CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/NFSDU 16/38/7**

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

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

(At Step 3)

Governments and interested international organizations are invited to submit comments on **the proposed draft definition for biofortification as presented in Appendix I** at Step 3, and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: German Secretariat of CCNFSDU, email ccnfsdu@bmel.bund.de with copy to Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email codex@fao.org **by 30 September 2016.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

1. Introduction

1. CCNFSDU36 agreed to initiate new work on a definition for biofortification and agreed to establish an electronic working group, led by Zimbabwe and South Africa. The CCEXEC70 recommended that CAC38 approve the development of a Codex definition and/or Biofortified foods as new work. Zimbabwe and South Africa were tasked to lead an electronic working group to develop definitions of Biofortification and Biofortified foods and to indicate where the definition will be used.

2. At CCNFSDU37 the delegations of Zimbabwe and South Africa, as co-Chairs of the eWG, introduced the paper and the Committee agreed not to discuss the proposed definitions and considered whether the criteria contained in the working document were suitable in general to guide the further work of the eWG. The Committee further agreed to establish an eWG co-chaired by Zimbabwe and South Africa with the following Terms of References:

- consider the replies to the request for comments at Step 3 on the proposed draft definition and the comments made at the session;
- consider the request from CAC38 on how the definition would be used and where it would be best placed; and
- Propose a draft definition for further consideration by the next session of the Committee.

3. Requests to participate in the eWG were received from 21 Codex Members, and 11 Codex Observers. The list of Members and Observers is attached as **Appendix III.**

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

4. First and Second Consultation Papers were circulated to the eWG in March 2016 and May 2016 respectively. The focus of the first Consultation Paper was soliciting inputs from eWG members on the proposed draft definition for Biofortification based on the agreed upon criteria (**see Appendix II for the proposed Criteria)**. Furthermore eWG members were requested to consider where the definition would be used and where it would be best placed. The first Consultation Paper also provided an opportunity for eWG to comment on other additional issues that should be taken into consideration during the development of a draft definition for Biofortification. Members were asked to provide justification for their answers as well as provide alternative wording if an amendment was recommended. Six submissions were received from the first Consultation Paper from 2 Codex Members and 4 Codex Observers.

5. The Second Consultation Paper took into consideration the submissions from the First Consultation Paper and included a summary of eWG member comments regarding the proposed draft definition for Biofortification and how the definition would be used and where it would be best placed, as requested by the CAC38. Some eWG members indicated that the definition criteria were not exhaustively discussed and agreed upon. Members were therefore requested to comment further on the definition criteria.

6. The Second Consultation Paper also highlighted key areas that still need further discussion and agreement by members. Furthermore, in the Second Consultation Paper, the eWG members were requested to continue reviewing the two proposed draft definitions for biofortification.

7. There were 9 submissions received (seven Codex Members and two Codex Observers) on the Second Consultation Paper. The co-Chairs noted from the responses received, that some members did not receive both the First and Second Consultation Papers during the given consultation periods. The Chairs took a decision to re-circulate both papers to all eWG members, including those who could have been missed during the two rounds of consultations, with extension of the submission deadlines to the 13 July 2016. This was done to give all eWG members a fair chance to submit their responses on the Consultation Papers. The Chairs used feedback from both consultation papers to prepare this report.

3. Discussion Points

3.1 Revision of the proposed criteria for the Biofortification Definition

8. The eWG Members were requested to review the proposed criteria in line with the comments received at CCNFSDU37. Fewer criteria would assist in developing a clearer definition. Various amendments to the criteria were proposed. There was support for the removal of Criteria 7, 8 and 9 since criteria 7 and 8 refer to whether to specify the method of production in the definition. The methods of production will be determined by the competent authorities and furthermore, listing all the production methods would be too cumbersome and would require to re-open the definition any time a new method is introduced. Criteria 9 was referring to a labelling issue which would be dealt with once the definition has been agreed upon.

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.

3.2 The Proposed Draft Definition for Biofortification

9. As part of the First Consultation Paper, eWG members were requested to comment on the newly draft definition for Biofortification that was developed based on the criteria **(Appendix II)** and additional comments made by members to the criteria during CCNFSDU37. The proposed draft definition for biofortification that was circulated for comments to eWG members is reflected below.

Agro-fortification is the process by which the nutritional quality of agricultural food produce (e.g. plant crop) and products (e.g. eggs) are increased through any agricultural practice* without adding the nutrient through normal food processing in a beneficially absorbable form*, in order to correct or prevent a demonstrated deficiency and provide a health benefit.

Footnotes: * To be determined by the competent National Authority

10. Electronic working group members were requested to provide comments and proposed texts to the draft definition for biofortification. The eWG members commented on the draft proposed definition and suggested various amendments to it. Based on eWG responses to the First Consultation Paper, the Chairs proposed the following draft text of the two draft definitions for biofortification as part of the Second Consultation Paper.

1. [Biofortification/Agro-fortification] is the process by which the nutrient quantity of agricultural food produce (e.g. plant crop) and products (e.g. eggs) are changed by a measurable level in a readily absorbable form, through an intervention in the source organism by any agricultural practice* in order to correct or prevent a demonstrated deficiency* and provide a health benefit*. Footnotes: * to be determined by the competent National Authority.

2. Bio-fortification is the process by which the nutritional quality of food is increased through any primary production process without adding the nutrient through normal food processing in a beneficially absorbable form, in order to correct or prevent a demonstrated deficiency and provide a health benefit.

11. The eWG members were requested to choose a preferred draft definition and also provide comments and suggested texts, as well as the rationale and the justification for their proposals.

Key issues that emerged during the consultations on the proposed draft definition for Biofortification

- **Application of Biofortification:** There was consensus amongst eWG members that biofortification should not only be applicable to plants, but also to other organisms such as animals, fungi, yeast, etc. In line with the principle of allowing for various practices, the term agriculture was also removed from the text.

- **"nutritional quality":** Several Members preferred retaining the term "nutritional quality" in the definition. However the term "nutritional quality may be subject to various interpretations. The co-Chairs propose that term "nutritional quality" be replaced with "nutrient content" since it provides for many different potential purposes for addition, not only improving the nutritional quality. The term "Nutrient" is already defined by *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) 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*". This term is also referenced in the Codex Nutritional Risk Analysis Principles. Therefore the substances whose levels are modified by the biofortification process will be limited to nutrients.

  Food composition tables generally report on nutrient content of foods analysed according to official methods of analysis (e.g. AOAC), not on nutritional quality. Nutrient content for foods as reflected in the food composition tables are not a reflection of the bioavailability of the nutrients. For example spinach contains on average 2.7mg iron of which 0.0mg is heme iron and 2.71mg non heme iron per 100g of which only 0.08mg is available for absorption (bioavailable). Bioavailability (as defined in the Codex Nutritional Risk Analysis Principles) is not a constant value as the presence of soluble enhancers such as ascorbic acid and inhibitors such as phytates, polyphenols and calcium will affect how much is absorbed.

- **"changed/increased"**

  There was no consensus amongst the eWG Members on whether the term that should replace either "changed" or increased"(5 Members - improve; 3 Members - increased; 2 Members - changed). However those who were in support of the term "increased" indicated that bio fortification is referring to the process of addition of a nutrient. Those who preferred the term "improved" indicated that Biofortification should improve nutritional quality through increased amounts of nutrients available for absorption and metabolism in line with the definition of "bioavailability" as defined in Codex Nutritional Risk Analysis Principles.

  According to the Oxford Dictionary the following proposed terms mean the following:

  "improve - make or become better"

  "change - make or become different"

  "enhanced - intensify, increase or further improve the quality, value or extend of"

  "increased - become or make greater in size, amount or degree"

- **"measurable level"**

  It was proposed that the term "level" be substituted with "amount" to align it or adopt the existing Codex term used in CAC/GL 9-1987). The eWG members also highlighted that it was important that there was a measurable change in the nutrient content of a food through biofortification to provide a physiological benefit.

- **"readily absorbable form"**

  There was an overwhelming support from the eWG Members to retain the term "readily absorbable form" in the definition since it addresses the quality aspects.

- **"Agricultural Practice"**

  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. In line with this criteria, the term "agricultural practice" was removed from the definition and replaced by the term "intervention" which could be determined by the National Authorities if there are concerns about the safety of other methods, as is the case for genetic modification.

- **"source organism"**

  Several eWG Members supported the retention of the term in the definition.

- **"to correct or prevent a demonstrated deficiency and provide a health benefit"**

  There was no general support amongst the eWG Members to retain these terms in the definition. A proposal was made by several Members that *"in order to correct or prevent a demonstrated deficiency and provide a health benefit"* be deleted from the definition since it was referring to the purpose of the definition, and be replaced with *"sufficient for the intended purpose"* to be consistent with text in CAC/GL 9-1987.

- **"The inclusion of a footnote"**

  There was consensus amongst the eWG Members to include 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 intended purpose.

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**

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

12. The eWG members were requested to indicate how the proposed definition for Biofortification will be used and where it would be best placed. A comment was made by one member that CCEXEC requested the committee to specify which Codex text would house the definition, rather than where in general the definition will be used. The member also mentioned that the Codex texts proposed in the First Consultation Paper were of secondary nature, and such proposals of mentioning these documents could pose a challenge when they had to be opened for amendment. The member further indicated that the definition should be placed in a document that is already referenced, where the context would fit best. It was also highlighted that the rationale and specific use of the definition should also be considered. The following document was proposed by the Chairs as the preferred document where the definition could be placed: **"The *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)"**. The eWG members supported the proposed Codex document.

Recommendation 3

Based on the collective comments of the eWG, the co-Chairs propose the following Codex texts where the Biofortification definition will be housed and where it will be used for consideration and discussion by the Committee:

Where will be the definition be used:

The definition will be placed in the '*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)' and it will also be used in the following:

i. It is proposed that the definition can be used in dictionaries, as guidance by researchers, regulatory authorities, food manufacturers, packers, traders, consumers, risk assessors (e.g. scientific bodies) et cetera.

ii. The definition can be used in the development of new breeds, labelling of foods, development of food regulations, acts and policies, in reports of risk assessments, marketing of products, and already existing codex texts.

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

3.4 Use of the term Biofortification

13. The CCNFSDU noted that the term biofortification did not always translate easily, as "bio" had different meanings in different regions of the world. The eWG was tasked to explore other ways of defining the term better. During consultations with eWG members the Chairs proposed the following terminology that could be used instead of biofortification, i.e. "Agro-fortification".' One Codex member indicated that the prefix "bio" could

be considered synonymous with “organic” in a number of EU languages and new term could provide clarity to the consumers as to the intended meaning of the term. Several members did not support the proposed new term of agro-fortification. They indicated that the term “biofortification” has been used in the past twenty years in various languages, and is widely known and used throughout the world. Members also felt that the term “agro-fortification” would limit the definition to agricultural crops and may not adequately capture all methods such as UV irradiation, genetic engineering, etc. Members also indicated that the use of new terminology could lead to confusion in the population and might be incorrectly interpreted. There was an overwhelming support from members to retain the "biofortification" terminology.

Recommendation 4

CCNFSDU consider retaining the "Biofortification" terminology.

3.5 Other Issues for Consideration by the eWG

3.5.1 Definition for “biofortified foods

14. It was noted during the consultations that there was no mention of a definition for “biofortified foods" in the Consultation Papers. It was highlighted that a consideration should be made on how biofortified foods should be distinguished from non-biofortified 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 can be embarked on once the development of a definition for biofortification is completed since that was what CCFL41 meeting requested CCNFSDU to do. Once CCNFSDU has adopted a definition for Biofortification, CCFL may need to take it further by addressing the labelling issues. The distinction between biofortified foods and non-biofortified foods could be considered as a type of nutrient claim, such as a nutrient comparative claim. In such case the definition could be housed as a new definition in a new paragraph 2.1.4 of the Codex Text “The *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)”. In the same document, under point 6. Comparative claims, additional or specific criteria relevant to a nutrient comparative claim for Biofortified foods can be added in a new paragraph 6.6, to provide guidance as to how to inform consumers further, for instance, a label statement that will clarify which type of agricultural method was used to obtain the changed level (as a percentage) of the nutrient in order not to mislead consumers.

Recommendation 5

The co-Chairs recommend that the CCNFSDU and CCFL consider a discussion on the labelling of biofortified foods once a definition for Biofortification has been adopted.

4. Issues that will require further discussion

15. Few Members were concerned on how the issue of anti-nutrients, would be accommodated in the definition and indicated that future discussion on the inclusion of “reducing anti-nutrients” should be considered.

5. Recommendations for CCNFSDU

16. Based on the Term of Reference for the eWG, the Chairs believe that they have achieved the required tasks. The Committee has been provided with a draft definition for Biofortification that can be used for further consultations. It is proposed that the Committee:

I. Take note of the recommendations in the report.

II. Consider the draft definition for biofortification for discussion.

Appendix 1

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(STEP 3)

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

Appendix II

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**

Appendix III

List of Participants

Codex Members	**Codex Observers**
Argentina	World Sugar Research Organization
Australia	NHF
Brazil	FoodDrinkEurope
Canada	ILCA
France	International Dairy Federation
European Union	IFPRI
Ghana	
Greece	IFT
India	IACFO
Ireland	ICBA
Malaysia	ICGMA
New Zealand	
Panama	
Poland	
Republic of Korea	
South Africa	
Switzerland	
Thailand	
United States of America	

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.