

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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Organization

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Agenda item 6 CX/NFSDU 18/40/7-Add.1

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

Fortieth Session

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Proposed Draft Definition for Biofortification Replies to comments at Step 3 to CL 2018/65-NFSDU

Comments of Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, Guatemala, Guyana, India, Iran, Iraq, Jamaica, Malaysia, New Zealand, Panama, Peru, Philippines, Senegal, Switzerland, United States of America, IFPRI, ICGMA, IUFOST, IBFAN,

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/65-NFSDU issued in September 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

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

GENERAL COMMENT	MEMBER / OBSERVER
Argentina agrees with this document	Argentina
<p>Australia considers that response to this recommendation should be deferred until the primary location of the definition is decided, since referral to other Codex bodies will depend on the CCNFSDU's decision. If the definition is agreed to be in a Codex labelling text, then CCFL is appropriate; if in the Procedural Manual, then CCGP is appropriate. Australia considers the definition for biofortification should be placed in the Codex Procedural Manual, most appropriately in Section 1: Basic texts and definitions of the Codex Alimentarius. This location enables use in relevant standards or Codex regional standards. Australia agrees that the primary use will be for Codex Alimentarius purposes such as subsidiary bodies and committees. Although a Codex definition could be used by other organisations, it is not the role of CCNFSDU to specify such uses. Any future consideration on label claims would be more appropriate to be referred to the Codex Committee on Food Labelling (CCFL). Australia agrees but equally considers that if conditions for use of biofortified labelling claims were agreed to be developed, CCNFSDU may need to make recommendations to CCFL. Such recommendations may need to consider the conditions for comparative claims (in the Codex Guidelines for use of Nutrition and Health Claims (CXG 23-1997)) as a starting point.</p>	Australia
<p>Australia supports the scope and intent of this definition but proposes to streamline the language and footnotes (see below). In particular, we support:</p> <ul style="list-style-type: none"> • a process of wide scope that specifically excludes conventional fortification that is determined by authorities • mention of the outcome in food as a general increase in nutrient content or bioavailability without further qualification as 'measurable' • replacement of organism with food source <p>However we consider the text could be further streamlined by:</p> <ul style="list-style-type: none"> • including (or equivalent term) in the text and deleting footnote 1. The use of equivalent in the main definition provides for an alternative term to biofortification that would convey the same meaning in a local context. The placement and intended use of the biofortification definition in Codex documentation will guide which group is appropriate to devise an alternative term. In our view, this may not necessarily be confined to member governments. • deleting footnote 5 because food sources will be determined by authorities in accordance with their definition of food or the Codex definition of food (Procedural manual, Section 1) • streamlining wording of footnotes 3 and 4 (now new footnotes 2 and 3) • deleting footnote 6 and replacing list of purposes with existing reference to CXG 9-1987 (now new footnote 2). 	Australia
<p>Brazil agrees with Recommendation 1 with some amendments. In our opinion, the proposed definition has considered all the main criteria related with this issue, answering clearly and directly what is biofortification (process other than conventional addition of nutrient to food), what is its purpose (to increase nutrient or become more bioavailable for the intended nutritional purposes) and where it can be applicable (all potential food sources, e.g. animal, plant, fungi, yeasts, bacteria): Moreover, the footnotes give flexibility to competent national/regional authorities use equivalent terms and/or to establishes the process that will be used. However, aiming to harmonize the text with footnote 2, we propose the following amendments: 1) Competent national/regional authority may use equivalent terms. Brazil supports Recommendation 2. We consider that the term biofortification is widely used and recognized to refer to the process under discussion. Moreover, the proposed footnote 1 the footnotes give flexibility to competent national/regional authorities use equivalent terms. Brazil supports the Recommendation 3.</p>	Brazil

<p>CCFL requested that the CCNFSDU consider working on a definition for biofortification (para. 127 of REP 13/FL). Based on that, Brazil understands that the Committee should focus on finalizing the definition first and that it is the responsibility of CCFL to indicate how and where the definition will be used.</p> <p>In relation to recommendation 4 Brazil suggests that the Codex Secretariat be consulted to clarify where the definition of biofortification could be placed while CCFL does not clarify its use.</p> <p>Recommendation 5: If the definition of biofortification be accepted, Brazil considers that the CCFL is the responsible Committee to clarify the possible uses of the proposed definition and the need of establish differences between it and non-biofortified foods.</p>	
<p>Canada generally supports an approach to the labelling of biofortified foods that is consistent with current relevant Codex standards. As mentioned in past discussion papers, we recognize the need for the development of some guiding principles or guidelines for the use and sale of biofortified foods, and for the development of some minimum standards that should be met when a food is labelled as such. Any labelling issues should be brought to the attention of CCFL for their consideration, as this would go beyond the scope of the work that was tasked to the CCNFSDU.</p> <p>CCFL requested CCNFSDU to develop a definition of “biofortified foods” (REP 13/FL). Canada believes this definition should be finalized first before further discussions of the labelling of biofortified foods takes place.</p> <p>Canada believes that the definition of biofortification does not belong in the Codex procedural manual as the definitions in the manual should only refer to text present in the document.</p> <p>Canada supported the initial proposal to house the definition in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) as it is the intention of Codex to eventually develop guiding principles or guidelines related to labelling of biofortified foods. However, CCFL should ultimately make the decision as to where the definition should be housed.</p> <p>Canada supports the use of the term “biofortification” in the definition. Canada being a bilingual country (English and French) acknowledges that the term “bio” when used independently in French means “organic” and this can be confusing. However, when it is joined together with a different word (e.g. “biofortification”), it does not necessarily translate the same way. The term “biofortification” has been used over the past 20 years in both English and French. It originates from the Greek word “bios” which is a prefix meaning “life” or “living matter”.</p>	Canada
<p>Considering that the definition proposed in the preliminary draft, takes into account each of the determining factors that clearly differentiate biofortification from the direct addition of natural or synthetic nutrients to food (conventional fortification), as a country we agree and welcome the definition.</p> <p>Colombia supports the definition of Biofortification proposed in the preliminary draft.</p>	Colombia
<p>Costa Rica thanks Zimbabwe and South Africa for coordinating the working group. We present our position with respect to the formulated recommendations below:</p>	Costa Rica
<p>Cuba appreciates the opportunity to comment on this document. With respect to Recommendation 1 of the Proposed Draft Definition of Bioenrichment, it believes there has already been ample discussion and that the terms bioenrichment/biofortification should be accepted. With the footnotes, it is easier to adapt the definition as needed. It is essential that the definition of bioenrichment/biofortification be translated in the CAC for adoption in step 5/8.</p> <p>With respect to Recommendation 2, Cuba believes that the CCNFSDU should agree to the use of the term bioenrichment in the draft definition.</p> <p>We support the use of this term. Remember it is important to use the same term as the one used for the commercial sale of biofortified foods.</p> <p>With respect to Recommendation 3, Cuba supports having a debate in the CCFL concerning integration of the definition.</p>	Cuba

<p>With respect to Recommendation 4, Cuba believes that this definition should be in the Codex Procedural Manual. Regarding Recommendation 5, the CCNFSDU agree that the CCFL will initiate the debate on the distinction between bioenriched and non-bioenriched foods once a definition of bioenrichment has been adopted. Cuba believes that before agreement can be reached in the CCNFSDU on the definition for distinguishing between food types, there must first be a full discussion of this topic. It would be advisable to have the discussion take place in the CCFL once agreement has been reached on the definition in the CCNFSDU.</p>	
<p>(i) General comments The evidence regarding biofortification is still insufficient. Therefore, its implementation entails a risk because it does not take account of the consequences of the cultivation methods used or of the deleterious effects on small-scale farmers. For Ecuador, the biofortification of foods requires a detailed analysis because the country's constitution, in Art. 401, states "Ecuador is declared free of transgenic crops and seeds". For this reason, the state would regulate, in accordance with strict biosafety regulations, the use and development of modern biotechnology and its products as well as experimentation with and the sale of such biotechnology; it is prohibited from applying risky or experimental biotechnologies.</p> <p>(ii) Specific comments Ecuador has serious doubts about whether the term biofortification is adequate, considering that the processes used involve genetic modification and should be recognised as such in the definition. In addition, the term "for intended nutritional purposes" is not clear. Malnutrition is not due merely to a deficiency of one or two nutrients. It is the result of a series of structural, underlying and immediate causes; it is also the result of barriers to access and the availability of foods that form part of a varied diet as well as safe food and water.</p>	<p>Ecuador</p>
<p>Guatemala agrees with the draft definition of bioenrichment.</p>	<p>Guatemala</p>
<p>With the exception of comments for 1 and 2 Guyana agrees with all other points in this document.</p>	<p>Guyana</p>
<p>Recommendation 1: That CCNFSDU agree to the proposed draft definition for biofortification and its accompanying footnotes: Biofortification¹ is any process² other than conventional addition to food³ whereby nutrient⁴ content is increased or become more bioavailable in all potential food sources⁵ for the intended nutritional purpose⁶.</p> <ol style="list-style-type: none"> 1) Some Member governments may prefer to use the equivalent term. 2) Process to be determined by the competent national/regional authority. 3) Conventional addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987). 4) Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985). 5) e.g. animal, plant, fungi, yeasts, bacteria 6) Nutritional purpose: <ul style="list-style-type: none"> - 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 nutrients; - maintaining or improving health; and/or - maintaining or improving the nutritional quality of food. <p>New Zealand generally supports the development of the definition and the direction of the current drafting. A simple definition which is self-explanatory without the use of multiple footnotes is preferable. Where footnotes do exist they should clarify how the text should be interpreted in association with other Codex texts.</p>	<p>New Zealand</p>

<p>Footnote 1: We support the ability for national or regional authorities to use alternative terms to biofortification as suited to their national context.</p> <p>Footnote 2: We support the ability of national and or regional authorities to determine the processes which are permitted.</p> <p>Footnote 3: We do not consider it necessary to include this footnote.</p> <p>Footnote 4: We do not consider it necessary to include a definition of ‘nutrient’. The term ‘nutrient’ is consistently defined within Codex texts and does not need to be defined in every document where it is used. Within the Guidelines on Nutrition and Health Claims, the term ‘nutrient’ is used multiple times without the need for a definition to be contained within the Guideline.</p> <p>Footnote 5: We support the inclusion of this footnote. Clarification that the examples are related to the term ‘food sources’ would be useful.</p> <p>Footnote 6: We support cross referencing the Codex text which describes the intended nutritional purposes as outlined in this proposed footnote rather than listing every type of nutritional purpose here.</p> <p>New Zealand supports a definition that describes biofortification as the inherent improvement in nutrient content or bioavailability of the potential food source and excludes conventional fortification.</p> <p>New Zealand proposes the following changes to the proposed draft definition:</p> <p>Biofortification¹ is any the process² other than conventional addition to food³ whereby nutrients⁴ content is are increased or become more bioavailable within all any potential food sources⁵³ for the an intended nutritional purpose⁶⁴.</p> <ol style="list-style-type: none"> 1) National and/or regional authorities may prefer to use an equivalent term. 2) The processes used to achieve biofortification should be determined by the national and/or regional authority 3) Food sources refers to any animal, plant, funghi, yeast or bacteria used in the production of food 4) an intended nutritional purpose as stated in Paragraph 3.1.1, Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987). <p>Recommendation 2: That CCNFSDU agree to the use of the term “biofortification” in the proposed draft definition</p> <p>New Zealand supports the use of the term ‘biofortification’ in the proposed draft definition with the associated footnote 1 which enables national and/or regional authorities to use an equivalent term.</p> <p>Recommendation 3: That CCNFSDU entertain the discussion on the placement of the definition for biofortification with CCFL after the finalisation of the development of the definition.</p> <p>New Zealand supports the approach to discuss the placement and use of the definition with CCFL once the definition has been developed.</p> <p>Recommendation 4: CCNFSDU agree that the proposed areas of use for the biofortification definition should not be stipulated if the definition will be placed in the Codex Procedure Manual</p> <p>This discussion should be had in conjunction with the discussion at CCFL on the use and placement of the definition. We do not support a decision on this prior to this.</p> <p>Recommendation 5: That CCNFSDU agree that CCFL entertain the discussion on the distinction between biofortified and nonbiofortified foods once a definition for biofortification has been adopted.</p> <p>New Zealand agrees that criteria and conditions for making a biofortified claim should be further discussed. We would support a discussion on the labelling of biofortified food once a definition and placement of the definition have been agreed.</p>	
<p>Panama believes it is important to advance to step 5/8, noting that this debate has taken place over the past five years largely in the CCNFSDU and that Panama is working with biofortification to improve the health of its population. Therefore, coming to an agreement on the definition of biofortification is crucial for being able to continue the activities.</p> <p>There is interest in Panama in maintaining the Draft Definition of Bioenrichment. We should note that the initiative regarding</p>	<p>Panama</p>

<p>these biofortified foods has been made under the concept of expressing that there are several ways to increase the content of nutrients such as iron, vitamin A and zinc, including conventional genetic improvement, agronomic improvement through the use of fertilizers and genetic modification.</p>	
<p>The opinion of the National Technical Committee on nutrition and foods for special regimens in the framework of the Codex Alimentarius with respect to the document CL 2018/65/OCS-NFSDU is to be in agreement with the document. However, it has comments in its specific observations.</p>	Peru
<p>The Philippines supports the Proposed Draft Definition for Biofortification with footnotes. These footnotes outline the criterion which makes up the proposed definition for bio fortification. These will facilitate a harmonized international definition for bio fortification with common parameters that will serve as basis for a relevant meaning for this type of nutrient addition.</p>	Philippines
<p>Recommendation 1: Senegal approves this definition. Recommendation 2: Senegal approves this proposal. Recommendation 3: Senegal approves this proposal.</p>	Senegal
<p>As expressed by the EU in the eWG, Switzerland considers that this concept should be inserted in the General principles for the Addition to Essential Nutrients to Foods (CXG 9-1987).</p>	Switzerland
<p>The United States supports a broad definition that includes any method of production and excludes the addition of essential nutrients to foods as described in CAC/GL 9-1987. The United States suggests that the terms 'rational and safe addition' or 'nutrient addition' used in GL 9-1987 be used instead of 'conventional addition' as the GL 9-1987 does not define conventional addition.</p> <p>If the methods of production are addressed in the definition, the United States prefers deleting proposed footnote 2 to allow for the global applicability of the text and facilitate trade. The United States has already experienced trade restrictions related to foods produced with genetic engineering (GE) that were not grounded in science. Allowing competent authorities to prescribe methods of production instead of identifying the desired outcome for biofortification will similarly result in trade restrictions. The United States still considers that an increase in nutrient content should be statistically significant when measured and bioavailable. Changing "or" to "and" in the proposed wording ensures that the nutrient increase will be physiologically meaningful and therefore addresses the intended nutritional purpose.</p> <p>Recommendation 2 – Use of the term "biofortification" The United States supports the use of the term biofortification in the proposed draft definition. "Biofortification" is a term that has long been used and is both widely accepted and commonly understood around the world. . However, we understand other regions may require alternative terms and therefore are not opposed to using an alternative term, such as "agro-fortification" so long as a single alternative is agreed upon to avoid more confusion. Using a prefix such as agro or agri could broadly encompass the cultivation and breeding of source organisms for intended nutritional purposes.</p> <p>Recommendation 3 – discussion on the placement of the definition for biofortification 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.</p> <p>Recommendation 4 – proposed areas of use for the biofortification definition</p>	USA

<p>The United States agrees that a list of potential uses of the definition is not needed if the definition is placed in the Codex Procedural Manual. The inclusion of the definition for “biofortification” may be best situated in the definition section of the Codex Procedural Manual in “Definitions For The Purpose Of Codex Alimentarius” section (p23, 25th ed.), since the term “biofortification” could be applicable to a wide variety of Codex texts (commodity standards, claims guidelines, etc.).</p> <p>Recommendation 5 – distinction between biofortified and non-biofortified foods</p> <p>The United States notes that consideration of potential nutrient claims for biofortified foods versus non-biofortified foods is outside of the scope of the Terms of Reference for this EWG. Such a discussion is appropriate for the CCFL and is outside of the scope of the CCFNSDU. After the definition has been established by CCFNSDU, we suggest this matter be referred to CCFL for their consideration.</p>	
<p>Recommendation 1: Support this definition—this proposed definition has taken into account all the finally agreed five criteria and has addressed the most controversial and discussed major issues. The definitive acceptance of the word itself, Biofortification, is clearly stated. The footnotes give considerable flexibility to National Governments to add criteria to the definition which ease restrictions imposed by existing legislative, cultural, or political situations whilst respecting the available science in regards to biofortified food. Footnote 5 is expressed as examples of sources for the creation of biofortified food. It is not necessarily definitive and the suggestion of algae may be raised. It can be noted that the sources mentioned are examples only and this is not a definitive source listing. In the Step process we would recommend that this definition proceed to the CAC for adoption at Step 5/8</p> <p>Recommendation 2: That CCFNSDU agree to the use of the term “biofortification” in the proposed draft definition Support completely. The CCFNSDU gave adequate opportunity for an examination of suggested alternate terminology and the flexibility remains for National Governments’ decisions as to what the suitable local terminology may be. The vast majority of Countries are awaiting an agreed definition before writing it into legislation. it is recognized that if alternate terminology is developed for the domestic situation, this could present equivalency issues arising in the international trade of biofortified food.</p> <p>Recommendation 3 That CCFNSDU entertain the discussion on the placement of the definition for biofortification with CCFL after the finalisation of the development of the definition. Support completely. Given the mandate of the CCFL and the expertise represented in that Committee, the Membership could add significantly to the discussion as to the placement of the definition.</p> <p>Recommendation 4 CCFNSDU agree that the proposed areas of use for the biofortification definition should not be stipulated if the definition will be placed in the Codex Procedure Manual. Support completely The preferred option is to have the definition placed in the Codex Procedural Manual. This would then serve to allow any Codex Committee where the subject of biofortified food is raised to refer to a commonly accepted definition, within the Codex</p>	<p>International Food Policy Research Institute</p>

<p>Alimentarius context. The issue of the word biofortification being recognized and placed in dictionaries can be left to the Lexicographers. Recommendation 5 CCNFSDU agree that CCFL entertain the discussion on the distinction between biofortified and nonbiofortified foods once a definition for biofortification has been adopted Support completely This discussion is best suited to the mandate of CCFL. Data will become very important to the discussion and CCFL can identify what relevant data (ie levels of minerals and vitamins) will be necessary to be identified to inform the discussion.</p>	
<p>ICGMA supports the definition with suggested edits. In particular, we support removal of the footnote #2 that would direct competent National/Regional authorities to prescribe methods of production. From a public health perspective, such prescription could result in populations not receiving the nutritional benefit intended through the use of biofortification. It is also very likely to result in conflicting determinations and definitions that could hamper trade. 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. Further, references to the national/regional authority are problematic and not in the spirit of Codex providing international standards for food. We also note that it would be helpful to define what terms are considered to be equivalent to biofortification.</p>	<p>ICGMA</p>
<p>A very vague text that is not clear enough to enable understanding the concept intended.</p>	<p>IUFOST</p>
<p>SPECIFIC COMMENTS</p>	
<p>Biofortification¹ is any process²¹ other than conventional addition to food³² whereby nutrient⁴³ content is increased or become <u>becomes</u> more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶².</p>	<p>Australia Australia supports biofortification as the primary term for the proposed definition given its long history of use around the world.</p>
<p>Biofortification¹ is any process² other than conventional addition to food³ whereby nutrient⁴ content is increased or become <u>more and is</u> bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.</p>	<p>Canada Canada supports the proposed definition with one exception, we propose to replace “or become more bioavailable” with “and is bioavailable” as the nutrient just needs to be bioavailable, not necessarily be more bioavailable. We also propose a small editorial change for footnote 4.</p>
<p>Biofortification¹ is any process² other than conventional addition to food³ whereby nutrient⁴ content is increased or become more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.</p>	<p>Costa Rica Costa Rica supports the proposed definition with the following change,the contents and the bioavailability Reason: It would not make sense that the content of the nutrients</p>

	increases if its bioavailability is low.
Biofortification ¹ is any process ² other (other than conventional addition <u>of nutrients</u> to food ³ -) whereby nutrient <u>nutrients</u> ⁴ content <u>is-are</u> increased or become more bioavailable in all potential food sources ⁵ for the intended nutritional purposes ⁶ .	India
Iran suggests below definition for biofortification: - "Biofortification is a process including mineral fertilization, plant breeding or genetic engineering to increase the content and/or bioavailability of micronutrients in widely consumed foods such as cereals and legumes". The other compartments could be written as new definitions or explanations not bullet.	Iran
Biofortification ¹ is any process ² other than conventional addition to food ³ whereby nutrient ⁴ content is increased or become <u>becomes</u> more bioavailable in all potential food sources ⁵ for the intended nutritional purposes ⁶ .	Jamaica
Biofortification ¹ is any process ² other than conventional addition to food ³ whereby nutrient <u>nutritional quality of food is improved</u> ⁴ content is increased or become more bioavailable in all potential food sources ⁵ for the intended nutritional purposes ⁶ .	Malaysia Malaysia is of the opinion that the proposed definition is broader and not only increasing nutrients. The issue of anti-nutrients should be included in the definition. This will ensure that the criteria of anti-nutrients be taken into account when carrying out the selection during breeding and agricultural treatments for biofortification so as to reduce or eliminate antinutrients from staple plant foods. This is important to meet the overall objective of biofortification, that is for improved nutrition and thus give health benefit.
Biofortification ¹ is any process ² other than conventional addition to food ³ whereby nutrient ⁴ content is increased or become more bioavailable in all potential food sources ⁵ for the intended nutritional purposes ⁶ .	Panama Panama proposes this change: Bioenrichment/biofortification is the process by which the quantity or bioavailability of the nutrients of possible originating bodies or good food is increased.
Bioenrichment <u>Biofortification</u> ¹ ⁴ -refers to all processes ² other than the conventional addition of <u>nutrients</u> to foods ³ which increase the amount or the bioavailability of the nutrients <u>these</u> ⁴ -in any of the possible food sources ⁵ for intended nutritional purposes ⁶ .	Peru Peru suggests that the text be modified as follows: Biofortification ¹ refers to all processes ² other than the conventional addition of nutrients to foods ³ which increase the amount or the bioavailability of the nutrients ⁴ in

	<p>any of the possible food sources⁵ for intended nutritional purposes⁶. In addition, we would like to note that in Peru we use the term “biofortification”.</p>
<p>We are of the opinion that the proposed draft definition is broad enough and allows flexibility to include other preferred or equivalent terms for biofortification. The discretion to use specific process is given to the competent national authority where such process is acceptable. In this way, the proposed definition will allow all processes. All potential food sources are also identified in the footnote</p> <p>The Philippines is in agreement 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 authority. However, it is critical to specify that these methods of production exclude conventional fortification.</p> <p>We also support the nutritional purposes of biofortification as outlined in Footnote 6. The focus of biofortification is the improvement of nutrients in both plants and animals’ food sources, where the amount of nutrient content can promote health, prevent and correct specific nutrient deficits affecting the regions/countries. The biofortification process is intended to improve or maintain health; maintain or improve the nutritional quality of food in order to meet the requirements and/or recommended intakes of one or more nutrient. It is only appropriate that the definition includes the purpose of biofortification.</p> <p>We reiterate that “OR” remains because “become more bioavailable” should refer to, for example, when phytic acid is reduced to allow higher iron absorption but not for every case. Demonstrating increased bioavailability for every bio-fortified crop will be a big barrier for releasing such crops. Also, the decision to have the discussion on the process defined by each authority is the right one as all methods should be allowed and must be labelled so that we all make informed choices.</p> <p>We support that intervention whether agronomic practice, conventional plant breeding (Bouis 2013) or modern biotechnology (WHO, 2016. Casal, et al 2016; Khush, 2012; Nestel et al, 2006; Saltzman et al, 2012)) will have to be determined by the competent National/Regional authority depending on the practice acceptable to the national or regional legislations.</p> <p>Based on Ross et al (2013), genetic engineering is a way to improve some vitamins and other nutrients in certain staple food crops that cannot accumulate them in their edible portions such as pro-vitamin A carotenoids in rice grain.</p> <p>Agronomic biofortification is a holistic approach to eliminate micronutrient deficiency in food crops through agronomic practices by the means of soil and foliar applications; thus, it has been considered as a sustainable strategy for immediate solution to tackle the problems of micronutrient deficiencies in human beings and animals. (Hulihalli and Fakeerapa 2015).</p>	<p>Philippines</p>
<p>Biofortification¹ is any process² other than conventional addition to food³ whereby <u>essential</u> _nutrient⁴ content is increased or become more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.</p>	<p>Switzerland</p> <p>Switzerland agrees in large parts with the proposed definition, it looks to be a good compromise because the term biofortification and the applicable processes remain flexible for Codex Members. Moreover the conventional fortification remains clearly excluded from the definition and last but not least the bioavailability is part of the definition.</p>

	<p>Switzerland still considers that the definition should only refer to 'essential nutrients' and not to 'nutrients' in general, in line with the General principles for the Addition to Essential Nutrients to Foods. The concept of fortification agreed at Codex level is linked to the addition of essential nutrients which should not be considered differently when other methods than the conventional addition of nutrients are used i.e. when only a prefix is added.</p>
<p>Biofortification¹ is any process² other than conventional addition to food³ whereby nutrient⁴ content is increased or become more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.</p>	<p>Switzerland Switzerland supports recommendation 2, because the definition allows Members governments to use an equivalent term, like the proposed terms nutri-improvement, nutri-enhancement or nutri-boosting instead of biofortification.</p>
<p>Biofortification¹ is any process² other than conventional-nutrient addition to food³ whereby nutrient⁴ content is increased or become by a significant level and or more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.</p>	<p>USA</p>
<p>Footnote 1</p>	
<p>¹⁾ Some Member governments may prefer to use an equivalent term.</p>	
<p>⁴⁾ Some Member governments may prefer to use an equivalent term.</p>	<p>Australia</p>
<p>¹⁾ Some Member governments-Competent national/regional authority may prefer to use an equivalent term terms.</p>	<p>Brazil The footnotes give flexibility to competent national/regional authorities use equivalent terms and/or to establishes the process that will be used. However, aiming to harmonize the text with footnote 2, we propose the following amendments to read as: 1) Competent national/regional authority may use equivalent terms.</p>

<p>¹⁾ Some Member governments may prefer to use an equivalent term.</p>	<p>Guyana Definitions provide guidance to the users of a standard as to the meaning of words used throughout a standard. This should be no different for biofortification. The definition should be standardized and not be equivalent. Having an equivalent definition is creating room for misinterpretation and missue. Definitions should be clear and accepted by everyone.</p>
<p>¹⁾ Some Member governments may prefer to use an equivalent term.</p>	<p>Panama It is possible that some member states would prefer to use the equivalent terms (agroenrichment, agrofortification, nutritional enrichment or nutritional fortification) Support: Panama believes that the term biofortification/bioenrichment and other alternate terms chosen by the committee should be in line with the terms that are being considered by the CCFL Labelling Committee for statements regarding added nutrients.</p>
<p>The United States supports the use of the term biofortification in the proposed draft definition. “Biofortification” is a term that has long been used and is both widely accepted and commonly understood around the world. . However, we understand other regions may require alternative terms and therefore are not opposed to using an alternative term, such as “agro-fortification” so long as a single alternative is agreed upon to avoid more confusion. Using a prefix such as agro or agri could broadly encompass the cultivation and breeding of source organisms for intended nutritional purposes</p>	<p>USA</p>
<p>Footnote 2</p>	
<p>²⁾ Process to be determined by the competent national/regional authority.</p>	
<p>²⁾ Process to be determined by the competent national/regional authority.</p>	<p>Australia</p>
<p>Agree with the determination of the process to be done by the relevant authority/competent authority.</p>	<p>Guyana</p>
<p>Existe la posibilidad de que los estados miembros quieran utilizar términos equivalentes pero eso lo definirán las autoridades competentes en conjunto con sus respectivos comité técnicos.</p>	<p>Panama</p>

<p>2) Process Process includes all methods of production to be determined by the competent national/regional authority.</p>	<p>USA If the methods of production are addressed in the definition, the United States prefers deleting proposed footnote 2 to allow for the global applicability of the text and facilitate trade. The United States has already experienced trade restrictions related to foods produced with genetic engineering (GE) that were not grounded in science. Allowing competent authorities to prescribe methods of production instead of identifying the desired outcome for biofortification will similarly result in trade restrictions.</p>
<p>2) Process to be determined by the competent national/regional authority. ICBA generally supports the definition but suggests deletion of Footnote 2. Leaving such decisions to the National/Regional Authorities could be precedent-setting, and lead to a lack of international harmonization. ICBA believes that efforts by competent National/Regional authorities to prescribe methods of production could result in trade restrictions. Further, such prescription could result in populations not receiving the nutritional benefit intended through the use of biofortification. With regard to Footnote 1, we also note that it would be helpful to suggest equivalent terminology.</p>	<p>ICBA</p>
<p>We propose to delete footnote 2 since the reference to the national/regional processes may result in diverse approaches which is not in the spirit of Codex providing international standards for food.</p>	<p>IFU</p>
<p>Footnote 3</p>	
<p>³⁾ Conventional addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).</p>	<p>USA</p>
<p>³⁾ Conventional- Nutrient addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).</p>	<p>USA</p>
<p>³⁾²⁾ Conventional addition to food As given in the Codex G is covered by the General-eneral principles for the addition of essential nutrients to foods (CXG 9-1987).</p>	<p>Australia</p>
<p>³⁾ Conventional addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).</p>	<p>Iraq Any nutrition should mention in the label.</p>
<p>Footnote 4</p>	
<p>⁴⁾ Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985).</p>	
<p>⁴⁾³⁾ Nutrient NAs defined in the Codex is defined by the Guidelines on nutrition labelling (CXG 2-1985).</p>	<p>Australia</p>
<p>⁴⁾ Essential nutrient is defined by the General principles for the addition of essential nutrients to foods (CXG 9-</p>	<p>Switzerland</p>

<p>1987)Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985).</p>	
<p>Footnote 5</p>	
<p>⁵⁾ e.g. animal, plant, fungi, yeasts, bacteria</p>	
<p>⁵⁾ e.g. animal, plant, fungi, yeasts, bacteria</p>	<p>Australia</p>
<p>⁵⁾ e.g. animal, plant, fungi, yeasts, bacteria</p>	<p>International Baby Food Action Network IBFAN does not agree with the definition. We wish to take note of the concerns expressed by the delegates to 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. Biofortification is not a solution to address malnutrition. Malnutrition is rarely the result of a deficiency of a single or few select 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 and environmental risks. In many jurisdictions the term “bio” refers to organically produced foods and food products. The term “biofortification” is</p>

	<p>promotional and should therefore be considered a nutrient claim, hence a marketing tool.</p>
<p>Footnote 6</p>	
<p>⁶⁾Nutritional purpose:</p>	
<p>⁶⁾Nutritional purpose:</p> <ul style="list-style-type: none"> –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 nutrients; –maintaining or improving health; and/or –maintaining or improving the nutritional quality of food 	<p>Australia</p>
<p>⁶⁾Nutritional purpose:</p> <p><u>- improving a particular nutritional status.</u></p>	<p>Iran</p> <p>It's better another option to add.</p>