Background

1. Introduction

1. The 36th session of the CCNFSDU (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 summarised the nine criteria identified as the source of the proposed definition and presented four options for a definition. The Committee agreed not to discuss the proposed definitions at this time and considered whether the criteria contained in the working document were suitable in general to guide the further work of the eWG. The Committee discussed the proposed nine criteria extensively and agreed that they would be used to guide the development of a proposed draft definition for Biofortification.

3. At CCNFSDU38, Zimbabwe, as the co-Chair of the eWG, introduced the paper and noted that the eWG had revised the nine criteria to 6 (six); and based on these, a draft definition had been developed. Accordingly, the eWG made five recommendations for consideration by CCNFSDU. The Chairperson proposed to the Committee to first discuss recommendation 1 (Criteria) and recommendation 2 (the definition for Biofortification) before considering other recommendations.

4. At CCNFSDU39, Zimbabwe, as the co-chair of the eWG, introduced the paper and noted that the eWG had focused on further development of the five criteria to assist in guiding the drafting of the definition. Accordingly, the eWG had made six recommendations (five related to the draft criteria and one on the draft definition) for consideration by the Committee.

5. The Committee noted that a number of aspects in the definition needed further consideration, as well as the questions on where the definition would be placed and how it should be used, and agreed that further work need to be carried on with regard to the proposed draft definition. Some members were of the view that the production methods should not be part of the definition as their inclusion could create potential barriers as competent authorities would seek verification of production methods.

6. The Committee agreed to re-establish the eWG, led by Zimbabwe and South Africa, to further develop the proposed draft definition for Biofortification with the following terms of reference:

- Refine the draft definition and its accompanying footnotes texts on the basis of comments received and CCNFSDU39 recommendations.
- Explore other alternative terms to biofortification.
Consider the request from CAC38 on how the definition would be used and where it would be best placed.

2. The process followed by the Electronic Working Group

The eWG has considered one Consultation Paper to inform the agenda paper for CCNFSDU40 (List of participants is attached as Appendix II). The focus of the Consultation Paper was on refinement of the proposed draft definition for biofortification and its accompanying footnotes texts, explore other alternative terms to biofortification and also indicate where the definition would be best placed and how it would be used. The Consultation paper was posted on the Codex online platform in March 2018.

The following abbreviations have been used throughout this paper: CM: Codex Member; CMO: Codex Member Organisation; CO: Codex Observer; eWG: Electronic Working Group.

The Chairs of the eWG have used feedback from the eWG consultation to prepare this Agenda Paper, which contains five recommendations. A draft definition has been provided at Appendix I.

3. Discussion Points

3.1 Proposed definition for biofortification

At CCNFSDU39 the Chairs proposed the draft definition for biofortification for consideration by the Committee. The Committee noted that a number of aspects in the definition needed further consideration. During the 2018 eWG consultative process the Chairs considered the decisions made by the Committee as well as written comments by members. The Chairs used the proposed texts by CCNFSDU39 as a departure point for the proposed draft definition for biofortification and its accompanying footnotes. The Chairs further proposed another draft definition for biofortification which did not include the last part on “The process applies to any method of production” (and excludes conventional addition of nutrients to food) for the eWG’s consideration.

3.1.1 Responses from the eWG Members on the proposed draft definitions for biofortification

Members who were in support of option one were of the view that it includes methods of production which should be included to allow national/regional competent authorities to decide their preferred methods of production (CM=6, CMO=1, CO=1). Including the methods of production in the definition would ensure that the definition is comprehensive and transparent to member states. This would also be useful to member states that different methods of production were acceptable and they have the authority to decide what methods of production would be acceptable for their jurisdiction. Furthermore, members also indicated that the definition should be clear that it excludes conventional addition of nutrients to foods. One member indicated that allowing competent authorities to prescribe methods of production instead of identifying the desired outcome for biofortification could result in trade restrictions.

Those who were in support of option two were of the view that a simpler definition without the use of many footnotes would be preferable (CM=4, CO=1). Some members indicated that methods of production should not be included in the definition with specific reference to the role of competent national/regional authorities on deciding the methods of production, which could create technical barriers to trade. It was also highlighted that clarity should be made to avoid confusion with conventional fortification to ensure that it was excluded from the definition.

Two members were not in support of any of the two options and they were of the view that the term biofortification should not be permitted in any Codex texts or other related documents since it could hide other methods of production such as genetic modification and other technologies which may have health risks. Two members did not support the proposed two options as currently drafted for various reasons such as the inclusion or exclusion of either method of production and reference to conventional fortification in the draft proposed options, and therefore proposed alternative definitions.

1 REP18/NFSDU
3.1.2 Comments from members on specific texts of the proposed definition

14. One member indicated that the scope of the definition should focus solely on nutrients (as defined in footnote 1) and should not be limited to a specific source organism and the text “of all potential source organisms” should be removed since it may exclude foods that may be biofortified through feed (e.g. vitamin D biofortified eggs). Furthermore, the removal of the text would allow for other sources such as feed to be used and will keep the definition simple. Three Members proposed replacing ‘source organisms’ with ‘food’ which would make it easier to understand since it is a language commonly used to cover all types of suitable food and ingredients. It was also reiterated that the term ‘organism’ should be clarified so that it could be understood that ‘organisms’ that were being referenced within this context were food related, in order to exclude all non-food organisms (e.g. viruses).

15. Two Members reiterated that the amount of a nutrient(s) should be increased by a measurable level and that the nutrient(s) should be bioavailable for the intended purposes. Therefore, both criteria are important and should be reflected in the definition as an increase in a nutrient level may not necessarily result in a more available form of the nutrient to the body. Therefore, changing “or” to “and” in the proposed wording would ensure that the nutrient increase will be sufficient to provide a physiological benefit and therefore address the public health concerns. However, one member was of the view that the inclusion of the term ‘measurable level’ was very specific and would be difficult to measure in relation to increases in the bioavailability of a nutrient. It was also indicated that if ‘biofortified’ claims would be allowed when using the biofortification definition, specific criteria would need to be established to ensure that the claims are not misleading.

16. One Member proposed that any “intended purposes” in the definition should not be specified since a reference in footnote 3 covers the intended purposes reflected in the General Principles for the Addition of Essential Nutrients to Foods (CXG 9-1987). Furthermore, the member did not support the use of any of the three square bracketed terms following the source organisms (i.e. [for] OR [of] OR [and]). It was proposed that the term “in” be used to provide clarity that increased level of a nutrient or enhanced bioavailability happens in the final food.

17. One member indicated that the term nutrient is consistently defined within Codex texts and may not be necessary to define it in the definition and proposed that if it is included it should include a cross-reference to the Guidelines on Nutrition Labelling (CXG 2-1985). One member was in support of clarifying the scope of the proposed definition by continuing to exclude conventional fortification by inserting the exclusion into the main body of the definition, while retaining citation of the Codex General principles for the addition of essential nutrients to foods (CXG 9-1987) in footnote 5 similar to Option 1. This would make clear the scope of ‘conventional addition’ and to adopt the terminology in the General Principles. However, another member was of the view that it may not be necessary to include a statement which expressly excludes conventional fortification if the definition is revised in a manner which is simple and clearly distinguishes between biofortification and conventional fortification. Since fortification is not defined in Codex, the use of the term might create confusion.

3.1.3 Conclusion on proposed draft definition for biofortification

18. The Chairs have noted the comments of members who were in support of either option one or two of the proposed draft definitions for biofortification. Although majority of the members were in favour of option one because of its comprehensiveness since it also includes methods of production, various members made several proposals to the draft texts of this option. Those who were in favour of option two preferred a simplified version of the definition with limited footnotes. The Chairs have looked at both definitions and comments received from the eWG members. The only difference between the two definitions was whether to include the methods of production or not. Several members were of the view that methods of production should be included in the definition and they also made several inputs on the texts that could be included to ensure that the proposed definition still makes reference to the methods of production. The Chairs propose a simplified version of the definition for biofortification, which would still include all the important aspects of the definition, including the methods of production.
Recommendation 1

That CCNFSDU agree to the proposed draft definition for biofortification and its accompanying footnotes:

Biofortification\(^1\) is any process\(^2\) other than conventional addition to food\(^3\) whereby nutrient\(^4\) content is increased or become more bioavailable in all potential food sources\(^5\) for the intended nutritional purposes\(^6\).

1) Some Member governments may prefer to use the equivalent term.

2) Process to be determined by the competent national/regional authority.

3) Conventional addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).

4) Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985).

5) e.g. animal, plant, fungi, yeasts, bacteria

6) Nutritional purpose:

- preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;
- meeting requirements and/or recommended intakes of one or more nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of food.

4. Use of the term biofortification

19. CCNFSDU\(^3\) noted that the term biofortification did not always translate easily, as “bio” had different meanings in different regions of the world. The 2016 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 European Union (EU) languages and the 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 the eWG members to retain the “biofortification” terminology.

20. At CCNFSDU\(^3\) some members observed that in some Member organisations there were legally binding regulations on the use of the term “bio” where it is reserved for organic production. Therefore, a claim for biofortification on a food label of any foods not produced through organic farming could not be supported. One member reiterated the views expressed at previous committee sessions that the focus of biofortification was the breeding of conventional crops as one of the strategies to combat micronutrient deficiencies in the population. However, alternative, but equivalent terminologies to biofortification existed, e.g. agro-fortification, agri-fortification, nutri-fortification, and these could be used in different countries. To bring clarity around the definition, the observer proposed that the Committee could consider inserting a footnote: “Some member governments may prefer to use the equivalent terms such as agri-fortification, agro-fortification, nutri-fortification” to this effect. Noting the potential limitation to the use of the term biofortification in some regions/countries where it was associated with organic agriculture, the Committee agreed that the use of alternative term(s) to “biofortification” be explored.

\(^2\) REP16/NFSDU, para 65
\(^3\) REP18/NFSDU, paras 75-78
21. The 2018 eWG was tasked to consider other alternative terms to biofortification. In order to avoid confusion in some member governments through the use of the prefix “bio” which could be considered synonymous with “organic”, inserting a footnote as proposed by the committee could provide clarity to the consumers as to the intended meaning of the term. The eWG was requested to suggest other alternative terms to biofortification that could be inserted as a footnote. To kick start the discussion by the eWG, the Chairs proposed three alternative terms, namely: agri-fortification, agro-fortification, nutri-fortification for the eWG members’ consideration.

4.1 The eWG Members responses to the use of alternative terms to biofortification

22. Majority of members were not in favour of other alternative terms that could be used instead of biofortification. There was widespread support for the current term of biofortification (CM=10, CO=3). Reasons given for not supporting the alternative terms were that biofortification is a term that has been used for a long time, and is widely accepted and understood by many member states, and is also recognized in other members’ regulatory frameworks. Some members indicated that the use of other alternative terms such as “agro-fortification” or “agri-fortification” could be misleading and would not adequately capture all methods that could be potentially used for biofortification, such as UV irradiation. This could also limit the definition to agricultural crops and exclude animals or animal products such as meats or eggs if such alternative terms could be used. Several members also did not support the use of the alternative term Nutri-fortification as it has the potential to be confused with conventional fortification where nutrients are added to food. One member who supported the use of the term nutri-fortification indicated that the term ‘Nutri-fortification’ which could cover any fortification technique and is fully relevant as the prefix ‘nutri’ indicates that the food has been improved for a nutritional purpose could be used in place of biofortification. Therefore, nutri-fortification could be considered since the concept definition already excludes the conventional fortification which further clarifies the scope of the term.

23. However, some members were not opposed to other regions using an alternative term which could be expressed in a footnote to accommodate other member organizations wherein the prefix “bio” may not be compatible with the existing legislation (for example, “bio” referring to organic farming methods). Another alternative option that was proposed by a member was that the choice of an alternative term be left for national/regional authorities to determine as applicable for their local needs and regulations.

24. Members who were supportive of the use of alternative terms indicated that the term “biofortification” could not be used worldwide as it would not be acceptable in other member organizations where the prefix “bio” was strictly reserved for organic agriculture and organic food products (CM=1, CMO=1, CO=1). One Member indicated that the term ‘biofortification’ was still part of the concept definition, it would not be appropriate as the prefix ‘bio’ did not allow the inclusion in some member organisations of a number of methods currently used to fortify foods by other methods than the conventional fortification. Therefore, footnote would allow Member governments to use an equivalent term. Furthermore, it would be preferred that a single term for the concept definition be agreed on in order to avoid any confusion or misunderstanding.

4.2 Conclusion

25. There was widespread support for the use of the term “biofortification by the eWG members. However, there was an acknowledgement amongst the eWG Members about the use of the prefix “bio” by some member organisations, with a proposal that the use of the alternative term as a footnote could be considered. There was consensus amongst the eWG Members that the use of a single term would be a preferred option for the definition to avoid confusion and misunderstanding. However, the existing legislation in other member organisations wherein the prefix “bio”, was reserved for organic agriculture and organic products might bring challenges in having a common term which could be acceptable by all member organisations. The Chairs are proposing that the term “biofortification” be the preferred term for the concept definition, and a footnote be inserted to the definition to allow other member governments to use an equivalent term. The Chairs are also proposing that an alternative term be left to Member governments to decide in line with their legislative frameworks since there was no consensus amongst the eWG members on the use of other alternative terms.
5. Where the biofortification definition would be best placed

26. CCEXEC70⁴ requested the Committee to clarify how the definition will be used and where it would be best placed. The 2016 eWG members were requested to indicate how the proposed definition for biofortification would be used and where it would be best placed. There was general support amongst the eWG members that the definition should be placed in “The Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)”. It was further indicated that the definition should be placed in a document that is already referenced, where the context would fit best.

27. During the 2018 consultative process the eWG Members were requested to indicate whether they were in agreement with the proposal that biofortification definition be placed in “The Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)” or whether they had alternative proposals.

5.1 Responses from the eWG Members

28. Some members were in support of the proposal to house the definition in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) (CM=4, CO=3). Reasons given for the support were that Codex should eventually develop guiding principles or guidelines related to the labelling of biofortified foods. The discussions should also include defining the appropriate conditions for the use of biofortification, and also conduct further discussions on how the definition would be used.

29. Several members did not support the placement of the biofortification definition in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) (CM=8, CMO=1, CO=2). Reasons given by several members why the proposed document might not be suitable were that the scope of CAC/GL 23-1997 relate to the use of nutrition and health claims in food labelling. The existing conditions for nutrient content claims in CXG 23-1997 might not apply to biofortification or the existing criteria could be too strict. Members were of the view that labelling issues and specific criteria relevant to a nutrient claim or comparative claim for biofortified foods should be discussed first in collaboration with CCFL before determining the placement of the definition. It was emphasized that the use of “biofortified” as a nutrition claim in food labelling is within the scope of CCFL and requires other independent or additional work. Some Members proposed that the definition could be placed in the definition section of Codex Procedural Manual (Definitions for the purposes of Codex Alimentarius, Section 1 – Codex Texts and Definitions, CAC Procedural Manual for member organisations to use or for use in relevant standards or Codex regional standards. This might require referral to CCGP if the Committee were to decide that General Principles should consider a new term defined by consensus in a subsidiary body of the Codex Alimentarius, such as CCNFSDU.

30. Several members indicated that the proposed concept definition does not fit in the scope of the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) as the definition is a concept related to a fortification process which has no link with claims. They would consider that the definition should be inserted in the General principles for the Addition to Essential Nutrients to Foods which addresses fortification in general and where a reference is already made to different types of addition of essential nutrients to food for the purposes described in the document.

⁴ REP 15/EXEC, para 26
5.2 Conclusion

31. The Chairs note the responses from the eWG Members. It was noted that several Members highlighted the shortcomings and challenges that could arise if the biofortification definition were placed in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997). The existing conditions on nutrient and health claims for labelling in CXG 23-1997 may not be suitable for biofortification. A need to develop general principles and criteria on biofortified foods should first be entertained with CCFL before the Committee could consider placing the biofortification definition within the proposed document. The Chairs also note a proposal made by the eWG Members that the definition could be better placed in the definition section of Codex Procedural Manual for use in relevant Codex texts.

Recommendation 3

That CCNFSU entertain the discussion on the placement of the definition for biofortification with CCFL after the finalisation of the development of the definition.

6. How the biofortification definition could be used

32. The 2016 eWG members were requested to propose areas wherein the definition for biofortification could be used, as per CCEXEC70 request. Members proposed the following uses for the definition for biofortification:

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.

33. In order to start the discussion on how the definition could be used, the Chairs requested the 2018 eWG to revisit these proposed areas for use of the proposed biofortification definition, and indicate whether they were in agreement or not.

6.1 Responses from the eWG Members

34. Several Members supported the proposed areas of use for the biofortification definition such as primarily within the existing Codex texts and other areas (CM=7, CO=3). However, two Members were of the view that the proposed biofortification definition was not suitable for use in food labelling because the additional requirements or conditions for use have not been defined. It was also highlighted that the proposed areas of use were illustrative and not exhaustive since the definition could be used by different stakeholders in future. One member emphasized that the internationally recognized definition of biofortification was important for countries in developing their legislation and policies, since biofortification was currently used to increase the nutrient content of certain foods.

35. Some Members who were not in support of the proposed areas of use for the biofortification definition (CM=5, CMO=1, CO=3) were of the view that if the definition was to be included in the Codex Procedure Manual, its primary use would be for Codex Alimentarius purposes such as subsidiary bodies and committees. The inclusion of the biofortification definition into the Codex Procedure Manual could assist in avoiding specifying a list of potential uses. One Member indicated that the Committee should focus on finalizing the definition first and allow CCFL to indicate how and where the definition could be used. Two Members (including the CMO) were of the view that the definition for biofortification should be inserted in the General principles for the Addition to Essential Nutrients to Foods. Furthermore, it is neither the role nor the remit of Codex to develop definitions unless they were linked to a Codex standard, guideline or other text.
6.2 Conclusion

36. Although there was an acknowledgement by the eWG Members on the proposed areas of use for the biofortification definition, such a list may not be exhaustive since Codex may not have control on the use of such a definition for other purposes outside of the Codex texts. Noting the responses from the eWG Members the Chairs are proposing that since the primary use of the biofortification definition will be for Codex, and if the Committee agrees with the placement of the definition for biofortification in the definition section of the Codex Procedure Manual, other proposed areas of use should not be stipulated. It will be assumed that once the definition is placed in the Codex Procedure Manual, it will be primarily used for Codex Alimentarius purposes and other potential uses outside Codex.

Recommendation 4
CCNFSDU agree that the proposed areas of use for the biofortification definition should not be stipulated if the definition will be placed in the Codex Procedure Manual.

7. The distinction between biofortified and non-biofortified foods

37. The 2018 eWG Members were requested to make a consideration on how biofortified foods should be distinguished from non-biofortified foods in order to provide guidance to CCFL, since that was what CCFL41 meeting requested guidance from CCNFSDU. This would enable CCFL to take the process of labelling in relation to biofortified foods further. The Chairs proposed an approach that the eWG should look at in order to provide guidance to CCFL on how biofortified foods could be distinguished from non-biofortified foods.

7.1 The eWG responses

38. Several eWG Members were of the view that the discussion on biofortified foods should be dealt with once the biofortification definition is completed since it was not part of the CCNFSDU mandate. Furthermore, the development of guiding principles and criteria for the use and labelling of biofortified food should be developed. It was proposed that CCNFSDU finalize the establishment of the biofortification definition first, and then refer the matter to CCFL for their consideration.

7.2 Conclusion

39. The Chairs note the responses from the eWG Members that a discussion with CCFL on the distinction between biofortified and non-biofortified foods be entertained once the biofortification definition is completed.

Recommendation 5
That CCNFSDU agree that CCFL entertain the discussion on the distinction between biofortified and non-biofortified foods once a definition for biofortification has been adopted.

8. Recommendations for CCNFSDU

40. 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 the 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 (Appendix I) for discussion.
PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION
(for comments at Step 3 through CL 2018/65-NFSDU)

Biofortification\(^1\) is any process\(^2\) other than conventional addition to food\(^3\) whereby nutrient\(^4\) content is increased or become more bioavailable in all potential food sources\(^5\) for the intended nutritional purposes\(^6\).

1) Some Member governments may prefer to use an equivalent term.
2) Process to be determined by the competent national/regional authority.
3) Conventional addition to food is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).
4) Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985).
5) e.g. animal, plant, fungi, yeasts, bacteria
6) Nutritional purpose:
   - preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;
   - reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;
   - meeting requirements and/or recommended intakes of one or more nutrients;
   - maintaining or improving health; and/or
   - maintaining or improving the nutritional quality of food.
Appendix II

List of Participants

Codex Members

1. Argentina
2. Australia
3. Austria
4. Brazil
5. Burkina Faso
6. Canada
7. Chile
8. Colombia
9. Costa Rica
10. Croatia
11. Ecuador
12. Egypt
13. France
14. India
15. Iran
16. Japan
17. Kazakhstan
18. Korea
19. Malaysia
20. Mali
21. Mexico
22. New Zealand
23. Peru
24. South Africa
25. Sweden
26. Switzerland
27. Thailand
28. Uruguay
29. United States of America
30. Zimbabwe

Codex Member Organisation

1. European Union

Codex Observers

1. AACC International
2. FoodDrinkEurope
3. Food and Agriculture Organisation
4. IACFO
5. IFPRI
6. ILCA
7. Institute of Food Technologists
8. International Baby Food Action Network
9. International Chewing Gum Association
10. International Council for Grocery Manufacturer Association
11. International Council of Beverages Association
12. International Fruit & Vegetable Juice Association