CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 10 **CX/NFSDU 14/36/11**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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DISCUSSION PAPER ON BIOFORTIFICATION WITH ESSENTIAL NUTRIENTS

Presented by the Government of the Republic of Zimbabwe with comments from the Republic of South Africa

Introduction

Biological Fortification or BIOFORTIFICATION as it is commonly known, allows a greatly increased micronutrient content of crops and animals to be bioavailable for human consumption. This phenomenon of considering the content and availability of micronutrients, especially in crops, is relatively new. Crops have traditionally been bred with careful attention being paid to such desirable traits as productivity, pest resistance, and drought resistance among others.

Programs are being introduced globally to fight "hidden hunger" which result in the consumption of staple food crops which are high in the three micronutrients that have been identified by the WHO as causing the greatest incidence of malnutrition. The 3 micronutrients are Iron, Zinc and Vitamin A deficiencies of which are associated with anemia, stunting and blindness in children.

For example, progress has been made in South Africa to control micronutrient deficiencies through supplementation and food fortification, but new approaches are needed, especially to reach the rural poor who only have access to small scale millers who have not fortified some of their staple food crops. Biofortification is an option. Scientific evidence shows this is technically feasible without compromising agronomic productivity. Predictive cost-benefit analyses also support biofortification for controlling micronutrient deficiencies. Meanwhile in Zimbabwe, the 2010-11 Demographic and Health Survey demonstrated geographic areas of severe malnutrition. In order to assist in combating these deficiencies, biofortification has been incorporated into the 5 year costed National Nutrition Strategy as an acceptable nutrition intervention.

The Issue

There is no internationally recognized definition for biofortification although some Member Governments are starting to include biofortification in Country Regulations and also write it into National Policies i.e. Nutrition and/or Agriculture as an intervention to combat micronutrient deficiencies in populations.

Prior Discussions on Biofortification in the Codex Alimentarius

- In 2005, a discussion document was brought to CCNFSDU by Canada on the possibility of opening the **Codex General Principles for the Addition of Essential Nutrients to Foods** (CAC/GL 09-1987) to clarify its applicability to biofortified foods. This paper noted that while fortification of foods was a well established nutritional concept which had proven positive public health outcomes, augmentation or enhancement of the essential nutrients in foods of plant and animal origin was a rapidly evolving area which may have a significant impact on the nutritional profiles of traditional foods and the intake of essential nutrients by consumers. Addition of essential nutrients to foods was being achieved through genetic modification of the animal or plant organism that is the source of the

food (e.g., beta-carotene production in rice) or through alterations to livestock feed composition resulting in nutritionally enhanced animal products (e.g., higher levels of nutrients in eggs or dairy products). It was argued that similar considerations are appropriate regardless of the means used to increase the essential nutrient content of a food. The General Principles guiding the addition of essential nutrients to foods would generally equally apply to the augmentation or enhancement of essential nutrients in foods through non-traditional means, as would many of the Basic Principles included within the General Principles. This proposal was not discussed at that meeting and when it was brought to the next session, the proposal to open the General Principles was expanded to cover other changes.

- During CCNFSDU 29 in 2007 a discussion paper (Alinorm 08/31/26) on the **Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods** (CAC/GL 09-1987) was introduced. Three separate issues within the Principles were to be addressed. One of the 3 issues was "addition or enhancement of the levels of essential nutrients to foods by indirect methods, including biofortification."

  At that time, some delegations "acknowledged the importance of taking into account issues arising frombiofortification in the overall vitamin intake, but were skeptical about the capability of the CCNFSDU to tackle all the issues that would be relevant to biofortification in the framework of these general principles." At the same time it was also "pointed out that the last session of Task Force on Foods Derived from Biotechnology had noted that the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) elaborated by this Committee were applicable to foods elaborated by these new technologies." Indeed, an Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants was completed in 2008 entitled, "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits" which includes this statement. The Committee concluded that a revised document be prepared taking into account Members' comments.

- At CCNFSDU 30 in 2008 (Alinorm 09/32/26 para. 130) a revised discussion paper was considered and an opinion in reference to the inclusion of biofortification was noted as "not considering it appropriate at this stage to enlarge the scope of the General Principles beyond the direct addition of nutrients to foods and that biofortification as well as other forms of indirect fortification should be eventually addressed by a separate activity due to their complexity."

- At CCNFSDU 31 in 2009 (Alinorm 10/33/26 para. 90) the Committee, based on the Report from the eWG led by Canada, agreed to initiate new work on the amendment of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987). There was no reference to the subject of biofortification.

- At CCNFSDU 32 in 2010 (REP11/NFSDU para. 62) "the Committee considered the WHO definition of fortification. Several delegations pointed out that it was preferable to use the current Codex terminology, which was more consistent with the *Nutritional Risk Analysis Principles*, and that the WHO definition includes the concept of biofortification which the committee had specifically agreed to exclude from consideration in the discussions of the General Principles"

- At CCNFSDU 34 in 2012 (REP 13/NFSDU) IFPRI alerted the Committee to the urgent need to consider the subject of biofortification within the mandate of the Committee as there has been a greatly accelerated rate of foods biofortified through conventional breeding reaching hundreds of thousands of households. It was explained that this work is occurring in the absence of definitions and internationally accepted Standards or Guidelines.

- At CCFL 41 (REP13/FL para.123-125), that Committee "generally agreed that existing Codex guidelines provide adequate guidance for claims for products with higher micronutrient content. However, challenges for labelling may arise in expressing the true nature of a food or ingredient if a processed product is biofortified or is based on a biofortified ingredient since no definition for biofortification exists. "It was also mentioned that crops derived from biofortification could be standardized by the relevant commodity committee."

Definitional Issues

- In REP13/FL, the request to CCNFSDU from CCFL is identified in paragraph 127 as a request to consider defining "biofortified food" and in the Summary and Conclusions section as a request to consider defining "biofortification". Generally speaking, where there are definitions, they tend to be for the term "biofortification". In that report, it says that, "Some delegations noted that terms including "bio" refer to organic agriculture in their countries so that a different term than biofortification might have to be used. Other delegations were of the view that "biofortification" might be interpreted as modern biotechnology."

Examples of existing definitions of biofortification, while having similarities, demonstrate the lack of harmonization, even in the scientific literature, on this subject. The following are examples:

- Biofortification is food fortification achieved by plant breeding or genetic modification to give a higher content of nutrients---Bender, Dictionary of Food and Nutrition

- Biofortification is the process of increasing the nutritional content of the edible portion of plant foods to levels that consistently exceed the average content observed---Wiktionary

- Biofortification (specific) is an effort to add nutritional value to cassava by increasing the contents of protein, minerals, starch and beta-carotene.---Montagnac et al, Comprehensive Reviews in Food Science and Food Safety

- Biofortification –no standard online English dictionary entries found for "biofortification" (Search conducted August 3, 2013 using http://www.onelook.com/)

- Biofortification is a nutrition-specific intervention designed to enhance the micronutrient content of foods through the use of agronomic practices and plant breeding.-FAO, State of Food and Agriculture, 2013 http://reliefweb.int/sites/reliefweb.int/files/resources/The%20State%20of%20Food%20and%20Agriculture%202013.pdf

- The process of breeding and disseminating new varieties of staple food crops that are rich in vitamins and minerals is called biofortification---IITA

As well, the subject is discussed on page 30 of the FAO/WHO Guidelines on Food Fortification with Micronutrients: "The biofortification of staple foods, i.e. the breeding and genetic modification of plants so as to improve their nutrient content and/or absorption is another novel approach that is currently being considered."

Consideration of Issues raised in the REPORT OF THE THIRTY FIFTH SESSION OF THE CODEX COMMITTEEON NUTRITION AND FOODS FOR SPECIAL DIETARY USE (REP14/NFSDU).

It was noted that during the discussion on Biofortification in the thirty-fifth session of CCNFSDU, the report captured the following issues as raised by Delegates during the Discussion on Agenda Item# 9 "Discussion Paper on Biofortification" presented by the IFPRI with comments from Canada:

1. **Bioavailability of nutrients - the need for scientific evidence**

   Bioavailability, which is defined as the amount of an ingested nutrient that is absorbed and available for physiological functions, is dependent on digestion, release from the food matrix, absorption by intestinal cells, and transport to body cells. Staple food crops such as beans, rice, cassava, wheat, sweet potatoes, maize and pearl millet, when biofortified with iron, zinc and pro-vitamin A carotenoids have been proven to be bioavailable in human populations after cooking using traditional methods. (La Frano et. al 2014).
   A number of studies have been carried out to determine and measure bioavailability, efficacy and effectiveness of biofortification of staple crops and there is growing evidence to show that nutrients from these crops can be bioavailable and absorbed at sufficient levels to improve micronutrient status. In rural India, iron biofortified pearl millet was shown to improve nutrition status of children, (Bouis et al, 2014). Haas et al. (2005) have also shown that high-iron rice can indeed improve the

iron status of women while van Jaarsveld et al. (2005) have shown that the consumption of orange-fleshed sweet potato improves the vitamin A status of children in Mozambique: with 100 μg/g of beta-carotene and 80% retention when consumed in boiled form, and even a 50 gram consumption of this crop was sufficient for meeting 75% of the recommended daily allowance (RDA) of vitamin A for children.

2. Quality of biofortified food

The importance of protecting the desirable quality attributes of biofortified foods is well recognized. As an example, colour can change as the micronutrient level of pro-vitamin A carotenoids is increased in maize. Pillary et al (2011) have shown that it was difficult to market vitamin A biofortified maize which changes to yellow and orange. The aroma and flavor also changes. Orange fleshed sweet potatoes were initially resisted due to the orange colour which consumers did not recognise (Tumuhimbise et. al 2013), however Van Jaarsveldet al. (2005) did find that the orange colour was very attractive to children. A study carried out by Chowdry and others in Uganda showed that adoption of biofortified crops by mothers increased considerably after education. Low et al(1997) showed that vitamin A biofortified sweet potato was not acceptable in developing countries due to low level of dry matter. Breeders have increased the dry matter contents of the biofortified sweet potato in order to maintain desirable texture attributes (Tumuhimbise et al. 2013).

3. How would the distinction between bio-fortified and non-bio fortified crops be made?

For crops that have been biofortified using conventional breeding or agronomic biofortification, germplasm screening can be used to test for the presence of an increased nutrient level. It is done to assess the micronutrient concentrations in seeds.

For crops that have been biofortified using modern biotechnology (genetic engineering), DNA screening can be used to confirm the presence of the transgene in the DNA sequence of the organism. Quantitative Real-Time Polymerase Chain Reaction (QRT-PCR) is the method of choice to quantitatively measure amounts of transgene DNA in a food or feed sample.

Physical distinction is easy in a lot of cases where there is obvious colour change after biofortification.

The issue of labelling was introduced in the CCFL; however, the conclusion of the committee was that a definition of biofortification should be undertaken by CCNFSDU before consideration of any further discussion on labelling issues.

A global logo is also proposed which has traceability characteristics.

4. What considerations could be given to staple food crops that are already in the market place?
There are biofortified crop varieties that have already been released. These food crops are in compliance with all National regulations in the Countries where they have been released. In many cases, this includes multi locational varietal data from a minimum of two growing seasons as well as passing the distinctiveness, uniformity and stability (DUS) tests. These crops are high yielding and have been shown to have enhanced agronomic traits of interest to farmers. In regards to their increased nutritional value, the awareness of these crops has been achieved through educational campaigns.

5. Consumer perception of new crops

In order to ascertain consumers' perception to biofortified staple crops, considerable attention has been paid to the importance of holding focus groups and conducting consumer acceptance studies. Studies have shown that with advocacy and proper education, consumers can be made to accept the biofortified crops. Studies have compared the acceptability to consumers of new biofortified varieties to that of the most popular non-biofortified varieties in the market in terms of their sensory attributes and willingness to purchase. In general, consumers have shown a willingness to purchase based on the enhanced nutritional attributes (Meenakshi et al. 2010).

6. Work on biofortification should not lead to impediments to trade

The policy environment should not impede trade. Products should be introduced to the market carefully in such a way as not to disadvantage traders, consumers and farmers still planting non-biofortified crops. Global and regional communication strategies can be adapted and adopted to

support national governments. All national import and export requirements would be respected in reference to international trade in biofortified food. Countries have to be urged to adhere to their World Trade Organisation (WTO) transparency obligations when crafting regulations on biofortified crops and foods.

7. Biofortified food must be safe

In consideration of the three micronutrients (iron, zinc and vitamin A) that have been increased through biofortification, no concerns have been expressed with regards to toxicity of zinc or iron due to the relatively small levels involved. Toxicity questions have been raised in relation to vitamin A only, however, the biofortified crop contains precursors of vitamin A which are pro-vitamin A carotenoids such as beta-carotene, alpha-carotene and beta-cryptoxanthin. Once in the body their conversion to vitamin A is controlled by a physiological self-regulating mechanism that prevents excess formation and storage of vitamin A.

8. Effect on Small holder farmers and traditional methods of farming

Concerns have been expressed in general that Biofortification could undermine traditional farming systems and affect small farmers. It is noted that the costs of production to the farmer should not be increased when producing biofortified crops. For example, there is a need to promote the notion that inter cropping can still be maintained together with traditional farming practices and may even enhance these practices. High pro-vitamin A orange fleshed sweet potato are planted by community, school and home gardens in South Africa. Bio-fortification is compatible with inter cropping and does not negatively affect traditional farming systems even with the use of fertilizers.

Conclusion:

It is proposed that CCNFSDU consider new work to define biofortification or biofortified foods.

References

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PROJECT DOCUMENT

Prepared by the Government of the Republic of Zimbabwe with comments from the Government of the Republic of South Africa

1. PURPOSE AND SCOPE OF THE STANDARD

There is no internationally recognized definition for Biofortification although some Member Governments are starting to include Biofortification in Country Regulations and also write it into National Policies i.e. Nutrition and/or Agriculture, as an intervention to combat micronutrient deficiencies in populations. The purpose of the requested new work is to bring clarity to the subject of biofortification through the development of an internationally accepted definition for biofortification and/or biofortified food. The scope of the standard is a definition of biofortification and/or biofortified food that would apply to any food or food ingredient that fits the definition. The scope to be covered would be reflected in the definition.

2. RELEVANCE AND TIMELINESS

The use of biofortification as an effective micronutrient nutritional intervention is now under discussion or implementation in many countries. With no international guideline, standard or reference to harmonise to, many different approaches will be taken.

3. MAIN ASPECTS TO BE COVERED

The main aspect to be covered is the establishment of a common definition for biofortification and/or biofortified food that could describe, or be used to determine appropriate descriptors for, the foods or ingredients so fortified or enhanced. These terms would be applicable in food labelling and in documents of Codex or competent national or regional authorities that refer to such food commodities under development or in trade. Another aspect is to ensure that the definition is sufficiently broad to cover the various organisms and methods of biofortification. Consideration should be given as to whether the definition should include an indication of the size of the change in nutrient required to be considered biofortified in order to guide further standard-setting.

It would be expected that once a definition is established it could be placed in the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987), however, this would be a committee decision.

4. ASSESSMENT AGAINST THE *CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES*

Criteria

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Micronutrient deficiencies have been identified by the WHO as an issue of extreme concern, particularly in developing countries. To assist in reducing micronutrient deficiencies, Biofortified crops are currently being consumed. Without a definition of biofortification, it is difficult to establish a Strategic Country Framework in which biofortification policies can be developed.

Fair practices in food trade:

Once again, in the absence of internationally accepted standards, guidelines and recommendations, trading practices can become disorganized and non-compliant.

Food security:

To be truly food secure, a country must have available an adequate supply of safe and nutritious foods for its population. Biofortified staple food crops can make a considerable contribution to enhancing the nutritional quality of traditionally consumed foods.

Criteria applicable to general subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade*

The lack of a definition for biofortification could result in many differing definitions being developed for the purposes of inclusion in national legislation, regulations, protocols or guidelines. Lack of standardization could result in impediments to trade. Also there could be abuse by sellers who may make claims that their product is biofortified when it is not and there is no national legislation to protect the consumer.

(b) *Scope of work and establishment of priorities between the various sections of the work.*

The scope of work at this point is of necessity limited to the establishment of a definition.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)*

The World Organisation for Animal Health (OIE) will be considering the subject of biofortification as it relates to animal products during their upcoming commissions. High Selenium and omega-3 eggs are now being produced and consumed to address certain micronutrient deficiencies in human populations.

(d) *Amenability of the subject of the proposal to standardization*

Once a definition is established the need for further work could be ascertained.

(e) *Consideration of the global magnitude of the problem or issue*

Over 3 billion people worldwide are micronutrient malnourished with iron, zinc and vitamin A accounting for two thirds of early childhood deaths. Societal costs include learning disabilities among children, increased morbidity and mortality rates, lower worker productivity and high healthcare costs. All factors diminish human potential and national economic development (Welch, 2002 and Welch and Gordon, 2004). Biofortification can have a substantial positive influence on this global problem. As biofortification is implemented, foods produced will increasingly enter international trade requiring a common set of terms and a common understanding of the meaning of those terms used to describe both the raw and finished products.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

The proposed work is in line with the Commission's mandate for the development of international standards, guidelines and other recommendations for protecting the health of consumers and ensuring fair practices in food trade. The new work proposal will contribute to:

Strategic Goal 1, Objective 1.2. -'Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards'

The subject of biofortification has been clearly identified as an emerging issue of great importance for developing countries who are struggling with the health issue of reducing micronutrient malnutrition. Attention to the creation of a definition will be of great assistance in institutionalizing biofortification as a potentially powerful nutrition intervention.

Strategic Goal 3, Objective 3.1. – 'Increase the effective participation of developing countries in Codex'.

The Countries where biofortification is most needed are developing Countries. Discussions on biofortification have resulted in some cases in the formation of National Biofortification Committees. Often, this is resulting in having the departments of Agriculture and Health at the same table for the first time. The fact that biofortification is now tied into the CODEX Alimentarius process has resulted in a much heightened level of awareness and appreciation for the CODEX Alimentarius and its work. In many cases, this has served as an introduction to CODEX Alimentarius.

6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The only CODEX documents that have any reference to biofortification are those that have been enumerated in the background section of the Discussion Paper and they refer to discussions in both CCFL and CCNFSDU. . However, the definition, once adopted, would be available for use as appropriate in future amendments of specific commodity standards as well as nutrition-related standards and guidelines.

7. REQUIRMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

No expert advice other than that which is to be found in the CCNFSDU is required at this time.

8. REQUIREMENT FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES

No technical input other than that which is to be found in the CCNFSDU is required at this time.

9. PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK

a. Start date: November 2014

b. Proposed date for adoption at step 5: July 2016, however if this were to go through the accelerated step procedure, it might be possible to have adoption at step 8 in July 2016

c. The proposed date for adoption by the commission: July 2016

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