CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 5 **CX/NFSDU 17/39/5**

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

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Berlin, Germany

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PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(Prepared by the electronic working group led by Zimbabwe and South Africa)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL2017/76-NFSDU available on the Codex webpage/Circular Letters 2017: http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/. Comments will only be accepted through the online commenting system within the deadline indicated in the CL 2017/76-NFSDU

1. Introduction

The 36th session of the CCNFSDU (CCNFSDU36) agreed to initiate new work on a definition for Biofortification and agreed to establish an electronic working group (eWG), led by Zimbabwe and South Africa. The CAC38 approved the development of a Codex definition for biofortication as new work. Zimbabwe and South Africa were tasked to lead an eWG to develop a definition of Biofortification and/or Biofortified foods and to indicate where the definition will be used.

At CCNFSDU37 Zimbabwe and South Africa, as co-Chairs of the eWG, introduced the paper and summarised the nine criteria identified as the source of the proposed definition and presented four options for a definition. The Committee agreed not to discuss the proposed definitions at that time and considered whether the criteria contained in the working document were suitable in general to guide the further work of the eWG. The Committee discussed the proposed nine criteria extensively and agreed that they would be used to guide the development of a proposed draft definition for Biofortification.

At CCNFSDU38[1], Zimbabwe, as the co-Chair of the eWG, introduced the paper and noted that the eWG had revised the nine criteria to 6 (six); and based on these, a draft definition had been developed. Accordingly the eWG made five recommendations for consideration by CCNFSDU.

The Committee noted that there was need for further discussion on some of the criteria especially criterion 6 (Methods of production and its corresponding footnote) and agreed to:

i. re-establish an eWG hosted by Zimbabwe, and co-hosted by South Africa and working in English only to revise the criteria on the basis of the discussion at the session and the written comments submitted to the session, and to further develop the definition on biofortification for consideration at its next session;
ii. revise the timelines for completion of the work to 2018 by CCNFSDU and adoption by the Commission in 2019, and accordingly inform CCEXEC.

Additionally, the Committee agreed to consider recommendations 3-5 at the next session.

Requests to participate in the eWG were received from 21 Codex Members, 1 Codex Member Organisation and 9 Codex Observers. The list of Members and Observers is attached as **Appendix IV.**

2. The process followed by the Electronic Working Group (eWG)

First and Second Consultation Papers were circulated to the eWG in March 2017 and May 2017, respectively. The first consultation paper focused on the finalization of the proposed criteria for the development of the draft definition for Biofortification, taking into consideration the discussion and the comments received at CCNFSDU38. Responses to the First Consultation Paper were received from 10 Codex Members, 1 Codex Member Organisation and 5 Codex Observers.

[1] REP17/NFSDU, para 128 - 147

The second consultation paper took into consideration the findings of the first consultation paper and included a summary of eWG Member comments regarding the proposed criteria for the development of the draft definition for Biofortification. The consultation paper also provided a proposed draft definition for Biofortification based on the identified criteria for inputs by the eWG Members. Responses to the Second Consultation Paper were received from 10 Codex Members, 1 Codex Member Organisation and 3 Codex Observers. The Second Consultation Paper also highlighted key areas with specific reference to the proposed criteria that still need further discussion and agreement by members. The following abbreviations have been used throughout the paper: CM - Codex Member; CMO - Codex Member Organisation; and CO - Codex Observer.

3. Discussion Points

3.1 Revision of the proposed criteria for the Biofortification Definition

During CCNFSDU38, the Chairs introduced the proposed six criteria to the Committee which are reflected in **Table 1**. The Committee considered all the six criteria in general, proposed changes and made specific comments which are captured under each criteria.

TABLE 1: SUMMARY OF PROPOSED CRITERIA TO BE COVERED BY THE DEFINITION

1	2	3	4	5	6
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	increased nutrient levels that are measurable	Method of production* **To be determined by the competent National/Regional authority**

3.1.1 Criterion 1: Source Organisms

The CCNFSDU38 agreed that animal feed and fertilisers should be excluded from this criterion as well as methods of production as they would be considered under criterion 6. It was also proposed that the definition could also rely on Codex's definition of food since it was inclusive. Based on the comments received from member states, observers (CX/NFSDU16/38/7-Add 1) and discussions at the 38th Committee session, the Chairs proposed the draft text for Criterion 1 as reflected in Appendix I during the consultative process to the eWG Members for comments. In the eWG several members were in support of criterion 1 and numerous comments were made on the proposed text. The eWG Members emphasized the importance of simplifying the criteria to avoid misinterpretation of the words and also ensuring that it is broad enough to accommodate all possible source organisms. Some Members were of the view that the criterion should not qualify the type of source organism since the purpose of Biofortification was to improve the nutritional quality of food, therefore, all possible means of conveying this benefit through the food supply should be considered.

Initially, the phrase ‘prior to processing’ was proposed by Chairs to distinguish biofortification from conventional fortification. However some eWG Members felt that this phrase can be confusing as to which precise stage is considered as ‘prior to processing’. Members who were in support of the retention of the word "prior to processing" (CM=4, CMO=1, CO=2) indicated that Biofortification can occur at any stage before processing and would also allow the added nutrients to become part of the food from the beginning of the Biofortification stage. Two member states and one observer were opposed to use of the phrase ‘prior to processing’ and one expressed flexibility on its use. Members (CM=3, CO=2) who were not in favour of retain the word "prior to processing" were of the view that the word 'source organism' proposed in the criterion was broad enough as a qualifying language for 'food' and 'prior processing', therefore these two words should be deleted from the proposed text. It was noted that the word 'processing' was unclear with regard to the step of the production process it referred to as Biofortification could still be applied in certain organisms during the production process (e.g. irradiated fungi to increase vitamin D content). Some Members proposed that the word 'indigenous' should be included in the criterion to distinguish Biofortification from conventional fortification. Two Members proposed adding a footnote which would read thus: "Biofortification does not include conventional fortification covered by CAC/GL 9/1987". Another Member was in agreement with ‘prior to processing' but questioned the word potential. The word potential was used since some of the sources of nutrients were not food in themselves until modified to be sources of nutrients e.g. bacteria.

Conclusion

The Chairs are proposing that the Committee should consider that since "source'' is clarified in the brackets, it would be enough to differentiate between conventional fortification and biofortification. Therefore there will be no need to use the word "prior processing" in the criteria and the proposed definition. In addition the Chairs are proposing that a footnote be included in the proposed draft definition which explains that biofortification is different from conventional fortification as proposed by some eWG members and remove the word "prior processing" from the criterion 1.

Recommendation 1

That CCNFSDU agree with the proposed text for Criterion 1.

Criterion 1: Source Organism

All potential source organisms ((e.g. animal, plant, fungi, yeasts, bacteria) [and/or] food may be

Biofortified*

**Biofortification does not include conventional fortification covered by CAC/GL 9/1987.*

3.1.2 Criterion 2: Nutrient and Related Substances

During CCNFSDU38, the Committee agreed that the criterion should not only cover essential nutrients but all nutrients (micro and macro) as defined in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985). Some Members were of the view that the word "essential" should be deleted from the proposed text of criterion 2 so that it conforms to the Codex definition of nutrient in the Codex Nutritional Risk Analysis Principles and Guidelines for application to the work of CCNFSDU. Based on comments received from Member states and Observers (CX/NFSDU16/38/7-Add 1), the Chairs proposed the draft text for Criterion 2 as reflected in Appendix I. There was an overwhelming support from the eWG Members on the proposed text (CM=8, CO = 4). However various proposals were made for the amendment of the proposed text. The eWG Members indicated that the proposed criteria was broad enough to allow for all potential nutrients. Several Members also indicated that the criterion should also take into consideration other substances such as phytochemicals, antioxidants, anti-nutritional factors that are neither considered essential nor nutrients, which could be one of the intended purposes for biofortification (CM=4). The Nutrition Risk Analysis Principles in the Codex Procedure Manual has a definition of 'a related substance in footnote 41, which reads: "A related substance" is a constituent of food (other than a nutrient) that has a favourable physiological effect".

Some Members proposed the addition of a footnote in criterion 2 for the definition of nutrient as stipulated in the Codex Procedure Manual. Section IV of the Codex Procedure Manual, under the section on Nutrition Risk Analysis Principles gives a definition of 'nutrient' in footnote 40 as follows: "Nutrient" is defined by *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur".

One Member indicated that the criterion should only refer to "essential nutrients" in line with the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987). The rationale for this approach was that the general purpose of biofortification was to address micronutrient deficiencies, and the principles applicable to conventional fortification should also apply. Another Member was of the view that the word 'nutrient' already encompasses both micro- and macronutrients, as well as other substances such as amino acids, etc. The Member also reiterated that the word 'related substances' was not consistent with what was defined in CAC/GL 09-1987).

In order to accommodate other substances such as phytochemicals and anti-nutritional factors that may not fall within the definition of "nutrients", the Chairs proposed the inclusion of 'related substances' in criterion 2 to address this concern during the second consultation. There was widespread support by the eWG Members on the inclusion of the word 'related substances on criterion 2.

Recommendation 2

That CCNFSDU agree with the proposed text for Criterion 2.

Criterion 2: Nutrient and Related Substance

To allow for all nutrients and related substances.

3.1.3 Criterion 3: Outcome

At CCNFSDU38 the Committee proposed that a reference to bioavailability be considered under this criterion since it allowed for reductions in the amounts of nutrient inhibitors, since these words "increased nutrient" or "bioavailability" are already defined in the Codex *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of CCNFSDU*. Based on the comments received from Member states and observers (CX/NFSDU16/38/7-Add 1) and the Committee session discussions, the Chairs proposed the text for criterion 3 as reflected in Appendix I for comments by the 2017 eWG Members. There was general agreement amongst the eWG Members on the phrasing of the criteria (CM=8, CO=3). However there were diverse views amongst the eWG Members on whether the two proposed outcomes of 'increased nutrient content' and 'bioavailability' should be pursued through biofortification.

Seven eWG Members were of the view that both outcomes should be reflected in the definition to ensure that an increase in nutrient content is measurable and bioavailable as well as physiologically meaningful in order to address public health issues such as the improvement of nutritional status, and also address the issue of reducing or eliminating anti-nutritional factors that may inhibit nutrient absorption. Six eWG Members indicated that the outcome should address either one of the proposed outcomes for biofortification, since it would be difficult for authorities to obtain the necessary scientific evidence to demonstrate the outcome on increased bioavailability. A concern was raised that making increased bioavailability mandatory could be expensive to small producers to support the claim. Five eWG Members supported the use of "and" to account for both outcomes on increased nutrients and bioavailability. Some Members supported the use of "and/or" to take care of the difficulties in measurability of bioavailability. One Member was of the view that the term "measurable" was not necessary since any scientific justification of an increased content or bioavailability could be demonstrated only by being measured in the food.

Conclusion

The Chairs note the responses from the eWG Members. However the inclusion of both "and" and "or" might be important. In certain instances where nutrient content is increased, the bioavailability may not necessarily be higher, but as the nutrient content is higher, the more it becomes available for absorption. On the other hand, when anti-nutrients (e.g. phytic acid) are decreased the nutrient content may not be higher, but bioavailability of the intended nutrient becomes higher. Noting that proving bioavailability may not be easy for most competent authorities and developing countries, the Chairs are proposing that the "and/or" be kept in the criterion.

Recommendation 3

That CCNFSDU agree with the proposed text for Criterion 3.

Criterion 3: Outcome

Measurable increased nutrient and related substance content [and/or] bioavailability

3.1.4 Criterion 4: Intended Purpose

CCNFSDU38 indicated that the general purpose for Biofortification should be the goal of improved nutritional quality for human health. Some committee Members felt that the "intended purpose" as proposed in criterion 4 (Table 1) was too vague. The changes to the proposed text would assist in differentiating the purpose of Biofortification intentionally for human health from other reasons such as incidental changes or efficient agriculture, etc. The Committee also highlighted that the fundamental principles for improving the nutritional quality of foods through Biofortification should be consistent with those of the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) with specific reference to section 3.1.1, which reads:

"*Essential nutrients may be appropriately added to foods for the purpose of contributing to:*

- *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".*

Based on the comments received from the Members, Observers (CX/NFSDU16/38/7-Add 1) and the Committee, the Chairs proposed the draft text for Criterion 4 as reflected in Appendix I for comments by the eWG Members. There was general support by the eWG on the proposed intended purpose for biofortificationon "improving the nutritional quality of food"(CM=8, CO=4). Several Members indicated that the intended purposes for biofortification have been set out in the newly revised Codex *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987, Revision 2015) and could be referenced in a footnote in the criteria. Some Members were of the view that the proposed intended purpose on 'improving the nutritional quality of food' was too narrow, and it was just one of the purposes as outlined in CAC/GL 9-1987, therefore all the other purposes should be reflected. In order to address the concerns raised by Members, the Chairs in the Second Consultation proposed the addition of the words "improved for human health" in the proposed criteria to encompass the 5 purposes in CAC/GL 9-1987, in section 3.1.1. There were diverse views amongst the eWG Members on whether the words "improved for human health" should be added as it was viewed to be too broad and might be subjected to misinterpretation. However other eWG Members were in support of adding a footnote that refers to the 5 purposes of fortification as stated in CAC/GL 9-1987 instead of referring to one of them.

Conclusion

In order to include all the potential purposes for Biofortification and articulate them in the criteria, and also avoiding making reference to one of the purposes, the Chairs recommend that the wording for the criteria be amended so that it is inclusive. This would also allow for the inclusion of all the principles in section 3.1.1. of CAC/GL 9 - 1987 by the inclusion of a footnote. The Chairs also recommend to the Committee to delete the words "improved for human health" from the criterion.

Recommendation 4

That CCNFSDU agree with the proposed text and the associated footnote for Criterion 4.

Criterion 4: Intended Purpose

The nutrient or related substance is added in an amount sufficient for the intended purpose*

*Paragraph 3.1.1. of the *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).

3.1.5 Merging of Criterion 5 with Criterion 3

CCNFSDU38 commented on criterion 5 (Table 1) and indicated that biofortified foods should have a significant increase in nutrient levels beyond the normal variation. It was noted that it would not always be possible to have consistent nutrient levels because of natural variation. It was also highlighted that measurable levels of nutrients were directly linked to nutritional quality of food. The improvement could be made by either increasing the nutrient (e.g. zinc) or decreasing the anti-nutrient (e.g. phytate). Thus measurement of suitable change may require measure in food or in the consumer (i.e. bioavailability).The increased levels of nutrients in biofortified food should be significant (or higher) than the natural variation when compared to non-biofortified food. The criterion should be clarified further to indicate that the increase in nutrient levels was in the food. During the consultation the Chairs proposed that criterion 5 (in Table 1) be merged with criterion 3 since a reference to 'bioavailability' was already covered under criterion 3. There was an overwhelming support from the eWG Members on the proposal (CM=11, CMO=1, CO=4). The Chairs noted the responses from the eWG Members and agreed to merge the two criteria.

4. The Role of Competent Authorities on Determining the Methods of Production

CCNFSDU38 noted that there was a need for further discussion on criterion 6 (Methods of production and its corresponding footnote in Table 1). The discussion should include methods of production and how to avoid potential trade restriction that could arise and the role of Competent Authorities.

4.1. Methods of production

The three, non-mutually exclusive methods which are used to develop biofortified crops: application of fertilizer (agronomic Biofortification), conventional plant breeding, and bioengineering or genetic modification (including trans-genetic manipulation) have been a point of discussion by the Committee and amongst the eWG Members. In line with the principle of allowing for various practices, during the 2016 consultations several eWG Members indicated that there was no need to specify methods of production in the definition since this may inadvertently impose arbitrary limits or limit innovation. The 2016 eWG also recommended the inclusion of a footnote referencing the competent National/Regional authorities so that each country could indicate the type of a Biofortification methodology to be used as well as the intended purpose. However at CCNFSDU38 there were diverse views amongst Members and Observer organizations on whether the methods of production should be included and clearly articulated in the definition. When such a decision is made, the eWG Members should take cognisance of how potential trade restrictions could be avoided that could arise from the production methods that Member states could choose for their Biofortification.

The Chairs posed a question to the 2017 eWG Members on whether the definition should specify any method of production. There was wide spread support amongst the eWG Members that the definition should not specify any method of production (CM=8, CO=4). The eWG did not specify any preferred method that should be included in the definition, since this would enable the current and future methods of production to be entertained in biofortification.

The Chairs further proposed that the discussion on the methods of production for biofortified foods be entertained when labelling of biofortified foods is held once a definition has been adopted and criteria or conditions for making a biofortified claim has been agreed upon. There was general support by eWG Members on postponing the discussion on the methods of production (CM=7, CO=3). Some Members indicated that methods of production could be addressed later or be provided in a separate guidance once the technical/concept definition on biofortification and labelling provisions have been adopted.

Most of the eWG Members were of the opinion that methods of production need not be specified in the definition. Of the five that did not agree, three wanted methods of production to be specified and two wanted this criterion removed completely. Those that did not agree considered that method of production should be specified in the definition to ensure transparency and also be clear about the scope of the definition. Furthermore, there is no certainty that criteria for labelling of biofortified foods would be developed, as such Criterion 5 should be considered. One eWG Member also raised a concern that the term 'biofortified' may not be acceptable in certain regions if it would be used on the labelling of foods.

The Chairs noted that the development of a definition for biofortified foods as reflected in the discussion document, CX/NFSDU 14/36/11, is important. This discussion on labelling can be embarked on once the development of a definition for biofortification is completed since that was what CCFL41 requested CCNFSDU to do. Once CCNFSDU has agreed on a definition for Biofortification, CCFL may need to take it further by addressing the labelling issues. The proposed definition could be housed as a new definition in the Codex Text "The *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)", wherein specific criteria relevant to a nutrient comparative claim for Biofortified foods can be added, to provide guidance as to how to inform consumers. Furthermore, a labelling statement that will clarify which type of agricultural method was used to obtain the increased nutrient levels (as a percentage) of the nutrient content of the source organism could be provided in order not to mislead consumers.

4.2 The Role of Competent Authorities

The CCNFSDU38 session noted that there was a need for further discussion on role of Competent National/Regional authorities and the corresponding footnote (Table 1). The 2016 eWG recommended the inclusion of a footnote referencing the competent National/Regional authorities so that each country could indicate the type of a Biofortification methodology to be used as well as the intended purpose.

The Chairs posed a question to the 2017 eWG Members on what role should the National and Regional competent authorities play in deciding whether certain methods of production were acceptable or not. The eWG Members were divided on this matter and various reasons for and against the role of the competent authorities were raised. There were mixed views amongst the eWG Members on the role that National and Regional competent authorities should play in deciding on the acceptable methods of production. Several Members indicated that if the competent authorities could be allowed to determine the acceptable method of production, it could create a barrier to trade if the used method is not acceptable in the importing country. Furthermore, several Members were of the view that the role of the competent authorities should not be entertained or included since the Committee is developing a concept/technical definition at this stage. The Chairs further noted that the issue of competent authorities prescribing methods should be discussed to make sure it would not be used to restrict trade.

Two Members further indicated that since the proposed definition was a concept/technical definition, there was no need to include a footnote which references the determination of methods of production by Competent National/Regional authorities. Furthermore the reference to such competent authorities would not determine their legal status in Member states and therefore the question of possible trade restriction was irrelevant and goes beyond the scope of this exercise.

The importance of a footnote was reiterated by one Member who indicated that it would cover the right of Member states to select the method of production of biofortified foods based on their regulatory frameworks. Such Members are protected by the provisions of the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO), which recognize the sovereign rights of Competent Authorities to establish whatever measures they wish in food production, taking into consideration public health consequences in their countries. There is need to bear in mind that Codex standards are voluntary and Member states still have the right to decline certain foods to enter their territory in accordance with the SPS agreement although they are bound to provide scientific basis for such decline. So prescribing methods of production might not be helpful.

Conclusion

The Chairs note that majority of the eWG Members do not want the methods of production to be included in the proposed biofortification definition. The Chairs also noted that although majority of the eWG Members (CM=7, CO=3) wanted a discussion on the methods of production to be postponed and be addressed later or be provided in a separate guidance once the technical/concept definition on biofortification and labelling provisions have been adopted, some of these Members also supported the retention of a footnote which references the role of competent national/regional authorities in determining the methods of production. Since there was no consensus amongst the eWG on whether the proposed footnote referencing the roles of Competent National/Regional authorities should remain as part of the definition and whether the proposed role of competent authorities in determining methods of production could create a barrier to trade, the Chairs recommend that the Committee consider retaining a footnote which references the roles of Competent National/Regional authorities in determining the method of production as part of the criterion for the proposed definition for biofortification. The Committee should further discuss whether the text which reference the footnote should be included as part of the proposed definition for biofortification or not.

Recommendation 5

a. That the Committee consider whether the text which reference the footnote should be included as part of the proposed definition for Biofortification.

b. That the Committee consider the proposed text for criterion 5, if the Committee agrees on the inclusion of the text which references the role of the Competent National/Regional Authorities.

[Criterion 5: Methods

Methods* of Production

* To be determined by the competent National/Regional authority]

5. The Proposed Draft Definition for Biofortification

The Chairs proposed the following draft definition for biofortification for consideration by the eWG Members during the second consultation. The proposed draft definition was circulated to the eWG Members during the second consultation, and is reflected below.

Biofortification is the process whereby any nutrients[1] or related substances[2](criterion 2) of all potential source organisms or foods(criterion 1) are increased by a measurable level [and/or] become more bioavailable[3](criterion 3)prior to processing for the purpose of improving nutritional quality of food for improved human health[4].criterion 4).

[1]***Nutrient*** *is defined by General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.*

[2]***A related substance*** *is a constituent of food (other than a nutrient) that has a favourable physiological effect.*

[3]***Bioavailability*** *- The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.*

[4]*Appropriate purposes for addition are listed in paragraph 3.1.1. of the Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).*

Various suggestions were made to the proposed text. Several Members proposed the amended definitions based on their responses to the consultation paper. The Chairs noted the responses from the eWG Members and also considered specific comments made for each criterion. Based on the responses received and the revised draft criteria for Biofortification in Appendix II, the Chairs recommend the following draft definition to the Committee.

Recommendation 6

That CCNFSDU consider the proposed draft definition for Biofortification and associated footnotes for discussion.

Biofortification is the process whereby any nutrients[1] or related substances[2](criterion 2) of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* [of]/[and] foods(criterion 1) are increased by a measurable level [and/or] become more bioavailable[3] (criterion 3) for the intended purposes[4] (criterion 4). The process applies to any method of production[5] (criterion 5) [and excludes conventional fortification[6]].

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Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)*of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [and excludes conventional fortification[6]].

[1]**Nutrient** is defined by *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.

[2]**A related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.

[3]**Bioavailability** - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.

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

[5]**Method of production** should be determined by the competent National/Regional authority.

[6]Biofortification does not include conventional fortification covered by CAC/GL 9/1987.

6. Other Issues for Consideration by the eWG

How the definition would be used and where it would be best placed

CCNFSDU38 did not discuss how the proposed definition would be used and where it would be best placed. The Chairs recommend to the Committee to embark on this discussion once the definition is approved.

7. Recommendations for CCNFSDU

Based on the Term of Reference for the eWG, the Chairs believe that the required tasks have been achieved. It is proposed that the Committee:

I. Take note of the recommendations in the report.

II. Consider the draft criteria and proposed draft definition for biofortification.

Appendix I

PROPOSED TEXT FOR DIFFERENT CRITERION IN THE CONSULTATION PAPERS

Criteria	First Consultation Paper	Second Consultation Paper
Criterion 1	**[FOOD] or [TYPES OF FOOD]** All potential [organisms] (animal, plant fungi, yeasts) or [foodstuffs prior to processing] may be biofortified.	**SOURCE ORGANISMS** All potential source organisms((e.g. animal, plant, fungi, yeasts, bacteria) and food prior to processing may be biofortified.
Criterion 2	**[NUTRIENT]** To allow for nutrients (micro- and macro-nutrients).	**NUTRIENT AND RELATED SUBSTANCE** To allow for all nutrients and related substances.
Criterion 3	**[OUTCOME]** [increased nutrient content and/or bioavailability]	**OUTCOME** Measurable increased nutrient content and/or bioavailability.
Criterion 4	**[INTENDED PURPOSE]** [To improve the nutritional quality of food.]	**INTENDED PURPOSE** **To improve nutritional quality of food for improved human health*.** *Appropriate purposes for addition are listed in paragraph 3.1.1. of the *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).
Criterion 5	**[METHOD]**	**METHOD** To include all Methods* of production * To be determined by the competent National/Regional authority

Appendix II

SUMMARY OF PROPOSED CRITERIA TO BE COVERED BY THE DEFINITION

Criterion 1	Criterion 2	Criterion 3	Criterion 4	Criterion 5
Source Organism	**Nutrient and Related Substance**	**Outcome**	**Intended Purpose**	**Method**
All potential source organisms((e.g. animal, plant, fungi, yeasts, bacteria) [of]/[and] food may be biofortified.	To allow for all nutrients and related substances.	Measurable increased nutrient and related substance content and/or bioavailability	Nutrient or related substance is added in an amount sufficient for the intended purposes* *Appropriate purposes for addition are listed in paragraph 3.1.1. of the *Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).	[Methods* of production * To be determined by the competent National/Regional authority]

Appendix III

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(for comments at Step 3 through https://ocs.codexalimentarius.org)

Biofortification is the process whereby any nutrients[1] or related substances[2] of all potential source organisms (e.g. *animal, plant, fungi, yeasts, bacteria)* of]/[and] foods are increased by a measurable level [and/or] become more bioavailable[3] for the intended purposes[4].The process applies to any method of production[5] [excluding conventional fortification[6]].

[1]**Nutrient** is defined by *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food: which provides energy; or which is needed for growth and development and maintenance of healthy life; or a deficit of which will cause characteristic biochemical or physiological changes to occur.

[2]**A related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.

[3]**Bioavailability** - The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.

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

[5]Method of production should be determined by the competent National/Regional authority.

[6]Biofortification does not include conventional fortification covered by CAC/GL 9/1987.

Appendix IV

List of Participants

Codex Members

1. Argentina
2. Australia
3. Belgium
4. Brazil
5. Canada
6. Costa Rica
7. Estonia
8. Ethiopia
9. Grenada
10. India
11. Ireland
12. Japan
13. Malaysia
14. Mexico
15. New Zealand
16. Peru
17. South Africa
18. Switzerland
19. Thailand
20. United States of America
21. Zimbabwe

Codex Member Organisation

1. European Union

Codex Observers

1. Biotechnology Innovation Organization
2. NHF
3. FoodDrinkEurope
4. ICBA
5. IFT
6. ICGMA
7. International Dairy Federation
8. IFPRI