



Agenda Item 6

CX/NFSDU 15/37/6

October 2015

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

**Thirty-seventh Session**

**Bad Soden am Taunus, Germany**

**23 – 27th November 2015**

**PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION**

(Prepared by an 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 definitions as **presented in paragraph 11** 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 for CCNFSDU, email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de) with copy to Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email [codex@fao.org](mailto:codex@fao.org) by **30 October 2015**.

**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.

## BACKGROUND

1. The 36<sup>th</sup> Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU36) agreed to initiate new work on a definition for biofortification and agreed to establish an electronic working group, lead by Zimbabwe and South Africa to undertake this work. The CAC38 approved this new work.

2. We recall that IFPRI (International Food Policy Research Institute) presented the first discussion paper at the CCNFSDU35. The paper mentioned that nutritionally enhanced crops were produced through conventional breeding. This technique is important in that fortification can reach the rural poor who rarely purchase fortified foods sold in shops and supermarkets. The issue of hidden hunger as caused by micronutrient deficiencies remains critical. It was noted at this meeting that:

- i. Biofortification continues to grow at an accelerated rate in the absence of definition and internationally accepted standards and guidelines.
  - ii. There is no information in current Codex texts that deals directly with biofortification.
  - iii. This gap could lead to different regulatory approaches by different governments hence trade impediments.
  - iv. The work on revision of the *General Principles for the Addition of Essential Nutrients to Foods* could not inclusively tackle the complex issue of biofortification.
3. At that meeting delegates raised a number of issues with regards to the issue of biofortification.
- i. Bioavailability of nutrients - the need for scientific evidence.
  - ii. Quality of biofortified food.
  - iii. How would the distinction between bio-fortified and non-bio fortified crops be made?

- iv. What considerations could be given to staple food crops that are already in the market place?
  - v. Consumer perception of new crops.
  - vi. Work on biofortification should not lead to impediments to trade.
  - vii. Biofortified food must be safe.
  - viii. Effect on Small holder farmers and traditional methods of farming.
4. The delegations of Zimbabwe and South Africa offered to prepare a discussion paper on the matter to be tabled at CCNFSDU36. A project document was also drafted. At CCNFSDU 36, the two papers were presented, discussed and the meeting agreed to recommend to CAC38 (July 2015, Geneva) that it be approved as new work.

5. It is important to note that the issue of biofortification was first raised in CCFL and that the committee's decision was to request the CCNFSDU to undertake the development of a definition which could then be used by CCFL to consider the labelling aspect of biofortified foods(s).

#### **ACCEPTANCE AS NEW WORK BY THE COMMISSION**

6. The CCEXEC70 recommended that the Commission approve the development of a Codex definition for Biofortification and/or Biofortified foods as new work.<sup>1</sup> The CCEXEC also recommended that CCNFSDU should clarify how the definition will be used and where it would be best placed. CAC38 approved this new work and endorsed the recommendation of CCEXEC.<sup>2</sup> 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.<sup>3</sup>

#### **THE ELECTRONIC WORKING GROUP eWG**

7. An invitation was sent to the Codex Secretariat by Zimbabwe where member countries and organizations as well as observers of Codex were requested to join the electronic working group (eWG) by 31 July 2015. One member organization (the EU representing its member states), 23 member countries including, Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, Guatemala, Ghana, Greece, India, Iran, Kenya, Malaysia, Netherlands, New Zealand, Nigeria, Norway, Peru, Switzerland, Uruguay, USA and Observer organizations including FoodDrinkEurope, ICBA, IDF, IFPRI, Biotechnology Industry Organisation and IAFCO requested to join.

8. A first background information document containing some proposed definitions for consideration and comments was prepared and circulated to eWG members. Comments were received from, Argentina, Australia, Brazil, Canada, European Union (EU), Guatemala, Greece, Kenya, Netherlands, New Zealand, South Africa, USA, FoodDrinkEurope.

#### **DISCUSSION**

##### **eWG MEMBER COMMENTS**

9. The member countries and observer member organisations commented on the proposed definition in Appendix I. Some proposed new definitions and rationales for the definitions which have been summarised as follows:

- i. There seems to be nine (9) main criteria (both from proposed definitions as well as the rationale provided) which were highlighted.
- ii. Out of the 9 criteria there seems to be more consensus on the following top six (6) criteria (see summary on Appendix II):
  - (a) To allow for all essential nutrients (micro- and macro-nutrients);

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<sup>1</sup> REP15/EXEC, para. 26

<sup>2</sup> REP15/CAC, para. 88

<sup>3</sup> REP15/NFSDU, para. 165

- (b) All potential types of agricultural processes which include all potential organisms (animal and animal feed, plant and plant, fungi, yeasts and fertilizers thereof) that may be involved in biofortification;
- (c) Must increase/enhance levels or absorption of nutrient(s) sufficiently for intended purpose (bioavailability);
- (d) To decrease any anti-nutritional elements;
- (e) Are any changes in increased or enhanced nutrient levels measurable? and
- (f) Intended purpose or health benefits or improved nutritional.

10. Criteria 7, 8 and 9 may be criteria which are better suited to be dealt with in the labelling of the products. It is proposed that final decisions about these criteria can be left to national authorities.

### FINAL PROPOSED DEFINITIONS

11. From the comments provided by the eWG members above, the definitions below have been proposed to try and address all concerns raised by the members. The proposed definitions below are for consideration by CCNFSDU37.

- i. **Biofortification** is the process by which the essential nutrient quality of food including essential amino acids and fatty acids, is improved through the use of agricultural methodologies, as well as reducing anti-nutritional factors with the aim of making the nutrients bio-available to the body after ingestion, in order to provide a health benefit.
- ii. **Biofortification** is the process by which food is enhanced by increased essential nutrients to a measurable level ensuring an increased level of absorption and a reduction of anti-nutritional elements, resulting in a public health benefit.
- iii. **Biofortification** is the process by which nutritional quality of food is improved through intervention in the source organism by increasing or adding the essential nutrient(s) and/or reducing anti-nutrients.
- iv. **Biofortification** is the process by which the essential nutrient quality of food including essential amino acids and fatty acids, is improved through the use of agricultural methodologies, with the aim of making the nutrients bio-available to the body after ingestion, in order to provide a health benefit.

### ISSUES THAT MAY REQUIRE FURTHER DISCUSSION

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

- i. the issue of anti-nutrients. Should they be included or not. Members of the eWG differed on this issue.
- ii. Some members wanted bioavailability to be included in the definition while others thought it should not since it is not easy to measure bioavailability at the level of national food regulators.
- iii. Should 'bioprocessing' of food be included in the definition?

### WHERE THE DEFINITION WILL BE USED

13. It was requested by CCEXEC that the e-WG consider, once the definition was agreed, specifically how this definition can be used.

- 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 such as:
- iii. The definition can be used in Codex texts such as:
  - a) The Procedural Manual;
  - b) Other Codex texts such as, but not limited to:

- Principles of addition of micronutrients to foods;
- *Guidelines On Formulated Supplementary Foods For Older Infants And Young Children* (CAC/GL 08-19911);
- *Standard for Edible Fats and Oils Not Covered By Individual Standards* (CODEX STAN 19-1981);
- *General Standard for The Labelling of Prepackaged Foods* (CODEX STAN 1-1985);
- General Guidelines on Claims (CAC/GL 1-1979);
- *Guidelines for Use Of Nutrition And Health Claims* (CAC/GL 23-1997);
- *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987)
- *Standard for Processed Cereal-based Foods for Infants and Young Children* (CODEX STAN 74-1981).

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

### **RECOMMENDATIONS**

14. The Committee is invited to consider the definitions as presented in paragraph 11 and the additional issued as outlined in paragraph 12 above.

## APPENDIX I

## PROPOSED DRAFT DEFINITIONS FOR BIOFORTICATION

(Circulated in the eWG)

1. **Biofortification is** the process of addition of one or more essential nutrients to a food crop through plant breeding whether or not it is normally contained in the food crop for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups. It may involve reduction of anti-micronutrients in foods.
2. **Biofortification is** the process by which the nutritional quality of food crops is improved through plant breeding, with the aim of making the nutrients bioavailable to the body after ingestion, in order to correct or prevent a demonstrated deficiency and provide a health benefit.
3. **Biofortification** is the process by which the micronutrient quality of food crops, including essential amino acids and fatty acids, is improved through plant breeding, as well as reducing anti-nutritional factors in key food crops, with the aim of making the nutrients bioavailable to the body after ingestion, in order to correct or prevent a demonstrated deficiency and provide a health benefit.
4. **Definition of biofortification from the WHO: Biofortification** is the process by which the nutritional quality of food crops is improved through conventional plant breeding and/or use of biotechnology.

APPENDIX II

Summary of proposed criteria to be covered by the definition

	1	2	3	4	5	6	7	8	9
<b>Source</b>	<b>All potential types of agricultural processes which include all potential organisms (animal and animal feed, plant and plant, fungi, yeasts and fertilizers thereof) that may be involved in biofortification</b>	<b>To allow for all essential nutrients (micro- and macro-nutrients)</b>	<b>Must increase/enhance levels or absorption of nutrient(s) sufficiently for intended purpose (bioavailability)</b>		<b>Are any changes in increased or enhanced nutrient levels measurable?*</b>	<b>To decrease any anti-nutritional elements</b>	<b>Method of production</b>		<b>Distinguish between a biofortified versus a non-biofortified food</b>
			<b>Increased level of absorption</b>	<b>Intended purpose or health benefits or improved nutritional quality</b>			<b>Must be specified</b>	<b>No need to specify</b>	
<b>Argentina</b>		√	√	√		√			
<b>Australia</b>	√	√			√		√		

<b>Brazil</b>	√	√			√	√		√	
<b>Canada</b>	√				√	√		√	
<b>EU</b>	√		√		√	√	√		
<b>Greece</b>	√	√	√		√	√	√		
<b>Guatemala</b>	√	√	√			√	√		
<b>Kenya</b>	√	√		√	√		√		
<b>Nether-lands</b>	√	√	√			√			
<b>New Zealand</b>	√	√	√	√	√	√	√		
<b>South Africa</b>	√	√	√	√	√	√	√		√
<b>USA</b>		√	√	√	√		√		√
<b>Zimbabwe</b>		√	√	√	√	√			
<b>Food and Drink Europe</b>	√	√	√	√					
<b>IFPRI</b>	√	√		√	√			√	√
<b>ICGMA</b>	√	√	√	√		√			
<b>TOTAL</b> √	<b>13</b>	<b>14</b>	<b>11</b>	<b>9</b>	<b>11</b>	<b>11</b>	<b>8</b>	<b>3</b>	<b>3</b>

\* In order for a percentage change in nutrient levels to be established to distinguish between a biofortified versus a non-biofortified agricultural crop or produce, a baseline level for a nutrient needs to be established for instance through FAO, regional, or national food composition data bases.

\* √ denotes support of a criterion from proposed definition/rationale given.

**Annex****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 ~~strike through 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.