E

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 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/NFSDU 17/39/5-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-ninth Session

Berlin, Germany

4 – 8 December 2017

Proposed Draft Definition for Biofortification

Comments at Step 3 (Replies to CL 2017/76-NFSDU)

Comments of Albania, Australia, Brazil, Canada, Colombia, Costa Rica, Egypt, India, New Zealand, Paraguay, Philippines, Switzerland, Thailand, United States of America, International Baby Food Action Network (IBFAN), International Council of Beverages Associations (ICBA), International Council of Grocery Manufacturers Association (ICGMA), International Fruit and Vegetable Juice Association (IFU) and Food and Agricultural Organization (FAO)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/76-NFSDU issued in September 2017. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

Explanatory notes on the appendix

2. The comments submitted through the OCS are, hereby attached as **Annex** and are presented in table format.

ANNEX

Comments on the Proposed Draft Definition for Biofortification

<table>
<tr><th>GENERAL COMMENT</th><th>MEMBER/ OBSERVER</th></tr>
<tr><td>ok.
Category : EDITORIAL</td><td>Albania</td></tr>
<tr><td>Australia thanks Zimbabwe and South Africa for their co-leadership of the electronic working group.
Australia considers that the proposed definition is nearing completion and we offer the following suggestions and comments.
Recommendation 1
Australia suggests the following changes (other than editorial) to the Chair’s recommendations as shown.
<table>
<tr><th>1 FOOD</th><th>2 NUTRIENT</th><th>3 OUTCOME</th><th>4 PURPOSE</th><th>5 METHODS</th></tr>
<tr><td>All potential source organisms (animal plant, fungi, yeasts, bacteria) [and/or] food may be biofortified*

Biofortification does not include conventional fortification covered by CAC/GL 9/1987</td><td>To allow for all nutrients and related substances*

*Nutrient is….

Related substance is….</td><td>Measurable increased nutrient or related substance content [and/or] bioavailability

Bioavailability - the proportion of …..</td><td>The nutrient or related substance is added in an amount sufficient for the intended purpose

Paragraph 3.1.1 of the Principles….. (CAC/GL 9-1987)</td><td>Methods of production

*To be determined by the competent National/Regional authority</td></tr>
<tr><td>Australia supports the current text with the amendment to change ‘and/or’ to ‘of’ food’ to clarify these organisms are a source for food as consumed.
We agree that’ Prior to processing’ is not then required. We also note the convention for Codex docs use hyphens, not forward slashes i.e. CAC/GL 9/-1987</td><td>Australia supports the text and suggests the footnote for related substance refers to the source of the definition as CCNFSDU risk analysis principles.</td><td>Australia supports this text including deleting the square bracket from [and/or] except for ‘measurable’. This term is not meaningful because measurable differences can be very small given the sensitivity of current analytical methods. We consider measurable is already conveyed through the use of increased. We suggest the footnote for bioavailability refers to the source of the definition as CCNFSDU risk analysis principles</td><td>Australia notes that not all of this text is in the compiled definition at recommendation 6. We are wary of referring to an amount in one food that, of itself, could achieve a nutritional purpose. Since the footnote refers to CAC/GL 9-1987, as the source document, we have changed ‘intended purposes’ to ‘specific nutritional purpose’ as outlined in the referenced General Principles. This reintroduces nutritional to describe the purpose rather than just intended purpose.</td><td>Australia supports this text.</td></tr>
</table>
</td><td>Australia</td></tr>
</table>

Recommendation 6

Australia considers that the definition should be constructed on the basis of the 5 elements. We suggest the following amendments that reflect our comments above.

Track change

Biofortification is the process whereby a~~ny~~ nutrient~~s~~[1] or related substance~~s~~[2] **is increased ~~by a measurable level [and/or]~~ becomes more bioavailable[3]** ~~of~~ **in** ~~all~~ **a** potential source organism~~s~~ **of foods** (e.g. *animal, plant, fungi, yeasts, bacteria*) ~~[and]/[or] foods~~[1] for ~~the intended~~ **a specific nutritional** purpose~~s~~[4]. The process applies to any method of production[5] ~~and~~ exclud**ing**~~es~~ conventional fortification[6].

1 Nutrient is defined by….
2 A related substance is **described by the Codex Nutritional Risk Analysis Principles as**…..
3 Bioavailability ~~-~~ **is described by the Codex Nutritional Risk Analysis Principles as** the proportion…..
4 **See** paragraph 3.1.1 in **General** principles for the addition of essential nutrients to foods (CAC/GL 9-1987)
5 Method**(s)** of production should be determined by the competent national/regional authority
6 ~~Biofortification does not include conventional fortification covered by~~ **General principles for the addition of essential nutrients to foods** (CAC/GL 9**/-**1987)

Clean copy

Biofortification is the process whereby a nutrient[1] or related substance[2] is increased or becomes more bioavailable[3] in a potential source organism of foods (e.g. *animal, plant, fungi, yeasts, bacteria*) for a specific nutritional purpose[4]. The process applies to any method of production[5] excluding conventional fortification[6].

1 Nutrient is defined….
2 A related substance is **described by the Codex Nutritional Risk Analysis Principles as** …..
3 Bioavailability is **described by the Codex Nutritional Risk Analysis Principles as** the proportion…..
4 See paragraph 3.1.1 General principles for the addition of essential nutrients to foods (CAC/GL 9-1987)
5 Method(s) of production should be determined by the competent national/regional authority
6 General Principles for the addition of essential nutrients to foods (CAC/GL 9-1987)

Placement of the definition

Australia notes the Chairs' discussion of placement of the definition with respect to labelling in section 4.1 of the agenda paper. We note CCFL41's request to CCNFDU was confined to establishing a definition. We also note previous differences of view in Codex committees about need for methods of production to be included in labelling. In light of this, and if CCFL were not inclined to include the definition in a Codex labelling standard/guideline, possible alternative placements could include:

- the definition section of the Codex Nutritional Risk Analysis Principles (since the definition of *nutrient* and of *bioavailability* are already included).
- the definition section of the Codex Manual in Definitions For The Purpose Of Codex Alimentarius section (p22, 21st edition)
- the possibility of developing a regional standard for Africa.

Brazil appreciates the work done by Zimbabwe and South Africa and thanks for the opportunity to present the following comments about the proposed draft definition for biofortification. Initially, we would like to point out that it is very useful when the document presents a contextualization of the theme, the history of the discussion and the consolidation of the eWG comments. We believe that it facilitates the analysis and the proposal of suggestions. *Category : SUBSTANTIVE*	**Brazil**
Colombia appreciates the opportunity to present comments on the biofortification document. It also notes that all observations are made in reference to the Spanish document, CX/NFSDU 17/39/5. *Category : EDITORIAL*	**Colombia**
Costa Rica thanks South Africa and Zimbabwe for their work in coordinating the electronic working group and for preparing the document CX/NFSDU 17/39/5 PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION. It would also like to reiterate its gratitude for being able to submit specific comments on this topic, as detailed in the following recommendations. **Recommendation 1** That the CCNFSDU adopt the proposed text for Criterion 1. Criterion 1: Source organisms All potential source organisms (e.g. animals, vegetables, fungi, yeasts and bacteria) [and/or] foods may be bioenriched.* * Bioenrichment does not include conventional enrichment as covered in the document CAC/GL 9/1987. Costa Rica supports Recommendation 1 with one change: remove the phrase “[and/or] foods”, as the latter are already included in the term source organisms. It considers the clarification regarding the fact that this process does not include conventional enrichment to be very important in order to correctly differentiate bioenrichment, which is a method for adjusting the nutritional content of an organism by agricultural and technological means. **Recommendation 2** That the CCNFSDU adopt the proposed text for Criterion 2. Criterion 2: Nutrients and related substances Permit all nutrients and related substances Costa Rica supports Recommendation 2. **Recommendation 3** That the CCNFSDU adopt the proposed text for Criterion 3. Criterion 3: Result	**Costa Rica**

Greater nutrients content and related substances [or] higher measurable bioavailability. Costa Rica agrees with Recommendation 3. We prefer to keep the word "[or]" because demonstrating an increase in bioavailability is a costly process that may prevent small producers of natural varieties from making statements about high levels of nutrients as a result of biofortification. **Recommendation 4** That the CCNFSDU adopt the proposed text and corresponding footnote for Criterion 4. CX/NFSDU 17/39/5 6 Criterion 4 – Intended purpose Addition of the nutrient or refined substance in a quantity sufficient to achieve the intended purpose* *Paragraph 3.1.1 of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) Costa Rica supports Recommendation 4. **Recommendation 5** A. That the Committee examine whether the text referenced in the footnote should be included in the draft definition of bioenrichment. B. That the Committee examine the draft text of Criterion 5 to determine if it agrees with the inclusion of the text that refers to the role of the competent national or regional authorities. [Criterion 5: Methods Methods* of production *to be determined by the competent national or regional authority.] A definition must not specify methods of production. Costa Rica believes that it must be possible to apply all available methods of production, as the purpose of bioenrichment is to improve the nutritional quality of food. As we had indicated in our response to the second consultation in the eWG, we think that the debate on the production methods involved in biofortification should be conducted as part of a discussion about the labelling of such foods. We believe that the asterisk and the footnote should be eliminated, as the Codex seeks to develop scientific texts for food security and fair trade. Therefore, all available methods for achieving biofortification should be utilised, as the ultimate goal is to improve public health. Costa Rica believes that leaving it to the competent national and regional authorities to decide whether to accept different procedures or techniques will result in obstacles to international trade because some foods would be considered bioenriched in some countries but not in others. This means that the food must be labelled for each importing country or that, in order to save on costs, the labelling of food	

may not refer to the fact that it has been bioenriched.

Recommendation 6

That the CCNNFSDU examine the draft definition of bioenrichment and the corresponding footnotes in order to discuss them.

Bioenrichment is a process that increases the measurable level of the amount [or] bioavailability[1] of any nutrient[2] or related substance[3] of any source organisms (e.g. animals, vegetables, fungi, yeasts and bacteria) [from]/[and] foods for the intended purposes[4]. The process includes any method of production[5] [and excludes conventional enrichment[6]].

[1] Bioavailability: The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation as well as related intestinal and multiple organ factors related to the subject in question.

[2] Nutrient is defined by Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean:

Any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.

[3] A related substance is a component of food (other than a nutrient) that has a beneficial physiological effect.

[4] Paragraph 3.1.1 of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)

[5] The production method must be determined by the competent national or regional authority.

[6] Bioenrichment does not include conventional enrichment as covered in the document CAC/GL 9/1987.

Costa Rica agrees with the proposed definition with the following amendments:

Bioenrichment is a process that increases the measurable level of the amount [or] bioavailability[1] of any nutrient[2] or related substance[3] of any source organisms (e.g. animals, vegetables, fungi, yeasts and bacteria) ~~[from]/[and] foods~~ for the intended purposes[4]. The process includes any method of production[5] [and excludes conventional enrichment[6]].

[1] Bioavailability: The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation as well as related intestinal and multiple organ factors related to the subject in question.

[2] Nutrient is defined by Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean:

Any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.

[3] A related substance is a component of food (other than a nutrient) that has a beneficial physiological effect.

[4] Paragraph 3.1.1 of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) ~~[5] The production method must be determined by the competent national or regional authority.~~ [6] Bioenrichment does not include conventional enrichment as covered in the document CAC/GL 9/1987.	
New Zealand's Comments: a. Where the definition will be used: New Zealand considers that the best definition for biofortification will reflect where it will be used. We have been working under the assumption that the decision about where best to use the definition had already been made, and that it will be in: The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). When the initial request to work on a proposed definition for biofortification started, members were asked to indicate where the definition will be used and where it would be best placed. Based on the collective comments of the eWG, the co-Chairs suggested the following texts to house the Biofortification definition: The Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), and the following: i. It is proposed that the definition can be used in dictionaries, as guidance by researchers, regulatory authorities, food manufacturers, packers, traders, consumers, risk assessors (e.g. scientific bodies) et cetera. ii. The definition can be used in the development of new breeds, labelling of foods, development of food regulations, acts and policies, in reports of risk assessment, marketing of products, and already existing codex texts. iii. Once adopted the definition can be used by other subsidiary bodies such as CCFL, CCGP, etc. New Zealand agreed that the definition could provide more guidance and clarity for Codex members, researchers and consumers, but noted that although some dictionaries may draw on this definition, they ultimately would be responsible for coming up with their own definition in accordance with their practices and processes. New Zealand agreed the definition would be best placed in: The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). It is therefore a surprise to see that the paper supporting Agenda 5 "Proposed Draft Definition for Biofortification" has the following agenda item: Other Issues for Consideration by the eWG: How the definition would be used and where it would be placed and that the Chairs to the Committee propose to embark on a discussion on how the proposed definition would be used and where it would be placed – once the definition is approved. b. New Zealand prefers a simple definition, one that doesn't necessarily include all the criteria (although these would obviously have to be met for a biofortified claim to be made). Ideally the definition should be self-explanatory without footnotes – especially six of them. Accordingly we recommend: - removing the term 'all potential source organisms' (as this is not universally understood) - changing the word 'become' to 'made' - removing 'by a measurable level' (too much of a criterion) - a more targeted purpose (putting reference to providing a human health benefit or linking the principles for the addition of essential nutrients back in the definition) and - removing reference to methods of production (not necessarily a definition) We suggest: Biofortification* is the process whereby a nutrient1 or related substance2 of any potential source of food is increased [and/or] made more bioavailable3 to improve the nutritional quality of that food - in order to provide a human health benefit.	**New Zealand**

* Biofortification excludes conventional fortification. [1] Nutrient is defined by General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur. [2] A related substance is a constituent of food (other than a nutrient) that has a favourable physiological effect. [3] Bioavailability - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors. *Category : EDITORIAL*	
The Philippines supports the proposed definition of biofortification and associated footnotes for discussion and the retention of the bracketed texts with revisions. Thus, we support the following statements: Biofortification is the process whereby any nutrients or related substances of all potential source organisms of foods are increased by a measurable level and/or become more bioavailable for the intended purposes. These organisms include animal, plant, fungi, yeasts, and bacteria. The process applies to any method of production and excludes conventional food fortification. The Philippines supports Criterion 5: Methods* of Production. We are of the opinion that methods of production should be included in the definition and supports the footnote indicating that the methods of production be determined by the competent national/regional authority. However, it is critical to specify that these methods of production exclude conventional food fortification. We support that all methods of production whether agronomic practice, conventional plant breeding or modern biotechnology will have to be determined by the competent National/Regional authority depending on the practice acceptable to the national or regional legislations. We propose to delete the footnote *Biofortification does not include conventional fortification covered by CAC/GL 9/1987. We are of the opinion that the footnote on exclusion of conventional fortification maybe indicated at the end of the definition under methods of production where it is more appropriate. We propose to delete the footnote *Biofortification does not include conventional fortification covered by CAC/GL 9/1987. We are of the opinion that the footnote on exclusion of conventional fortification maybe indicated at the end of the definition under methods of production where it is more appropriate. The Philippines support Criterion 2: Nutrient and Related Substances. However, the footnote defining Related Substances should be revised to “A related substance is a constituent of food (other than a nutrient), the modification of which has a favourable physiological effect”. We prefer the term modification instead of increase to take into account the need to decrease anti – nutrients. *Category : SUBSTANTIVE*	**Philippines**
We agree with the document in principle. *Category : SUBSTANTIVE*	**Thailand**
The United States thanks Zimbabwe and South Africa for leading the eWG and preparing this report on the Proposed Draft Definition for Biofortification (at Step 3). General Comments The United States, in general, supports the amended criteria in Appendix II. Specific Comments	**USA**

Recommendation 1 –Criterion 1: Source organism The United States supports the Chairs' recommendation and agrees with comments from the EWG that criterion 1 be broad to encompass all possible source organisms and omit 'prior to processing' as the term processing is unclear and pre-harvest processing could be considered conceptually as a 'method of production'. The United States also supports the Chair's recommendation to include a footnote to explain that biofortification differs from conventional fortification, i.e. addition of nutrients to food during the manufacturing process. The United States notes that the footnote is not present in Appendix II. The United States interprets 'source' to mean a raw material or primary agricultural food product which could include animal, plant, fungi, yeast, and bacteria. One option to retain that concept and simplify the criterion could be to retain 'source' and omit 'organisms (e.g. animal, plant, fungi, yeasts, bacteria) as these examples are already considered 'food' if intended for human consumption (Section I of the Codex Procedural Manual). The United States offers the suggest text below: All potential source[s] of food may be biofortified. * Biofortification does not include conventional fortification covered by CAC/GL 9/1987. Recommendation 2 – Criterion 2: Nutrient and related substances To allow for all nutrients and related substances The United States agrees that phytochemicals and antioxidants, and anti-nutritional factors that are neither considered essential nor nutrients, could be a focus of biofortification. Thus, the United States agrees with the Chairs and EWG recommendation to use the term 'related substances' as it allows for a broad definition. The United States notes that a 'related substance' in the context of establishing a definition of biofortification should also meet the intended purpose of maintaining or improving nutritional status for human health, not just have a favorable physiological effect. (Footnote 41, Nutrition Risk Analysis Principles in the Codex Procedure Manual). As biomarkers for nutritional status of 'related-substances' may not exist, the United States suggests discussion of the threshold of evidence needed for an effect and a demonstrated effective level for biofortification. Recommendation 3 – Criterion 3: Outcome The United States supports Chairs recommendation to merge former criterion 5 into current criterion 3 and the proposed text with a minor edit. The United States considers that an increase in nutrient content should be measurable and bioavailable as well as physiologically meaningful to address public health issues such as the improvement of nutritional status. Thus, the United States suggests the criterion address both increased nutrient content and bioavailability in this criterion. In addition, the United States suggests that the concept of increased nutrient content and bioavailability sufficient to provide a physiological benefit be included in the definition. The United States acknowledges that a decrease in anti-nutrients may result in increased bioavailability. However, as the word 'fortify' is commonly defined in dictionaries such as the Oxford Living Dictionaries as 'to add to' or 'increase the nutritive value of (food) by adding vitamins', the United States continues to prefer that the 'or' in proposed wording be omitted. If another term is chosen that does not include 'fortification', the United States would consider not object to including the 'or'. measurable increased nutrient and related substance content and/or bioavailability Recommendation 4 – Criterion 4: Intended purpose The nutrient or related substance is added in an amount sufficient for the intended purpose* * Paragraph 3.1.1. of the Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987). The United States is not opposed to the proposed text and supports the Chairs recommendation to include paragraph 3.1.1 in a footnote and suggests listing the intended purposes from paragraph 3.1.1. in the footnote: 1) reducing risk of or correcting nutrient deficiency; 2) reducing risk of or correcting inadequate nutritional status; and 3) meeting requirements and/or recommended intakes; and 4)	

maintaining or improving the nutritional quality of foods.
Recommendation 5 – Criterion 5: Methods of production
The United States supports the majority EWG proposal to exclude the methods of production in the proposed definition of biofortification and prefers that a footnote citing the role of Competent National/Regional Authorities be omitted.
The United States prefers that the proposed text and footnote be omitted from the criterion and definition as it is not relevant to establishing a technical definition of biofortification and the Committee has not decided how the definition will be used in a Codex text.
The United States also notes that proposed text and footnote may be more appropriately addressed by the Codex Committee on Food Labeling as CCFL has addressed the labelling of methods of production previously (i.e. labelling of food derived from modern biotechnology.)
The United States views the proposed footnote as an issue that is not relevant to the technical definition of biofortification and including such a footnote would undermine the Codex mission of providing science based standards that are globally applicable. Further, if such a footnote were to be included, the United States considers that it could restrict trade of foods produced with modern biotechnology. The United States has experienced trade restrictions related to biotechnology already. The restrictions were not grounded in science and allowing competent authorities to prescribe methods of production instead of identifying the desired outcome for biofortification will likely result in trade restrictions based on similar arguments made about biotechnology that were not grounded in science.
Recommendation 6 – Proposed draft definition of Biofortification
Based on rational presented for recommendations 1-5, the United States offers the following edits:
Biofortification is the process whereby nutrients1 or related substances2 of potential source[s]3 of food are increased by a measurable level and are bioavailable4 for the intended purposes5.

[1] Nutrient is defined by General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.
[2] A related substance is a constituent of food (other than a nutrient) that has a favourable physiological effect. [Codex Nutritional Risk Analysis Principles, Codex Procedural Manual, footnote 41]
[3] Sources – Originating or source material of the final food product (e.g. animal, plant, fungi, yeasts, bacteria)
[4] Bioavailability - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors. [Codex Nutritional Risk Analysis Principles, Codex Procedural Manual]
[5] The nutrient or related substance is added in an amount sufficient for the intended purposes as stated in Paragraph 3.1.1, Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) (i.e. 1) reducing risk of or correcting nutrient deficiency; 2) reducing risk of or correcting inadequate nutritional status; and 3) meeting requirements and/or recommended intakes; and 4) maintaining or improving the nutritional quality of foods.) Biofortification does not include conventional fortification covered by CAC/GL 9/1987.
Other Issues for Consideration by the EWG: How the definition would be used and where it would be best placed:
The United States supports the co-chairs' recommendation to first establish a definition before addressing how it will be used and where it would be placed. The United States notes that further work related to the labelling of biofortified foods would fall under the remit of CCFL. Future discussion should consider existing Codex guidance on labelling to ensure consistency with other Codex texts.

Category : SUBSTANTIVE	
PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION (for comments at Step 3 through https://ocs.codexalimentarius.org) Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. animal, plant, fungi, yeasts, bacteria) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]]. [1] Nutrient is defined by General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur. [2] A related substance is a constituent of food (other than a nutrient) that has a favourable physiological effect. [3] Bioavailability - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors. [4] Paragraph 3.1.1, Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987). [5] Method of production should be determined by the competent National/Regional authority. [6] Biofortification does not include conventional fortification covered by CAC/GL 9/1987. General Comment: IBFAN does not agree with the definition. We wish to take note of the concerns expressed by the delegates the 2016 CCNFSDU regarding the lack of clarity to what the definition would cover and that it might include technologies not proven to be safe. IBFAN does not support the continuation of this work. IBFAN recommends that the CCNFSDU should reject the use of the "Biofortification" terminology. Rationale: • Biofortification is not a solution to address malnutrition. Malnutrition is rarely the result of a deficiency of a single or a select few micronutrients. Inadequate diets generally result in multiple nutrient deficiencies. A single nutrient approach can run counter to national nutrition policies and UN recommendations for diversified food- based approach to addressing malnutrition. • The term biofortification is a deceptive euphemism, which hides the method of production, that can include genetic modification and other technologies which may have health risks. • In many jurisdictions the term "bio" refers to organically produced foods and food products. • The term "biofortification" is promotional and should therefore be considered a nutrient claim, hence a marketing tool. *Category : TECHNICAL*	**International Baby Food Action Network**
IFU supports the definition, provided footnote #5 is deleted since this is not in the spirit of harmonised trade and Codex principles. *Category : TECHNICAL*	**IFU**
The definition in its current form gives rise to a number of questions: It is unclear whether the source organisms needs to be used as is, or whether any processing is allowed and if so to what extent. Ultimately that leads to the question of whether highly purified material from source organisms falls under bio-fortification even if it is chemically identified to synthetically prepared material. This question may even be more relevant if GM bacteria are used as source organisms.	**FAO**

The reference to "related substances" that are defined as a constituent of food (other than a nutrient) that has a favorable physiological effect, lead to additional questions: what is a favourable effect? Who would need to agree to such a claim and how would it need to be proven that (a) the effect is there and (b) it is favourable? Lastly, who would need to assess the safety and eventually make the judgement call that the favourable effects are larger than any unfavourable effects that are likely to be present too, considering some of the potential source organisms? The current language may open the door to all food supplements and other traditional foods and remedies most of which may claim a favorable physiological effects to be considered under the biofortification definition proposed here. Which again raises the questions about what proof will be required for efficacy, safety and what claims are recognized under Codex to qualify as "favorable". *Category : SUBSTANTIVE*	

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
Definition: Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) ~~of]/[and]~~ - **or** foods are increased by a measurable level ~~[and/or]~~ [and/-] become more bioavailable[3] **prior to processing** for ~~the intended~~ -purposes[~~44~~] ~~-~~**of improving nutritional quality of food.** The process applies to any method of production[5] [excluding conventional fortification[6]].	**Brazil** Brazil understands that definition should address both nutrient content and bioavailability. Therefore, we suggest deleting the word 'or' as following: 'foods are increased by a measurable level [and/or] become more bioavailable.' Brazil suggests including the sentence 'prior to processing' in order emphasize that biofortification does not cover conventional fortification. Brazil understands that the purpose of improving the nutritional quality of the food is sufficient to be included in the definition since it is difficult to reach consensus on other possible health benefits. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] ~~or related substances~~in[2] ~~of all potential source organisms (e.g.~~ foods are increased by a measurable level [and are] bioavailable~~*animal, plant, fungi, yeasts, bacteria) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable*~~[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Canada** • We agree that the definition should apply to all nutrients, and it should not be limited to a specific source organism. We believe the scope of the definition should be focused solely on nutrients (as defined in footnote 1) and propose one modification to remove the text and the footnote related to "related substances". We also believe the text "of all potential source organisms" should be removed. For example, eggs which are biofortified with vitamin D through the feed given to chickens are currently on the market globally. According to the proposed definition above, the feed would not fall under a "source organism" as listed. Removing the text will allow for other sources such as feed to be used and will keep the definition simple. We believe the "and" in the square brackets before "foods" should be changed to "in" and suggest deleting the word "of" after the list of source organisms, for better readability. • We agree that the amounts of the nutrients should be increased by a measurable level and be bioavailable for the intended purposes. Canada supports only the term "and" in the square brackets after the term "measurable level" but propose to also add the word "are". We also propose to delete the terms "become more" before "bioavailable" as the nutrient just needs to be bioavailable, not necessarily be more bioavailable. We agree with not specifying any "intended purposes" in the definition

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
	and with the reference in footnote 4 to the purposes reflected in the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL9-1987). *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Colombia** Colombia supports leaving “and/or” (y/o) in both the Spanish and the English versions of the phrase “by a measurable level...” *Category : TECHNICAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Colombia** Colombia supports leaving “de los” (“of the”) in the Spanish version *Category : TECHNICAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Colombia** Colombia emphasises the importance of maintaining the notes to and clarification of section 3.1.1 of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) with respect to the contribution to improving health because good health depends on a number of different factors. Colombia also suggests that a note be included to explain that antinutrients result in a reduction in health. It also supports keeping the bracketed text in the definition. *Category : TECHNICAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) ~~of]/[and]~~ [and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Egypt** *Category : TECHNICAL*

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* of]/[and] foods are increased by a measurable level [and/or] become more ~~bioavailable~~bioaccessible[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]]~~.~~. [3]*Bioaccessibility- The fraction of the total amount of a substance that is potentially available for absorption.*	**India** We propose to replace "bioavailable"with "bioaccessible", since the increase by biofortification need not get reflected in chemical analysis due to matrix effect of the food. On the other hand by in vitro digestion method nutrients will get liberated and bio-assessable content can be estimated. Insisting on bioavailability assay is not practical as it requires human volunteer. Moreover, bioavailability of many of the nutrients especially lipid soluble vitamins cannot be assessed due to body pool. We also propose the addition of a new definition "bioaccessibility" instead of "bioavailability"in the proposed draft definition for Biofortification. *Category : TECHNICAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Paraguay** We agree to remove the square brackets [excluding conventional fortification[6]] *Category : EDITORIAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* *for*~~of~~]/[~~and~~] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] ~~[excluding~~ [and excludes conventional fortification[6]].	**Switzerland** For Switzerland it should by retained “for” in criterion 1 (CX/NFSDU 17/39/5) and in the proposed draft definition for biofortification instead “[of]/[and]”. We oppose the phrase “[and/or food]” as it would not be guaranteed anymore that only source organisms (prior to processing) can be biofortificated. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Switzerland** For Switzerland e.g. of source organism should be placed as a footnote between footnote 2 (A related substance) and footnote 3 (Bioavailability). *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Switzerland** Switzerland proposes to place the list of “intended purposes” as a footnote. *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Thailand** And, to be clear, a concrete example of biofortification should be additionally provided for a greater understanding. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] ~~[excluding~~ excluding conventional fortification[6]~~]~~.	**Thailand** A square bracket should be removed from “excluding conventional fortification”. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level ~~[and/or]~~ and/or become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Thailand** A square bracket should be removed from “and/or”. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) ~~of]/[and]~~ and foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**Thailand** The word “of” should be deleted, meanwhile a square bracket should be removed from “and”. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]]. *The “[and/or]” with: “… increased by a measurable level [and/or] become more bioavailable …” should be included as one could: 1) increase the level of a nutrient without making it more available 2) make a nutrient more bioavailable without increasing the level 3) both increase the level and make*	**ICBA** *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
it more bioavailable. *For clarity, we think it would be best to include the last part of the final sentence"[excluding conventional fortification]" into the definition.*	
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding excluding conventional fortification[6]].	**ICGMA** For clarity, we think it would be best to include the last part [excluding conventional fortification] into the definition. *Category : TECHNICAL*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] foods are increased by a measurable level [and/or] and/or become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**ICGMA** The [and/or] with: increased by a measurable level [and/or] become more bioavailable should be included as one could: 1) increase the level of a nutrient without making it more available 2) make a nutrient more bioavailable without increasing the level 3) both increase the level and make it more bioavailable. *Category : SUBSTANTIVE*
Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria*) of]/[and] of] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].	**ICGMA** We think it is better to delete the [and] at the part on the source organism, as 'source organisms' of foods already covers all potential sources for biofortification (e.g. including eggs, milk etc.). *Category : TECHNICAL*
Footnote 2: A related substance is a constituent of food (other than a nutrient) that has a favourable physiological effect.	
[2]**A related substance** is is **defined by Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC, Procedural Manual, twenty-fifth edition, Section IV) to mean:** a constituent of food (other than a nutrient) that has a favourable physiological effect.	**Brazil** Brazil suggests including the reference used for the footnotes 2, i.e., the Codex Alimentarius Commission, Procedural Manual, twenty-fifth edition, Section IV - Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses. *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
[2]~~**A related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.~~	**Canada** We believe the scope of the definition should be focused solely on nutrients (as defined in footnote 1) and propose one modification to remove the text and the footnote related to "related substances". *Category : SUBSTANTIVE*
Footnote 3: Bioavailability - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.	
[3]~~**Bioavailability**~~**Bioavailability is defined by Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC, Procedural Manual, twenty-fifth edition, Section IV) to mean:**~~–~~ The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.	**Brazil** Brazil suggests including the reference used for the footnotes 3, i.e., the Codex Alimentarius Commission, Procedural Manual, twenty-fifth edition, Section IV - Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses. *Category : SUBSTANTIVE*
Footnote 4: Paragraph 3.1.1, Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).	
[4]~~**Paragraph 3.1.1**, *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).~~	**Brazil** *Category : SUBSTANTIVE*
[4]~~**Paragraph 3.1.1**~~**Intended purposes** ~~, *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).~~ preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population; - reducing the risk of, or correcting, inadequate nutritional status or intakes in the population; - meeting requirements and/or recommended intakes of one or more	**Switzerland** The "intended purpose" (i.e. reference to CAC/GL 9-1987) is too narrow (only essential nutrients) in regard to recommendation 2 (CX/NFSDU 17/39/5) where source organisms are allowed to be biofortificated with "all nutrients and related substances". Additionally, for Switzerland it is wrong to use the word "added", because in the biofortification process the nutrient or related substance content in the source organism is not added but increased in content or bioavailability.

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
nutrients; - maintaining or improving health; and/or - maintaining or improving the nutritional quality of foods.	Furthermore, Switzerland suggests to list the different purposes within the recommendation instead of pointing to paragraph 3.1.1 of CAC/GL 9-1987 which might change and then be even less suitable for purpose of biofortification. Also, this paragraph uses the term “added” which does not comply with the definition of biofortification. *Category : SUBSTANTIVE*
Footnote 5: Method of production should be determined by the competent National/Regional authority.	
[5]Method of production should be determined by the competent National/Regional authority.	**Brazil** Brazil understands that the definition should address all methods of production if scientifically supported and safe for human health, considering the Nutrition Risk Analysis Principles and other risk analysis Codex text. However, we consider that the decision on which methods are safe is out of the scope of this work and should be discussed by an appropriate Codex body, such as a guidance expert group or an expert scientific committee. If there is not a Codex decision on the acceptable methods, Brazil agrees with footnote 5 that allows national/regional authorities to define which methods should be considered. *Category : SUBSTANTIVE*
[5]Method of production should be determined by the competent National/Regional authority.	**Canada** Canada agrees that all methods of production should apply and that national/regional competent authorities should be left to decide if certain methods of production are acceptable. *Category : EDITORIAL*
[5]Method of production should be determined by the competent National/Regional authority. ICBA appreciates the efforts of the Chairs in considering comments of the eWG members when drafting this definition of biofortification. ICBA supports the proposed definition with one exception. With regard to the final statement on methods of production, ICBA maintains that the asterisk and footnote related to the statement on methods of production should be removed. The purpose of Codex is to develop science-based texts that promote food safety and fair trade. Thus, all agricultural and scientific methods should be available for accomplishing biofortification. ICBA believes that efforts by competent National/Regional authorities to	**ICBA** *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Definition	**Member/Observer/rationale**
prescribe methods of production could result in trade restrictions. Further, and potentially more detrimental in the case of biofortification, such prescription could result in populations not receiving the nutritional benefit intended through the use of biofortification.	
[5]~~Method of production should be determined by the competent National/Regional authority.~~	**ICGMA** With regard to the final statement on methods of production, ICGMA maintains that the asterisk and footnote related to the statement on methods of production should be removed. The purpose of Codex is to develop science-based texts that promote food safety and fair trade. Thus, all agricultural and scientific methods should be available for accomplishing biofortification. ICGMA believes that efforts by competent National/Regional authorities to prescribe methods of production could result in trade restrictions. Further, and potentially more detrimental in the case of biofortification, such prescription could result in populations not receiving the nutritional benefit intended through the use of biofortification. *Category : SUBSTANTIVE*
Footnote 6: Biofortification does not include conventional fortification covered by CAC/GL 9/1987.	
[6]Biofortification does not include conventional fortification covered by CAC/GL 9/1987.	**Brazil** Regarding footnote 6, we point out that the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9 – 1987) covers only essential nutrients while the proposed definition covers essential nutrients, non-essential nutrients and related substances. Thus, the Committee should discuss if this issue will cause any possible misinterpretation. *Category : SUBSTANTIVE*
[6]Biofortification does not include conventional fortification covered by CAC/GL 9/1987.	**Canada** We also agree that conventional fortification should be excluded, and the text should remain in the definition. *Category : EDITORIAL*