CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 6 **CX/NFSDU 16/38/7-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany

5 – 9 December 2016

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

Comments of Australia, Brazil, Canada, Costa Rica, Cuba, El Salvador, Guatemala, New Zealand, Nicaragua, Panama, Paraguay, Philippines, ICBA, ICGMA, IFPRI and IFT

AUSTRALIA

Recommendation 1

Australia has modified and re-ordered the proposed definitional criteria (using original numbering) by placing the intended purpose #4 first and deleting #5 in the table below. We have also explained suggested changes to the text as shown.

	4 PURPOSE	**1 FOOD**	**2 NUTRIENT**	**3 OUTCOME**	**5**	**6 METHOD**
Australia's suggested changes	~~Intended purpose~~ **To improve the nutritional quality of food intentionally for human health.**	All potential~~-types of food production processes which include all potential~~ **source** organisms **including** (animal**s** ~~and animal feed~~, plants ~~and plant~~, fungi and yeasts ~~fertilizers thereof) that may be involved in biofortification~~	To allow for all ~~essential~~ nutrients (micro- and macro-nutrients)	Increased **nutrient* content or bioavailability*** ~~level of absorption~~n *** defined in the Codex Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU**.	~~increased nutrient levels that are measurable~~	Method of production** ****** To be determined by competent national **or** regional authorit**ies**
Reasons for the suggested amendments	The 'intended purpose' is too vague. We suggest a general purpose that refers to the goal of nutritional improvement intentionally for human health. The changes to the text differentiate the purpose of biofortification intentionally for human health from other reasons such as incidental changes or efficient agriculture or health of stock or crops. Revised text: **To improve the nutritional quality of food intentionally for human health**	Australia does not support the current text. Biofortification does not apply directly to animal feed or fertilizers; these are methods of production. Also, the production process can be deleted from #1 since it is given in #6. We note and agree that the proposed definition does not need to qualify the types of source organism. The definition can rely on Codex's definition of food. Revised text: All potential-**source** organisms **including** animal**s,** plants, fungi and yeasts.	Australia supports the text with deletion of *essential* so that it conforms to the Codex definition of *nutrient* as quoted on page 3 of the agenda paper and given in the Codex Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU.	Australia does not support this text and suggests combining #3 and #5 as shown in our amendments. The reference to 'bioavailability' also allows for reductions in the amounts of nutrient inhibitors. Revised text: **Increased nutrient* content or bioavailability*** *** defined in the Codex Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU**	Australia does not support this text as it is not meaningful. The concept of *measurable* is covered by the use of *increased* in our revised text for #3. 'Measurable' differences can be very small given the sensitivity of current analytical methods.	Australia supports this text but we note that the proposed definition refers to 'intervention in …' which may imply that the foodstuff is only directly affected. Given the reference to animal feed and fertilizers as possible conduits for biofortification, and which we removed from criterion #1 (Food), Australia has revised the text 'intervention in' to 'intervention in the method of production of' which allows for changes to be made the growing conditions rather than the organism itself.

Recommendation 2

Australia considers that the definition should refer to each of the criteria. We suggest the following amendments that reflect our changes to the criteria under recommendation 1.

> Biofortification is ~~the~~ **a** process **to improve the nutritional quality of food intentionally for human health** ~~produce and products~~ by ~~which~~ **increasing** nutrient* content **or bioavailability*** ~~of food~~ ~~produce and products~~ ~~is increased~~ ~~by a measurable amount in a readily absorbable form,~~ through an intervention*** in **the method of production of** the source organism ~~for an intended purpose~~**.**
>
> *defined in the Codex *Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU*
>
> ** to be determined by competent national **or** regional authority~~y~~**ies**

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> Biofortification is a process to improve the nutritional quality of food intentionally for human health by increasing nutrient* content or bioavailability* through an intervention** in the method of production of the source organism.
>
> *defined in the Codex *Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU*
>
> ** to be determined by competent national or regional authorities

Recommendation 3

Australia does not support this recommendation because labelling has not been discussed by the Committee to date. We suggest one or more of the following documents to locate the finally agreed definition:

- the definition section of the Codex Nutritional Risk Analysis Principles (since the definition of *nutrient* and of *bioavailability* are already included).
- the definition section of the Codex Manual in Definitions For The Purpose Of Codex Alimentarius section (p22, 21st edition)
- the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9–1987) <u>as an exclusion</u>, for example:

> **1. Scope**
>
> These Principles do not apply to food produced through biofortification.
>
> **2. Definitions**
>
> 2.8 Biofortification means [insert agreed definition here]….

Recommendation 4

Australia supports this recommendation as the meaning of any defined term is qualified by its definition. In that context 'bio' is clearly understood.

Recommendation 5

As shown above, Australia has suggested the Codex defined term 'bioavailability' to address point number 4.

Australia does not support labelling of foods according to the method of production but accepts that the Committee may wish to discuss this further.

We note the suggestion of applying comparative claims based on provisions in the Codex Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997), which does not rely on a food being labelled or promoted as 'biofortified' if the food meets the labelling criteria.

We also note that the relevant paragraph 6.3.2 of these guidelines refers to only a numerator (10% NRV) and not to a denominator for vitamin or mineral comparative claims. However we note the principle in the General Guidelines on Claims (CAC/GL 1-1979) that no food should be described or presented in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding its character in any respect. Nevertheless the Committee may wish to consider referring this issue to CCFL for its consideration.

BRAZIL

General Comments

Brazil appreciates the work done by Zimbabwe and South Africa and thanks for the opportunity to present the following comments about the proposed draft definition for biofortification.

Specific Comments

Recommendation 1

Based on the comments received from the eWG Members, the co-Chairs propose the amended criteria in Appendix II for consideration by the Committee.

Brazil agrees, in general, with the amended criteria proposed in Appendix II. Nevertheless, we would like to make the following comments:

With respect to the criterion 1, we understand that it is necessary to clarify that the addition of essential nutrients to foods through normal food processing should not be considered biofortification. This type of addition is covered by CAC/GL 9 – 1987.

In relation to the potential organisms, there appears to be a typographical error in the list of potential organisms as the word 'plant' appears twice. We think that it should be 'plant and vegetables'.

Thus, we suggest the following amendment:

'All potential types of food production processes, **except for the method of adding the nutrient through normal food processing,** which include all potential organisms (animal and animal feed, plant and plant **vegetables**, fungi, yeasts and fertilizers thereof) that may be involved in biofortification.'

Regarding criterion 4, we are of the opinion that the purposes of the biofortification should not be included in the definition. The definition should address the meaning of biofortification and not its purposes.

Recommendation 2

Based on the comments received from the two consultations of the eWG, the Chairs propose the following Draft Definition for Biofortification for consideration and discussion by the Committee:

Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*.

*** to be determined by the competent National/Regional authority**

Brazil agrees with the draft definition proposed in Appendix I with the following amendment:

Biofortification is the process by which the nutrient content of food produce and **[**products**]** is **[intrinsically]** increased by a measurable amount in a readily absorbable form, through an intervention* in the **[**source organism**] [,without adding the nutrient through normal food processing,]** for an intended purpose*.

* to be determined by the competent National/Regional authority

Brazil is of the opinion that it is necessary to amend the draft definition in order to make clear that the direct addition of essential nutrients to foods through normal food processing is not considered biofortification as this type of addition is covered by CAC/GL 9 – 1987. Thus, Brazil presents two alternatives: a. to include the word 'intrinsically' before 'increased'; or b. to include the sentence 'without adding the nutrient through normal food processing' before 'source organism'.

Moreover, we would like to ask a clarification for including 'food products' in the definition and not only 'foods' as the interventions involved in biofortification are in foods.

It would also be advisable to better clarify the expression 'source organism'.

We also highlight that the Committee should discuss further how the issue of "reducing anti-nutrients" would be accommodated in the definition, as mentioned in paragraph 15 of CX/NFSDU 16/38/7.

Recommendation 3

Before including the definition in the '*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)' or in other Codex texts, it is necessary to take into account the issues mentioned in paragraph 14 of CX/NFSDU 16/38/7. Brazil considers that further discussion on labelling issues is needed in order to determine the placement of the definition. Consideration should be made on how biofortified foods should be distinguished from non-biofortified foods. Moreover, additional or specific criteria relevant to a nutrient comparative claim or a nutrient content claim for biofortified foods should be discussed.

Thus, Brazil understands that CCNFSDU should ask CCFL in which Codex texts the Biofortification definition should be housed and how it should be used.

Recommendation 4

Brazil agrees with retaining the "Biofortification" terminology.

Recommendation 5

Brazil agrees with recommendation 5.

CANADA

General Comments:

Canada would like to thank the Government of the Republic of Zimbabwe and the Republic of South Africa for chairing the electronic working group and preparing this report on the Proposed Draft Definition for Biofortification.

Specific Comments:

Recommendation 1 – Canada agrees with the removal of the word "agricultural" before "processes" in Criterion 1 to allow for all types of methods of biofortification, including modern biotechnology. Canada also agrees that the definition should be applicable to all organisms and not only include food crops. Recognizing that this Criterion discusses two concepts (processes and organisms), we suggest splitting up Criterion 1 and combining the processes reference with that of Criterion 6. Based on our proposed changes, we further suggest removal of terms in the bracket which do not relate to this scope (e.g. animal feed, plant feed, fertilizers). The text would read as follows:

> *Criterion 1:* ~~All potential types of food product processes which~~ **I**~~i~~nclude all potential organisms (animal ~~and animal feed~~, plant ~~and plant~~ **feed**, fungi, yeasts ~~and fertilizers thereof~~ **etc.)** that may be ~~involved in biofortification~~**biofortified**.
>
> *Criterion 6:* **All potential types of food** ~~Method of~~ production **processes***
>
> ***Acceptable processes** ~~T~~**t**o be determined by the competent National/Regional authority.

With respect to Criteria 2 and 4, Canada supports the changes that were made to allow for all essential nutrients to be included, and for the definition to not list a specific intended purpose. Once again, we wish to acknowledge that 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). For further clarity, we propose this reference be added to Criterion 4:

> *Criterion 4:* Intended purpose*****
>
> ***Appropriate purposes for addition are listed in paragraph 3.1.1. of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987, Revision 2015).**

With respect to Criterion 3, Canada thinks it should be clear that an increase in absorption alone should not be considered as biofortification and the emphasis of this criterion should be on the absorbability of the nutrient. An increase in absorption is not an addition, and would be very difficult to enforce. We propose the following change to the wording in Criterion 3: "**The nutrient should be in a readily absorbable form** ~~absorption.~~"

Canada supports the wording change to Criterion 5 with an important amendment. The definition should refer to a measurable change, but also that there is a nutritionally meaningful difference in the amount of the nutrient being added or increased through biofortification in the final food product. To properly reflect this, we propose to add "and nutritionally significant" at the end of this Criterion, as follows:

Criterion 5: increased nutrient levels that are measurable **and nutritionally significant**.

We are pleased to see that reference to anti-nutritional factors as a possible form of biofortification has been removed from Criterion 6 as well as from the proposed definition. Please see earlier comments for proposed changes to Criterion 6.

Canada further supports the removal of Criteria 7, 8 and 9. These relate more to the labelling of the products and could be addressed separately.

Recommendation 2 – Canada agrees with the wording of the proposed definition, with two changes:

> Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount **sufficient for the intended purpose*** in a readily absorbable form, through an intervention* in the source organism, ~~for an intended purpose*.~~
>
> * to be determined by the competent National/Regional authority. **Appropriate purposes for addition are listed in paragraph 3.1.1. of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987, Revision 2015).**

"Sufficient for the intended purpose" is consistent with text used in the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987, Revision 2015). As previously mentioned, the amount of a nutrient that is to be increased through biofortification should be measurable as well as sufficient for the intended purpose for addition. We propose the same text be added to the definition as we did with Criterion 4 to ensure this connection to the Codex General Principles is clear to those using the definition in future.

Recommendation 3 – Canada agrees with the proposal to house the definition in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) as we believe the term is in effect a type of nutrition claim.

Recommendation 4 – Canada agrees with the recommendation to retain the "biofortification" terminology.

Recommendation 5 – Canada supports sending the definition back to the CCFL once finalized. Any further work related to labelling of biofortified foods should be done by this Committee.

COSTA RICA

Costa Rica thanks Zimbabwe and South Africa, as co-chairs of the electronic working group, for preparing the draft document of the definition of biofortification as well as the opportunity to provide comments on the recommendations:

Recommendation 1:

Costa Rica supports the modified criteria detailed in Appendix II, with the following modifications:

	1	2	3	4	5	6
Criterion	All types of processes or techniques **<u>can be used for bioenrichment without adding nutrients during the normal processing of foods</u>** ~~food production~~, which includes all potential organisms (animals and animal feed, plants and vegetables, and fungi, yeasts and fertilizers derived from the foregoing). ~~that~~	Permit all essential nutrients (micronutrients and macronutrients)	Higher level of absorption	Intended purpose	Measurable increase in the level of nutrients	Method of production* *To be determined by the competent national or regional authority.
Justification	Given that this involves production processes, it is considered necessary to clarify that biofortification differs from the addition of nutrients as described in the General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 9-1987. Adopted in 1987. Amended: 1989 and 1991. Revised: 2015. In addition, production processes should not be confused with procedures or techniques for developing biofortified foods.	No change	No change	No change	No change	No change

Recommendation 2:

With respect to the proposed definition, Costa Rica recognises the advances that have been made, but, for the purpose of clarifying that the contents of nutrients that are modified are intrinsic, i.e. that they are not added during processing, it is proposed that this word be added before the phrase "nutrient contents".

In addition, because "food products" are not defined in the Codex, it is proposed that this term be eliminated, retaining only the term food (defined by the Codex in the Procedural Manual), which is considered to adequately cover the products to which the definition of biofortification is applied. This is to avoid erroneous interpretations.

In addition, it is suggested that the phrase "readily" that appears before the world "absorbable" be eliminated, as current processes already ensure that the nutrients are absorbable, so this word is not considered necessary. In addition, because the term "source organism" is not defined it is suggested that it either be clarified or discussed in more depth in order to avoid erroneous interpretations here too.

The following modifications are proposed:

Biofortification is the process by which the **intrinsic** nutrient content of food ~~and food products~~ is increased by a measurable amount in a**n** ~~readily~~ absorbable form through an intervention* **without adding nutrients during food processing**. [in the source organism] for an intended purpose*. *To be determined by the competent national or regional authority.

Recommendation 3:

Costa Rica supports the focus proposed by the chair of the eWG to include and use the definition of biofortification.

Recommendation 4:

Costa Rica supports the use of the term biofortification. Other terms that have been proposed such as "agroenrichment" are restrictive and are not known or used. The definition of biofortification that has been developed will prevent confusion from arising, for example, as a result of the prefix "bio", so the term will not have to be modified but will be defined as the Committee has done.

Recommendation 5:

Costa Rica supports this recommendation, as it deems it necessary to establish the use of the term for food labelling at a later point and in coordination with the Labelling Committee. This is to avoid the misuse of the term or the formulation of statements that are not clear or that cause confusion on the part of end consumers.

CUBA

Cuba agrees and does not have any additional comments.

EL SALVADOR

General comments:

El Salvador thinks it is important to use the term "biofortification" in the documents; the term in Spanish is "biofortificación" (biofortification), not "bioenriquecimiento" (bioenrichment).

Anti-nutrients should not be included in the definition of biofortification, as they are related more to the bioavailability of nutrients in the organism.

Comments on the recommendations by the eWG:

Recommendation 1: In general, we support criteria 1 to 6 included in Appendix II of document CX/NFSDU 16/38/7, with the understanding that criterion 1 refers to primary production (agricultural and livestock), and that criterion 5 solely refers to "measurable at nutrient levels".

Recommendation 2: The following definition is supported:

Biofortification: is the process by which the nutrient content of food produce and products is increased by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*.

*To be determined by the competent national or regional authority.

In El Salvador, the national authority uses the term "biofortification", by which means the nutrient content of traditional and consumer crops, such as yucca, beans, rice, corn and sweet potato, is augmented using plant breeding techniques that improve the agronomic and nutritional characteristics of these products.

Recommendation 3: El Salvador supports the recommendation to include the definition in the Guidelines for the Use of Nutritional Claims (CAC/GL 23-1997) and will also use it in the following contexts:

i. It is proposed that it be possible to use the definition in dictionaries and that it serve as a guide for researchers, regulatory agencies, food manufacturers, packing companies, merchants, consumers, risk evaluators (e.g., scientific bodies), etc.

ii. It will be possible to use the definition for the development of new varieties, the labelling of food and the creation of standards, laws and policies regarding food. It will also be possible to use it in reports on the evaluation of risks, product marketing materials and existing Codex texts.

iii. Once the definition is approved, it can be used by other subsidiary bodies, such as the CCFL, the CCGP, etc.

Recommendation 4: The continued use of the term "biofortification" by the CCNFSDU is supported.

Recommendation 5: The suggestion that the CCNFSDU and the CCFL examine ways of implementing the labelling of biofortified foods after the definition of biofortification has been adopted is supported.

GUATEMALA

Given that Guatemala, via its competent agencies, is involved in biofortification work at regional level and that it is promoting materials that have high levels of certain minerals at local level it is very important to reach agreement on a definition of biofortification. Although we have not participated in all of the discussions, we do have access to the various documents that the electronic working group has produced.

In this respect and having read the draft definition for we have the following comments:

(i) General comments

Guatemala expresses its agreement as well and supports Recommendation 3 to adopt the term biofortification and therefore to remove Recommendation 4, which implements Recommendation 5, and Guatemala also expresses its concern that antinutrients are not included in the current definition. In this context, Guatemala expresses the need for future debate on the inclusion of the text "reducing the antinutrients" in the definition of biofortificaton.

(ii) Specific comments

With respect to the five recommendations, Guatemala requests that, in relation to criterion 1, consideration be given to specifying that the process of intervention is in a living organism and that it expressly state that the readily absorbable form of the nutrients is in the human body rather than for an intended purpose. Guatemala also agrees with criteria 2, 3, 4, 5 and 6.

Based on the foregoing, Guatemala proposes the following definition:

Biofortification is the process of intervention* in a living organism that increases the level of nutrients of foods and food products derived directly from said organism in a measurable quantity and in a readily absorbable form by the human body.

*To be determined by the competent national or regional authority.

NEW ZEALAND

General Comments

New Zealand continues to support the development of a Codex definition for biofortification, and considers that broad definition should be sought with associated criteria on the use of the term "biofortification" on product labels. Consistency and reference to applicable Codex texts should be sought in defining criteria for the use of the term biofortification on labels, with specific reference to:

- the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987); and
- the *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997); and
- *Compilation of Codex Texts Relevant to the Labelling of Foods Derived from Modern Biotechnology* (CAC/GL 76-2011).

It is considered that the focus of the Committee should be on the recommendations 2 and 3. Recommendation 1 has been critical in establishing the key criteria applicable to biofortification, and New Zealand believes that some of these criteria may be best associated with the use of the term/claim "biofortification" rather than included in the definition. This would allow sufficient detail to be provided to explain the concepts of "improved nutritional quality" and "methods of use" without creating a lengthy definition. This approach would be similar to other Codex Labelling claims, for example the use of the terms "organic" or "halal".

It is suggested that once a definition is agreed to by the Committee that this is placed in the Codex Guidelines for use of Nutrition and Health Claims (CAC/GL 23-1997) and that further work is conducted on developing a new section within the Guideline entitled: "10. Biofortification". This section could provide detail on the associated criteria required for products to use the term biofortification on the label. We provide more detailed comments in relation to specific recommendations.

Use of the definition

New Zealand agrees that the definition could provide more guidance and clarity for Codex but that the creation of a definition must lead to its use in additional Codex texts for it to be beneficial. It is generally considered that the use of the definition will be to enable the term biofortification to be used on labels for the following reasons:

- distinguish between conventional fortification and biofortification;
- to differentiate between non-biofortified ingredients; and
- to identify the true nature of the food (General Labelling).

As such, we support the definition being placed within the '*Guidelines for Use of Nutrition and Health Claims'* and that further work is conducted to determine the necessary associated criteria to use the term biofortification on labels. This would not preclude the use of the definition in other relevant Codex texts as outlined under Recommendation 3. Our full comments are provided overleaf.

Specific Comments

New Zealand has provided specific comments against each recommendation in the report, in the attached table.

New text = **underlined/bold**

Deletion = ~~strikethrough~~

Recommendation 1
New Zealand considers that the criteria developed by the eWG have been critical in establishing the key criteria applicable to biofortification, however it is believed that some of these criteria may be best associated with the use of the term/claim for "biofortification" rather than included in the definition. As such we have highlighted the critical elements that should be considered in the development of the definition: - that biofortification is applicable to all foods (animal, plant, funghi, yeast); - that biofortification can be achieved through any means **prior to processing** (e.g. through fertiliser use, selective breeding, irradiation, biotechnology); - that biofortification must be for the purpose of providing a human health benefit through improved nutritional quality (including increased nutrient content and/or bioavailability). We consider that the fundamental principles for improving the nutritional quality of foods through biofortification should be consistent with those for the general principles for the addition of essential nutrients to foods (CAC/GL 9-1987, Section 3.1.1): - Preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population; - Reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population; - Meeting requirements and/or recommended intakes of one or more essential nutrients; - Maintaining or improving health; and/or - Maintaining or improving the nutritional quality of foods. Further elaboration of these key criteria may need to be established outside of the definition. We therefore propose changes to the criteria in the table below, and recommend that the next step in this work programme should be to clarify what criteria or conditions would have to be met for a biofortification claim to be made once the committee has agreed to the definition.

1 What types of food	**2 (Remove)**	**3 (Remove)**	**4 Outcome**	**5 Purpose**	**6 Method**
All potential types of food ~~production processes~~ which include all potential organisms (animal ~~and animal feed~~, plant and plant fungi, yeasts ~~and fertilizers thereof)~~ ~~that~~ may be involved in biofortification	~~To allow for all essential nutrients (micro- and macro- nutrients)~~	~~Increased level of absorption~~	~~Intended purpose~~* **<u>For the purposes of providing a human health benefit</u>**	~~Increased nutrient levels that are measurable~~ **<u>Biofortification is the process by which the nutritional quality of food is intentionally improved</u>**	Via any method of production *, **prior to processing.** *to be determined by the competent National/Regional authority
New Zealand recommends removing the text 'production processes' and leaving it as simply all potential types of food. We also suggest removing animal feed and fertilizers as these are ways that biofortification can be carried out, and we consider these will be captured by Criteria 6.	New Zealand considers this to be a criteria or condition best suited outside of the definition to enable more specific clarification. If this criteria is retained, New Zealand proposes the text **"to allow for all essential nutrients (micro and macro nutrients) and/or factors or substances that impact on their nutritional qualities".** This is to enable those products with reduced anti-nutritional factors to be included (e.g phytic acid).	New Zealand considers this to be linked to the outcome and (4) and purpose (5). Increased levels of absorption may not need to be proved for many vitamins, minerals or macronutrients. It is noted that this is not a requirement for the declaration of nutrient content and it should be sufficient to either increase the nutritional content and/or increase the absorption of the nutrient.	We support the inclusion of a more targeted purpose statement and propose the text **"For the purposes of providing a human health benefit".** We consider that the fundamental principles for improving the nutritional quality of foods through biofortification should be consistent with those for the general principles for the addition of essential nutrients to foods (CAC/GL 9-1987, Section 3.1.1).	For the purposes of the definition, New Zealand considers simply stated aim here is to intentionally improve the nutritional quality of food. However, should this criteria be retained, New Zealand recommends using the word **'or'** in front of this criteria as demonstrating increased bioavailability for every biofortified crop may be a barrier for small producers of natural varieties as it is expensive.	New Zealand supports an approach whereby biofortification can be carried out via any method. Recognising that many Codex Members would like clarification of the use of the use of biotechnology this should be specifically referenced in the footnote. We do consider it significant to include the text **prior to processing,** as it is important to distinguish biofortification from conventional fortification.

Recommendation 2	Our comments and suggestions
Biofortification is the process by which the ~~nutrient content~~ nutritional quality of food ~~produce and products~~ is **intentionally** ~~increased~~ **improved**, ~~by a measureable amount in a readily absorbable form~~, ~~through an intervention*~~ ~~in the~~ ~~source organism~~, **through any means*,** ~~prior to processing,~~ ~~for an intended purpose~~* **for the purposes of providing a human health benefit**. * **different approaches regarding the inclusion of foods derived by modern biotechnology should be** determined by the competent National/Regional authority **in accordance with already adopted Codex provisions (CAC/GL 76-2011).** **Clean version** Biofortification is the process by which the nutritional quality of food is intentionally improved, through any means*, prior to processing, for the purposes of providing a human health benefit. * different approaches regarding the inclusion of foods derived by modern biotechnology should be determined by the competent National/Regional authority in accordance with already adopted Codex provisions (CAC/GL 76-2011).	New Zealand supports the use of the term '**nutritional quality**' instead of 'nutrient content'. We propose 'quality' as this encompasses the reduction of anti-nutritional factors, and takes into account improved dietary fat and protein quality. New Zealand considers it is unnecessary to refer to both food produce and products, when this can be simply referred to as 'food' ***and*** reference to the fact that this takes place 'prior to processing' is included in the definition. New Zealand recommends the use of the word 'intentionally'. New Zealand proposes use of the term **'improved'** rather than '**increased**' when the term nutritional quality is used, this is particularly relevant in cases where anti-nutritional factors are decreased for a health benefit. For example, when phytic acid is reduced to allow higher iron absorption New Zealand suggests the removal of the text 'by a measurable amount in a readily absorbable form'. We consider this to be criteria that would have to be met to enable a biofortified claim to be made rather than a necessary part of the definition. We suggest the removal of 'through an intervention' and replacement with the text "through any means" as this indicates the concept that any method can be used more simply. New Zealand considers the reference to source organism should be removed. It's not certain that biofortification will always take place in the source organism. For example, chickens fed omega-3 pellets may produce biofortified eggs that are omega-3 rich. The intervention took place via the chicken feed fed to chickens - not with the eggs. We support the inclusion of the text 'prior to processing' as we consider this to be one of the significant factors that separates biofortification from conventional fortification. New Zealand considers the text 'for an intended purpose' to be too vague. We suggest adding the text 'for the purposes of providing a human health benefit' and that biofortification is 'intentional'. New Zealand notes that some Codex Members seek clarification as to whether biofortification also includes those foods derived from modern biotechnology. We support the use of the footnote, but consider that more specific related to this issue could be included. For the purposes of consistency test used in the Codex Standards Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology (CAC/GL 76-2011) could be adopted: *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.

Recommendation 3

New Zealand agrees that the definition should provide more guidance and clarity for Codex but that the primary purpose of the text must be for use in additional Codex documents. The focus of the Committee should now be on determining where this definition will be used and for what purpose.

Although it may be useful for dictionaries, researchers and consumers, to refer to this definition, they ultimately would be responsible for coming up with their own definition in accordance with their own practices and processes.

New Zealand supports that the definition would be best placed in the *'Guidelines for Use of Nutrition and Health Claims'*, under **Section 1. Definitions.**

We also propose creating a new section (Section 10) in the guidelines entitled **'Biofortification Claims'** after Section 9. Claims related to Dietary Guidelines or Healthy Diets. Under this section more specific details on how the term biofortification could be used in labelling must be specified.

Under this new section it could be stated: *'Biofortification claims should be permitted provided that all of the following conditions are met:* [These would have to be agreed on by Codex members first – and we suggest this as the next step in this work].

In addition to this, there may be other instances where the term biofortification would be used in Codex documents and New Zealand is open to further consideration.

Recommendation 4

New Zealand supports the use of the term biofortification.

Recommendation 5

New Zealand supports a discussion on labelling once a definition has been adopted, ***and*** criteria or conditions for making a biofortification claim have been agreed by Codex members.

Any approach (to labelling) implemented by Codex members should be consistent with already adopted Codex provisions, e.g. CAC GL 76/2011 and CAC/GL 2-1985.

NICARAGUA

(i) General comments

CODEX Nicaragua thanks Zimbabwe and all of the participants of the electronic working group for producing the working document and for providing the opportunity to be involved in the commenting process.

It is recommended that the Spanish translation of the term "biofortification" be revised, that "bioenrichment" be defined in the working document and that it be defined as "biofortification" in the agenda.

(ii) Specific comments

Biofortication is the process **during the primary production or conversion process** ~~that increases~~ **that improves** the content of nutrients in foods and food products **through an intervention*** in a measurable quantity, **taking account of the absorbability of the nutrients** ~~and in a ready absorbable form, through an intervention*~~ in the source organism**(s)** for an intended purpose*****.

*To be determined by the competent national or regional authority.

Justifications:

a. It is proposed that the phrase "**during the primary production or conversion process"** be added so that the definition identifies when the bioenrichment process is carried out.

b. Nicaragua agrees with the recommendation to use the term **improves,** as bioenrichment is focused on improving the quantity of nutrients in food as well as their absorption.

c. The following word order is recommended to improve clarity: "**through an intervention*** in a measurable quantity, **taking account of the absorbability of the nutrients".**

d. It is proposed that the phrase "in the source organism**s**" be included, as bioenrichment may be carried out on food from one organism or food from a combination of different organisms.

PANAMA

General comments

Panama appreciates the excellent work carried out by the Electronic Group eWG under the coordination of Zimbabwe and South Africa, and the opportunity to present the following comments about the draft proposal regarding the definition of biofortification.

Specific comments:

Recommendation 1

Panama agrees with the proposed modified criteria contained in Appendix II.

Recommendation 2

Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*.

*To be determined by the competent national or regional authority.

Panama agrees with the proposed draft definition in Appendix I, with the following modifications:

> **Biofortification/bioenrichment** is the process by which the nutrient content of food produce *{and other food products}* is increased*{intrinsically}* by a measurable amount and in a readily absorbable form through the intervention*, ***{without adding nutrients in the normal processing of the food},*** *{in the source organism}* for an intended purpose*.
>
> *To be determined by the competent national or regional authority.
>
> Note: The proposed definition has two alternatives that use the word *{intrinsically}* or *{without adding nutrients in the normal processing of the food}*.

A. Criteria

1. Panama supports criterion 1 with the following comments:
    a. Given the references to production processes it is considered necessary to clarify that biofortification/bioenrichment does not involve the addition of nutrients through normal food processing in order to distinguish it from fortification.
    b. In order to prevent confusion of production processes with procedures or techniques used to develop biofortified/bioenriched foods the following modification is proposed:
        i. All types of processes can be used for the biofortification/bioenrichment procedure without adding nutrients through the normal processing of foods, which includes all potential organisms.
2. Panama agrees with criteria 2 and 3.
3. Criterion 4
    a. Panama agrees with this criterion, with the comment that it is not necessary for the definition to take account of the particular purpose, as the definition should be limited to what it is, not what it is for.
4. Definition:
    a. Panama recommends that the concepts “food products and source organism” be clarified, given that these concepts are not defined in the Codex Alimentarius, where they included in the concept of “food”.
    b. Panama recommends that the difference between biofortification/bioenrichment and the addition of essential nutrients referred to in the document CAC/GL 9 - 1987 be clarified.
    c. Panama supports recommendation 3 in document CX/NFSDU 16/38/7.
    d. Panama supports recommendation 4 in the document CX/NFSDU 16/38/7, and it prefers to maintain the concept of “biofortificación/bioenriquecimiento” (biofortification/bioenrichment) in the Spanish translation.
    e. Panama supports recommendation 5 in the document CX/NFSDU 16/38/7, as it will be discussed in the Labelling Committee once the definition has been finalised.

Panama suggests that the underlined/bolded text in the draft definition be included for the purpose of making clear that the direct addition of essential nutrients to food through normal food processing should not be considered biofortification/bioenrichment. This type of addition is covered by CAC/GL 9 - 1987.

We agree that the issue of “reducing anti-nutrients” should be examined as mentioned in para. 15 of the document CX/NFSDU 16/38/7.

PARAGUAY

(i) General comments

We believe that the proposed definition is correct and avoids any misunderstanding when it is applied.

(ii) Specific comments

We propose that the phrase “based on the existing scientific evidence” be included in order to avoid the use of procedures or claims that are not based on scientific evidence or the use of which has not been verified and/or validated.

Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*. *To be determined by the competent national or regional authority **in line with existing scientific evidence**.

PHILIPPINES

General Comments:

The Philippines supports the Proposed Draft Definition and Recommendations 1 to 5. The proposed definition for biofortification and EWG recommendations are consistent with the previous submitted Philippine positions on two consultation papers on biofortification based on current scientific evidence.

RATIONALE

Specific Comments:

Recommendation 1

The Philippines supports the general criteria outlined in Appendix II namely, all types of food production processes, inclusion of macro and micro essential nutrients, increased level of absorption, intended purpose, increased nutrient levels and method of production which is to be determined by competent authority. These general criteria 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. These proposed criteria highlight the use of agricultural and nutritional science to address malnutrition. They are broad enough and are not limited to plants only.

Recommendation 2

Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount or in a more readily absorbable form, through selection or an intervention, using acceptable approaches*,without compromising sensorial properties and agronomic traits, in order to promote better health outcomes, prevent and correct apparent nutrient deficiencies of individuals throughout the life cycle.

*** to be determined by the competent National/Regional authority**

Adding the phrase “or in a more” would mean increased absorption 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.

Adding the phrase “selection or” is also important to include in the definition varieties of food that make part of natural biodiversity and can be selected for their higher nutritional value in order to promote agricultural biodiversity for improved diets. Inclusion in the definition of such foods will enable also eventual inclusion in the labelling guidelines. In the mind of consumers, intervention sounds very different from selection.

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 the nutrient-dense traits in high yielding crop varieties with preferred agronomic and consumption traits. We believe that the definition should include the purpose of biofortfication.

We are of the opinion that this broad definition covers the criteria as proposed in Annex II. 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. Further, the source organism for an intended purpose is also left to national/regional authority to decide.

Based on Ross et al (2013), genetic engineering is the only way to improve some vitamins and other nutrients in certain staple food crops that cannot accumulate them in their edible portions such provitaminA carotenoids in rice grain.

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).

Recommendation 3

The Philippines supports that the definition of biofortification be placed in the Guidelines for Use of Nutrition and Health Claims. Since addition of nutrient is the main purpose of biofortification, nutrition claims will be declared on the label or advertisement of biofortified foods and this declaration will be governed by the Codex Guidelines for Use of Nutrition and Health Claims. We agree with the identified uses (labeling, food regulations, policies, risk assessment, product marketing) of the proposed definition of biofortification. 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 and policies, in risk assessments, marketing of products, and already existing Codex Procedural Manual and other Codex texts.

Whatever definition that can be approved will be used in relevant existing Codex texts (food labeling and general principles).

Recommendation 4

We are in agreement in retaining the term “Biofortification” to avoid confusion among consumers and regulatory authorities and other intended users and to establish this term to mean other process of nutrient addition. The term “biofortification” has been established for several years and has been used in several languages.Use of another term may mislead users and be misinterpreted to mean otherwise.

We do not support the use of agro-fortification to mean biofortification. It can create misrepresentation or different interpretation. Besides, the word biofortification has long been accepted and used by scientists, researchers, agriculturists, etc.

Recommendation 5

It is necessary that guidelines on the labeling of biofortified foods be issued once a definition for biofortification has been agreed upon. Labeling of biofortified foods is critical to distinguish these foods from other conventional foods.

References

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ICBA - International Council of Beverages Associations

SPECIFIC COMMENTS:

ICBA supports the proposed draft definition with the following revisions:

Biofortification is the process by which the **readily absorbable** nutrient content of food produce and products is **changed** by a measurable amount ~~in a readily absorbable form,~~ through an intervention* in the source organism for an intended purpose*.

~~* to be determined by the competent National/Regional authority~~

Rationale: Relocation of 'readily absorbable':

- Moves the quality distinction forward in the definition and directly associates it with "nutrient content"
- Leaves open the option of interventions whereby non-adjusted nutrient content remains the same (i.e. the measurable amount doesn't change), but the amount of the nutrient available to the body is increased. The current wording is applicable only to an increase in the non-adjusted nutrient content, which doesn't reflect the current and future state of the art related to bioavailability.
- Addresses, indirectly, anti-nutrients

Rationale: 'changed' versus 'increased'

- The noted interventions in the definition could be undertaken to increase or decrease the level of a nutrient. Thus, *biofortification* could benefit consumers by modifying the nutrient profile of food produce and products through either an increase or decrease in the presence of a nutrient. For example, the fatty acid profile of food produce could be modified to favor the presence of unsaturated fatty acids through an intervention that decreases the content of saturated fatty acids.

Rationale: deletion of the footnote '** to be determined…*'

- What/who defines an 'intervention' shouldn't be the subject of a definition for biofortification,
- Agricultural practices are regulated at the national level making the footnote irrelevant, and
- Reference to National and Regional authorities potentially undermines the purpose of Codex Alimentarius in developing harmonized standards and guidelines

TEXT IN CX/NFSDU 16/38/7	ICBA COMMENTS and SUGGESTED REVISIONS
RECOMMENDATION 1 CX/NFSDU 16/38/7 7 Appendix II **SUMMARY OF PROPOSED CRITERIA TO BE COVERED BY THE DEFINITION** 1: All potential types of food production processes which include all potential organisms (animal and animal feed, plant and plant, fungi, yeasts and fertilizers thereof) that may be involved in biofortification 2: To allow for all essential nutrients (micro- and macro-nutrients) 3: Increased level of absorption 4: Intended purpose 5: increased nutrient levels that are measurable 6: Method of production* **To be determined by the competent National/Regional authority**	ICBA supports the amended criteria as demonstrated in Appendix II
RECOMMENDATION 3	ICBA supports the noted placement of the definition and proposed uses and suggests an additional placement: General principles for the addition of essential nutrients to foods (CAC/GL 9-1987)
RECOMMENDATION 4	ICBA supports retaining 'biofortification' terminology.
RECOMMENDATION 5	ICBA supports the recommendation.

ICGMA - International Council of Grocery Manufacturers Association

Recommendation 1
ICGMA supports the amended criteria however suggests that the use of the footnote in criteria 6 of Appendix II be further discussed.

Recommendation 2

ICGMA supports the proposed definition with the suggested modifications.

Biofortification is the process by which the nutrient content of food produce and products is ~~increased~~ **changed** by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*.

* to be determined by the competent National/Regional authority

ICGMA suggests that the use of footnotes in this definition be further discussed.

Recommendation 3

ICGMA supports the recommendation and suggests that the definition also be referenced in the '*General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987)'

Recommendation 4 and 5

ICGMA supports the recommendation.

IFPRI - International Food Policy Research Institute

General Comments:

The HarvestPlus Program of the International Food Policy Research Institute (IFPRI) appreciates the work that has been done by the Governments of Zimbabwe and South Africa to bring the Report of the eWG document to this stage through two rounds of consultation. We have appreciated the opportunity to provide comments and carefully note the proposed definition. Realizing that, at one point in the history of the eWG there were a total of 18 definitions to be considered and that that number was progressively reduced to 4 rather lengthy definitions, now finding ourselves studying one definition is indeed a tribute to the effectiveness of the Co-Hosts of the eWG.

As HarvestPlus plays a lead role in the breeding and dissemination of biofortified staple food crops that are high in the micronutrients of ProVit A, Iron and Zinc and thus contribute to the fight against hidden hunger and malnutrition, we welcome the elaboration of a Codex definition for biofortification which has come to mean many things to many people.

Specific Comments:

The proposed definition:

"Biofortification is the process by which the nutrient content of food produce and products is increased by a measurable amount in a readily absorbable form, through an intervention* in the source organism for an intended purpose*. * to be determined by the competent National/Regional authority"

Is very broad in Scope and meets many of the criteria that have been considered by the eWG.

We believe that this definition, is one that can be displayed to the Plenary Session of CCNFSDU for further comment and refining.

IFT - Institute of Food Technologists

(i) General comments:

The Institute of Food Technologists (IFT) exists to advance the science of food. Our long-range vision is to ensure a safe and abundant food supply contributing to healthier people everywhere. Founded in 1939, the Institute of Food Technologists is committed to advancing the science of food. Our non-profit scientific society—more than 17,000 members from more than 95 countries—brings together food scientists, technologists and related professionals from academia, government, and industry. As an international non-governmental organization with Observer Status within the Codex Alimentarius Commission, IFT appreciates the opportunity to actively participate in the Codex process as it is an important means to our mutual aims. We thank the chairs for their excellent work to develop this draft definition.

(ii) Specific comments on the 5 recommendations and proposed definition:

IFT supports the current draft definition of biofortification as shown in Appendix 1 that captures the considerations made related to Recommendations 1 and 2.

IFT agrees with Recommendation 3 on placement and use of that definition.

IFT agrees with Recommendation 4 that the term Biofortification could be retained as it has gained common use status in a number of countries.

IFT agrees with Recommendation 5 that CCNFSDU and CCFL consider labeling needs of biofortified foods once a definition of Biofortification is finalized. In that discussion, the committee should give careful consideration to the potential for inadvertent creation of a claimable description for advertising purposes.

IFT supports further discussion on the issue related to anti-nutrients.