CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **NFSDU/41 CRD 5**

Original language only

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

Forty-first Session

Dusseldorf, Germany
24 – 29 November 2019

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

Comments of IFPRI

Background Information

HarvestPlus: The Vision

Our **vision** is a world free of hidden hunger. We believe that hidden hunger can be solved by actively adding micronutrients to the diets of those who are deficient. With our partners, we develop new, more nutritious varieties of staple food crops that provide higher amounts of vitamin A, iron, or zinc—three of the micronutrients identified by the World Health Organization as most lacking in diets globally.

We use a process called **biofortification**, which adopts conventional breeding to improve crops. Our innovative approach complements other nutrition interventions, and is evidence-based, cost-effective, and sustainable.

We believed that obtaining an internationally accepted definition of Biofortification would assist in Standards development for biofortified food and therefore we entered the processes of the Codex Alimentarius where we originally collaborated with the Government of Canada in preparing a discussion paper at the request of the CCNFSDU. New work was commenced on the subject of Biofortification and we supported the Co-Hosts of the eWG, South Africa and Zimbabwe as the discussion moved forward and criteria were developed.

Eventually, the subject of Biofortification was referred to the CCFL where a very helpful conclusion was reached by Committee Members, however there are still outstanding issues that deserve the consideration of the CCNFSDU.

Conclusions from the Codex Committee on Food Labelling (CCFL)

CCFL Committee Members and Observers, having available to them the considerable documentation of the discussions within the CCNFSDU , reached a very useful and helpful conclusion regarding the labelling of a food that contained a biofortified ingredient. Following the conclusion that there were no scientific differences in the material, that is the nutrient itself was not changed, the existing CCFL texts would be applicable to a biofortified food.

The relevant CCFL text (REP19/FL) is as follows:

“Conclusion

11. The Committee acknowledged the tremendous work done by CCNFSDU, but agreed that current labelling texts were adequate for CCFL purposes and there was no need for a definition on biofortification in the context of food labelling.”

Note that this conclusion refers only to a definition in the context of food labelling and does not address biofortification in the context of nutrition issues, which can only be done by the CCNFSDU

See annex A for the labelling examples of biofortified staple food crops, following the CCFL Guidelines.

Conclusions of the Codex Alimentarius Commission (CAC)

In Rep19/CAC the following conclusion is stated in the report:

“10. In addition, CAC42: ii. clarified that work on the development of the definition on biofortification, was the responsibility of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), which should further discuss the issue and consider discontinuation following feedback from the Codex Committee on Food Labelling (CCFL).”

With several outstanding issues that can only be addressed by the CCNFSDU and the helpful conclusions reached by the CCFL, it would be inappropriate to consider discontinuation of work, at this point.

Remaining Responsibilities of the CCNFSDU

1. Fortification

There has been a recent updating (11 February 2019 09:31 CET) of the WHO information on Biofortification.

https://www.who.int/elena/titles/biofortification/en/

"Fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Biofortification is the process by which the nutritional quality of food crops is improved through agronomic practices, conventional plant breeding, or modern biotechnology. Biofortification differs from conventional fortification in that biofortification aims to increase nutrient levels in crops during plant growth rather than through manual means during processing of the crops. Biofortification may therefore present a way to reach populations where supplementation and conventional fortification activities may be difficult to implement and/or limited.

Examples of biofortification projects include:

- iron-biofortification of rice, beans, sweet potato, cassava and legumes;
- zinc-biofortification of wheat, rice, beans, sweet potato and maize;
- provitamin A carotenoid-biofortification of sweet potato, maize and cassava; and
- amino acid and protein-biofortification of sourghum and cassava."

In the Codex Guidelines on Fortification it is stated:

"6. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION

6.1 Fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area. CAC/GL 09-1987 (amended 1989, 1991)"

The issue for consideration by CCNFSDU41 is:

Having considered the Guidelines for Fortification, does the CCNFSDU consider that biofortification falls within the Guidelines on Fortification?

2. Definitions required to indicate an enhanced nutritional status in a food

During the copious discussions that the CCNFSDU has had, whilst attempting to reach consensus on a definition of Biofortification, the word biofortification itself has presented many problems in relation to being readily translatable. In addition the prefix "bio", in relation to food, has very specific contexts in some Countries.

Therefore and because of the complexity in reaching consensus on a definition of Biofortification, but at the same time accepting that there are three methods of production that can result in a biofortified food being available for Consumers, the logical way for CCNFSDU to proceed is to define each of those three methods. This will then serve a valuable reference point for Countries (especially developing Countries) that have made a decision to utilize one of these three methods to offer a Public health benefit to their populations and are considering legislating Standards.

It is understood that in all cases the goal would be to increase the dietary intake of the target micronutrient.

a) Agronomic Fortification is the deliberate use of mineral fertilizers to increase the concentration of a target mineral in edible portions of crops above a base line range.

b) Fortification using conventional breeding techniques is the development or improvement of cultivars using conventional breeding techniques and methods in the development of varieties using variaition from the existing genetic diversity spectrum and to increase the concentration of a targett micronutrient in edible portions of crops above a base line range

c) Fortification using the techniques of modern biotechnology is the introduction of desirable traits into crops through genetic modification so as to increase the concentration of a target micronutrient in edible portions of crops above a base line range.

The issue for CCNFSDU41 is to consider these definitions and determine if they are acceptable.

3. Addition in the context of Nutrition

If one considers, for example, the Commodity standard for rice, which is one of the very few commodity standards which even has a reference within it to "optional ingredients inclusive of nutrients" note that the standard refers to an ingredient being "added".

Codex Standard 198-1995

"3. OPTIONAL INGREDIENTS Nutrients Vitamins, minerals and specific amino acids may be added in conformity with the legislation of the country in which the product is sold. (Governments accepting the Standard are requested to indicate the requirements in force in their country.)"

Note that the standard refers to an ingredient being "added" although addition is not defined in Codex Nutrition Texts.

The issues for the CCNFSDU41 to consider:

In the context of the nutrition texts should addition be defined? Is biofortification an "addition" and therefore subject to all the conditions for "addition"?

4. The Commodity Standards

The Commodity Standards are under the jurisdiction of the Codex Committee on Cereal Pulses and Legumes (CCCPL). Although the format is well designed and useful, it should be noted that there is almost, without exception, no nutrition information in the Standards. The rare exception to this is the case mentioned above where rice has a mention of Nutrients, in a very general manner, under optional ingredients.

It is noted that there is, for example, a Standard for Whole and Decorticated Pearl Millet Grains (CXS 169-1989) and for Pearl Millet Flour

(CXS 170-1989).

A biofortified high iron pearl millet has now been developed through conventional breeding and is being distributed in India. It would be very practical and useful to have the commodity standards include a range of iron levels in the standard in addition to the Proximate values.

The issue for the CCNFSDU41 would be to refer commodity standards to the CCCPL to see if there is is the possibility of the adding a section in the standards regarding the nutrient profiles. This would be particularly important for the micronutrients Iron, Zinc and Vitamin A, which have been designated by the WHO as responsible for the vast majority of Micronutrient deficiencies globally.

Current Situation

In the absence of an internationally agreed definition for biofortification, many jurisdictions are proceeding in the elaboration of Standards for biofortified food, including a range of different definitions.

See Annex B, Rwandan Standard 305, Iron Bio-fortified Beans. Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

Whilst this is very useful for the domestic standards situation and is indeed laudable, it creates difficulties in the global understanding of biofortification. Also, trade difficulties arise and there is no possibility of harmonizing to an agreed international standard.

Conclusion

It is important that CCNFSDU41 carefully consider the outstanding issues that have been identified in this Conference Room Document by following the direction given to the Committee by the Codex Alimentarius Commission (CAC42), which"clarified that work on the development of the definition on biofortification, was the responsibility of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), which should further discuss the issue".

This direction clearly falls within the mandate of the CCNFSDU, one element of which states that it is“ to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues”

Many jurisdictions are awaiting the guidance to be provided by the CCNFSDU41 on the subject of Biofortified food.

The Evidence Base (selected listing)

Brauw, A., Moursi, M., & Munhaua, A. (n.d.). Vitamin A Intakes Remain Higher Among Intervention Participants Three Years After a Biofortification Intervention in Mozambique. *British Journal of Nutrition,* 1-24. doi:10.1017/S0007114519002162

Lena Wortmann, Ulrich Enneking, Diemo Daum. German Consumers' Attitude towards Selenium-Biofortified Apples and Acceptance of Related Nutrition and Health Claims February 2018 Nutrients 10(2) DOI:10.3390/nu10020190

Annals of the New York Academy of Sciences: Volume 1390, Issue 1, Special Issue: Staple Crops Biofortified with Vitamins and Minerals: Considerations for a Public Health Strategy,Pages: 1-114, February 2017

Garcia-Casal MN, Peña-Rosas JP, Pachón H, De-Regil LM, Centeno Tablante E, Flores-Urrutia MC. Staple crops biofortified with increased micronutrient content: effects on vitamin and mineral status, as well as health and cognitive function in the general population (protocol) Cochrane Database of Systematic Reviews. 2016; Issue 8. Art. No.: CD012311

Bouis HE, Saltzman A. Improving nutrition through biofortification: A review of evidence from HarvestPlus, 2003 through 2016. Glob Food Sec. 2017;12:49–58. doi:10.1016/j.gfs.2017.01.009

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Lividini K, Fiedler JL, De Moura FF, Moursi M, Zeller M. Biofortification: A review of ex-ante models. Global Food Security. 2017 Nov 23.

Pérez S, Buriticab A, Oparinde A, Birol E, Gonzalez C, Zeller M. Identifying Socioeconomic Characteristics Defining Consumers’ Acceptance for Main Organoleptic Attributes of an Iron-biofortified Bean Variety in Guatemala. International Journal on Food System Dynamics. 2017 Jul 10;8(3):222-35

African Journal of Food, Agriculture, Nutrition and Development,Volume 17 No. 2 (2017) Special Issue devoted to Biofortification

https://www.ajfand.net/Volume17/No2/index.html

Annex A

Comparison of biofortified and non-biofortified crops according to Codex*

* CAC/GL 2-1985, Guidelines on Nutrition Labelling

* CAC/GL 23-1997, Guidelines for Use of Nutrition and Health Claims

Micronutrient	NRV*	15% (source)	30% (high)
Iron (Fe)	22 mg	3.3 mg/100g	6.6 mg/100g
Zinc (Zn)	14 mg	2.1 mg/100g	4.2 mg/100g

* CAC/GL 2-1985, Guidelines on Nutrition Labelling

BEANS (whole grain, 8% MC) – COLOMBIA

Biofortified variety BIO-101 (75% of the full target)

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV in a 100g Portion	Claim
Iron (Fe)	8.3 mg/100g	22 mg	38%	**High**
Zinc (Zn)	4.4 mg/100g	14 mg	31%	**High**

Nutrient content claim: **Bean high in iron and high in zinc**

Comment: This released variety meets claims for Fe and Zn because it contains more than 30% of NRV for Fe and Zn, in a reference portion of 100 g of dried whole grain beans. Future varieties with full target level will have 43% of NRV for Colombia and could also have the same claims.

Non-biofortified control variety

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV	Claim
			Portion 100g	
Iron (Fe)	5.0 mg/100g	22 mg	23%	Source
Zinc (Zn)	2.8 mg/100g	14 mg	20%	Source

Nutrient content claim: **Bean source of iron and zinc**

Comment: The average non-biofortified variety meets claims form Fe and Zn because it contains more than 15% of NRV for Fe and Zn, in a reference portion of 100 g of dried whole grain beans.

PEARL MILLET (whole grain flour, 12% MC) – INDIA

Biofortified variety Danashakti (90% of the full target)

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV	Claim
			Portion 100g	
Iron (Fe)	7.4 mg/100g	22 mg	34%	**High**
Zinc (Zn)	2.8–4.2 mg/100g	14 mg	20–30%	**Source-High**

Nutrient content claim: **Pearl millet high in iron and source of zinc**

Comment: This released variety meets claims because contains more than 30% of NRV for Fe and 15–30% of Zn (considerable variation in data indicates 2 different possibilities), in a reference portion of 100 g whole grain or flour (not decorticated).

Non-biofortified control variety

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV	Claim
			Portion 100g	
Iron (Fe)	4.7 mg/100g	22 mg	21%	Source
Zinc (Zn)	3.5 mg/100g	14 mg	25%	Source

Nutrient content claim: **Pearl millet source of iron and zinc**

Comment: The average non-biofortified variety meets claims for Fe and Zn because it contains more than 15% of NRV for Fe and 25% of Zn, in a reference portion of 100 g whole grain flour (not decorticated).

RICE (Traditional parboiling, polished, 7.5% DOM) – BANGLADESH

Biofortified variety BRRI dhan64 (67% or target level)

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV	Claim
			Portion 100g	
Zinc (Zn)	2.4 mg/100g	14 mg	17%	**Source**

Nutrient content claim: **Rice source of zinc**

This released variety meets a claim for Zn because contains more than 15% of NRV for Zn, in a reference portion of 100g of parboiled, polished grain.

Non-biofortified control variety.

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV	Claim
			Portion 100g	
Zinc (Zn)	1.6 mg/100g	14 mg	11%	Contains

Nutrient content claim: **Rice no claim**

The average non-biofortified variety does not meet any claim since it contains less than 15% of NRV for Zn, in a reference portion of 100 g of parboiled, polished grain.

RICE (Non-parboiled, polished, 7–10% DOM) – BOLIVIA

Biofortified variety CIAT BIO – 44 + Zinc (50% of target level)

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV Portion 100g	Claim
Zinc (Zn)	2.2 mg/100g	14 mg	16%	**Source**

Nutrient content claim: **Rice source of zinc**

This variety contains more than 15% of NRV for Zn, in a reference portion of 100 g of non-parboiled, polished (7–10% DOM) grain.

Non-biofortified control variety

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV Portion 100g	Claim
Zinc (Zn)	1.5 mg/100g	14 mg	10%	Contains

Nutrient content claim: **Rice no claim**

The average non-biofortified variety does not meet any claim since it contains less than 15% of NRV for Zn, in a reference portion of 100 g of non-parboiled, polished grain.**WHEAT (whole grain flour)– INDIA**

Biofortified variety BHU6 (100% of target level)

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV Portion 100g	Claim
Zinc (Zn)	4.2 mg/100g	14 mg	30%	**Source-High**

Nutrient content claim: **Wheat source or high zinc**

This variety meets the source claim and could meet the high claim because it contains more than 15% of NRV for Zn and could contain up to 30% with good agronomic management (considerable variation in data indicates 2 different possibilities) in a reference portion of 100 g of whole grain flour.

Non-biofortified

Nutrient	Content	Daily Nutrient Reference Value (NRV)	NRV Portion 100g	Claim
Zinc (Zn)	3.5 mg/100g	14 mg	25%	**Source**

Nutrient content claim: **Wheat source of zinc**

The average non-biofortified wheat variety in India meets a claim for Zn since it contains more than 15% of NRV for Zn, in a reference portion of 100 g of whole grain flour.

Annex B

The Rwanda Standard 305, Iron bio-fortified Dry Beans