

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 4

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

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### CCEXEC SUB-COMMITTEE ON NEW FOOD SOURCES AND PRODUCTION SYSTEMS – REPORT

*(Prepared by the Chairperson of the sub-committee)*

#### Introduction

1. Since FAO and WHO first introduced new food sources and production systems (NFPS) as an issue that needed attention, Codex has held discussions and collected information on several occasions. Discussions began at 81st session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC81), which established a CCEXEC sub-committee to consider this issue further<sup>1</sup>. CAC44 subsequently considered the issue, supported the need for Codex to be prepared to address cross-cutting, overarching and emerging issues, and requested the Codex Secretariat to issue a Circular Letter<sup>2</sup> (CL) to collect information from Members and observers on ongoing developments related to NFPS. The CCEXEC sub-committee supported the development of the CL and in addition a letter was sent to all Codex Members and observers inviting informal conversations with the Chairperson and Vice-Chairpersons of the Commission to share views on this issue. A detailed overview of this first phase of the work was presented to CCEXEC82 as an interim report of the sub-committee<sup>3</sup>.

#### Overview of discussions at CCEXEC82 and ongoing work of the sub-committee<sup>4</sup>

2. CCEXEC82 considered the interim report of the sub-committee and underlined the complexity of this area. CCEXEC Members expressed different views about the pathway forward, including the need for sufficient time to consider the issues, and the need for specific expertise, or other working mechanisms to engage with the wider Codex membership (e.g. the establishment of an electronic working group (EWG) of the Commission). CCEXEC82 recognised that this ongoing CCEXEC work on NFPS did not preclude Codex committees from undertaking new work on such emerging issues falling within their respective mandates, using existing Codex working mechanisms. In noting the interim report of the sub-committee, the comments put forth during the debate and the extensive amount of data received in response to the CL, CCEXEC82 agreed that the subcommittee should continue its stepwise consideration of the issues, informed by an analysis of the information collected through the CL, CRDs and report of CCEXEC82.

3. With the support of FAO, a summary of the replies to the CLs was subsequently commissioned and is included as Appendix 2 to this report. This was considered further by an informal virtual meeting of the sub-committee.

4. Based on the summary of the replies from the CL, which allowed for a better understanding of the breadth of information about NFPS that was collected through the CL and the informal discussions, a virtual meeting of the sub-committee considered the potential way forward. Members recognized that NFPS presented both a

<sup>1</sup> REP21/EXEC 22/82/4, para 110

<sup>2</sup> The CL received replies from 25 Members and 10 Observers. Informal conversations were held with the six Regional Coordinators, CCAFRICA (Uganda), CCASIA (China), CCEURO (Kazakhstan), CCLAC (Ecuador), CCNASWP (Fiji) and CCNE (Saudi Arabia) and with the European Union, FAO, the Good Food Institute (GFI), International Dairy Federation (IDF), Germany and the United States of America

<sup>3</sup> CX/EXEC 22/82/4

<sup>4</sup> REP22/EXEC1, paragraphs 70-85

challenge and an opportunity for Codex, and that Codex needed to work based on its mandate to keep food safe and promote fair food trade practices.

5. Views on whether Codex was prepared to manage NFPS were divided. Some Members expressed the view that the existing procedures and subsidiary bodies were well prepared to manage proposals for NFPS, although Codex Members could benefit from a reminder of how use those procedures to submit work proposals for new or revised standards. Others underlined the need to have a more in-depth conversation that included the wider membership of the Codex Alimentarius Commission.

**Way forward:**

6. Through the different discussions and interactions that have taken place since this topic was first introduced as a discussion document for CCEXEC81, there is already a considerable amount of information generated within Codex, in addition to the documents already developed by FAO and WHO on this topic. Bearing in mind goal one of the Codex Strategic Plan 2020-2025 that says Codex should address current, emerging and critical issues in a timely manner, CCEXEC83 may consider making recommendations to CAC45 based on the original questions presented by FAO and WHO. Based on the work of the sub-committee CCEXEC83 is invited to consider the following:

(i) Advice on the mechanisms through which FAO/WHO can share these topics of interest with relevant Committees;

- CCEXEC83 could consider:

- o Highlighting to CAC45 the existence of the agenda item titled “Matters arising from FAO and WHO” present in all Codex meetings, which provide an opportunity for FAO/WHO to share topics of interest with relevant Codex Committees.
- o Noting that the Codex Secretariat regularly shares information on relevant FAO and WHO reports and publications with the wider Codex membership through the Codex-L and Codex webpage.

(ii) Modalities to consider how further work could be initiated and taken up by Codex on these cross-cutting issues;

- CCEXEC83 could consider:

- o Highlighting to CAC45 that the existing procedures in Codex can effectively receive and consider work proposals related to NFPS, to develop new or review existing standards. These procedures are contained in Appendix 1.
- o Recommending to CAC45 to invite Members and Observers to take note of the information collected in response to the CL and as a consequence of the informal discussions.
- o Recommending to CAC45 to encourage Members to submit proposals on NFPS using the existing mechanisms.

(iii) Processes that would allow Codex to holistically evaluate and prioritize potential need for actions on these cross-cutting issues.

7. Some Members and Observers mentioned that current procedures and structures are not enough to address all challenges on NFPS, that some NFPS presented a need for a more coordinated and holistic approach from the Codex system, and that Codex Members and Observers could benefit from a more in-depth discussion on how to address current, emerging and critical issues in a timely manner.

8. To that end, CCEXEC83 could consider the possibility of recommending to CAC45 to convene an EWG reporting to CAC to explore possibilities to promote better coordination between subsidiary bodies or review the existing Codex structure (procedures and/or subsidiary bodies), recognizing that this should not prevent Members from presenting proposals on NFPS using the existing procedures.

**APPENDIX I****Current Codex procedures relevant to new work proposals**

The following Codex procedures described in the Procedural Manual should be considered before embarking on new work on NFPS:

- General Principles of the Codex Alimentarius (Section I Basic texts of the Codex Alimentarius, Codex Procedural Manual)
  - Purpose: The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.
  - Scope: The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined.
  - Nature: Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented.
  - Codex definition of food: Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food”.
- Guideline on the Application of the Criteria for the Establishment of Work Priorities. (Section III Elaboration of Codex Texts, Codex Procedural Manual)
  - In principle, an evidence-based approach that addresses multiple factors shall be taken when the Executive Committee examines proposals for new work to develop or revise commodity standards. Project proposals should include:
    - i. Volume of production and consumption in individual countries and volume and pattern of trade between countries.
    - ii. Diversification of national legislation and apparent resultant or potential impediments to international trade.
    - iii. International or regional market potential.
    - iv. Amenability of the commodity to standardization
    - v. Coverage of the main consumer protection and trade issues by existing or proposed general standards.
    - vi. Number of commodities which would need separate standards indicating whether raw, semi-processed or processed.
    - vii. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).
- Procedures for prioritization in subsidiary bodies: some committees have created mechanisms to do horizon scanning to prioritize work and improve their capacity to develop or amend standards in a timely manner.

**SUMMARY REPORT OF THE SUBMISSIONS FROM CODEX MEMBERS AND OBSERVERS AS  
CONTAINED IN DOCUMENTS CX/EXEC 22/82/4, CCEXEC 83 REP22/EXEC1 AND EXEC 82/CRD 2**

**TABLE OF CONTENTS**

<b>Introduction .....</b>	<b>5</b>
<b>Chapter 1: The landscape in NFPS .....</b>	<b>5</b>
<b>Cultivated meat, seafood, and dairy .....</b>	<b>5</b>
<b>Fermentation-derived ingredients .....</b>	<b>6</b>
<b>Plant-based protein alternatives .....</b>	<b>7</b>
<b>Seaweed .....</b>	<b>8</b>
<b>Edible insects .....</b>	<b>8</b>
<b>3-D printed foods .....</b>	<b>9</b>
<b>Microalgae .....</b>	<b>9</b>
<b>Chapter 2: Codex structure to address NFPS .....</b>	<b>10</b>
<b>Summary of responses to questions regarding existing Codex texts and structures to     address NFPS .....</b>	<b>10</b>
<b>Codex way forward for NFPS .....</b>	<b>12</b>

## Introduction

1. New foods sources and production systems (NFPS) is an area that is already growing fast, and it is very likely to grow even more over time, consequently discussions have begun in the Codex Alimentarius Commission on if and how to address NFPS. In line with these debates, a Circular Letter (CL 2022/06-EXEC) was issued to all Members and Observers to seek inputs on NFPS. This report provides an analysis of the information received through the CL<sup>5</sup>, and informal consultations<sup>6</sup> between the chairperson of the sub-committee and interested Members and observers held between April and June 2022. Any time terms such as some, many, most members etc. are used in this report it refers to the sub-group of Codex Members and Observers that provided input on this issue and not the full Codex membership.

2. Responses indicate that while some Members have experience with many of the NFPS, there is still a need to understand and learn more about the potential food safety, regulatory, labelling, nutritional, and quality issues of specific NFPS. Members and Observers underlined the complexity of this area and expressed different views about the possible impacts and the pathways forward.

3. With regard to the need for Codex to start work on this issue, most Members and Observers agree that the modification of existing Codex standards or the development of new standards could reduce future trade barriers and provide a more harmonized global regulatory framework for these products. The new or amended rules should be flexible enough not to stifle future technological innovation. There is no agreement on the mechanisms to be used by Codex to address NFPS, most Members and Observers commented that the existing subsidiary bodies, as well as the procedures contained in the procedural manual, are respectively well equipped and adequate to start work on NFPS, while other Members and Observers think there is a need for new subsidiary bodies to be created. The main suggestions and concerns identified by Members and Observers are presented in chapter 2 of this document.

## Chapter 1: The landscape in new foods and production systems

4. For better clarity, some Members and Observers believe the definition of “new food” should be further explained and discussed. Various Members consider the majority of the new foods highlighted in the document are not foods themselves, but rather non-traditional processes to produce food. Some Members, especially from low- and middle-income countries, still lack the knowledge and basic information to conduct safety assessments of alternative protein production processes. Most Observers express concern about the labelling of these products, especially those intended to replace an existing product.

5. The main topics highlighted in the Circular Letter by Codex Members and Observers for NFPS are discussed below.

### Cultivated meat, seafood, and dairy

#### *Regulatory concerns*

6. In many regions, a regulatory framework already exists and cultivated meat products require pre-market authorization. Some of the responding Members have already had applications and have approved products for sale. Meanwhile, others have not yet received applications for such foods. In other Member countries there are no national standards or frameworks to address new foods. Various Observers expressed the need for a common acceptable definition for tissue engineered food such as cell culture/cultivated meat

#### *Labelling aspects relevant to consumer protection and fair-trade practices*

7. Some Members agree there would not be any specific requirements for the labelling for these products. Other Members and Observers pointed out that new foods may have additional specific labelling requirements to provide information on any specific characteristic or food property and to ensure that consumers are not misled and have the knowledge to make informed, healthy and sustainable food choices. In addition, some Members believe there could be food allergen related concerns when it comes to new food sources. One Member stated

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<sup>5</sup> Comments from Argentina, Australia, Canada, Chile, China, Consumer Goods Forum, Costa Rica, Denmark, Ecuador, Egypt, ENSA, EU Specialty Food Ingredients, European Union, European Vegetable Protein Association, Fiji, Food Industry Asia, Good Food Institute, IAEA, ICUMSA, IDF/FIL, India, Indonesia, International Meat Secretariat, Japan, Kazakhstan, Kingdom of Saudi Arabia, Malaysia, New Zealand, Norway, Republic of Korea, Thailand, Uganda, United Kingdom, Uruguay, United States of America.

<sup>6</sup> Informal discussions were held with the European Union, FAO, the Good Food Institute (GFI), International Dairy Federation (IDF), the United States of America and the six regional coordinators: CCAFRICA (Uganda), CCASIA (China), CCEURO (Kazakhstan), CCLAC (Ecuador), CCNASWP (Fiji) and CCNE (Saudi Arabia).

that consumers have long been accustomed to the use of the word “cultured” in the context of “milk”, which they know refers to fermented milk products which have been inoculated with bacterial cultures. When the term “cultured” is also used to describe milk that is made from cell culture technology, consumers may inadvertently be misled.

*Nutritional aspects*

8. For Members who carry out pre-market assessments for new foods, the nutritional profile of the food is considered. Some Members stressed that the nutritional value of new foods does not differ significantly from the food it is intended to replace. The fortification with vitamins and minerals to align the nutritional profile or the creation of alternatives with a ‘healthier’ nutritional profile (e.g. lower saturated fat, higher fibre) was also highlighted.

*Food safety aspects*

9. Many Members agree that new foods should undergo a safety evaluation, food safety authorities should also ensure that production facilities are hygienic, are implementing measures to minimize or prevent contamination, and that good manufacturing practices are followed. Some Members identify the implementation of a HACCP based preventative approach or regulatory infrastructure as very relevant. Other Members considered that the primary emphasis from a food safety perspective should be on testing the end product to confirm the safety of the foods for consumption. One Member considered that due to possible upregulation of protein allergens relative to primary cells, it would be useful for the development of species-specific allergen lists that could be tested for cultured meats, prior to consumption or trade. A Codex Observer considered that given the great number of cell multiplications taking place, the possibility of genetic alterations should be assessed.

*Quality aspects*

10. Several Members considered that new products should be fully characterized, including a detailed description of the manufacturing process and composition of the food, food safety aspects and quality. The pre-market assessment of cultivated meat, seafood or dairy established by many Members should consider the quality attributes of the new food.

*Any other matters relevant to the mission of Codex*

11. Research is being carried out in some regions by the government, academia, and/or the private sector. In certain Member countries, the halal status of cultivated meat, seafood and dairy (i.e. source of stem cell) is one of the main concerns.

**Fermentation-derived ingredients**

*Regulatory concerns*

12. Some fermentation products may not be new and are already distributed in some Member countries. However, new types of fermentation-derived ingredients might require pre-market approval. Some ingredients could be regulated as food additives under existing regulations in some territories. Various Members are in the process of reviewing the national policy and legislation of these products. One Member Country highlighted the case of Steviol glycosides from fermentation (INS 960b), which after a review by JECFA, was considered by Codex and provisions for Steviol glycosides for a range of food categories were included in the General Standard for Food Additives.

*Labelling aspects relevant to consumer protection and fair-trade practices*

13. Most Members agreed that regarding fermentation-derived ingredients, labelling guidelines must consider proper allergen labelling including the prominent declaration of ingredients that may cause hypersensitivities using terms that are fully understood by consumers.

*Nutritional aspects*

14. Some Members mention that in nutritional terms it is important to establish the content of protein, fats, amino acids, and other compounds. As the digestibility of this nutritional content is also relevant. The nutritional contribution of this type of products could also be analysed.

*Food safety aspects*

15. Some Members proposed the use of Risk Analysis methodology to identify the chemical, physical or microbiological hazards, and to evaluate the effect of each of the identified processes on risk associated with the

defined hazards. New microbes may require pre-market approval to assess the safety of the ingredients they produce. Likewise, guidelines should be provided to support evaluation of whether fermented ingredients contained toxic contaminants and/or organisms with antibiotic resistant genetic elements. One Observer considered that the use of non-pathogenic strains which do not produce harmful metabolites should be assured.

*Quality aspects*

16. Members discussed the importance of having validated methods in place to characterise products of fermentation

*Any other matters relevant to the mission of Codex*

17. One Member was concerned about the alcohol level of these products and referred to national legislation in some Member countries that are based on religious grounds and required that all products must be alcohol free. Another Member and one Observer believed it may be helpful for Codex to consider distinguishing between biomass and precision-based fermented products, given the differences in the technologies and the resulting products, as well as their regulatory status.

**Plant-based protein alternatives**

*Regulatory concerns*

18. Many Members reported that a wide range of plant-based proteins have been consumed as food for a long time in their regions, therefore they are not considered as new foods. However, certain new plant-based ingredients may require regulatory assessment. For example, infant formula based on alternative proteins is required to undergo pre-market assessment and are considered new within the infant population.

*Labelling aspects relevant to consumer protection and fair-trade practices*

19. Terminology that is/isn't permitted for these products has also been raised as an issue by some Members and Observers. For some Members these issues are related to the use of traditional animal food names in plant based food products (e.g. almond milk, oat milk), for other Members, the issue was declaration of misleading or ambiguous nutritional values on the labels of plant products. Moreover, an Observer stated that the definition of "plant-based" and "100% plant-based" has yet to be clearly defined worldwide, which is creating consumer confusion in terms of whether the products labelled as such are vegan, vegetarian, contain animal-derived ingredients, or have been produced using animal or microbial genes. Another Observer highlighted their belief these products should not be named with reference to animal species or meat/fish trade terminology.

*Nutritional aspects*

20. Plant-based meat and dairy substitutes may have nutritional profiles that differ from traditional foods. Some Members allow the fortification of plant-based products; however, others have limitations in this regard. Another concern expressed by some Members is the bioavailability and quality of the plant proteins, as well as other nutrients. In recent years, issues have arisen regarding high levels of sodium, saturated fat, and sugar in some plant-based protein alternatives.

*Food safety aspects*

21. Some Members indicated that the main considerations for safety included the production system (fermentation, mechanical processing, and chemical extraction), the products (protein of interest) and by-products (antinutrients, toxicants), amino acid profile, stability, dietary exposure, and their safety in the intended use. Another Member considered that the primary emphasis from a food safety perspective should be on testing the end product to confirm the safety of the foods for consumption.

*Quality aspects*

22. One Member suggested a minimum content of crude protein, fat, and additional ingredients could be established to secure the quality of products. Another Member recommended the use of sensitive methods to detect process-related impurities and antinutritional components that might be present.

*Any other matters relevant to the mission of Codex*

23. According to some Members, plant-based products and other alternative proteins do not fit into the existing Harmonized System (HS) codes established by the World Customs Organization (WCO), a Codex Observer organization. The HS codes do not reflect the range of ingredients currently used in alternative plant-based

proteins or the various formulations that are evolving in this category, leading to ambiguity and, in some cases, higher duty rates for producers exporting their products to other markets.

## **Seaweed**

### *Regulatory concerns*

24. Seaweed is already consumed and regulated in many regions, where this is the case, it is not considered a new food and falls within existing regulatory frameworks. Some of these products are also used in feed. Some Members mentioned that new species of seaweed may require pre-market approval as new foods. Other Members do not have specific legislation for seaweed.

### *Labelling aspects relevant to consumer protection and fair-trade practices*

25. Most Members don't have specific labelling requirements for seaweed. One Member established a voluntary labelling system for products with high iodine content, to inform consumers on a possible risk by eating too much, particularly for vulnerable groups. Codex has already established a regional standard for seaweed, CXS 323R-2017 Regional Standard for Laver Products. This regional standard addresses the labelling needs for this product using the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985).

### *Nutritional aspects*

26. Currently there is limited information from the Members regarding nutritional aspects of seaweed. One Member noted that there are a lot of reported nutritional benefits in the literature on the use for both food and feed. There are however no authorised health claims that can be attributed to consumption of seaweed as food.

### *Food safety aspects*

27. The main food safety concerns discussed by the Members and Observers include the possibility of heavy metals, excess iodine levels, and other pollutants such as pesticides and marine toxins. It is very important to be aware of the great differences between different species of seaweed as regards their constituents, including content of hazards as iodine and metals and other hazards as biotoxins. Some Members establish limits for heavy metals in seaweed.

### *Quality aspects*

28. Codex has already established a regional standard for seaweed, CXS 323R-2017 Regional Standard for Laver Products. This regional standard addresses the essential composition and quality factors, weights, and measures. Methods of analysis and sampling are covered within the regional standard by a reference to the Recommended Methods of Analysis and Sampling (CXS 234-1999).

## **Edible insects**

### *Regulatory concerns*

29. Currently, there is a growing interest in the use of insects for food and feed, and new products are under development. While in some territories a variety of edible insects are very popular and have a history of safe use for human consumption, certain edible insect species and products may be considered as a new food. Some Members have no legislation regarding insects and in others, edible insects are considered on a case-by-case basis to determine whether pre-market approval is necessary. In Members following the Islamic approach in regulating some food products, some insects are considered non-halal.

### *Labelling aspects relevant to consumer protection and fair-trade practices*

30. The main concern regarding labelling of edible insects is allergens. The potential cross-reactivity with shellfish/crustacean allergy was also noted by some Members.

### *Nutritional aspects*

31. The nutritional composition of edible insects is difficult to generalize, due to the large number of species consumed. Edible insects are known to have high levels of protein, consequently some Members believe they could be good alternatives to traditional sources of this macronutrient.

### *Food safety aspects*



32. The main food safety concerns from various Members point of view were linked to the production practices related to feeding, breeding conditions and general management of insects that can determine their contamination with microbiological and chemical contaminants. Some Members and Observers indicated the need to carry out an allergenic risk assessment for insect and insect-based products, particularly due to insects and crustaceans belonging to the same arthropod family and in turn there being a degree of allergenicity cross over.

*Quality aspects*

33. One Member suggested the implementation of a standard to guarantee the minimum moisture content, crude protein, fat, and additional raw materials that can ensure microbial safety.

**3-D printed foods**

*Regulatory concerns*

34. This production process is in current use in some regions for a number of different product applications and will likely be used for additional applications over time, including assembly of plant-based, animal cell, and microbial ingredients. 3-D printed foods would not require additional review unless the printed use is significantly different than those uses already allowed for the ingredient. It is likely these foods will be made up of many ingredients, which may or may not require pre-market approval.

*Labelling aspects relevant to consumer protection and fair-trade practices*

35. One Member suggested that when manufacturing 3-D printed foods, pre-treated food ink was absolutely necessary, and since specific nutrients and functional ingredients were pre-packed or distributed in cartridge form as food ink, the food ink should be marked as “Ink for 3-D printed foods” so that it can be distinguished from general food ingredients.

*Nutritional aspects*

36. One Member highlighted their belief that given the significant degree of processing involved in producing 3-D printed foods, fortification with vitamins or minerals may be needed to make up for processing losses. 3-D printed foods may help provide nutrition to people with digestive disorders, such as problems with swallowing. Another Member argued that it was not clear that this production process would have any significant relationship to nutrition.

*Food safety aspects*

37. One Member reported that this technology could cause some food safety problems, such as potential migration of chemicals from the 3-D printer to food, inability to clean all surfaces that come in contact with the food ink. Another Member highlighted their belief that it may be helpful to consider whether there are any broad commonalities in potential sources of microbial hazards associated with this production process that could be a useful focus for development of broadly applicable good manufacturing practices (GMP) beyond those already in use in food production.

*Quality aspects*

38. In one Member country, sensory and quality attributes were tested to make sure the product met specifications. Another Member considered that due to the nature of ink containing a large amount of nutrients and functional ingredients, it was necessary to set standards for quality assurance.

*Any other matters relevant to the mission of Codex*

39. One Member highlighted their belief that there was a need to secure consumer trust on these products. Another Member considered; it may also be worth considering the inclusion of 4-D printing. The 4th dimension is time and so something that is 4-D printed has the ability to change characteristics over time or with addition of an external factor like temperature (e.g., changes shape).

**Microalgae**

*Regulatory concerns*

40. A few types of microalgae and products derived from microalgae are already used in food products in most territories. In some cases, pre-market approval may be required as a new food. Depending on the intended use of microalgae (or products derived from microalgae), it may require pre-market approval as a nutritive substance.

*Labelling aspects relevant to consumer protection and fair-trade practices*

41. Members did not point out any relevant aspects regarding labelling of microalgae. One Observer pointed out that a common agreed definition of microalgae does not exist.

*Nutritional and quality aspects*

42. One Member highlighted their belief that a standard should establish the minimum protein content, vitamin content, and essential fatty acid content in microalgae to ensure consistent quality.

*Food safety aspects*

43. According to one Member, bioaccumulation of heavy metals, pesticides and other pollutant may occur in microalgae and present a health risk. A different Member pointed out that as with any plant used for food, it was important to consider whether there were toxins and antinutrients produced either constitutively or in response to certain growth conditions that could raise safety concerns.

**Chapter 2: Codex structure to address new foods and production systems**

44. Some Members and Observers highlighted their belief that existing Codex horizontal and product standards could partly cover some of the NFPS requirements, but do not appear to be suitable for direct application to some new foods already marketed in certain jurisdictions. Most Members believe it may be premature to consider changing existing structures (subsidiary bodies) and processes (contained in the Codex Procedural Manual) when a specific issue to be addressed by Codex has not yet been identified by a committee or a Member; these Members were of the opinion that unless a specific need is presented by a Member or Observer that cannot be addressed by the current structure, there was no justification for a novel approach within Codex.

45. Most Members and Observers considered work was needed to identify gaps on food safety and trade related to the emergence of new agri-food technologies. Should gaps be identified, consideration could be given as to why they exist and possible solutions. New work should proceed when it was supported by sufficient science and there was significant international trade, consistent with the Working Principles for Risk Analysis in Codex and an evaluation according to the Codex Criteria for the Establishment of Work Priorities.

46. Some Members mentioned the need to create new subsidiary bodies or review the terms of reference of existing ones to accommodate the demand for international reference standards for NFPS.

**Summary of responses to questions regarding existing Codex texts and structures to address new foods and production systems**

*Do existing Codex standards cover the issues(s) identified?'*

47. Most Members and Observers trust horizontal Codex standards partly cover food safety and labelling issues. Some of the current vertical standards may also be applicable to new foods if they are related to a product that already has a Codex standard (e.g.; CXS 323R-2017 Regional Standard for Laver Products; General Standard For Vegetable Protein Products (VPP) - CXS 174-1989 - General Standard For Soy Protein Products (SPP) - CXS 175-1989 - Standard for Wheat Protein Products Including Wheat Gluten – CXS 163-1987 - Regional Standard for Fermented Soybean Paste (Asia) - CXS 298R-2009 - Regional Standard for Non-Fermented Soybean Products - CXS 322R-2015; General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods (CXG 4-1989)). However, the extent to which existing Codex standards cover all relevant health and safety, labelling or trade concerns would require further assessment and existing texts which cover aspects such as the assessment of allergenicity (e.g. CXG 45-2003) may need updating . Specific committees can use existing mechanisms to assess whether current standards sufficiently address the issues identified in the Circular Letter. Moreover, some Members and Observers consider these are new products, therefore current Codex standards would not cover the issues identified.

*If not, what would be the need for and benefit of a Codex Standard in the areas you have identified?*

48. Various Members and Observers trust the setting of Codex standards for new foods/new food sources would help to enhance human health protection at global level, fair trade practices, provide a more harmonized global regulatory framework for such products and deliver useful tools for control and enforcement authorities. These new or amended standards should be flexible enough to avoid stifling innovation and allow for maximum flexibility in the technology used to produce foods. Other Members consider specific committees can use existing mechanisms to assess whether current standards sufficiently address the issues identified in this Circular Letter.

*How would you recommend the issues you have identified as needing a Codex Standard be prioritized?*

49. A group of Members believed Codex procedures could be used to select the key issues, and they proposed CCEXEC could provide advice to the Commission on prioritization of issues affecting multiple committees. Another group of Members suggested a proposal on the issues which should be prioritized. As first priority, most Members would develop food safety and hygiene standards, and then nutrition and labelling.

*What is your assessment of the scientific basis needed to work on the issues identified?*

50. Various Members considered that advice from the FAO/WHO scientific bodies would be necessary taking on board a One Health approach to food safety risk assessment. In accordance with the process in the Procedural Manual for proposing new work or revision of a standard, a proposal would need to identify any requirement for and availability of expert scientific advice. Through this process, it could be assessed whether the existing expert bodies were well placed to provide the necessary advice, and if not, explore additional options. One Observer was concerned about the quality of the available literature and believed there is little progress to date.

51. Members indicated data were required on

- Nutritional aspects.
- Effects of production processes on new food.
- Food history of the source of origin of the new food.
- Intended use of the new food and the expected amount of consumption.
- Information on previous human consumption of the new food.
- Relevant microbiological information of the new food.
- Toxicity of the food or its components.
- Allergenicity of the new product or some of its components.

*What additional information, evidence or analysis would be required for new work proposals to be developed for any of the issues you have identified in your answer to question a.?*

52. Various Members concurred that once their safety was established, consumer information, perception and acceptance of the new foods and new food sources were key determinants for their successful contribution to healthy diets from sustainable food systems. Another Member suggested that in order to prepare standards and/or guidelines for new food sources and production systems, consumption-related data from Members could be collected. The need for new work would also depend on the specific nature of the foods and should take into consideration the purpose of the foods.

*Approaches to developing Codex standards.*

53. Most Members believed that consideration of new approaches for developing additional standards was premature. The information received through this Circular Letter might help determine whether there were key emerging issues that relevant Codex committees could provide further advice on. Otherwise, they considered the existing process for proposing new work, provided the necessary mechanism to assess which committee/s were best placed to address the particular issue identified. Certain Members and Observers proposed the work should be first addressed vertically for products and then horizontally in general standards or texts.

*Codex already has a range of working mechanisms (e.g., committees (some adjourned sine die with potential to reactivate), task forces, working groups, matters referred, and cross-committee working groups).*

- i. Do these mechanisms provide Codex with sufficient tools to address the issues you have identified?

54. The Members and Observers who answered this question agreed the majority of issues for NFPS can be addressed by the standing general subject committees and fall within the existing mandates of those committees. However, from what was indicated in the replies to other questions it can be deduced that other Members and Observers do not agree and would not consider current Codex structures to be enough.

- ii. If so, how can they be best used to do that? (e.g., if there is no obvious committee entry point for a new work proposal, how could this be considered within the current structure?)

55. Some Members suggested the proposed work could begin by consulting FAO experts so that they could provide a basis/guideline for the development of standards or guidelines to be developed with these issues. Other Members and one Observer believed it would be preferable for CAC to either establish an ad hoc intergovernmental task force with a specific mandate to work on these emerging topics or to establish a working group

- iii. Do you think existing Codex tools need to be adapted to ensure they are sufficiently flexible to address these issues and if so how (e.g., broadening/revising Terms of Reference of Committees) or do we need to consider any new/additional working mechanisms?

56. Various Members agreed current Codex working mechanisms were enough to address the emerging issues. However, other Members suggested that more flexibility should be given to existing Codex committees to ensure that some new issues could be considered or addressed. Some Members proposed all Codex committees should review and assess whether any Codex standards, guidelines, or codes of practice within their scope needed to be updated to address these new foods and report back to the Codex Alimentarius Commission on their findings and recommendations for potential new work in this area. Other Members and one Observer considered that NFPS are being developed and expand rapidly with the development of food tech, therefore the establishment of a new Codex committee or task force was necessary for pre-emptive safety management and risk communication on these issues.

### **Codex way forward for new foods and production systems**

57. Two main categories of options were identified among the replies to the CL as possible pathways for Codex to start work on NFPS; on the one hand Members and Observers were content that the current Codex structure was well prepared for NFPS, while others expressed the need to create a new structure.

### ***The existing Codex structures are sufficiently flexible to start work on new foods and production systems.***

58. Within the existing Codex structures and mechanisms, the following could be considered:

- a. New work proposals must be brought to the CAC in accordance with procedures set forth in the Procedural Manual.
  - The Procedures for the Elaboration of Codex Standards and Related Texts were mentioned, with special emphasis on the critical review:
    - Prior to approval for development, each proposal for new work or revision of a standard shall be accompanied by a project document, prepared by the Committee or Member proposing new work or revision of a standard. The decision to undertake new work or to revise standards shall be taken by the Commission taking into account a critical review conducted by the Executive Committee.
- b. Give more flexibility to existing subsidiary bodies to ensure they can address the new scenario of NFPS.
- c. The standing committees should consider the issues raised in the collective response to CL 2022/06/OCS-CCEXEC to identify issues that fall under their mandates, seek additional information as to which products/production methods are in use in international trade, and develop an approach for the management of the work on the issues identified by Members, including requesting scientific advice from the FAO/WHO expert bodies and/or expert consultations. For example:
  - i. Labelling would be largely covered by existing general Codex labelling standards. Where specific labelling was needed because a new food may require consideration of allergen labelling requirements, as maybe the case with some insects, or naming issues of some of the plant-based protein alternatives, these could be developed in the Codex Committee for Food Labelling (CCFL).
  - ii. Processed foods including, cultivated meats could be put to the Codex Committee on Food Hygiene (CCFH).
  - iii. Nutrition issues, such as nutrient expectations of consumers with varied nutrient content of alternatives to milk, could be considered by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

**Existing/active subsidiary bodies are not adequate or sufficiently prepared to start work on NFPS, and there is a need for the establishment of a new subsidiary body on new foods and production systems and or revision of procedures and or terms of reference of existing subsidiary bodies, for example:**

59. Proposals relating to this view included:

- a) Creation of a new Committee on NFPS
- b) Give more flexibility to existing subsidiary bodies to ensure they can address the new scenario of NFPS, this could probably mean reviewing/amending their terms of reference)
- c) Establishment of a Task Force.
- d) Activation of subsidiary bodies that are currently in *sine die* mode.

60. One Member highlighted their belief that the new foods mentioned in the document are foods for which there is no relevant trade, nor is their consumption disseminated worldwide or regionally, nor have relevant issues been identified that currently justify the development of standards in this regard, which is the purpose of Codex. Therefore, it would not be justified to allocate resources or prioritize this issue when the budget is limited, as manifested annually, having relevant issues that impact on trade today. These new issues may need to be addressed, at this stage, by national, regional or international bodies whose priority is research.

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