### **SIERRA LEONE**

Proposed Draft Standard for Ware Potatoes, REP18/FFV para 60(ii) and App. IV

Main issues:-

The revised proposed Draft Standard for Ware Potatoes was introduced at CCFFV20 by India (Chair of the EWG).

The Committee agreed to consider each section of the proposed Draft Standard and align the various sections of the Draft Standard with the Proposed Layout for Standards for Fresh Fruits and Vegetables.

Section 2 - Definition of produce

The term "hybrids" was deleted from the definition of the produce as the term "varieties" in the standard was considered to account for hybrids.

Sprouting of Ware potatoes was restricted to not more than 1 mm as sprouting beyond this maximum was considered to adversely affect the quality of the Ware potatoes.

The Committee also noted that green colouration was not a defect in ware potatoes (unlike products like French fries). The Committee noted the need to set limits to prevent the accumulation of high levels of solanine in ware potatoes.

With regards to quality tolerances, the Table for Tolerances was not easy to understand and to apply. There is a need to redesign the Table for Tolerances.

The Committee agreed to forward the draft standard to the 41<sup>st</sup> Session of the Codex Alimentarius Commission (CAC41) for adoption at step 5 and establish an EWG chaired by India and co-chaired by Cameroun and Peru working in English, French and Spanish to revise the draft standard and submit it for consideration at CCFFV21.

## RECOMMENDATION POSITION

Sierra Leone support the adoption of the proposed Draft Standard for Ware Potatoes at Step 5.

## **SENEGAL**

Contexte : Le projet révisé de norme pour les pommes de terre de conservation a été introduit au CCFFV 20 par l'Inde (président de GTE). Le Comité a accepté d'examiner chaque section du projet de norme proposée et d'aligner les diverses sections du projet de norme sur la présentation proposée de normes pour les fruits et légumes frais.

En ce qui concerne les tolérances de qualité, il a été proposé de revoir le tableau des tolérances du fait qu'il

n'était pas facile à comprendre et à appliquer

Ainsi, le Comité a décidé de transmettre le projet de norme à la 41 e session de la Commission du Codex Alimentarius (CAC 41) pour adoption à l'étape 5 et de créer un GTE présidé par l'Inde et coprésidé par le Cameroun et le Pérou en anglais, en français et en espagnol pour réviser le projet de norme et le soumettre à l'examen de CCFFV 21.

Position : le Sénégal supporte l'adoption du projet de norme à l'étape 5

Justification : Le projet de norme est examiné par un GTE présidé par l'Inde et coprésidé par le Cameroun et le Pérou. Les questions soulevées au sujet du tableau des tolérances seront traitées par le GTE avant le CCFFV 21. Nous pouvons continuer d'apporter nos contributions à travers le GTE et la prochaine session du CCFFV.

## **GAMBIA**

BACKGROUND: The revised proposed Draft Standard for Ware Potatoes was introduced at CCFFV20 by India (Chair of the EWG).

POSITION: The Gambia supports the adoption of the proposed Draft Standard for Ware Potatoes at Step 5.

RATIONALE: The Draft Standard is being considered by an EWG Chaired by India and co-chaired by Cameroun and Peru. Issues raised with regards to the Table for Tolerances will be addressed by the EWG, prior to CCFFV21. Africa can continue to shape the draft standard through the EWG and at CCFFV21.

## **LIBERIA**

Background/Issues

The revised proposed Draft Standard for Ware Potatoes was introduced at CCFFV20 by India (Chair of the EWG).

The Committee agreed to consider each section of the proposed Draft Standard and align the various sections of the Draft Standard with the Proposed Layout for Standards for Fresh Fruits and Vegetables.

Section 2 - Definition of produce

The term "hybrids" was deleted from the definition of the produce as the term "varieties" in the standard was considered to account for hybrids.

Sprouting of Ware potatoes was restricted to not more than 1 mm as sprouting beyond this maximum was considered to adversely affect the quality of the Ware potatoes.

The Committee also noted that green coloration was not a defect in ware potatoes (unlike products like French fries). The Committee noted the need to set limits to prevent the accumulation of high levels of solanine in ware potatoes.

With regards to quality tolerances, the Table for Tolerances was not easy to understand and to apply. There is a need to redesign the Table for Tolerances.

The Committee agreed to forward the draft standard to the 41<sup>st</sup> Session of the Codex Alimentarius Commission (CAC41) for adoption at step 5 and establish an EWG chaired by India and co-chaired by Cameroun and Peru working in English, French and Spanish to revise the draft standard and submit it for consideration at CCFFV21.

Recommended Position for CAC41

Liberia supports the adoption of the proposed Draft Standard for Ware Potatoes at Step 5.

#### **GHANA**

POSITION: We support the adoption of the proposed Draft Standard for Ware Potatoes at Step 5.

RATIONALE: The provision of description of classes is in accordance with Proposed Draft Layout for Codex Standards for Fresh Fruits and Vegetables.

#### **EUROPEAN UNION**

#### **Mixed Competence**

#### Member States vote

The European Union and its Member States (EUMS) consider that in accordance with Article 1(b) of the statutes of the Codex Alimentarius, Codex standards should "promote coordination of all food standards work undertaken by international governmental and non-governmental organizations".

There are two international standards on potatoes established by the UNECE and by the OECD. Contrary to these two existing standards, the draft Codex standard does not cover "early potatoes", this should be clarified in the scope of the draft Codex standard and the EUMS suggest to add a footnote defining early potatoes mentioned in the scope: "Early potatoes are obtained from early varieties and/or are harvested at the beginning of the season in the country of origin. Early potatoes means potatoes harvested before they are completely mature, marketed immediately after their harvesting, and whose skin can be easily removed without peeling" In line with the purpose of Codex Alimentarius standards to facilitate trade, the EUMS consider that the producers and traders using this Codex standard should be informed of the existence of other international standards; a new section at the end of the Codex standard for ware potatoes should be added: NOTE:

The UNECE has published the Standard FFV-52 concerning the marketing and commercial quality control of early and ware potatoes. This Standard is available at:

 $\underline{\text{http://www.unece.org/fileadmin/DAM/trade/agr/standard/fresh/FFVStd/English/52\_EarlyAndWarePotatoes\_2}\\ \underline{\text{011.pdf}}$ 

The OECD Scheme for the Application of International Standards for Fruit and Vegetables has published an explanatory illustrated brochure on the application of this standard. The publication may be obtained from the OECD bookshop at:

http://www.oecd.org/agriculture/fruit-vegetables/publications/brochures/

The EUMS support the adoption of the draft standard for ware potatoes at step 5 and will continue to contribute actively to the elaboration of the draft Codex Standard on ware potatoes.

- Committee on Nutrition and Foods for Special Dietary Uses
- Comité sur la nutrition et les aliments diététiques ou de régime
- Comité sobre nutrición y alimentos para regímenes especiales

Review of the Standard for Follow-up Formula (CXS 156-1987): Essential composition requirements for older infants and young children (Proposed Draft) (REP18/NFSDU Para. 71, Appendix II)

Comments of Philippines, Sierra Leone, Senegal, Ecuador, Gambia, Liberia, Ghana

## **PHILIPPINES**

The Philippines supports the current draft of the essential compositional requirements for older infants and children at Step 5 for adoption by the Codex Alimentarius Commission in the Revision of the Codex Standard for Follow Up Formula since these are consistent with previous Philippine Positions as justified by current generally accepted scientific evidence. The minimum and maximum values presented in the draft were aligned with the proposal in the Philippine Positions. We also support retention of the bracketed texts.

The Philippines supports the review of the Codex Standards for Follow Up Formula and agrees with Recommendations 1-37 since these are consistent with previous Philippine Positions as justified by generally accepted scientific evidence.

The Philippines is of the opinion that the minimum value of 1.65g/100kcal should be considered as the minimum nutritional requirements for protein for older infants as defined by expert authorities. Expert authorities have lowered the protein requirements for infants and young children over the last decade (WHO/FAO/UNU, 2007; EFSA, 2013; Koletzko et al, 2013).

Similarly an expert group coordinated by the Early Nutrition Academy (ENA) provided guidance for protein levels of follow-up formula for older infants and recommended protein levels be lowered to 1.65 g/100 kcal based on metabolic requirements (Koletzko, 2013).

We recommend to retain the bracketed texts "2.25 g/100 kcal (0.54 g/100 kJ" in Footnote # 5. We also support deletion of brackets in these footnote statements: For follow up formula based on soy protein isolate a minimum value of 2.25g/100kcal (0.54g/100kJ applies. Follow up formula based on non-hydrolized milk protein containing less than 1.8 g protein/100 kcal (0.43 g/100 kJ) and follow up formula based on hydrolysed milk protein containing less than 2.25 g protein /100 kcal (0.54 g/100 kJ) should be clinically evaluated and assessed by competent national and/or regional authority.

#### Recommendation 2

The Philippines is in agreement with Guidance Upper Level for Docosahexanoic acid of 30 mg/100 kcal and a minimum level of 13 mg/100 kcal (3.1 mg/100 kcal). The minimum and GUL values are equivalent to average levels of DHA in breastmilk ((EFSA 2014; Brenna, 2007). The GUL of 30 mg/100 kcal is the maximum set in Infant Formula Codex standard in which DHA is an optional ingredient only.

#### Recommendation 3

We support the proposed minimum level of 3.5 g/100 kcal for fat. This is closely similar to the levels found in breastmilk and concur with the requirements for older infants by 2014 EPZA.

#### Recommendation 4

The Philippines support a maximum limit of 12.5 g/100 kcal (3.0 mg per 100 kJ) for total carbohydrates to ensure nutritionally appropriate contributions from follow-up formula for young children. This is consistent with the recommendation of Suthutvoravut et al (2015) that available carbohydrates should contribute 9-14 g/100 kcal with >50% from lactose.

#### Recommendation 5

We reiterate support for a maximum 12.5 g/100 (3.0 mg per 100 kJ) kcal for available carbohydrate. However, sugar content (mono and di-saccharides), other than lactose should not exceed 10% of total energy (20% of available carbohydrates)based on WHO Recommendation. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

These statements are consistent with other Codex Standard for Infant Formula and Codex Standard for Cereal Based Foods for Older Infants and Young Children.Restriction on sugar is also based on 2015 WHO recommendation that both adults and children reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy.

#### Recommendation 6

We will await for the approved maximum level of carbohydrates before we decide if we prefer conversion of the percentage limit for sugar based on the energy density or product for young children.

We support the retention of the bracketed text Mono and disaccharides, other lactose, should not exceed 20% of availabale carbohydrate. Mono and disaccharides include sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate. Sucrose and/or fructose and other carbohydrate contributing to the sweet taste of [name of product]should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.

#### Recommendation 7

The Philippines supports a calcium to phosphorus ratio specifying a minimum 1:1 and maximum 2:1 should be included for product for young children. This ratio is consistent with the current Codex Standard for Follow up Formula and the latest EPZA recommendation. The ratio is necessary to ensure mineral balance to support bone mineralization.

#### Recommendation 8

A mandatory addition of vitamin D to product for young children at a minimum of 1.5µg/100kcal as proposed by ENA is supported by the Philippines. Vitamin D insufficiency in young children still exist even in some lower latitude countries. A maximum of 4.5mcg/100kcal, which corresponds to 3 times the minimum level seems to

be appropriate GUL level. We believe an upper limit for vitamin D is needed due to the potential toxicity of Vitamin D.

#### Recommendation 9

We are in agreement of the need to include scientific reference to relevant WHO documents and WHA resolutions to the Preamble in the Standard for Follow up Formula. Thus, we support the following statements: The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where, necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts.

The production, distribution, sale and use of follow up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account as appropriate, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy of Infant and Young Child Feeding. Relevant WHO Guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that been endorsed /supported by member states may provide guidance to countries in this context. We believe that statements on the reference to WHO documents and WHA resolutions should be definite considering their relevance. Hence, we recommend deletion of bracketed texts "as appropriate" and "may also".

#### Recommendation 10

We support the statement "1.1 This section of the Standard applied to Follow-Up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

#### Recommendation 11

We support retention of the bracketed text in the statement "This section of the Standard contains compositional, quality, safety, labeling and analytical requirements for Follow-Up Formula for Older Infants.".

#### Recommendation 12

The Philippines supports deletion of the brackets in the statement on Section 1.3: Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as Follow-up Formula for Older Infants. The use of shall connotes mandatory requirements.

#### Recommendation 13

The Philippines is in agreement with inclusion of reference to WHO documents and WHA resolutions within the Preamble rather than the Scope and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3. However, in the event that the Standard for [Name of Product] for Young Children is presented on a separate Standard, the subsequent Preamble should make reference to WHO documents and WHA resolutions.

#### Recommendation 14

The Philippines supports the labeling requirements of follow up formula to be in compliance with the Codex General Standard for the Labeling of Pre-packaged Foods, the Guidelines on Nutrition Labeling and the Guidelines for Use of Nutrition and Health Claims. We strongly support the prohibition on the use of health and nutrition claims for foods for infants and young children as provided in the Guidelines for Health and Nutrition Claims.

## Recommendation 15

We fully support Recommendation 15 on the prohibition of the use of health and nutrition claim for the Standard for Follow Up Formula consistent with the Guidelines on Health and Nutrition Claims and in compliance with the International Code of Marketing Breast-milk Substitutes; the Philippine local regulations (Executive Order 51 or the Milk Code) and WHO Guidance on Ending Inappropriate Marketing of Food for Infants and Young Children. If allowed, promotion of nutrition and health claims on this product for young children may potentially undermine breastmilk and breastfeeding practices. Therefore, any nutrition and health claims should not be allowed on the labels of follow up formula for older infants.

## Recommendation 16

We support deletion of the brackets in the statement "The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1 or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

We prefer to retain Option 1 deleting the brackets:

- 9.1.4 a) If name of animal milk is the only source of protein, the product may be labelled 'Follow Up Formula Older Infants Based on name of animal protein.
- 9.1.4 b) If name of plant milk is the only source of protein, the product may be labelled 'Follow Up Formula Older Infants Based on name of plant protein.
- 9.1.5 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase." In addition to 9.1.4. The use of "shall" is more reinforcing rather than the use of "may" which connotes "optional use".

#### Recommendation 17

We will not object to this statement deleting the bracketed text:

9.2.1 A complete list of ingredients [including optional ingredients] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

We support retention of the bracketed text in this statement with revision:

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. Food additives maybe optionally declared as INS number in addition to declaration of specific or common name.

## Recommendation 18

We are in agreement to delete the brackets and will not object to deletion of bracketed or:

9.3 Declaration of Nutritive Value

The declaration of nutrition information [for follow up formula for older infants] 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 grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

## Recommendation 19

The Philippines is of the opinion that there is a need to modify the proposed text on Date Marking and Storage Instructions as necessary and adopt any changes proposed at CCFL to be consistent with the text and outcomes of the discussions at the Codex Labeling Committee meeting in October 2017.

#### Recommendation 20

We support the following statements with deletion of the bracketed texts and revision of Section 9.5.1 for brevity:

- 9.5 Information for Use
- 9.5.1 [Ready to use]products in liquid form may be used [either] directly or in the case of concentrated liquid products and [powdered product], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- 9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label.
- 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- 9.5.4 The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.
- 9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

[9.5.6 The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, [is not to be used as a sole source of nutrition] and that older infants should receive complementary foods in addition to the product.].

#### Recommendation 21

We support Option 2 with the following revisions in letter d:

- 9.6 Additional Labelling Requirements
- 9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
- [a) the words "important notice" or their equivalent;]
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- [c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.
- d) It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue up to two years of age or beyond.
- It is critical to include statement under letter d to comply with the International Code of Marketing Breastmilk Substitute.
- 9.6.2. We support Option 2 retaining the square brackets:

The label shall have no pictures of infants and women nor any other picture [,] or [text] which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might with retention of deleted texts except "nearly":

- 9.6.2.1 idealize the use of follow-up formula for older infants
- 9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);
- 9.6.2.2 recommend or promote bottle feeding;
- 9.6.2.3 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;
- 9.6.2.4 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body. We do not support addition of the phrase "unless this has been specifically approved by relevant nation regional or international regulatory authority" since it may open allowance for endorsement tantamount to undermining breastmilk or practice of breastfeeding.
- 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

We support inclusion of this statement as 9.6.4 and retention of the bracketed text "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, in particular as to the text, images and colours used.]

#### Recommendation 22

We are in agreement with this statement for Section 1.1. "This section of the Standard applies to [name of product] for young children, as defined in Section 2.1 in liquid or powdered form."

#### Recommendation 23

We are in agreement with this statement for Section 1.2 deleting the brackets containing the text labelling and analytical: "This section of the Standard contains compositional, quality, safety, [labeling and analytical] requirements for [name of product] for young children.

#### Recommendation 24

We are of the opinion that this statement is clearer and should indicate that only products that comply with the provisions of this Standard shall be named as (Name of product) for Young Children: "Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as (Name of product) for Young Children.

#### Recommendation 25

The Philippines supports inclusion of reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented with Section 5.3 of this paper. We recommend inclusion of the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children. We are of the opinion that its inclusion is critical since label is considered part of promotional or advertising material.

We prefer that the reference to WHO documents and WHA resolutions be reiterated under Scope.

#### Recommendation 26

The Philippines supports the labeling requirements of [name of product] for young children to be in compliance with the Codex General Standard for the Labeling of Pre-packaged Foods, the Guidelines on Nutrition Labeling and the Guidelines for Use of Nutrition and Health Claims. We strongly support the prohibition on the use of health and nutrition claims for foods for infants and young children as provided in the Guidelines for Health and Nutrition Claims.

#### Recommendation 27

We fully support Recommendation 26 on the prohibition of the use of health and nutrition claim for the Standard for [Name of Product] consistent with the Guidelines on Health and Nutrition Claims and in compliance with the International Code of Marketing Breast-milk Substitutes; the Philippine local regulations (Executive Order 51 or the Milk Code) and WHO Guidance on Ending Inappropriate Marketing of Food for Infants and Young Children. If allowed, promotion of nutrition and health claims on this product for young children may potentially undermine breastmilk and breastfeeding practices. Therefore, any nutrition and health claims should not be allowed on the labels of [name of product] for young children.

#### Recommendation 28

The Philippines is in agreement with the following:

- 9.1 The Name of the Product
- 9.1.1 the text of the label and all other information accompanying the product shall be written in the appropriate language(s)
- 9.1.2 The name of the product shall be (Name of Product) for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

We are of the opinion that this Standard should use the national language as understood by the majority of the population.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

The Philippines supports splitting the statement 9.1.4 into two deleting the brackets

- 9.1.4.a) If [name of animal] milk is the only source of protein [\*], the product may be labelled 'Name of Product for Young Children based on [name of animal] milk [protein].
- 9.1.4b) If [name of plant] is the only source of protein [\*], the product may be labelled 'Name of Product for Young Children based on [name of plant].[protein]

We do not support Option 2 of 9.1.4.

9.1.5 A product which contains neither milk nor any milk derivative [shall] be labelled "contains no milk or milk products" or an equivalent phrase." In addition to 9.1.4. The use of "shall" is more reinforcing rather than the use of "may" which connotes "optional use".

#### Recommendation 29

We will not object to this statement deleting the bracketed text:

9.2.1 A complete list of ingredients [including optional ingredients] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

However, we support retention of the bracketed text in this statement with revision:

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. Food additives may be optionally declared as INS number in addition to declaration of specific or common name.

## Recommendation 30

We are in agreement to delete the brackets and will not object to deletion of bracketed or:

9.3 Declaration of Nutritive Value

The declaration of nutrition information [name of product] for young children 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 gramsof protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold [as

well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

#### Recommendation 31

The Philippines is of the opinion that there is a need to modify the proposed text on Date Marking and Storage Instructions as necessary and adopt any changes proposed at CCFL to be consistent with the text and outcomes of the discussions at the Codex Labeling Committee meeting in October 2017.

#### Recommendation 32

We support the following statements with retention of bracketed texts and deletion of the bracketed texts in 9.5.1 for brevity:

9.5 Information for Use

- 9.5.1 [Ready to use]products in liquid form may be used [either] directly or in the case of concentrated liquid products and [powdered product], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- 9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label.
- 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- 9.5.4 The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.
- 9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- [9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age, and should be used as part of a [diversified] diet.

## Recommendation 33

9.6 Additional Labelling Requirements

The Philippines

- 9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
- [a) the words "important notice" or their equivalent;]
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- [c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.
- d) It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond.

We support retention of the bracketed statement "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"

#### Recommendation 34

We wish to reiterate this definition for product for young children:

• (Name of Product) for young children means a product specially manufactured for use as a substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a liquid part of the progressively diversified diet.

This product for young children can still be considered as breast-milk substitute and as part of a progressively diversified diet to help meet the nutritional requirements of young children. It serves as a transition from the introduction of complementary foods to eventual consumption of family meals. Labelling for this product should also indicate that (Name of Product) For Young children is only a substitute in cases where breastfeeding is impossible.

## Recommendation 35

We maintain that the product for young children could be considered as a breastmilk substitute and is covered by the International Code of Marketing Breastmilk Substitute, hence we proposed that this be considered in the definition. We support retention of the bracketed texts with revision.

Name of product] for young children means a product specially [formulated and] manufactured for use as a liquid part of the [progressively] [diversified] diet of young children andfor use as a substitute for breast-milk [in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].

#### Recommendation 36

The Philippines is supportive of this statement:

That CCNFSDU agree to adopt the name Follow-up Formula for Older Infants as the name of product for the 6 – 12 month age group (older infants).

## Recommendation 37

We support "Formulated Milk-Based Drink for Young Children". There may be no need to indicate milk based or plant based in the product name since the source of protein is part of mandatory declaration on the label. The product name would be too long if the source of protein is part of the product name.

## **SIERRA LEONE**

Review of the Standard for Follow-up Formula: Proposed draft Essential composition requirements for older inants and young children REP18/NFSDU 71 and App.II

Main issues:-

Adoption of Protein at 1.8 mg/ 100Kcal and DHA at minimum of 20 mg/100kcal and GUL of 30 mg/100kcal RECOMMENDATION POSITION

Sierra Leone recommend adoption of the composition requirements for older infants and young children at step 5.

## **SENEGAL**

Contexte: À la 38 e session, un groupe de travail électronique présidé par la Nouvelle-Zélande, coprésidé par l'Indonésie et la France, a été établi avec le mandat suivant :

- -Finaliser les exigences minimales en protéines et les niveaux pour l'ajout facultatif de DHA dans la composition essentielle de la formule de suivi pour les nourrissons âgés plus (6-12 mois) (Sous-section 3 de la section A) ;
- -Finaliser les exigences en suspens pour la composition essentielle des produits pour les jeunes enfants (12 36 mois) (Sous-section 3 de la section B) ;
- -Finaliser les définitions du produit contenues dans la définition 2.1, y compris le nom du produit pendant 12-36 mois ;
- -Examiner les sections sur la portée et l'étiquetage avec un point de différenciation à 12 mois, pour la section A et la section B du projet de norme sur la base des discussions menées au CCNFSDU 38, et proposer un projet de texte.

Le comité s'est accordé sur les taux suivants :Protéine à 1,8 mg / 100 Kcal et DHA à 20 mg / 100 kcal et GUL à 30 mg / 100 kcal

Position : le Sénégal marque son accord pour l'adoption des exigences relatives à la composition des nourrissons âgés et des jeunes enfants à l'étape 5

Justification : Les exigences de composition essentielles pour les nourrissons et les jeunes enfants sont fondées sur les conseils de RASB.

#### **ECUADOR**

## Comentarios generales

 Considerando el interés primordial de la primera infancia, esta sección de la norma debería considerar las decisiones basadas en la evidencia científica vigente, en lugar de basarse en consensos de orden político. Por lo tanto, se exalta a considerar la evidencia científica más relevante y convincente al momento.

- Considerando que la alimentación no saludable es la mayor causa subyacente de la enfermedad a
  nivel mundial, las normas del Codex dirigidas a productos para lactantes y niños pequeños no
  deberían fomentar la existencia de productos con el potencial de aumentar el riesgo de obesidad y
  sobrepeso infantil debido al consumo excesivo de azúcares, sodio y grasa. Por lo tanto, en el marco
  de la evidencia científica disponible, las normas Codex deberían priorizar el prevenir el desarrollo de
  hábitos alimentarios no saludables en la primera infancia.
- Ya que todo estado miembro de la OMS está vinculado a las resoluciones WHA69.9 "Eliminación de la promoción inadecuada de alimentos para lactantes y niños pequeños" y 63.23 "Nutrición de infantes y niños pequeños" de la AMS, se considera de vital importancia que exista coherencia entre estas resoluciones y las normas estudiadas dentro de este comité.
- Ecuador se alinea a las observaciones de IBFAN y IACFO en anteriores revisiones: si los preparados en cuestión van a ser dirigidos a niños mayores de 6 meses, su composición debería alinearse a la de los preparados de inicio (en la medida de lo posible). Considerando que cuando los infantes no son amamantados, los preparados para lactantes pueden ser usados durante los primeros 12 meses de vida, por lo tanto, y de acuerdo con lo establecido por la Organización Mundial de la Salud los preparados de continuación no son necesarios.

## Comentarios específicos

#### SECCIÓN A: PREPARADOS COMPLEMENTARIOS PARA LACTANTES DE MÁS EDAD

- Mejorar la traducción al español de "preparados complementarios para lactantes de más edad", ya que el término más edad es de difícil comprensión. De preferencia debería indicarse el rango de edad para el que está destinado.
- En el pie de página de la sección 3.1.3 para proteínas debe incluirse: todos los preparados de continuación basados en proteínas hidrolizadas de soya deben ser evaluados clínicamente.
- En el pie de página 9 de la sección 3.1.3 para carbohidratos, se debe eliminar la frase "salvo que sean necesarias como fuente de carbohidratos y siempre que la suma de estas no supere el 20 % del contenido total de carbohidratos". Debido a que es contradictorio ya que, por ninguna razón, se debe incluir azúcares añadidos en los productos destinados a los niños menores de 2 años.¹
- Las secciones de "ingredientes facultativos" deberán mejorar su traducción como "ingredientes opcionales".
- En cuanto a la sección 3.2.3, referente al ácido docosahexaenoico, tomando en cuenta las inconsistencias de la evidencia disponible en cuanto a la eficacia del DHA en niños de 6-12 meses, se exalta a que se limite el uso de los ingredientes opcionales. Esto debido a que la adición de este tipo de ingredientes se realiza con fines de promoción del producto. Por lo tanto, debería usarse el principio de precaución y sólo utilizarse ingredientes opcionales cuando se ha determinado que son esenciales.
- En cuanto a la sección 3.2.3, referente a los cultivos productores de ácido láctico L(+), se debe considerar para el uso con fines de suplementación, se requiere que para la reconstitución se utilicen temperaturas más bajas que las recomendadas para una preparación segura. Esto incrementa el riesgo de infecciones por Salmonella y Cronobacter. Los mismos riesgos se amplifican en niños que no se alimentan con lecha materna ya que son vulnerables a las infecciones. Por lo tanto, deberán utilizarse sólo con el propósito de acidular y no suplementar.

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<sup>&</sup>lt;sup>1</sup> Organización Mundial de la Salud. Directriz: Ingesta de azúcares para adultos y niños. Ginebra: OMS, 2015. Vos, M. B., Kaar, J. L., Welsh, J. A., Van Horn, L. V., Feig, D. I., Anderson, C. A., ... & Johnson, R. K. (2017). Added sugars and cardiovascular disease risk in children: a scientific statement from the American Heart Association. Circulation, 135(19), e1017-e1034.

## SECCIÓN B: [NOMBRE DEL PRODUCTO] PARA NIÑOS PEQUEÑOS

• Ecuador considera que (nombre de producto) para niños pequeños no es necesario desde el punto de vista nutricional ya que la leche de fuentes animales es una fuente de nutrientes más segura y accesible y puede ajustarse fácilmente la alimentación complementaria para lactantes y niños pequeños. Por lo tanto, de existir este tipo de productos, su composición debe ser similar a la de los preparados de inicio o a la leche de animales (sin azúcares añadidos, ni saborizantes ya sean naturales o artificiales). Adicionalmente, se debe considerar que a partir de los 6 meses de edad se introduce la alimentación complementaria; es decir, los niños mayores de 12 meses ya están integrados a la dieta familiar y por ende tienen una variedad de fuentes de nutrientes. De tal manera que, al establecer una norma para este tipo de productos, se estaría fomentando el consumo de productos que no son realmente necesarios para los niños mayores de 12 meses.

- En cuanto a la sección 3.1.3, específica para carbohidratos, debe eliminarse la frase "a menos que sean necesarios como fuentes de carbohidratos" ya que la AHA²indica que los niños menores de 2 años deben evitar consumir cualquier azúcar añadido ya que necesitan dietas ricas en nutrientes y están desarrollando preferencias gustativas. Por lo tanto, de ninguna manera deberán añadirse sacarosa ni fructosa ni otros carbohidratos que contribuyan al sabor dulce. Adicionalmente, los límites deben estar alineados con las recomendaciones de la OMS para limitar los azúcares libres³. La OMS ha expresado su preocupación con respecto a los posibles efectos negativos para la salud de los productos alimenticios destinados a los niños menores de 2 años. Esto considerando su influencia detrimente en la prevalencia de lactancia materna exclusiva durante los primeros 6 meses y conjunta a la alimentación complementaria, por lo menos hasta los dos años. Así como, su influencia en un mayor riesgo de obesidad infantil o factores de riesgo relacionados con enfermedades cardiovasculares, diabetes y cáncer debido al consumo excesivo de energía, azúcares libres, sodio y o grasa.
- En cuanto a la sección 3.2 de "Ingredientes opcionales", se exalta a que la composición de estos productos debe estar alineada con los preparados de inicio o con la leche (sin azúcar y sin sabores añadidos) ya que su propósito es sustituir a la leche materna. Esta sección debería establecer:
  - a) todos los ingredientes utilizados deberán ser usados después de una investigación rigurosa e independiente (con especial cuidado con las nuevas tecnologías, como las nanotecnologías;
  - b) las revisiones sistemáticas de la evidencia disponible deberían llevarse a cabo independientemente de los fabricantes y distribuidores de los productos en cuestión;
  - c) la evidencia debería revisarse regularmente para asegurar que los niños no estén expuestos a niveles de nutrientes que puedan poner una carga en su metabolismo (una preocupación ya planteada por la EFSA<sup>4</sup>);
  - d) debe realizarse vigilancia permanente de estos productos una vez que se encuentran en el mercado.
  - e) los ingredientes alimentarios no enumerados como esenciales deben mantenerse al mínimo ya que la adición de ingredientes opcionales responde a fines de promoción y publicidad.
- En cuanto a los ingredientes opcionales, al igual que IFBAN e IACFO en otras revisiones, consideramos importante tomar en cuenta la declaración del Comité Asesor Científico sobre Nutrición del Reino Unido (SACN), respecto a la noción de ingredientes opcionales: "... Si un ingrediente es inequívocamente beneficioso como lo demuestra la revisión independiente de datos científicos, no sería ético negarlo por razones comerciales. Más bien debería convertirse en un ingrediente necesario de la fórmula infantil para reducir los riesgos existentes asociados con la alimentación artificial. Hacer lo contrario no es lo mejor para los niños, y no reconoce la distinción crucial entre estos productos y otros alimentos"<sup>5</sup>

## **GAMBIA**

BACKGROUND: At the 38<sup>th</sup> Session, an electronic working group (eWG) chaired by New Zealand, co-chaired by Indonesia and France was established with the following terms of reference:

<sup>&</sup>lt;sup>2</sup> Vos, M. B., Kaar, J. L., Welsh, J. A., Van Horn, L. V., Feig, D. I., Anderson, C. A., ... & Johnson, R. K. (2017). Added sugars and cardiovascular disease risk in children: a scientific statement from the American Heart Association. Circulation, 135(19), e1017-e1034.

<sup>&</sup>lt;sup>3</sup> Organización Mundial de la Salud. Directriz: Ingesta de azúcares para adultos y niños. Ginebra: OMS, 2015.

<sup>&</sup>lt;sup>4</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (2014). Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 12(7), 3760.

<sup>&</sup>lt;sup>5</sup> Jones, W. (2013). Breastfeeding and Medication. Routledge.

- Finalise the minimum protein requirements and levels for the optional addition of DHA on the Essential Composition of Follow-up Formula for older infants (6-12 months) (Sub-section 3 of Section A);

- Finalise the outstanding requirements for the Essential Composition of product for young children (12
   36 months) (Sub-section 3 of Section B);
- Finalise the product definitions contained within Definition 2.1 including the name of product for 12-36 months;
- Review the Scope and Labelling Sections with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text.

POSITION: The Gambia supports the adoption of the composition requirements for older infants and young children at step 5.

RATIONALE: The Proposed draft Essential composition requirements for older infants and young children are based and the advice of competent RASBs and sound science.

#### **LIBERIA**

Adoption at Step 5

Review of the Standard for Follow-up Formula: Proposed draft Essential composition requirements for older infants and young children REP18/NFSDU 71 and App.II

Background/Issue

Adoption of: Protein at 1.8 mg/ 100Kcal and DHA at minimum of 20 mg/100kcal and GUL of 30 mg/100kcal

Recommendation

Liberia supports adoption of the composition requirements for older infants and young children at step 5

## **GHANA**

POSITION: We support the adoption of the composition requirements for older infants and young children at step 5. That is Protein at 1.8 mg/ 100Kcal and DHA at minimum of 20 mg/100kcal and GUL of 30 mg/100kcal.

RATIONALE: The Proposed draft Essential composition requirements for older infants and young children are based on the advice of competent RASBs and sound science.

- Committee on contaminants in foods
- Comité sur les contaminants dans les aliments
- Comité sobre contaminantes de los alimentos

COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils (REP18/CF) (Para. 102 (ii) and (iii) Appendix VI)

Comments of Sierra Leone, Thailand, Liberia, Ghana

#### **SIERRA LEONE**

Main issues:-

Edible vegetable oils are produced from fruits, seeds, and nuts and refining of edible vegetable oils (at temperatures of about 200°C or higher) can produce 3-MCPD, 3-MCPDE and glycidyl esters. A JECFA evaluation (JECFA 83 in 2016) reported that 3-MCPDE are carcinogenic and usually target the kidney and male reproductive organs. JECFA further established a group PMTDI of 4ug/kg for 3-MCPD and 3-MCPDE. JECFA also concluded that glycidol is genotoxic and also poses a health concern. CCCF11 (2017) decided to prepare a COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils through an EWG led by the USA. This work was approved by CAC40 (2017).

#### RECOMMENDATION POSITION

Sierra Leone support the decision to adopt the COP at Step 5 for further drafting and comments.

#### **THAILAND**

Thailand does not oppose the adoption of COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils at Step 5. Nonetheless, we would like to note that this draft contained so much details and some are from experimental methods that may not be practical to the related industries. We therefore propose to CCCF to carefully consider the draft, particularly those in the square brackets.

#### **LIBERIA**

COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils REP18/CF para 102 (ii) and (iii)

#### Background/Issue

Edible vegetable oils are produced from fruits, seeds, and nuts and refining of edible vegetable oils (at temperatures of about 200°C or higher) can produce 3-MCPD, 3-MCPDE and glycidyl esters. A JECFA evaluation (JECFA 83 in 2016) reported that 3-MCPDE are carcinogenic and usually target the kidney and male reproductive organs. JECFA further established a group PMTDI of 4ug/kg for 3-MCPD and 3-MCPDE. JECFA also concluded that glycidol is genotoxic and also poses a health concern. CCCF11 (2017) decided to prepare a COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils through an EWG led by the USA. This work was approved by CAC40 (2017)

#### Recommendations

Support the decision to adopt the COP at Step 5 for further drafting and comments

#### **GHANA**

POSITION: Ghana supports the decision to adopt the COP at Step 5 for further drafting and comments.

RATIONALE: The COP will provide guidance on 3-MCPDE and GE in refined oils. 3-MCPD and GE are both formed during the heating process but by different mechanisms and are known to pose health concerns. GE forms at temperatures above 200°C and its formation increases with increasing temperature. 3-MCPDE is formed at lower temperatures (160- 200°C) in the presence of chlorinated compounds but formation does not increase at higher temperatures. JECFA has noted that dietary exposure to 3-MCPD for formula-fed infants could exceed the PMTDI by up to 2.5 fold depending on the country.

Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established (REP18/CF) (Para. 124 (i) Appendix IX)

Comments of Sierra Leone, Liberia, Ghana

## **SIERRA LEONE**

Main issues:-

This work was approved by CAC40 (2017). CCCF12 discussed and revised the document providing more clarification on its purpose.

These guidelines are aimed at contaminants which fall outside the normal regulatory framework. It includes groups of contaminants such as chemicals used to address specific environmental and climate-change related issues, contaminants from materials used during processing of food such as non-regulated packaging materials, printing inks, oils, lubricants, resins used as manufacturing maintenance compounds, newly characterized mycotoxins or phytotoxins, and environmental contaminants such as flame retardants and fragrances.

Compounds such as food additives, pesticides, veterinary drugs etc. for which regulatory requirements exist are excluded.

## RECOMMENDATION POSITION

Sierra Leone support the decision to adopt the document at Step 5 for further drafting and comments.

#### **LIBERIA**

Background/Issues

This work was approved by CAC40 (2017). CCCF12 discussed and revised the document providing more clarification on its purpose.

These guidelines are aimed at contaminants, which fall outside the normal regulatory framework. It includes groups of contaminants such as chemicals used to address specific environmental and climate-change related issues, contaminants from materials used during processing of food such as non-regulated packaging materials, printing inks, oils, lubricants, resins used as manufacturing maintenance compounds, newly characterized mycotoxins or phytotoxins, and environmental contaminants such as flame retardants and fragrances.

Compounds such as food additives, pesticides, veterinary drugs etc. for which regulatory requirements exist are excluded.

#### Recommendations

Liberia supports the decision to adopt the document at Step 5 for further drafting and comments

## **GHANA**

POSITION: Ghana supports the adoption of the document at Step 5.

RATIONALE: The guidelines are meant for chemicals not anticipated previously to be present in food but likely to be of very low public health concern and have potential impact on international trade.

Proposed draft MRL for flumethrin (honey) (REP18/RVDF) (Para. 73 Appendix IV)

Comments of Philippines, Ghana

## **PHILIPPINES**

The Philippines support the adoption of the established MRLs at Step 5.

The Philippines would like to express its support for the established MRLs for flumethrin (honey) as evaluated by the 85<sup>th</sup> JECFA as follows:

## FLUMETHRIN (insecticide)

Microbiological Acceptable Daily Intake (mADI)	0–0.004 mg/kg bw based on the NOAEL of 0.37 mg/kg bw per day for skin lesions in parental animals and reduced survival and bodyweight gain in pups in a two-generation toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)
Acute Reference Dose (ARfD)	0.005 mg/kg bw based on the NOAEL of 0.5 mg/kg bw for salivation in dams in a developmental toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)

Estimated Chronic Dietary Exposure (GECDE)	0.008 μg/kg bw per day (for the general population), which represents 0.2% of the upper bound of the ADI.	
	$0.006~\mu g/kg$ bw per day (for children), which represents 0.2% of the upper bound of the ADI.	
	Note: As flumethrin is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA 85 report. Results below are only for use as veterinary drug	
Estimated Acute Dietary Exposure (GEADE)	0.1 µg/kg bw per day (for the general population), which represents 2.2% of the ARfD.	
	0.1 μg/kg bw per day (for children), which represents 2.2% of the ARfD	

Residue Definition: Flumethrin (trans-Z1 and trans Z2 diastereomers at a ratio of approximately 60:40)

Species	Tissue	MRLs (μg/kg) recommended by the 85 <sup>th</sup> JECFA	Step	JECFA
	Honey	6	3	85

Note: the 85th JECFA set an MRL for honey of 6  $\mu$ g/kg, which is twice the limit of quantification (LOQ; 3  $\mu$ g/kg) of the most reliable analytical method (liquid chromatography coupled with tandem mass spectrometry; LC–MS/MS) used in the residues studies

## **GHANA**

CCRVDF: Proposed Draft MRL for Flumethrin

POSITION: We support the adoption of MRL at Step 5

RATIONALE: Based on JECFA 85<sup>th</sup> assessment of the MRLs of Flumethrin (honey 6µg/kg) and subsequent recommendations.