

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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REVISED PROJECT DOCUMENT SUBMITTED BY THE UNITED STATES OF AMERICA

NEW WORK PROPOSAL TO DEVELOP A STANDARD FOR COMPLEMENTARY FOODS, FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

I. Purpose and Scope of the New Work

The purpose of this project is to develop a Standard for Complementary Foods- Baby Foods, and Processed Cereal-based Foods, which include complementary foods, for Older Infants and Young Children (persons aged 6 months to 36 months).

*The Guidelines on formulated complementary foods for older infants and young children (CXG 8-1991) defines **Formulated Complementary Foods** as foods that are suitable for use during the complementary feeding period. These foods should be specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement family foods derived from the local diet and should provide nutrients which are either lacking or are present in insufficient quantities.*

CXG 8-1991 defines the **Complementary Feeding Period** as the period when older infants and young children transition from exclusive feeding of breastmilk and/or breast milk substitutes to eating the family diet.

The scope of the proposed new standard would be:

- The standard applies to complementary food-baby foods, and processed cereal-based foods, which includes complementary foods, for older Infants and young children, including but not limited to meat, vegetable, fruit or pulses-based products, and other formulated complementary foods foods for older infants and young children, and includes canned baby foods and processed cereal-based foods. This standard does not apply to beverages (follow-up formula and product/drink) for older infants and young children. The complementary foods in this standard can be provided in the form of canned baby foods, cereal based foods, or other formats.

Breastmilk substitutes are a separate category of products from complementary foods and will not be considered in the proposed standard. In accordance with the Codex definition of complementary foods, complementary foods are intended to complement the feeding of breastmilk as older infants and young children make the transition from sole source nutrition from breastmilk or infant formula to dietary patterns composed of solid foods. Therefore, the products covered by the proposed standard are not breastmilk substitutes and should not be formulated or presented as such.

II. Relevance and Timeliness

Complementary feeding of children between the ages of 6 and 36 months is necessary for healthy growth and development at this critical period. In 2023 the WHO issued an update of the WHO Guideline for complementary feeding of infants and young children 6-23 months of age.¹ These guidelines use a food-based approach and recommend a diet diverse in daily animal-source foods, daily fruits and vegetables, and adequate pulses, nuts, and seeds. The Guideline also recommends limiting foods high in sugar, salt, and trans fat.

In December of 2023 an expert consultation was held to consider the recommendations of the updated WHO Guideline and approaches to making food systems work for complementary feeding in low and middle-income countries, including through support from international assistance programs, such as USAID. This consultation concluded that food systems are not meeting the needs of children in low- and middle-income countries and that two in three children are not able to be fed diverse diets needed for healthy growth and development

¹ World Health Organization. "Guideline for complementary feeding of infants and young children 6-23 months of age." (2023): 96-96.

during this critical period of development. This same conclusion was reached in a 2021 report published by UNICEF.² When possible, food systems should be improved to provide affordable, locally grown, nutrient-dense foods needed for the nutritional needs of older infants and young children. When this is not possible, formulated complementary foods can play an important role in meeting dietary and nutritional needs of this age group.

Market research has shown that complementary foods have increased in volume and diversity in the global trade.³ However, international standards to guide composition and labelling for complementary foods are lacking, outdated, or not followed. A recent report found that most commercially available fortified complementary foods are not nutritionally adequate.⁴

The Codex Secretariat's recent review of CCNFSDU standards ([CX/NFSDU 24/4/7](#)) identified both the *Standard for Canned Baby-Foods* (CXS 73-1981) and the *Standard for Processed Cereal Based Foods for Infants and Young Children* (CXS 74-1981) as standards in need of revision and/or update. The proposed new standard would replace these standards and establish science-based nutrition, quality, and safety provisions for the foods currently covered by these outdated standards and for complementary foods for which there are no current Codex standards.

It is therefore both relevant and timely that Codex develop a Standard on **Complementary-Foods for Older Infants and Young Children**.

III. Main Aspects to be Considered

The proposed standard would incorporate the foods from the two existing standards related to **complementary foods for older infants and young children** (CXS 73-1981 and CXS 74-1981). The main aspects that this proposed standard would consider are as follows:

- Relevant updates in light of current scientific findings and recommendations for complementary feeding for persons aged 6-36 months
- **Complementary**-foods **for older infants and young children** comprised of basic food groups including animal-source foods, fruits and vegetables, cereals and grains, pulses, nuts, and seeds as individual foods or in food group combinations
- Essential compositional and safety factors, including food group requirements and nutritional composition
- Additional food safety, quality, packaging, labelling, and analytical methods and sampling provisions, as appropriate
- Name and structure of the standard

IV. Assessment Against the Criteria for the Establishment of New Work Priorities General Criteria:

A standard on **complementary**-foods for older infants and young children will provide:

- Scientifically supported, evidence-based direction and guidance to Codex Members, policymakers, and non-governmental organizations who wish to establish and use up-to-date, science-based guidelines for the formulation of **complementary**-foods **for older infants and young children** and implement associated policies;
- Food business operators with a clear and consistent direction on nutritional criteria for product formulation; and
- Consumers with more consistent and nutritionally balanced products to reduce their risk of potentially inadequate or excess nutrient intakes.

Criteria applicable to general subjects:

a. Diversification of national legislation and apparent resulting or potential impediments to international trade

² United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

³ <https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-foodtrends-canada-united-states-mexico-cusma#a>

⁴ Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr.* 2017; 13:e12421. <https://doi.org/10.1111/mcn.12421>

The lack of a science-based standard to guide the nutritional composition, safety, quality, and labelling for complementary-such foods as the market size of and consumption of these products grow⁵ has led to divergence and/or variability in approaches to managing the nutritional composition of these products. The absence of Codex guidance to promote more harmonized approaches can result in impediments to trade.

A 2017 report found that most commercially available fortified complementary foods are not nutritionally adequate, and a 2021 UNICEF report states that few affordable products are appropriately formulated in low-income countries.^{6,7} There is currently no international, science-based standard to ensure that the foods that are being traded meet the nutritional needs of the target population, resulting in health risks and impediments to international trade. Developing a Codex standard would help address issues of availability, affordability, and accessibility of appropriately formulated products. It is necessary to take action to develop a science-based, international standard to reduce existing and potential impediments to trade.

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

The proposed standard would include a food-based approach including animal-source foods, fruits and vegetables, cereals and grains, pulses, nuts, and seeds as individual foods or in food group combinations to provide nutritional composition guidance that is aligned with international, science-based dietary guidance for the target age group. Essential compositional and safety factors, including mandatory and optional nutrient addition and guidance on quality, packaging, labelling, analytical methods and sampling considerations would also be addressed with the aim of providing an international standard with which countries could harmonize their regulations for complementary-foods for older infants and young children.

All sections of the proposed standard are of high priority for the text to be maximally useful, but first priorities will be to develop a scope that covers all complementary-such foods and to update nutritional composition provisions to reflect current science.

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

The WHO recently updated its guidelines on complementary infant feeding.⁸

d. Amenability of the subject of the proposal to standardization

Codex has developed standards for specific categories of complementary-foods for older infants and young children—in the past—the *Standard for canned baby-foods* (CXS 73-1981) and *Standard for processed cereal based foods for infants and young children* (CXS 74-1981)—so it is clear that this category of foods is amenable to standardization. As established in the introduction and paragraph on relevance/timeliness, complementary-foods for older infants and young children have expanded to encompass more food groups and product varieties and an international standard that covers all these products is needed. Based on the success of past work to develop standards for complementary-such foods, there is no reason to question the amenability of the subject of this proposal to standardization.

e. Consideration of the global magnitude of the problem

The recently updated WHO guideline demonstrated through its dietary modelling work that nutrient gaps exist even in best-case food patterns. A further consultation supported by USAID found that food systems are not meeting the nutritional needs of children in low- and middle-income countries and that two in three children in the target group (aged 6-36 months) are not able to be fed diverse diets needed for healthy growth and development during this critical period. Recent UNICEF findings confirm this is a global public health challenge and other studies have found that most commercially available fortified complementary foods are not nutritionally adequate.⁹ Developing a Codex standard for complementary foods to ensure they are nutritionally adequate and safe can help address these global issues in a timely manner.

⁵ <https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-food-trends-canada-united-states-mexico-cusma#>

⁶ Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr.* 2017; 13:e12421. <https://doi.org/10.1111/mcn.12421>

⁷ United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

⁸ https://cdn.who.int/media/docs/default-source/nutrition-and-food-safety/complementary-feeding/cf-guidelines/dietarymodelling.pdf?sfvrsn=8e2abbff_3

⁹ United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

V. Relevance to the Codex Strategic Plan's¹⁰ Goals and Objectives

The proposed work is consistent with the Commission's mandate to develop standards, guidelines and other international recommendations to protect consumer health and to ensure fair practices in the food trade. The new standard will contribute to the achievement of Strategic Goals 1, 2, 3, and 4.

- **Goal 1: Address current, emerging and critical issues in a timely manner**

Recent research has found that food systems are not meeting the complementary feeding needs of children, especially in low- and middle-income countries. Two in three children in the target group are not able to be fed diverse diets needed for healthy growth and development during this critical period.¹¹ Complementary foods have increased in volume and diversity in the global trade,¹² but most commercially available fortified complementary foods are not nutritionally adequate¹³ and not all foods currently marketed are covered by existing Codex standards. While food systems should be improved to provide affordable, locally grown, nutrient-dense foods, this proposal recognizes that critical issues have emerged in older infant and young child nutrition and that developing a Codex standard for complementary- such foods to ensure they are nutritionally adequate and safe can help address these issues in a timely manner.

- **Goal 2: Develop standards based on science and Codex risk-analysis principles**

The proposed standard would be based on recent science and Codex risk analysis principles. This project may seek scientific advice if needed to set composition requirements for individual complementary-foods or food groups for the target population. The standard will seek and rely on globally representative nutrition data and input from all Codex Members and may request additional scientific advice from the Joint Expert Meeting on Nutrition (JEMNU) as required to complete the work.

- **Goal 3: Increase impact through the recognition and use of Codex standards**

This proposed new work would need to incorporate and update the relevant information from the existing related Codex standards and would be complementary to the work CCNFSDU has completed in the development of the *Standard on infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981) and the *Standard on follow-up formula for older infants and product for young children* (CXS 156-1987) providing guidance to governments to ensure that foods for infants and young children are safe and nutritionally appropriate. This will fill important gaps and thereby increase the impact and use of Codex standards.

- **Goal 4: Facilitate the participation of all Codex Members through the standard setting process**

Complementary-foods for older infants and young children are relevant to all Codex Members and regions. In particular, the proposed standard would provide a food-based approach, either as individual foods or food group combinations, applicable globally. The participation of all Codex Members is necessary to set a standard that serves all Codex regions and the development of a proposed standard that is relevant to all Members encourages and facilitates participation in the standard setting process. The proposed new work would seek to use all available means, electronic, virtual, and physical, to reduce barriers to active participation in this standard setting process.

VI. Relationship Between This Proposal and Other Existing Codex Documents

CCNFSDU has three texts related to complementary feeding of older infants and young children: *Guidelines on Formulated Complementary Foods for Older infants and Young Children* (CXG 8-1991), *Standard for Canned Baby-Foods* (CXS 73-1981), and *Standard for Processed Cereal Based Foods for Infants and Young Children* (CXS 74-1981).

The *Guidelines* (CXG 8-1991) provide nutrient targets for complementary foods that are based on WHO/FAO data that are two decades old.¹⁴ The Codex Secretariat's recent review of CCNFSDU standards ([CX/NFSDU 24/4/7](#)) identified both the CXS 73-1981 and the CXS 74-1981 as standards in need of revision and/or update. CXS 73-1981 and CXS 74-1981 provide requirements for composition of canned baby foods and cereal-based complementary-foods; they only cover canned baby foods without a designated age range and cereal-based

¹⁰ For more information, please see the [Codex Strategic Plan 2021-2025](#)

¹¹ Choudhury, Samira, Derek D. Headey, and William A. Masters. "First foods: Diet quality among infants aged 6–23 months in 42 countries." *Food Policy* 88 (2019): 101762.

¹² <https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-foodtrends-canada-united-states-mexico-cusma#a>

¹³ Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr.* 2017; 13:e12421. <https://doi.org/10.1111/mcn.12421>

¹⁴ World Health Organization. *Vitamin and mineral requirements in human nutrition*. World Health Organization, 2004.

foods for infants and young children. Codex standards are lacking for other complementary foods, such as meat, vegetable, fruit or pulses-based products. Other related texts are the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979), *General principles for the addition of nutrients to foods* (CXG 9-1987), and the Committee's ongoing work to establish General Principles and Nutrient Reference Values-Requirements (NRVs-R) for persons aged 6-36 months.

The new work will take into consideration all the existing Codex texts in developing a single new standard for ~~complementary~~ foods for older infants and young children. It will incorporate and update the relevant aspects of existing texts and replace two Codex texts: CXS 73-1981 and CXS 74-1981.

VII. Requirement For and Availability of Expert Scientific Advice

CCNFSDU may need scientific advice from the Joint Expert Meeting on Nutrition(JEMNU).

VIII. Need for Technical Input to the Standard from External Bodies

None anticipated.

IX. Proposed Timeline

The work can be completed in four (4) sessions, with final adoption at Step 8 by 2029.

ASSESSMENT AGAINST THE CCNFSDU PRIORITIZATION CRITERIA

CCNFSDU Prioritization Criteria:

a) Impact on public health:

The target group for this new work proposal is older infants and young children aged 6 to 36 months, consistent with the target group for the three Codex texts that this new work proposes to consolidate, update, and replace. Recent research has found that food systems are not meeting the needs of children in low- and middle-income countries.

- Two in three children in the target group are not able to be fed diverse diets needed for healthy growth and development during this critical period of development.¹
- A 2021 UNICEF report found that 48 percent of children in this age group are not fed with the minimum meal frequency and 71 percent do not have minimally diverse diets, leading to nutritional inadequacy.²
- Science-based international standards to guide composition and labelling for complementary foods are lacking and/or outdated.
- There is currently no international standard to ensure that the products that are being traded meet nutritional needs of the target group

The new work would have a positive impact on an urgent, global public health issue by developing an international standard to help meet the nutritional needs of the target group. This new work would address:

- a. nutritional inadequacy of formulated complementary foods given the lack of standards for these foods,
- b. outdated standards for certain limited foods in this category, and c. issues with accessibility, affordability, and availability of nutrient-dense foods in local food systems for the target group. Furthermore, the new work would be developed using a food-based framework that encourages food-based dietary patterns and nutritional composition consistent with the WHO's recent infant feeding recommendations.

As there is currently no recent international standard to guide the composition, safety, and quality of complementary foods and the need to develop one to address a public health issue is well evidenced by international and scientific studies, this proposal views that there would not be any unintended public health impacts to the target group if this new work is undertaken by CCNFSDU.

b) Impact on food safety

The proposed new work will have a positive impact on food safety in that it seeks to establish nutrition, quality, and safety parameters for complementary foods.

The Codex Secretariat's recent review of CCNFSDU standards ([CX/NFSDU 24/4/7](#)) identified both the CXS 73-1981 and the CXS 74-1981 as standards in need of revision and/or update. The single standard proposed in the project document would establish up-to-date nutrition, quality, and safety provisions for the foods currently covered by outdated as well as many foods for which there are no current Codex standards.

Food safety considerations in this new work will include but not be limited to: processing methods, contaminants, hygiene, food additives, packaging, and labelling for foods for which there currently are no such provisions or outdated provisions in existing standards.

c) Impact on trade practices

Complementary foods are a diverse and growing market, and recent international studies have demonstrated that many foods in this category are not appropriately formulated to be nutritionally adequate for the target group which can lead to a lack of harmonization in regulations relevant to these foods. There is a need to develop an international standard to guide the nutritional, quality, and safety standards for these foods. The lack of a standard has resulted in current and potential future trade barriers where there is a divergence of national regulations. The proposed new work would enable national authorities to harmonize their regulations

1 Choudhury, Samira, Derek D. Headey, and William A. Masters. "First foods: Diet quality among infants aged 6–23 months in 42 countries." *Food Policy* 88 (2019): 101762.

2 : United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

and facilitate fair practices in the food trade, positively impacting the accessibility, affordability, and availability of nutritionally adequate complementary foods globally.

d) Global impact

The proposed new work is suitable for addressing a worldwide nutrition problem, as established in multiple recent studies by scientific bodies and international organizations.

- A 2021 UNICEF report found that 48 percent of children in this age group are not fed with the minimum meal frequency and 71 percent do not have minimally diverse diets, leading to nutritional inadequacy.³ The report further states that few affordable products are appropriately formulated in low-income countries, indicating the need for an international standard to guide the nutritional composition of these foods.
- In December of 2023 an expert consultation of international experts hosted by the Micronutrient Forum considered the recommendations of the updated WHO Guideline and aspects of making food systems work for complementary feeding in low and middle-income countries through support from USAID.⁴ This consultation concluded that food systems are not meeting the needs of children in low- and middle-income countries and that two in three children in the target group are not able to be fed diverse diets needed for healthy growth and development during this critical period of development.
- A 2017 study found that most commercially available fortified complementary foods are not nutritionally adequate and an international standard for these foods is necessary.⁵

Science-based international standards to guide composition, safety, and labelling for complementary foods are lacking and/or outdated and there is a worldwide nutritional inadequacy for the target group of this proposed new work. Developing an international standard for these foods that provides food-based nutritional, quality, and safety parameters directly contributes to improving worldwide nutrition for the target group.

3 : United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

4 Micronutrient Forum. Making food systems work for complementary feeding in low- and middle-income countries: Meeting report. Washington, D.C.: Micronutrient Forum; 2024.

5 Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr.* 2017; 13:e12421.

<https://doi.org/10.1111/mcn.12421>

REVISED PROJECT DOCUMENT SUBMITTED BY CANADA AND THE UNITED STATES
NEW WORK PROPOSAL TO DEVELOP GENERAL GUIDELINES AND PRINCIPLES FOR THE
NUTRITIONAL COMPOSITION OF FOODS FORMULATED WITH PROTEIN FROM PLANT SOURCES

1. Purpose and Scope of the New Work

- The purpose of this project is to develop general guidelines and principles for the recommended nutritional composition of foods⁶ formulated with protein from plant sources, which are substitute foods⁷ for animal-based products.
- The scope of products for this project:
 - includes processed foods formulated with protein derived from plants, which are substitutes for animal-based products, such as meat, poultry, fish/seafood, or dairy products. Examples of these products are included in the **Annex**.
 - excludes animal-based protein products and animal cell-based protein products (i.e. cell-cultured foods); and
 - excludes non-plant alternative protein sources (e.g., bacteria, fungi)

2. Relevance and Timeliness

- In the last decade dietary guidance has evolved to encourage more plant-based foods, and consumer interest in plant-based foods has increased. As a result industry has innovated numerous new plant-based substitute food products, found in markets internationally. Currently, international policies and regulations on nutritional composition that apply to these products vary greatly, which has resulted in a lack of consistency in products across global markets, created trade barriers, and impacted consumer understanding. Taking steps now to establish base principles for jurisdictions to use in the development of guidance and regulations, while the market is still growing and evolving, will increase international harmonization and help mitigate these issues.
- The nutrient profile of foods formulated with protein from plant sources varies widely, and their composition is often very different from the animal-based foods they resemble and are intended to replace. When consumers replace animal-based foods with products formulated with protein from plant sources, which are not nutritionally similar to the animal-based food, nutritional adequacy of diet patterns may be affected, having both positive and negative public health impacts.
 - The FAO recently completed a literature review to assess the nutritional composition of foods made from plant-based and other alternative protein sources, which are intended to replace animal-based products, and compared the nutritional composition of these products to their animal based counterparts.⁸
 - An important finding was that plant-based products intending to replace meat and dairy products had large variability in nutrient composition within food subgroups. For example, the protein content of plant-based products imitating seafood and sausage ranged from 1 - 44g/100g and 8 – 25g/100g, respectively.
 - The work also highlights that across several categories, plant-based alternatives had significantly lower protein content than the animal-based counterparts. This was particularly evident for plant-based products intending to replace dairy products. For example, plant-based products imitating cheese contained an average of 10-fold lower protein than cheese. Apart from soy-beverages, plant-based products intending to replace milk also had an average of approximately

⁶ For the purposes of this project, foods includes beverages, aligning with the definition of “food” in the Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) which includes drinks. Available from: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf

⁷ Substitute foods, per the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987), are foods which resemble a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles. Available from: [fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B9-1987%252FCXG_009e_2015.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B9-1987%252FCXG_009e_2015.pdf)

⁸ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

- 3-fold lower protein than milk, with coconut beverages⁹ having the lowest protein content (over 8-fold lower than milk).
- While some plant-based alternatives had lower levels of nutrients to limit i.e., saturated fat, sugars and sodium, others did not. For example, coconut beverages had approximately 3-fold higher saturated fat content compared to milk, and oat and rice beverages had 2-3 fold higher sugar content than milk. Plant-based products intending to replace chicken and fish fillets also had 2-fold higher sodium content than animal-based chicken and fish.
 - Evidence from published research on micronutrient content was limited.
- Recent market shifts in the plant-source of substitute foods further raise concerns regarding nutrient composition, as substitute foods made with lower protein content and/or from lower protein quality sources are taking up more of the market share. For example, in the United States soy beverages saw a drop in market share in 2023, falling to the 3rd largest segment for the category behind both almond and oat beverages. Importantly, coconut beverages were the only plant-based beverage to see growth in 2023, jumping to take the fourth spot in the market.¹⁰ On average, almond, oat and coconut contain significantly lower protein content and quality than soy beverages, with coconut beverages having the lowest protein content amongst plant-based beverages assessed in the FAO's recent literature review.
- There are existing Codex guidelines and principles for vegetable protein products and for substitute foods, however these do not accurately reflect the current food environment and do not provide advice specific to this growing sector. Tailored recommendations for these products are needed.
 - The existing Codex *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987) provides broad recommendations for the addition of essential nutrients to substitute foods.¹¹ Additionally, these general principles relate specifically to the addition of nutrients to foods, while the current proposal would be establishing nutrient composition with or without nutrient addition.
 - Similarly, the existing Codex *General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods* (CXG 4-1989) provides general recommendations for the nutritional quality of products using vegetable protein products that are partial or total replacements for animal protein foods. These guidelines have not been updated since 1989, and do not cover the full breadth of products or compositional aspects proposed for this project.
 - Neither of these existing general principles/guidelines provide recommendations specifically for the nutritional composition of foods formulated with protein from plant sources that are substitutes for animal-based products. This has led to inconsistent applications of the recommendations to these products.
 - Should the composition of these replacement products be based on the nutritional profile of the products they are replacing, in particular those nutrients in the animal-based foods that are a significant contributor to meeting dietary adequacy of essential nutrients? Should foods formulated with protein from plant sources be formulated to be nutritionally equivalent to the animal-based foods they are replacing? And, if so, for all nutrients? Or only essential nutrients?
 - Internationally, guidelines and regulations vary greatly for foods formulated with protein from plant sources. Canada, for example, has strict composition requirements for simulated meat and poultry products, and fortified plant-based beverages. Other jurisdictions have exercised limited oversight of foods formulated with protein from non-animal sources. This has resulted in inconsistent formulations of products globally, which may impact consumer understanding and contribute to trade barriers.

⁹ The report primarily used the term "(naming the plant source) milk", however for consistency with our proposal and to align with Codex *Standard for the Use of Dairy Terms* (CXS 206-1999) we have used the term "beverage" of "product intending to replace milk".

¹⁰ Good Food Institute. U.S. retail market insights for the plant-based industry. Available at: <https://gfi.org/marketresearch/#introduction>. Accessed on April 17 2024.

¹¹ "A food which resembles a common food in appearance and texture and is intended to be used as a complete replacement or partial replacement for the food it resembles" (Codex General Principles For The Addition Of Essential Nutrients To Foods)

- In an attempt to clarify the application of existing rules and promote market consistency, in 2023 Canada updated their guidelines for simulated meat and poultry products.¹² These updates provide additional guidance for industry to better understand when food products do and do not meet the definition of a simulated meat or poultry product, and also provide a clear summary of labelling and composition requirements for these products.
- In 2023 the United States published and consulted on draft guidance for industry on the labeling of plant-based beverages.¹³
- In March 2022, the Codex Secretariat requested information (CL 2022/06-EXEC) on new food sources and production systems (NFPS), with an emphasis on regulatory initiatives and nutrition and food safety aspects related to seven categories: cultivated meat, seafood, and dairy; fermentation-derived ingredients; plant-based protein alternatives; seaweed; edible insects; 3-D printed foods; and microalgae. A summary of the responses was presented at CCEXEC in June 2022, which highlighted the need for Codex to contribute to this topic by identifying gaps and assessing the need to develop Codex texts to allow for the safe consumption and fair trade of these products.¹⁴ NFPS was discussed again at CAC46 in December 2023, with the conclusion that it is important to address challenges posed by NFPS and that Codex could play an important role in this, and that current Codex mechanisms were adequate to address new work on NFPS. Members were encouraged to submit discussion papers and new work proposals on NFPS to active Codex committees or the Executive Committee.¹⁵

Codex general guidance and principles for the recommended nutritional composition of foods formulated with protein from plant sources has the potential to support consumer health as consumers move to more plant-based and alternative protein diet patterns, to improve consistency in global markets, and to reduce impediments to trade from more harmonized regulations. This current proposal may also align with the broader Codex interest in NFPS, in particular the nutrition and regulatory aspects of products based on proteins from plants, fermentation-derived ingredients, edible insects, and microalgae. During its discussions of these issues at CAC46, it was emphasized that Codex has an important role to play in addressing challenges posed by NFPS and that initiation of new work related to NFPS by Codex committees under their existing terms of reference is encouraged.

3. Main Aspects to be Considered

It is proposed to establish general guidelines and principles for foods formulated with protein from plant sources which are substitutes foods for animal-based products, for:

- guiding the development of policies and regulations for the recommended nutritional composition of these products, taking into account regional differences in dietary patterns and consumption;
- establishing recommended nutritional profiles for these products based on nutritional equivalence (e.g., protein quality, essential nutrients); and
- addressing nutrients of public health concern when consumed in excess of recommendations (e.g., saturated fat, sugars, sodium) and anti-nutritional factors in these products.

It is proposed the guidance cover the following aspects:

- Purpose (see section 1)
- Scope (see section 1)
- Definitions, if needed and appropriate
- General Principles, may cover:
 - essential nutrients;

¹² Government of Canada. Simulated meat and simulated poultry products. Available at: <https://inspection.canada.ca/food-labels/labelling/industry/meat-and-poultry-products/simulated-products/eng/1631881284839/1631882112387>. Accessed on April 17 2024.

¹³ U.S. Food and Drug Administration. Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>. Accessed on April 17 2024.

¹⁴ CX/EXEC 22/82/4, Agenda Item 4, CCEXEC sub-committee on new food sources and production systems – interim report.

¹⁵ CAC46, Agenda Item 4, [fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%25E2%2598%2585Final%2BReport%252FREP23_CACe.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%25E2%2598%2585Final%2BReport%252FREP23_CACe.pdf)

- protein quality;
- nutrients of public health concern when consumed in excess of recommendations (e.g., saturated fat, sugars, sodium); and
- anti-nutritional factors
- Guidelines may include guidance for:
 - identifying the foods and beverages within scope of the guidelines and that are considered substitutes foods for animal-based products; and
 - recommended composition and nutrient profiles

The placement of this guidance (standalone or as an amendment to existing text) is proposed to be considered at a later stage.

4. Assessment Against the Criteria for the Establishment of New Work Priorities

General Criteria:

- Clear general guidance and principles for the recommended composition of substitute foods formulated with protein from plant sources, which take into account regional differences in dietary patterns and consumption, can provide:
 - Codex Members and policy makers globally who wish to establish science-based guidelines, policies, or regulations with harmonized, evidence-based direction and guidance;
 - Industry with a clear and consistent direction for nutritional criteria for product formulation; and
 - Consumers with more consistent and nutritionally balanced products to reduce their risk of potential inadequate or excess nutrient intakes.

Criteria applicable to general subjects:

- (a) *Diversification of national legislation and apparent resulting or potential impediments to international trade*

The plant-based protein food market is growing rapidly internationally. Currently, there is substantial variability in approaches to manage the nutritional composition of these products through regulations and guidance. Given the increased awareness and interest from both industry and consumers, greater global harmonization of policies related to the nutritional composition of these products would help reduce barriers to trade and minimize potential negative health impacts. Action in this area is needed in the near future as this market is still evolving and developing.

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

Develop general guidance and principles for the recommended nutritional composition of foods formulated with protein from plant sources which are substitute foods for animal-based products with the aim to inform policies of regions and countries wishing to provide greater oversight of these products.

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

Other international organizations have not developed guidance for the nutritional composition of foods formulated with protein from plant sources. However, there is some internationally relevant work that can be leveraged (e.g., FAO protein work, FAO healthy and sustainable dietary guidelines¹⁶, etc.). FAO asked the Codex Executive Committee (CCEXEC) to consider how Codex could contribute to guidelines and policies related to NFPS, and it was concluded that existing Codex committees should encourage proposals for new work in this area.^{17,18}

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

¹⁶ <http://www.fao.org/3/I5640E/i5640e.pdf>

¹⁷ CX/EXEC 22/82/4

¹⁸ CAC46, Agenda Item 4, fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%252E2%2598%2585Final%2BRReport%252FREP23_CACe.pdf

As this is an emerging topic and most jurisdictions do not have standards or guidelines in place, standardization on a voluntary basis of the nutritional composition of foods formulated with protein from non-animal sources is possible.

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

The rapid increase in availability and use of plant protein source foods is a global trend marked by innovation by industry, and is expected to continue to increase as consumer interest in these products and dietary recommendations world-wide encourage plant-based protein foods. There are also global environmental sustainability benefits associated with plant-based protein diets compared to diets rich in animal products, highlighted by some recent dietary recommendations such as the planetary health diet.¹⁹ Variability in the nutritional composition of these products and lack of current science-based oversight creates the potential for consumer health impacts on a global scale and may create barriers to trade.

5. Relevance to the Codex Strategic Plan's²⁰ Goals and Objectives

The proposed work is consistent with the Commission's mandate to develop standards, guidelines and other international recommendations to protect consumer health and to ensure fair food trade practices. The new guidelines will contribute to the achievement of Strategic Goals 1, 2, 3, and 4.

- **Goal 1: Address current, emerging and critical issues in a timely manner**
 - Objective 1.1. To identify needs and emerging issues
 - Objective 1.2. To prioritize needs and emerging issues
 - The plant protein source food market is booming globally, and dietary recommendations are now encouraging consumption of more plant-based protein foods. The need for Codex engagement has already been recognized by the CCEXEC Sub-Committee on NFPS. General guidance and principles on the recommended nutritional composition of these products is consistent with considerations in the CCEXEC Sub-Committee and at CAC46.
 - Currently, international policies and regulations that apply to these products vary greatly, which has resulted in a lack of consistency in products across global markets, created trade barriers, and increased consumer confusion. Providing general nutrition guidance and principles for countries who wish to establish science-based guidance, policies, or regulations – now while the market is still growing and evolving - would support the goal of achieving a basic level of global harmonization.
- **Goal 2: Develop standards based on science and Codex risk-analysis principles**
 - Objective 2.1. Use scientific advice consistently, in line with Codex risk-analysis principles.
 - Objective 2.2. Promote the submission and use of globally representative data in developing and reviewing Codex standards.
 - Submission of data from around the world will be encouraged, and available global data will be used throughout the process. For example, recent data from the FAO that may be leveraged used a global lens to compare the nutrient composition of foods made from plant-based protein sources internationally.
 - Therefore, the development of general guidance and principles for foods formulated with protein from plant sources will be consistent with the use of scientific advice and risk analysis principles, and will be globally-representative.
- **Goal 3: Increase impact through the recognition and use of Codex standards**
 - Objective 3.2: Support initiatives to enable the understanding and implementation/application of Codex standards
 - This work would enable better understanding and application of the substitute food section of the Codex *Principles for the Addition of Essential Nutrients to*

¹⁹ <https://eatforum.org/eat-lancet-commission/eat-lancet-commission-summary-report/>

²⁰ For more information, please see the Codex Strategic Plan 2021-2025 at <https://openknowledge.fao.org/server/api/core/bitstreams/873535ff-0f01-4305-822e-2ff3b5f9b003/content>

Foods (CAC/GL 9-1987, Rev. 2015) and the *Codex General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods* (CXG 4-1989).

- This project will consider whether it is necessary or appropriate to apply or extend the application of the substitute food section of the *Codex Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987, Rev. 2015) to plant-based and other alternative protein source foods.
- **Goal 4: Facilitate the participation of all Codex Members through the standard setting process**
 - Objective 4.1: Enable sustainable national Codex structures in all Codex Member Countries.
 - Objective 4.2: Increase sustainable and active participation of all Codex Members.
 - Objective 4.3: Reduce barriers to active participation by developing Countries.
 - Foods formulated with protein from plant sources are a globally relevant sector, impacting both developed and developing countries. The project will need to consider whether Codex commodity standards may require updating to accommodate the application of plant-based raw materials to the formulation of foods formulated with protein from plant sources.
 - This work is relevant to all Codex regions with respect to both production of raw materials and manufacturing of finished products.
 - Developing general guidance and principles for the recommended nutritional composition for foods formulated with protein from plant sources within the CCNFSDU would enable all Codex Members and Observers with an interest in these products to participate in the discussion.

6. Relationship Between This Proposal and Other Existing Codex Documents

- The proposal relates to the CCEXEC interim report on NFPS (CX/EXEC 22/82/4) and subsequent discussions on NFPS at CAC46 as products within scope of this proposal overlap with the food category, plant-based protein alternatives, included in the circular letter.²¹ Members have been encouraged to submit discussion papers and new work proposals on NFPS to active Codex committees or the Executive Committee.
- The proposal relates to the nutritional equivalence principle in the *Codex General Principles for The Addition of Essential Nutrients to Foods* (CXG 9-1987) and the *Codex Guidelines on Nutrition Labelling* (CXG 2-1985). As described above, the application of the *General Principles for The Addition of Essential Nutrients to Foods* to these products is unclear and has resulted in inconsistent implementation of the guidance, and does not provide advice specific to these products which is needed.
- The proposal relates to the compositional guidelines for foods using vegetable protein products that are partial or complete substitutes for animal protein in the *Codex General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods* (CXG 4-1989). As described above, these guidelines have not been updated since 1989 and do not cover the full breadth of products or compositional aspects proposed for this project.
- The proposal may also relate to Codex commodity standards for products which would be used as ingredients in plant-based protein source foods, such as the *Codex General Standard for Vegetable Protein Products* (CXS 174-1989), the *Codex General Standard for Soy Protein Products* (CXS 175-1989), and the *Codex Standard for Wheat Protein Products Including Wheat Gluten* (CXS 163-1987).

7. Requirement For And Availability Of Expert Scientific Advice

- CCNFSDU may consult the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) on scientific matters regarding nutritional adequacy/equivalence, including protein quality.
- The FAO recently completed a literature review to assess the nutritional composition of foods made from plant-based protein sources, which are intended to replace animal-based products , and compared the nutritional composition of these products to their animal based counterparts. This work also established a database of alternative protein foods currently sold in the USA and

²¹ CL 2022/06/OCS-CCEXEC

EU, and proposed nutrient profiles for the assessment of alternative protein sources. This information and database likely addresses the key information required for the proposed work.

- The FAO has also recently commissioned a robust set of systematic reviews to assess the impacts of animal source alternatives on nutrition and health, food safety, environment and socioeconomics. The results of these reviews may provide additional evidence and information to support the proposed work.
- The FAO also published an issue paper in 2021 in response to the recent growth of the edible insect sector.²² This paper highlighted both challenges and opportunities for the sector, and provides advice regarding food safety considerations for edible insects.

8. Need For Technical Input From External Bodies

- No need identified at this stage.

9. Proposed Timeline

- The project document will be submitted for consideration ahead of the 44th CCNFSDU in October 2024.
- It is expected that the CCNFSDU may require four (4) sessions to complete its work, further to the relevant contributions and subsequent agreement of the Members.
- The resulting text would then be submitted for the approval of the Commission by 2028, with final adoption expected to take place by 2029.

²² FAO. 2021. Looking at edible insects from a food safety perspective. Challenges and opportunities for the sector. Rome. <https://doi.org/10.4060/cb4094en>

Examples of products within scope for this project

Plant protein-based alternatives to ground meat:



Plant protein-based alternatives to meat burgers and meatballs:



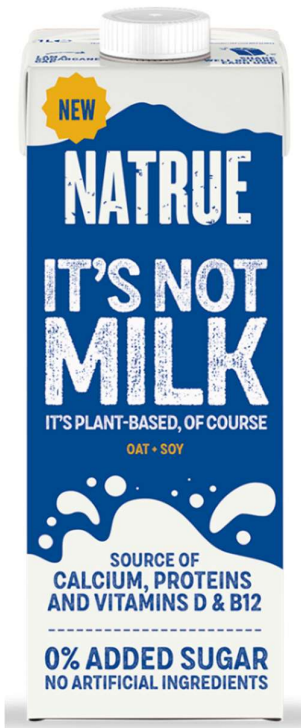
Plant protein-based alternatives to chicken:



Plant protein-based alternatives to fish and seafood products:



Plant protein-based alternatives to milk:



Plant protein-based alternatives to dairy products:

