CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/NFSDU 15/37/6 Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

Comments of Brazil, Canada, Chile, Mali, New Zealand, Paraguay, Philippines, Rwanda, United States of America, African Union, IBFAN, ICBA, ICGMA, IDF and IFPRI

BRAZIL

Brazil believes that the following aspects should be considered when defining biofortification:

- The definition should be broad enough to include all potential types of organisms (animal, plant, microrganisms) that may be involved in biofortification. Hence, the definition should not be limited to food crops;
- The definition should not be limited to micronutrients. It may refer to essential nutrients in general;
- The definition should include the case of the reduction or elimination of anti-nutrients;
- The definition should not list the biofortification techniques, given that new techniques may be developed in the future and the national authorities could choose those that consider more appropriate;
- The definition should make reference to improving the nutritional quality of the food. Nonetheless, the definition should not lead to the misunderstanding that biofortification is the only strategy to overcome nutrient deficiencies. Thus, it should not make reference to correcting or preventing a demonstrated deficiency of one or more nutrients in the population or specific population group and providing a health benefit. As pointed out in the WHO/FAO Guidelines on food fortification with micronutrients (2006), *"(…) in the long-term, measures for the prevention and control of micronutrient deficiencies should be based on diet diversification and consumer education about how to choose foods that provide a balanced diet, including the necessary vitamins and minerals. (…) FAO and WHO have continued to work to achieve this goal and in doing so have adopted four main strategies improving dietary intakes through increased production, preservation and marketing of micronutrient-rich foods combined with nutrition education; food fortification; supplementation; and global public health and other disease control measures. Each of these strategies have a place in eliminating micronutrient malnutrition. For maximum impact, the right balance or mix of these mutually reinforcing strategies need to be put in place to ensure access to consumption and utilization of an adequate variety and quantity of safe, good-quality foods for all people of the world*".

Given the aspects mentioned above, Brazil proposes the following definition for biofortification based on the WHO definition:

Biofortification is the process by which the nutritional quality of food is improved through intervention in the source organism by increasing or adding the essential nutrient(s) and or reducing anti-nutrient(s).

CANADA

General Comments:

Canada supports the development of a definition for "biofortification".

Specific Comments:

Paragraph 9 – It is noted that in the summary table (Appendix II), Canada should have a check mark for criteria #2 ("To allow for all essential nutrients (micro- and macro-nutrients)") as we had indicated support for this in our previous comments. With regards to column #6, we were not supportive of including anti-nutritional elements in the definition. Please see further discussion on this topic in paragraphs 12 i/ii below.

The total count for column 2 should be changed from “14” to “15” and for column 6 from “11” to “10”, accordingly.

Paragraph 9 ii (f) – Canada would support further discussion on the intended purpose of the addition. In columns 3 and 4 of Appendix II, it would be useful to see a separation of comments between those related to having the definition refer to a change in the nutrient content and those related to referring to a change in bioavailability, as well as those specifying whether the definition should refer to an intended purpose and what that might be, e.g. for a health benefit, or for improved nutritional quality. Canada’s position is that although providing a health benefit is a useful and appropriate reason for biofortification, the definition should not be limited to only this application. We acknowledge there is a potentially broader range of applications that may be in accordance with the appropriate purposes for addition set out in the newly revised Codex *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987, Revision 2015). Therefore, we recommend not specifying the purpose in the definition (see Paragraph 11, below).

Paragraph 10 - Canada agrees that Criteria 7, 8 and 9 are better suited to be dealt with in the labelling of the products. Although we agree the final decisions about these aspects can be left to national authorities, existing Codex documents provide at least some guidance. For example, with respect to Criterion 9, biofortified foods which are sold prepackaged, and their ingredients, should meet the guidelines for establishing a common name in the Codex *General Standard for the Labelling of Prepackaged Foods* (Codex STAN-1 1985). We believe this standard means that a biofortified food or ingredient would have to be identified as such in a list of ingredients through its common name. Strategies are needed to ensure identity preservation throughout the supply chain to identify raw ingredients and non-prepackaged foods.

Paragraph 11 - Canada would support a definition based on the third proposed definition for consideration by CCNFSDU37, with the following modifications:

Definition iii:

> Biofortification is the process by which **the essential nutrient content** ~~nutritional quality~~ of **a** food is improved through **an** intervention in the source organism ~~by~~ **to** increas**e**~~ing~~ or add~~ing~~ ~~the~~ **one or more** essential nutrient~~(s)~~ **up to a nutritionally significant amount** ~~and/or reducing anti-nutrients.~~

(Clean version of revised definition:

> *Biofortification is the process by which the essential nutrient content of a food is improved through an intervention in the source organism to increase or add one or more essential nutrient up to a nutritionally significant amount.)*

As noted in our comments on paragraph 9 ii (f) above, the terms “nutritional quality” was replaced with “the essential nutrient content”, which provides flexibility for the addition, but avoids having to specify the purpose.

Please see comments on paragraph 12 i and ii regarding the rationale for removing “and/or reducing anti-nutrients” from the proposed definition.

Regarding the proposed addition of “up to a nutritionally significant amount” - Canada believes the definition should refer to a nutritionally meaningful difference in the amount of the nutrient added or increased through biofortification in the final food product and that any changes should be measurable.

The other minor changes were grammatical corrections.

Paragraph 12.i and 12.ii – Canada believes the definition should not include reducing anti-nutritional factors in foods or increasing bioavailability as a possible meaning of biofortification. Canada believes that the term, biofortification, should be limited to the addition of or increase in quantity of a nutrient in foods which can be objectively measured by available analytical methods for nutrients. It would be preferable to refer to foods manipulated with respect to anti-nutritional factors or bioavailability by terms that more directly describe these outcomes. If it is preferred that reduction in anti-nutritional factors be included within the definition of biofortification, consideration should be given to how authorities will recognize how a food has been nutritionally improved and how the improvement will be communicated on a food label.

Additional comments

We note that there is no mention of a definition of “biofortified food” which was included in the eWG discussion document. We note this term is mentioned in paragraph 6, and was a term the CCFL requested CCNFSDU to develop a definition for (REP13/FL). Furthermore, we note comments were received on this definition as reflective of the comments summarized under Criterion 9 of the table in Appendix II. Defining this term has different considerations compared to defining “biofortification” and leads to consideration of labelling implications. We would support further discussion of this definition.

Paragraph 13. iii (b) - The first bullet included in the list of Codex texts ("*Principles of addition of micronutrients to foods*") should be removed. This document was referenced in the first eWG discussion paper and we had noted that an incorrect title was used at that time. The correct title is "*General Principles for the Addition of Essential Nutrients to Foods"* (CAC/GL9-1987, Revised 2015), and this text is already included in the list.

CHILE

Based on the available background information and WHO's 2006 definition of fortification, we consider that the term "biofortification" falls within the definition of fortification, given that said definition includes all the methods by which the nutritional quality of food can be improved. Furthermore, we do not believe there is any need to distinguish between biofortification and fortification. Consequently, in our opinion a definition is not required.

MALI

Subject: Mali supports the drafting of a definition for the term "biofortification"

Explanation: The Codex Committee on Food Labelling (CCFL) called for a definition for use primarily in labelling in order to create a standard meaning for both the public and regulatory bodies.

NEW ZEALAND

General Comments

New Zealand is supportive of developing a definition for biofortification that can be associated with foods with enhanced nutrient content prior to processing.

The Agenda paper provides a lot of detail on the criteria which should be captured by the definition without much emphasis on the purpose of the definition, where specifically the definition will be placed or how it will be used. New Zealand recommends there is discussion on the purpose and placement of the definition and determination of how it will be used to help enable how best to proceed with the finalised wording. From this point, the criteria can be discussed, and the necessity of capturing all criteria within a single definition.

New Zealand would prefer a broad definition of biofortification that can have associated criteria captured either in the specific standard or other appropriate place but we do not support the development of an extremely detailed definition that attempts to incorporate all the criteria. It is considered that the rationale for establishing a definition is to distinguish between the nutrient content of biofortified and non-biofortified foods.

Specific Comments

Paragraph 9: Criteria for a Definition

Paragraph 9 provides an accurate reflection of the criteria considered important by the eWG for consideration within the development of a definition. As discussed in paragraph 9 ii) and Appendix II New Zealand strongly supports a definition which is able to:

- Include all potential agricultural processes (including modern biotechnology) and types of organisms (e.g plant, animal, funghi, yeast) that may be involved in biofortification (Criteria 1);
- Refer to the enhanced nutrition content of the food either through modifications to the macro- and/or micronutrient profile of the food (Criteria 2) or through reducing anti-nutritional factors (Criteria 6).

Criteria 3 to 5 refers to the need for the food to have a measurable increase in level or absorption of the nutrient, for the intended purpose. While New Zealand had stated that it was important for criteria associated with a biofortification definition to include reference to the biofortified food containing significant amounts of the nutrient, it is still questioned if this criteria is included in the definition itself, or provided as a separate linked criteria which enable a claim to be made. Further to this, the Committee should consider whether this is sufficiently managed through existing Codex texts, for example the ability to make nutrient content claims or nutrient comparative claims (Nutrition and Health Claims (CAC/GL 23-1997)). This could be considered further in relation to the labelling criteria (Criteria 7-9) associated with the use of a claim related to biofortifcation.

Paragraph 10: Labelling Criteria

New Zealand supports an approach to labelling of biofortified foods that is consistent with current relevant Codex Standards. As a point of clarification to Appendix II, New Zealand did not consider that the method of production must be specified in the definition or on the label of any biofortified food. As stated in the Codex Standards Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology (CAC/GL 76-2011): *different approaches regarding labelling of foods derived from modern biotechnology are*

used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. In the development of a Codex definition for biofortification, consistency with other relevant Codex texts should be sought where applicable. In the case of biofortification through the use of modern biotechnology, the same labelling requirements should be required as for those foods derived from biotechnology which are not considered biofortified.

Regarding the ability to distinguish between biofortified and non-biofortified foods, consideration should be given to whether the nutrient comparative claims criteria within the *Guidelines for use of Nutrition and health Claims (CAC/GL 23-1997)* would be sufficient.

Paragraph 11: Final Proposed Definitions

New Zealand's preference for a definition is to adapt the definition of biofortifcation from the WHO for consistency with a Codex parent organization. This definition includes reference to nutrient quality (bioavailability of nutrients) and also provides more detailed examples of how biofortification can arise.

The WHO definition refers to improvement of the "nutritional quality" of food, rather than "essential nutrients". The emphasis on essential nutrients may have issues when the fatty acid profile of a food is adapted. For example many long chain polyunsaturated fats are not considered essential, yet modification of a food to include a higher proportion of these would be beneficial. Focus on the nutritional quality of a food would also enable reductions in anti-nutritional factors to be included.

Paragraph 12: Issues for Further Discussion

A broad definition which also allows the modification of food crop through reduction of anti-nutritional factors should be included. At this time, biofortified food crops with reduced phytate levels are being developed.

Regarding the question of reference to bioprocessing, it is unclear what this term refers to from the Agenda paper. As such New Zealand would not support its inclusion in the definition at this time.

Paragraph 13: Where the Definition will be used

New Zealand notes the comments made at the Executive Committee of the Codex Alimentarius Commission (CCEXEC70) in which it was requested that CCNFSDU clarify how the definition will be used and where it would be best placed. The Committee will need to determine where this definition is best placed. From previous Committee discussions, the main use for a definition for biofortification is to enable claims to be made, particularly around the nutrient content of the biofortified food. As such, it would seem logical for this definition to be placed within the *Guidelines for use of Nutrition and health Claims (CAC/GL 23-1997).* This would not preclude the use of the definition in other relevant Codex texts.

As mentioned previously, the Committee should consider what, if any, conditions would be required to make a "biofortified" claim.

PARAGUAY

After having reviewed the document and the various criteria presented in Appendix II of the document, we believe that the most appropriate is **definition IV** with no further amendments:

iv. Biofortification is the process by which the quality of the essential nutrients in food, including essential amino acids and fatty acids, is improved through the use of agricultural methodologies in order to ensure the bioavailability of ingested nutrients within the body and thus provide a health benefit.

PHILIPPINES

The Philippines supports the Proposed Draft Definition of Biofortification specifically the first proposed definition "Biofortificationisthe process of addition of one or more essential nutrients to a food crop through plant breeding whether or not it is normally contained in the food crop for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population group with major modification. This definitionis consistent with the previous submitted Philippine positions on two consultation papers on biofortification based on current scientific evidence.

We propose to revise the definition of biofortication to wit "**Biofortification is the process of breeding higher levels of one or more essential nutrients to target retention concentration into staple crops across environment, for the development of nutrient-dense staple foods, using agronomic, conventional and transgenic breeding methods which can have biological impact on the nutritional and health status of among individuals throughout the life cycle, by increasing the adequacy of dietary intake without compromising sensorial properties and agronomic traits** (Saltzman et al, 2012; Bouis et al. 2011; Jacobs et al, 2009; White &Broadley, 2009; Holtz &McClafferty, 2007; Nestel et al, 2006).

Rationale

We support the first proposed defintion of biofortification since it covers most of the concerns presented during the last CCNFSDU Meeting namely: to allow for essential nutrients, types of agricultural processes inclulding potential organisms, bioavailability, and intended purpose or health benefits or improved nutrition. It is in line with the definition of biofortification by the World Health Organization.

We proposed the modification of the proposed definition with the following justifications:

1. The biofortification process of developing micronutrient-dense or nutritionally improved staple food crops once in-place is highly sustainable in providing a feasible means of reaching the at-risks & undernourished populationswho may have limited access to diverse diets & other intervention programs to reduce hidden hunger;

a. The focus of biofortification is on staple foods that dominate people's diets;

b. The additional micronutrient intake resulting from biofortification as a food-based strategy, would ideally fill the gaps between current intakes & the theoretical mean dietary requirement level or the estimated average requirement (EAR);

c. The biofortification process is intended to put the micronutrient-dense traits in high yielding staple crop varieties with preferred agronomic & consumption traits already.

2. This would mean that crop- and environment-specific traits have to be considered in the breeding of higher micronutrient levels for biofortified staple cropsaccording to common type of diet and expected outcome or benefits;

a. The target retention concentration for a specific micronutrient in the edible portion of a biofortified crop should consider the average intake or the amount required in the human diet,the contributions of each biofortified crop to the habitual diet of the affected population, the nutritional deficits observed in the affected population, the number of crops to be biofortified, nutrient losses and bioavailability of the micronutrients following processing and cooking.

b. Consider cross nutrients' synergy among biofortified staple crops where the action of food matrixon human biological systems is greater than or different from the action of individual food components at the cellular level.

i. The combination of food components in biofortified staple foods needs to address their interactions within the food and with the human homeostatatic system;

ii. The biofortified micronutrient-dense food crops consumption will have to take into consideration the food synergy concept which supports diet variety & selection of nutrient-rich foods.

iii. The micronutrient-dense biofortified foods are likely to be spread over several meals.

We are of the opinion that it is timely for Codex to adopt a common definition of biofortification which could be acceptable worldwide to foster common understanding and thus, pave the way in setting international standard or guidelines. We believe that it is necessary to set out criteria on the use of the terms "biofortification" or bio fortified foods or ingredients in food labelling to distinguish these foods from their non-bio fortified counterparts. This will also facilitate informed choice among consumers

Issues that may require further discussion:

1. When considering the definitions, the following issues will require further discussion:

i. On the issue of anti-nutrients, should they be included or not. Members of the eWG differed on this issue

We do not support the logic of including the issue of antinutrients in the definitions since some antinutrients have documented scientific benefits.

ii. Some members wanted bioavailability to be included in the definition while others thought it should not since it is not easy to measure bioavailability at the level of national food regulators.

In the definition of biofortification, it is imperativeand relevant to include the target retention for good bioavailability of specific micronutrients in the edible portion of a biofortified food crops relative to the average or habitual intake of individuals in the population**.**

iii. Should 'bioprocessing' of food be included in the definition?

Bio-processing is a method or operation of preparing a biological material, or a product of genetic engineering for commercial use (Ladish, 2004). Thus, Bioprocessing is the application of technology to commercialize particular crops towards the development of functional foods and beverages for food and

feed security, as well as for income generation possibilities (Sheikha& Ray, 2015). Bioprocessing can be applied to any biofortified staple crop for opportunities to commercialize the crop. *Thus, bioprocessing of foods should not be included in the definition.*

2. Where the definition will be used

We support the proposal that the biofortification definition once agreed upon can be used in dictionaries as guidance by researchers, regulatory authorities, food manufacturers, packers, traders, consumers, risk assessors in food labelling, development/implementation of food regulations & policies, in risk assessments, marketing of products, and already existing Codex Procedural Manual & other Codex texts.

References

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Whale PJ and Broadley MR (2009). Biofortification of crops with seven mineral elements often lacking in human diets-iron, zinc, copper, calcium, magnesium, selenium and iodine.**New Phytologist**; 182:49-84.

RWANDA

Four definitions as proposed by codex were used as reference for discussion :

1. Biofortification is the process of addition of one or more essential nutrients to a food crop through plant breeding whether or not it is normally contained in the food crop for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups. It may involve reduction of anti-micronutrients in foods.

2. **Biofortification** is the process by which the nutritional quality of food crops is improved throughplant breeding, with the aim of making the nutrients bioavailable to the body after ingestion, in order to correct or prevent a demonstrated deficiency and provide a health benefit.

3. **Biofortification** is the process by which the micronutrient quality of food crops, including essentialamino acids and fatty acids, is improved through plant breeding, as well as reducing antinutritional factors in key food crops, with the aim of making the nutrients bioavailable to the body after ingestion, in order to correct or prevent a demonstrated deficiency and provide a health benefit

4. Definition of biofortification from the WHO: **Biofortification** is the process by which thenutritional quality of food crops is improved through conventional plant breeding and/or use of biotechnology.

Conclusion and recommendations

- The ***first definition is based only on food crop excluding animal and biotechnology.***
- ***The second definition also includes food crop and excludes animal and biotechnology and reduction of anti-nutrients is not involved.***
- ***The Third definition contains almost all requirements but animal and biotechnology are left out.***
- ***The Fourth definition is about including all necessary requirements of the criteria but animal is excluded and reduction of anti-nutrients were not involved."***

In order to cater for all the requirements of the criteria, the national Codex Committee came up with its own proposal as follows:

Biofortification is the process of improving the content of one or more essential nutrients to an **agriculture original food** through **conventional or biotechnology breeding** for the purpose of preventing

or correcting a demonstrated deficiency **as well as** reducing anti-nutritional factors with the aim of making the nutrient available to the body after ingestion or to provide health benefit .

In this definition, the team included animal by using the Agriculture (for both plant and animal) and biotechnology as it is elaborated in the criteria provided above.

UNITED STATES OF AMERICA

General Comments

The United States supports a simple and broadly applicable definition of biofortification in response to the request by the Codex Committee on Food Labeling. We consider that further discussion about the placement of a definition of biofortification and how it would be interpreted in proposed Codex texts is needed in order to finalize a definition for biofortification and/or biofortified food.

Specific Comments

Paragraph 9. Criteria for a definition

(a) To allow for all essential nutrients (micro- and macro-nutrients);

(b) Includes all potential types of agricultural processes which include all potential organisms (animal and animal feed, plant and plant, fungi, yeasts and fertilizers thereof) that may be involved in biofortification;

(c) Must increase/enhance levels or absorption of nutrient(s) sufficiently for intended purpose (bioavailability);

(d) To decrease any anti-nutritional elements; (can be addressed broadly with nutritional quality)

(e) Are any changes in increased or enhanced nutrient levels measurable?

(f) Intended purpose or health benefits or improved nutritionally

The United States agrees that the above criteria are important to consider in establishing a definition for biofortification. The United States agrees that addressing concepts of bioavailability and absorption (criteria c and d) are important and suggests those concepts be addressed broadly with a term such as 'nutritional quality' since absorption and bioavailability are difficult to measure and the science surrounding these issues is complex.

The United States agrees that the change in nutrient levels (criteria e) should be measureable. The United States suggests that the conditions for the change in increased nutrient levels could be addressed by referencing existing Codex labelling texts guidelines.

The United States supports the intended purpose of providing a "health benefit" (criteria f). We also prefer a definition of biofortification that omits this phrase as the term is difficult to define clearly and can be interpreted by Codex member countries in different ways. The phrase "improving nutritional quality" would be preferable.

Paragraph 10. Criteria 7, 8, and 9 of Appendix II

7) Method of production – must be specified'

8) Method of production - 'no need to specify'

9) Distinguish between a biofortified versus a non-biofortified food'

The United States clarifies that in Appendix II the United States did not indicate 'Distinguish between a biofortified versus a non-biofortified food' (column 9). Thus, the table should not reflect a check mark in column 9 for the United States as we do not support distinguishing between a biofortified versus a non-biofortified food in a definition for biofortification, similar with the views expressed by the majority of eWG members.

Paragraph 11. Final proposed definitions

i. Biofortification is the process by which the essential nutrient quality of food including essential amino acids and fatty acids, is improved through the use of agricultural methodologies, as well as reducing anti-nutritional factors with the aim of making the nutrients bio-available to the body after ingestion, in order to provide a health benefit.

ii. Biofortification is the process by which food is enhanced by increased essential nutrients to a measurable level ensuring an increased level of absorption and a reduction of anti-nutritional elements, resulting in a public health benefit.

iii. Biofortification is the process by which nutritional quality of food is improved through intervention in the source organism by increasing or adding the essential nutrient(s) and/reducing anti-nutrients.

iv. Biofortification is the process by which the essential nutrient quality of food including essential amino acids and fatty acids, is improved through the use of agricultural methodologies, with the aim of making the nutrients bio-available to the body after ingestion,in order to provide a health benefit.

The United States considers that each proposed definition captures elements of the suggested criteria. The United States prefers a definition that captures concepts of anti-nutritional factors, increased level of absorption, making nutrients bio-available but does not refer to those concepts directly in the definition. As noted above, the United States would prefer not to include phrases referring to health benefits as the term is difficult to define clearly and can be interpreted by Codex member countries in different ways. The United States also prefers including the term 'agricultural methods' to satisfy the criterion (b) set forth in the main aspects to be covered in the project document and indicated by the majority of eWG members. The United States considers the term 'agricultural methods' as broad and inclusive, however, prefers the definition not list every method individually in the definition.

The United States prefers the following definition with suggested edits:

> Biofortification is the process by which [the] nutritional quality of food is improved through [the use of agricultural methodologies] ~~intervention in the source organism by increasing or adding the essential nutrient(s) and/or reducing anti-nutrients.~~

Clean version:

> *Biofortification is the process by which the nutritional quality of food is improved through the use of agricultural methodologies.*

Paragraph 12. Issues that may require further discussion: Anti-nutrients, Bioavailability, Bioprocessing

The United States supports discussion of these issues. The United States prefers that the concepts of anti-nutrients and bioavailability be addressed broadly in the definition. The United States prefers omitting the term 'bioprocessing' from the definition of biofortification as its meaning is unclear.

Paragraph 13. How the definition will be used and where it will be placed

From the eWG report, it appears that the purpose of developing a definition of biofortification is to have a clear, internationally accepted understanding of the term. The Executive Committee of the Codex Alimentarius Commission (CCEXEC70) requested that CCFNSDU clarify how the definition will be used and where it would be best placed. We believe that there needs to be further discussion on where the definition would be placed and how it might be incorporated and interpreted with other Codex texts. The United States notes that the CCNFSDU originally decided not to address "biofortification" and other forms of indirect addition in its work to revise the General Principles on Addition of Essential Nutrients to Foods (CAC/GL 09-1987).

With regard to claims on food labels, the United States considers that existing Codex texts provide guidance to claims that a food has increased nutrient amounts compared to its counterpart food (e.g., section 6.3 of the *Guidelines for Use of Nutrition and Health Claims, CAC/GL 23-1997*), or to claims that a food is either a "source of" or "high" in certain nutrients. In addition, Section 3.4 of the Guidelines on Nutrition Labelling provides for amounts of nutrients in foods to be identified on the nutrition label in metric units and/or as a percentage of the NRV. The United States notes that the same labeling requirements would apply to both biofortified and non-biofortified foods.

Annex 2 of the Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants (CAC/GL/45-2003) also provides relevant guidance and notes that the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) are generally applicable to the assessment of food derived from a plant which is modified by increasing the amount of a nutrient(s) or related substance(s) available for absorption and metabolism.

AFRICAN UNION

This agenda item was discussed in the context of para 5 of agenda item CX/NFSDU 15/37/2 on matter referred by CAC.

Issue: Reply to CAC

Position: AU supports the development of definition for the term Biofortification

Rationale: This definition was requested by CCFL to be used mainly for labeling purposes so as to provide a common understanding of the term to both the public as well as to the regulatory bodies.

IBFAN - International Baby Food Action Network

General comments:

Without a specific description of the method used to modify micronutrients, amino acids and fatty acids and a generic term such as “agricultural methodologies”, the term biofortification cannot be accurately defined.

IBFAN rejects biofortification achieved through cross breeding that includes genetic modification as an agricultural methodology resulting in products such as “golden rice”.

The method of using genetic modification as a means to “nutritionally enhance” crops has devastated many family farms; increased factory farming; increased the costs of agricultural inputs; destroyed bee populations; increased the prevalence of allergies in human populations and other unknown health impacts; claims of increased production and improved nutrient content has not materialized.

The impact of biofortified crops on malnourished and undernourished populations has not been has not been adequately investigated. Little is known about the safety and efficacy compared to increased dietary diversity and nutrition education in immunocompromised and vulnerable populations. Malnutrition in young children is a multifactorial condition and generally precipitated by infectious illness such as diarrheal disease and respiratory illness.

Questions have been raised about the possible impact of single nutrient focussed agriculture on biodiversity and the diversity of foods available to support local diets.

What claims will be made for these “enhanced” products. Will they be promoted to appear to be better than normal farm crops and indigenous food crops? What impact with these crops have on crop diversity?

Will the biofortification industries claim to reduce nutrient deficiencies and malnutrition? Will the claims being made on the rationale of reducing rates of malnutrition, obscure the real intent to increase the markets for agricultural inputs with industrially modified seeds? Is a similar model to genetically modified foods being used to promote its products as the champion to address global malnutrition?

Nutrients such as vitamin A can readily be accessed with emphasis on the growth of vitamin rich foods such as green leaves vegetable and other carotene rich foods and nutrition education which can cover the wide breadth of nutrients required and is a sustainable local solutions to addressing situations of nutrient undernutrition.

The lack of consumer acceptance of staple foods with altered colour and texture has also been documented.

Specific comments:

Proposed definitions for Biofortification

IBFAN sees no need to have a new definition that differs from definition 4 by the WHO. The WHO clearly states the methods used to achieve biofortification - conventional plant breeding and/or biotechnology. By omitting the methods used and in particular the information that biofortification can be accomplished through the use of biotechnology fails to fully inform consumers.

IBFAN’s comment on the WHO definition is to delete the “improved” and to replace this with “altered” to read:

*…nutritional quality of food crops is **altered** through conventional plant breeding and/or use of biotechnology.*

In Appendix ll, Columns 7 and 8, eight Codex members asked for the method of production to be specified and only three stated that there is no need to specify. This is a clear indication that Member States see a need for the method of production to be included in the definition.

Additionally IBFAN notes that methods of production also need to be included in the labelling provisions for foods and food ingredients altered through biofortification.

ICBA – International Council of Beverages Associations

ICBA has the following comments with respect to the *Proposed Draft Definition for Biofortification* at Step 4.

General Comments

ICBA still has questions whether CCNFSDU is the proper Codex committee to establish a definition for biofortification, and where new work would reside. However, we provide comments on our preferred definition of biofortification among those proposed, with clarifying changes and rationale.

Specific Comments to para 11 (CX/NFSDU 15/37/6)

Comments collected from the eWG were used to develop four proposed definitions for biofortification. ICBA prefers definition (i), with changes proposed below, and rationale as follows:

Definition (i) with proposed changes:

Biofortification is the process by which the essential nutrient ~~quality of~~ **quantity in a** food, including ~~essential amino acids~~ **micro- and macro-nutrients** ~~and fatty acids~~, is ~~improved~~ **changed by a measurable level** through the use of agricultural methodologies, as well as reducing anti- nutritional factors with the aim of ~~making~~ **ensuring that** the nutrients **are** bio-available to the body after ingestion, in order to provide a health benefit.

Rationale:

ICBA prefers the nutrient and anti-nutrient containing definition because it aligns with the criteria most important to the eWG and related Codex principles. ICBA proposes replacing "quality" with "quantity" because quantity can be measured. Further, it is important that there is a measurable change in the nutrient level through biofortification to deliver on nutrition for physiologic benefit. Additionally, ICBA proposes replacing "essential amino acids and fatty acids" with "micro- and macro-nutrients" to ensure the definition is clear that it covers all micronutrients (vitamins and minerals) and macronutrients (amino acids, fatty acids, and carbohydrates) that may be changed as a result of biofortification, in addition to reduction of anti-nutrition factors.

ICGMA – International Council of Grocery Manufacturer Associations

11. Proposed Definitions	ICGMA response
Biofortification is the process by which the essential nutrient ~~quality~~ of **quantity in a** food, including ~~essential amino acids~~ **micro- and macro-nutrients** ~~and fatty acids~~, is ~~improved~~ **changed by a measurable level** through the use of agricultural methodologies, as well as reducing anti-nutritional factors with the aim of ~~making~~ **ensuring that** the nutrients **are** bio-available to the body after ingestion, in order to provide a health benefit.	ICGMA supports this definition with the suggested edits. It is important that there is a measurable change in the nutrient content of a food through biofortification to provide a physiologic benefit. ICGMA proposes replacing "amino acids and fatty acids" with "micro- and macro-nutrients" as the current phrasing suggests vitamins and minerals are not included. ICGMA proposes replacing "making" with "ensuring" for grammatical purposes.
Biofortification is the process by which food is enhanced by increased essential nutrients to a measurable level ~~ensuring an increased level of absorption~~ **with the aim of ensuring the nutrients to be bio-available to the body after digestion** and a reduction of antinutritional elements, resulting in a public health benefit.	* ICGMA believes that an increased level of absorption does not automatically imply increased bioavailability. Therefore we propose the following change to be more in line with the first definition.
Biofortification is the process by which nutritional quality of food is improved through intervention in the source organism by increasing or adding the essential nutrient(s) and/or reducing anti-nutrients.	*ICGMA believes that this definition is too limited. Intervention in the source organism does not clearly refer to the agricultural methodologies needed for biofortification. Intervention in the source mechanism could also be done via food processing. Additionally, the definition does not cover use of fertilizers which feed nutrients to plants so they are built in the edible parts. Such an approach can hardly be called "intervention in the source organism".
Biofortification is the process by which the essential nutrient ~~quality of~~ **quantity in a** food including essential ~~amino acids~~ **micro- and macro-nutrients** ~~and fatty acids~~, is ~~improved~~ **changed by a measurable level** through the use of agricultural methodologies, with the aim of ~~making~~ **ensuring** the nutrients **to be** bio-available to the body after ingestion, in order to provide a health benefit.	*As noted with the first definition, ICGMA proposes replacing "amino acids and fatty acids" with "micro- and macro-nutrients" as the current phrasing suggests vitamins and minerals are not included.

12. Issue that may require further discussion	
The issue of anti-nutrients. Should they be included or not. Members of the eWG differed on this issue.	ICGMA supports the inclusion of the reduction of anti-nutritional factors (e.g. phytase to increase iron bioavailability) as that will also increase the nutritional quality of the food.
Some members wanted bioavailability to be included in the definition while others thought it should not since it is not easy to measure bioavailability at the level of national food regulators.	ICGMA believes just increasing the levels is not enough. Agricultural interventions should also be nutrient sensitive. Thus, in order to be effective the added nutrient should be bio-available.
Should 'bioprocessing' of food be included in the definition?	Even though ICGMA notes that 'intervention in the source mechanism could be done via food processing' (see above), ICGMA is of the opinion that the term 'processing' has a negative connotation for many and we therefore do not see a need to include the term in the definition. In any event, if the term 'bioprocessing' is to be considered for inclusion in the definition of Biofortification, the definition of bioprocessing should be made clear.

* These comments are provided to aid in discussion on these definitions. These comments are not a statement of support.

IDF – International Dairy Federation

IDF supports the following concepts:

- If there is a reference to bioavailability then there need to be agreement on how this would be defined and measured and how the differences between bio-fortified and non-fortified products would be assessed
- The bio fortification would need to be **intentional** and not include changes that occurred unintentionally

Therefore, IDF would support the proposed definition (iii) with an amendment to ensure that it captures intentional improvement:

Biofortification is the process by which nutritional quality of food is improved through **intentional** intervention in the source organism by increasing or adding the essential nutrient(s) and/or reducing anti-nutrients.

IFPRI - HarvestPlus/International Food Policy Research Institute

i) General Comments

First of all we wish to express our thanks to the Governments of the Republics of Zimbabwe and South Africa for hosting the electronic Working Group (eWG) and providing us with the necessary documents, including a preliminary Summary Discussion Paper followed by the Report of the eWG. The Report has taken into consideration many of the comments which were shared with eWG participants. Given that there were 18 different definitions submitted for consideration and analysis, the resultant 4 definitions presented in paragraph 11 of the Report along with the matrix showing consideration of relevant criteria, have resulted in a very workable Document for full Committee consideration, in our opinion.

It is understood that the commencement of discussion of this Agenda Item at CCNFSDU will serve to bring the process to Step 4 of the 8 Step adoption process followed in the Codex Alimentarius.

ii) Specific comments

Paragraph 11

Comments from IFPRI

It is noted that 4 definitions are presented for consideration.

We would support the adoption of Definition iv (four)

> *"Biofortification is the process by which the essential nutrient quality of food including essential amino acids and fatty acids, is improved through the use of agricultural methodologies, with the aim of making the nutrients bio-available to the body after ingestion, in order to provide a health benefit."*

Paragraph 12

We note that the Report suggests in paragraph 12 that there are 3 specific subjects that the CCNFSDU may wish to consider for further discussion as follows:

1. The issue of anti-nutrients. Should they be included or not. Members of the eWG differed on this issue.

Comments from IFPRI

We strongly believe that the anti –nutrient criteria mentioned in Definitions i ,ii and iii in paragraph 11 should not be considered as an factor to be included in the Definition of Biofortification.

If anti-nutrients are to be included then Promoters or Enhancers for bioavailability could also be considered for inclusion as a criteria. Classic examples of Promotors are Ascorbic acid which has been shown to enhance the bioavailability of Fe. Also, studies have shown that Inulin enhanced Ca absorption in human trials with resultant increases in bone density as one of the positive health outcomes.

Phytate is often cited as an anti-nutrient which interferes with the bioavailability of iron and zinc. On the other hand, compounds such as phytates and polyphenols can have positive health effects in both plants and humans. Phytic acid has be shown to be an anticarcinogen against colorectal cancers.

Reference

Shamsuddin, Abulkalam M. Anti-cancer function of phytic acid, International Journal of Food Science and Technology 2002, 37, 769–782

ii. Some members wanted bioavailability to be included in the definition while others thought it should not since it is not easy to measure bioavailability at the level of national food regulators.

Comments from IFPRI

We would encourage a discussion on bioavailability, very specifically as it is used in the field of Nutrition.

After this discussion it may become obvious as to whether it is necessary in a definition or not realizing that National Governments, once a definition is established, will determine their protocols and policies in regard to biofortification.

iii. Should ‘bioprocessing’ of food be included in the definition?

Comments from IFPRI

As to the specific question on “bioprocessing”, we would welcome a discussion on the word itself however note that it is very linked to only one method of production of biofortified food and therefore we would not see it being useful for inclusion in the definition as there are 3 well established Methods of Production for biofortification.

Additional Item: Biofortified Food

Comments from IFPRI

There will be the need for a definition for biofortified food at the same time as the definition for Biofortification is referred to the CCFL. CCFL will request such a definition to inform their discussion on labelling requirements for biofortified food. To preclude the possibility of further bouncing between the 2 sister Committees of CCFL and CCNFSDU, it would seem prudent, at this time, to have CCNFSDU consider a definition for biofortified food. We propose the following definition which is a slight modification to the definition for biofortified foods submitted by the Government of Canada.

“Biofortified foods are foods or food products which consist of or contain one or more ingredients from biofortified sources contributing a nutritionally significant amount of the nutrient(s) to the final food”

It is realized that this may necessitate a discussion on what is “nutritionally significant”, however that discussion is well within the mandate of CCNFSDU and should yield very positive results which would be most useful to future CCFL deliberations.