

DEVELOPMENT OF A PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(Chaired by Zimbabwe and South Africa)

Second Consultation Paper

June 2016

Please respond by **17TH June 2016**

To: miriebanda@yahoo.com, ancikaria53@gmail.com, tshitg@health.gov.za,
naickn@health.gov.za and copied to nepfoodsafety.zw@gmail.com, cacpsa@health.gov.za

1. INTRODUCTION

At the 37th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), The Committee agreed to re-establish the eWG, led by Zimbabwe and South Africa, working in English, to further develop the proposed draft definition of biofortification at step 4.

The terms of reference for electronic working group

- 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.

2. OVERVIEW

The EWG consists of 21 Codex Members and 11 Observers. The list of Members and Observers is attached as **Annexure 1**. Responses to the first consultation paper were received from 5 Members and 1 Observer. The list is also attached as **Annexure 2**.

Consultation Paper 1

The focus of the first consultation was on the following key areas based on the terms of reference:

1. Develop a draft definition for biofortification based on the agreed nine criteria identified as the source of the proposed definition. The draft document will also provide an opportunity for eWG members to comment on other additional issues

that should be taken into consideration during the development of a draft definition for biofortification.

2. To consider on how the definition would be used and where it would be best placed.

Consultation Paper 2

This second consultation paper takes into consideration findings of the first consultation paper and includes a:

- Summary of eWG member comments regarding the:
 - Proposed draft definition for biofortification.
 - How the definition would be used and where it would be best placed.
 - Highlight key areas that still need further discussion or agreement by members.
- Continued review of the proposed draft definition for biofortification.

3. Feedback from the First Consultation Paper

3.1 Proposed draft biofortification definition

As part of the First Consultation Paper, eWG members were requested to comment on the new proposed draft definition for biofortification. The proposed draft definition was developed based on the criteria (**Annexure 3**) and additional comments made by members to the criteria during CCFSDU37. The proposed draft definition for biofortification that was circulated for comments to eWG members is reflected below.

Agro-fortification^(concern 2.2) is the process by which the nutritional quality^(criteria 2) of agricultural food^(criteria 1) produce (e.g. plant crop) and products (e.g. eggs) are increased^(criteria 5) through any agricultural practice^{(criteria 1 and concern 2.3)*} without adding the nutrient through normal food processing in a beneficially absorbable form^{(criteria 3, 4 & 6 and concern 2.6)*}, in order to correct or prevent a demonstrated deficiency and provide a health benefit.

Footnotes: * To be determined by the competent National Authority

Several key issues emerged from submissions received and these are summarized below.

Electronic working group members commented on the draft proposed definition and suggested various amendments to it. Two members were in support of the inclusion of the new term “agro-fortification” in the definition. However the rest of the members were not in favour of this term for various reasons which are explained under section 3.3.

Several electronic working group members (five eWG members) were in support that biofortification should not only be applicable to plants, but also to other organisms such as animals, fungi, yeast, etc. However, one member felt that biofortification should only include food crops. One member country commented that the use of genetically modified Organisms (GMO) should not be included in the definition, but rather only conventional plant breeding methodology is included.

In order to address concerns raised by members and also inform consumers on how biofortified foods were obtained, one member country proposed that the following wording should be included in the definition: “such foods may be obtained through various agricultural methodologies and the methodology used should be clarified in order not to mislead the consumers”.

One eWG member commented that the word “nutritional quality” and “increased” be replaced by “nutritional quality” and “changed by a measurable level” respectively. The reason given for including the wording “changed by a measurable level” is that it is important that there is a measurable change in the nutrient content of a food through biofortification to provide a physiologic benefit. However one eWG member also proposed that the word “nutritional quality” be replaced with “nutritional content” because “nutritional content” provides is directly related to a specific change which is easily measured, and it also provides for many different potential purposes for addition which is not only related to the nutritional quality.

Two eWG members commented on the issue of anti-nutrients, with one member indicating that a future discussion on the inclusion of “reducing anti-nutrients” would be welcome. Another member proposed that the following wording on anti-nutrients be included in the definition: “reducing anti-nutritional factors in key food crops”.

One eWG member suggested that the wording “without adding the nutrient through normal food processing” be replaced with “through an intervention in the source organism”. However should the wording “without adding the nutrient through normal food processing” be retained the eWG member recommended that the word “normal” be deleted since it could raise questions of what is normal.

One eWG member commented that the phrase “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.

One eWG member requested that the phrase or term “beneficially absorbable form” be defined since it was not a recognizable term and was not commonly used by other UN agencies such as WHO.

3.2 Definition Criteria

Are the definition criteria as given in annexe 3 sufficient? Y/N

If not what are your proposals.

Are there any criteria in annexe 3 that you think must be removed?

3.3 New Proposed Definitions for Biofortification

CCNFSDU37 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. The Chairs requested eWG members to provide comments on the proposed terminology “**Agro-fortification**”.

Responses from eWG members on this proposal are reflected below.

Two eWG members were in support of the proposed term “agro-fortification” rather than biofortification.

Two Codex members also indicated that the prefix “bio” could be considered synonymous with “organic” in a number of EU languages. One member indicated that the new term could provide clarity to the consumers as to the intended meaning of the term.

Four members did not support the proposed new term of agro-fortification. Several members 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. One member commented that the use of new terminology could lead to confusion in the population and might be incorrectly interpreted.

Based on eWG responses, the Chairs propose the following draft text of two definitions for biofortification for your consideration:

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.

(a). Which definition do you prefer?

IBFAN does not agree with either of these definitions.

Based on the comments received from eWG members, the chairs request eWG members to further comment on the following issues:

(b) Do you think the term “biofortification” should be kept?

Yes

NoX

(c). Please provide justification for your answer

The term biofortification or agrof fortification are terms that obscure and hide the means by which the food is altered. A more precise definition would state that the food is genetically altered by means of a technological industrial process. The fact that the food is genetically changed should not be obscured by the

definition. As well the EU uses the term “bio” to label organic foods and food products and using the prefix bio could imply that the food is natural and organically produced.

Using the term “fortification” implies a claim that the food has a nutritional/health advantage over normal food. Since such a claim is unsubstantiated, using the term “fortification” would be misleading.

Food fraud is becoming a major consumer concern and using the term bio or agri fortification will confuse the public and obscure the reality of how these foods are altered.

(d). If you have other proposals, please provide a suggested draft of the terminology as well as the justification for the proposal?

The term genetically altered would be a term closer to the truth of how the food is changed and would not imply a claim that it has a benefit over normal food.

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

The electronic working group members were requested to indicate how the proposed definition for biofortification will be used and where it would be placed. As part of the first consultation paper, the chairs proposed the following areas wherein the proposed definition could be used within the Codex texts:

- 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.

Do you agree with proposals? NO

If not what are your alternative proposals?

It is important to ensure that the definition of these genetically altered foods reflects the truth and does not confuse the public or obscure how these foods are produced. Proposing where they should be placed is premature.

The proposed criteria do not mention safety. We strongly recommend that this be included.

Independent science should determine their safety before considering where a truthful informative definition can be used.

3.5 Other Issues for Consideration by the eWG

One Codex member noted that there was no mention of a definition for “biofortified foods in the First Consultation Paper.

CRITERIA 9, in Annexure 3 stipulate 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 2014 eWG discussion document is important. This discussion can be embarked on once the development of a definition for biofortification is completed since that was what the 41st CCFL meeting requested CCNFSDU to do.

In order to address concerns raised by members and also inform consumers on how biofortified foods were obtained, one member country proposed that the following wording should be included in the definition: “such foods may be obtained through various agricultural methodologies and the methodology used should be clarified in order not to mislead the consumers”.

Once CCNFSDU has adopted a definition for Agro/biofortification, CCFL may need to take it further by addressing the labelling issues as per Criteria 9. The distinction between biofortified/Agrofortified foods and non-agro/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 Codex 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 Agro/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.

ANNEXURE 1:

Codex Members

Argentina
Australia
Brazil
Canada
France
European Union
Ghana
Greece
India
Ireland
Malaysia
New Zealand
Panama
Poland
Republic of Korea
South Africa
Switzerland
Thailand
United States of America
Uruguay
Zimbabwe

Codex Observers

World Sugar Research Organization
NHF
FoodDrinkEurope
ILCA
International Dairy Federation
IFPRI
INFACT Canada
IFT
IACFO
ICBA
ICGMA

Annexure 2

Codex Members

Canada

Colombia

European Union

India

Panama

Codex Observers

ICGMA