

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization



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Agenda Item 6.2

CX/NFSDU 24/44/6 Rev¹

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

2-6 October 2024

Comments in reply to CL 2024/52-NFSDU

PROPOSALS FOR NEW WORK/EMERGING ISSUES

(Replies by Canada, the United States of America (USA), and the Calorie Control Council)

INTRODUCTION

1. The 43rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU43) agreed to establish an electronic working group (EWG) open to all Members and Observers, chaired by Canada and co-chaired by Germany, working in English and French with the following terms of reference:

to prepare a revised draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU, including the prioritization criteria and the decision tree, taking into account the comments made in the PWG held prior to CCNFSDU43 as well as the comments and decisions made at CCNFSDU43.

2. CCNFSDU43 also agreed to request that the Codex Secretariat issue a CL requesting for proposals for new work using the revised draft guideline, which would be implemented on a trial basis.

3. A physical working group (PWG), chaired by Canada and co-chaired by Germany, working in English, French and Spanish will be established and held in conjunction with CCNFSDU44 to consider the revised draft guideline on a trial basis and assess any new work proposals received in response to the aforementioned CL.

4. CL 2024/52-NFSDU was sent out to all Members and Observers in May 2024. Members and Observers were invited to provide proposals for new work relevant to CCNFSDU. In identifying emerging issues and/or proposals for new work / emerging issues, Members and Observers should provide information in line with the proposed Draft Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU.

5. Until 31 July 2024, one proposed amendment and two new work proposals were received in response to CL 2024/52-NFSDU.

CONCLUSION

6. This document presents:

- A comprehensive overview of all new work proposals (amendments and revisions) as well as potential future areas of work (review of existing standards and emerging issues) (Annex I).
- The proposals for amendments and new work received in response to CL 2024/52-NFSDU (Annex II).

RECOMMENDATIONS

7. A PWG will meet prior to CCNFSDU44 in order to consider and assess the new work proposals submitted in reply to the CL using the guidelines and criteria as outlined in the Draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU (see CL 2024/52-NFSDU, Appendix I).

8. CCNFSDU44 is invited to consider the report of the PWG and the new work proposals in light of the prioritization mechanism (see CL 2024/52-NFSDU, Appendix I).

¹The cover page and Annexes I and II (pages 1 to 6) were prepared by the CCNFSDU Secretariat.

INVENTORY OF CCNFSDU PROPOSALS AND POTENTIAL FUTURE AREAS OF WORK (ALL-TIME LIST)

No.	Year(s) discussed	Title of Work	Prepared/ Raised by	Result of prioritization process of PWG	State of Play
(A) PROPOSALS					
PART 1: AMENDMENTS/REVISIONS					
1.1	2023	Proposed amendment/revision: <i>Standard for canned baby foods</i> (CXS 73-1981)	Dominican Republic	PWG recommendation: Delete paragraph 9.5.2 from the standard CXS 73-1981. The amendment shall be submitted directly to CAC46 for adoption. (CRD6, CCNFSDU43)	CCNFSDU43 agreed to the recommendation of the PWG to delete paragraph 9.5.2 from Standard CXS 73-1981 and submit the amendment directly to CAC46 for adoption. (REP23/NFSDU, para. 100) CAC46 adopted the amendments to the <i>Standard for canned baby foods</i> (CXS 73-1981), (REP23/CAC, para. 53)
1.2	2023	Proposal to align the permitted uses of the folic acid source Calcium-L-Methyl-Folate with those of N-Pteroyl-L-Glutamic acid in the <i>Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children</i> (CXG 10-1979)	Switzerland	PWG recommendation: Revision of the Advisory List of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-Methyl-Folate by adding four additional checkmarks in the columns Sec. A, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies. The amendment shall be submitted directly to CAC46 for adoption. (CRD6, CCNFSDU43)	CCNFSDU43 agreed to the recommendation of the PWG to revise the Advisory list of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies and submit the revision directly to CAC46 for adoption. (REP23/NFSDU, para. 101) CAC46 adopted the amendment to the <i>Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children</i> (CXG 10-1979). (REP23/CAC, para. 53)
1.3	2024	Proposal to open and amend the 2009 Codex definition of dietary fibre included	Calorie Control Council	<i>to be completed</i>	<i>to be completed</i>

		under para. 2 in the <i>Guidelines on nutrition labelling</i> (CXG 2-1985)			
PART 2: NEW WORK					
2.1	2023	Harmonized probiotic guidelines for use in foods and food supplements	Argentina and Malaysia	PWG recommendation: It is recommended that Argentina/Malaysia further develop their discussion paper on the new work proposal by the next session. (CRD6, CCNFSDU43)	CCNFSDU43 agreed to establish an EWG to further refine and clarify Proposal and develop a revised discussion paper and project document (REP23/NFSDU, paras. 104-106).
	2024		Argentina, Malaysia and China	<i>to be completed</i>	The report of the EWG was published as CX/NFSDU 24/44/6 Add.1 (link). --- <i>to be completed</i>
2.2	2023	Guidelines including General Principles for the Nutritional Composition of Foods and Beverages made from Plant-based and other Alternative Protein Sources	USA and Canada	PWG recommendation: It is recommended that Canada and the United States of America refine the scope of the new work proposal. (CRD6, CCNFSDU43)	CCNFSDU43 agreed that Canada and USA would refine the scope of the new work proposal. (REP23/NFSDU, para. 113)
	2024	General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources	Canada and USA	<i>to be completed</i>	<i>to be completed</i>
2.3	2023	General Guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL)	Costa Rica, EU, Paraguay and USA	PWG recommendation: It is recommended to reject the proposal and advise Costa Rica that it could be submitted again in the future considering the comments received. (CRD6, CCNFSDU43)	CCNFSDU43 agreed that past and ongoing work in this area by WHO (CRD37) may be sufficient to meet the Committee's needs. CCNFSDU43 also agreed that due to the lack of support, the proposal should not be pursued at this time. (REP/NFSDU43, para. 114)
2.4	2023	Nutrient reference value (NRV-NCD) for trans-fatty acids	IMACE	PWG recommendation: Reject the new proposal in the absence of	CCNFSDU43 agreed to not take up the new proposal in the absence of Member support. (REP/NFSDU43, para. 115)

				Member support in the PWG. (CRD6, CCFSDU43)	
2.5	2024	New Work Proposal to Develop a Standard for Formulated Complementary Foods for Older Infants and Young Children	USA	<i>to be completed</i>	<i>to be completed</i>
(B) POTENTIAL FUTURE AREAS OF WORK					
PART 3: REVIEW OF EXISTING STANDARDS					
3.1				N/A	
PART 4: EMERGING ISSUES					
4.1	2023	Review of all standards under purview of CCFSDU	Codex Secretariat		<p>The Committee is invited to regularly review its standards and other texts to ensure that they are up to date. (CX/NFSDU 23/43/8, para. 16)</p> <p>CCFSDU43 agreed that the Codex Secretariat would consider approaches to review all texts under the purview of CCFSDU to assess if they were still fit for purpose and noted the willingness of FAO and WHO to assist in this task. (REP/NFSDU, para. 118).</p> <p>The results of this screening exercise were published as CX/NFSDU 24/44/7 (link).</p>

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Part 2: REQUESTS FOR NEW WORK

No.	Title of Work	Prepared by	Page
2.2	General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources	Canada and USA	11
2.5	New Work Proposal to Develop a Standard for Formulated Complementary Foods for Older Infants and Young Children	USA	45

² Proposals are listed in order of their current number in the all-time list/inventory.

Proposal 1.3

Proposal to open and amend the 2009 Codex definition of dietary fibre included under para. 2 in the Guidelines on Nutrition Labelling (CXG 2-1985)

Prepared by the Calorie Control Council

Discussion Paper*Introduction*

This paper outlines a request for the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to consider opening the 2009 Codex definition of dietary fibre to amend the definition, which is included under para. 2 in the *Guidelines on nutrition labelling (CXG 2-1985)*.

Background

The World Health Organization (WHO) and global regulatory and scientific bodies have identified dietary fibre as a nutrient of concern given that there is broad underconsumption compared to recommended intake levels internationally. Given the physiological benefits associated with intake of dietary fibre, including for gastrointestinal and metabolic health, as well as weight management, it is important that individuals consume adequate amounts of dietary fibre.

Many authoritative bodies recognize dietary fibres as those carbohydrate polymers with demonstrated physiological benefits with 3 or more monomeric units, including the United States' Food and Drug Administration¹, the European Food Safety Authority², Food Standards Australia and New Zealand³, Health Canada⁴, and the Institute of Medicine (IOM)⁵. Additionally, many countries recognize this definition as well, including the European Union⁶, Brazil, China, Indonesia, Japan, Korea, Singapore, and Thailand⁷. However, a handful of countries have adopted definitions that recognize only carbohydrates with 10 or more monomeric units as dietary fibre. This has resulted in certain carbohydrates which provide a physiological benefit being recognized as a dietary fibre in some countries but not others, which limits the availability of dietary fibre in certain regions and hinders bridging the fibre gap.

The definition and properties of dietary fibre were discussed within CCNFSDU for many years in the 1990's and 2000's. While much of the scientific consensus and debate leading to the finalization of the definition supported a definition of dietary fibre at a degree of polymerization (DP) of 3 or more monomeric units, the final Codex definition adopted in 2009 states:

Dietary fibre means carbohydrate polymers¹ with ten or more monomeric units², which are not hydrolyzed by the endogenous enzymes in the small intestine of humans and belonging to the following categories:

- *Edible carbohydrate polymers naturally occurring in the food as consumed,*
- *carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,*
- *synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.*

¹ *When derived from plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis: Fractions of lignin and other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates,*

¹ Food Labeling: Revision of the Nutrition and Supplement Facts Labels. 21 C.F.R. pt. 101 (2016).

² EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal (2010); 8(3): 1462.

³ Australia New Zealand Food Standards Code – Standard 1.2.8 – Nutrition information requirements.

⁴ Health Canada. (2017). *Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products*.

⁵ Institute of Medicine, National Academy of Sciences Dietary reference intakes: proposed definition of dietary fiber. Washington, DC: National Academy Press; 2001.

⁶ Regulation 1169/2011 on the provision of food information to consumers (2011) *Official Journal* L304, p. 42.

⁷ Dai F. and Chau C. (2017). Classification and regulatory perspectives of dietary fiber. *Journal of Food and Drug Analysis*; 25(1): 37-42.

PART 1: PROPOSAL BY THE CALORIE CONTROL COUNCIL

cutin, phytosterols, etc.) intimately “associated” with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

² *Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.*

Although the footnote of the Codex definition allows for national authorities to determine whether to allow for carbohydrate polymers with 3 to 9 monomeric units, the main Codex definition is recognized as 10 or more monomeric units.

Recommendation

CCNFSDU should revisit the definition for dietary fibre and should establish an electronic Working Group which would develop a discussion paper, project document, and draft text for further consideration at the next CCNFSDU Session.

Rationale

As noted, populations around the world fail to meet the recommended daily intake of dietary fibre and the WHO has indicated fibre intakes are “generally low” globally. Individuals are encouraged to consume more dietary fibre by national authorities and foods with added dietary fibre are important for bridging the fibre gap. Fibre is consistently recognized as a nutrient of concern and many people around the world do not consume sufficient dietary fibre to meet nutrient needs. This can have a negative health impact as dietary fibre aids in digestion, glycemic response, immune function, and weight management, among other benefits.⁸

Many authoritative scientific and regulatory bodies and countries around the globe recognize dietary fibres as carbohydrate polymers with demonstrated physiological benefits with 3 or more monomeric units. Given that a major tenet of Codex is harmonization and removing potential barriers to trade, the Codex definition should be better aligned with the definition of dietary fibre that is more globally recognized and potentially reduce changes to current country regulations which may be proposed without scientific justification. Further, revising the Codex definition to align with many countries’ regulations can aid in ensuring more products with dietary fibre are available which could result in a key public health benefit.

Therefore, given the potential confusion and inconsistent application of the current Codex definition as well as the above discrepancies and unintended consequences, there is a need to reconsider the Codex definition to more clearly reflect 3 or more monomeric units as the threshold for an edible carbohydrate polymer to qualify as a dietary fibre.

Conclusion

The Calorie Control Council (CCC) encourages the revision of the 2009 Codex definition of dietary fibre to align with the definition recognized by many Codex member countries.

⁸ World Health Organization. Carbohydrate intake for adults and children: WHO guideline. July 2023. <https://www.who.int/publications/i/item/97892400073593>.

Project Document

Purpose and Scope

The purpose of this work is to reopen and reconsider the Codex definition for dietary fibre to drive towards a clearer and more science-based definition which can be applied consistently to facilitate global harmonization, ensure fair trade, and improve public health.

Relevance and Timeliness

Dietary fibre is often recognized as a nutrient of public health concern as it is under-consumed by many people worldwide. As increased dietary fibre intake can aid in addressing various health outcomes which are proliferating globally, including cardiovascular disease, gastrointestinal disease, and obesity, it is important for populations to have greater access to products containing sources of dietary fibre. While most countries recognize carbohydrate polymers with demonstrated physiological benefits and three or more monomeric units as dietary fibres, some countries have adopted a definition which only recognizes those carbohydrate polymers with 10 or more monomeric units. This discrepancy furthers the fibre gap as populations may not have access to products which can provide the benefits of dietary fibre given the stricter definition.

Key Aspects of Proposal

The Calorie Control Council (CCC) is seeking a revision of the current Codex definition for dietary fibre. The proposed revision to the current definition is captured below with new proposed language **bolded and underlined** and language proposed for removal in ~~strikethrough~~.

*Dietary fibre means carbohydrate polymers¹ with ~~ten~~ **three** or more monomeric units², which are not hydrolyzed by the endogenous enzymes in the small intestine of humans and belonging to the following categories:*

- *Edible carbohydrate polymers naturally occurring in the food as consumed,*
- *carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,*
- *synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.*

¹ *When derived from plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis: Fractions of lignin and other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately “associated” with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).*

² *~~Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.~~*

Assessment on Criteria for Establishment of Work Priorities

Currently, most countries recognize dietary fibres as those carbohydrate polymers with demonstrated physiological benefits which have three or more monomeric units. However, some countries follow the main Codex definition for dietary fibre and only recognize those carbohydrate polymers with 10 or more monomeric units. Aligning the Codex definition with what is recognized as dietary fibre in most countries, which would still meet the definition in countries with more restrictive criteria, would provide better harmonization of the Codex Standard globally.

Relevance to Codex Objectives

Two of the key objectives of Codex are protecting consumer health and facilitating global trade. Most people around the world are deficient in their dietary fibre intake despite international recommendations to consume more dietary fibre. Food sources of added dietary fibre can help bridge the fibre gap globally, though stricter definitions of dietary fibre may prevent consumers from having access to more of these products which could

provide various benefits. Furthermore, having a Codex definition which more closely aligns with the definition that is utilized in most countries supports enhanced facilitation of global trade. Therefore, consideration should be given to revise the 2009 Codex dietary fibre definition to permit carbohydrate polymers with demonstrated physiological benefits with three or more monomeric units as dietary fibres.

Relation to Other Codex Texts

The proposed work would only focus on potential revision of the 2009 Codex definition for dietary fibre in the *Guidelines on nutrition labelling* (CXG 2-1985). While the Codex dietary fibre definition is referenced in other Codex Standards and texts, there should not be any need to update these texts with the possible exception of the date of adoption for the definition, if revised. However, efforts have been raised in other Codex committees, namely the Codex Committee on Methods of Analysis and Sampling (CCMAS), to adopt new methodologies for analyzing dietary fibres which would recognize more ingredients as dietary fibres. The current proposal alongside the work on adopting new methodologies should result in more ingredients being recognized as dietary fibres, ideally helping to address current dietary fibre gaps.

Need for Scientific Expert Advice

As the proposed revision to the Codex dietary fibre definition is aligned with the definition recognized by many Codex Members, there should be limited need for additional scientific expert advice.

Need for Technical Input to Standard

Given that the proposed change is minor to the Codex Standard, technical input should be minimal.

Proposed Timeline

Permitting time for Codex Members and Observers to review the proposal ahead of the next committee meeting, barring significant concerns raised during CCNFSDU45, the matter could be endorsed and referred to the Codex Alimentarius Commission (CAC) for adoption at CAC48.

Assessment Against Prioritization Criteria

Impact on Public Health

Globally, the average intake of dietary fibre is often well below the recommended intakes established by international scientific and regulatory bodies. Research on dietary fibre intake has found that higher intakes can help lower risk of cardiovascular disease and certain gastrointestinal diseases, as well as improve blood pressure and serum cholesterol.⁸ Additionally, increased dietary fibre intake can be helpful in weight loss⁹, which is critical given the global obesity epidemic.

While most countries recommend intake of 20 – 35 g/day of dietary fibre, depending on gender, most people are consuming an average of 15 – 26 g/day¹⁰, depending on region.¹¹ Further, the World Health Organization (WHO) recommends intake of 25 grams of naturally occurring dietary fibre per day.⁸ As populations seek improvements in their diet, including through consumption of more fruits, vegetables, and whole grains, sources of added dietary fibre can help to address this fibre gap. Employing a Codex definition that is less restrictive and permits more ingredients to be recognized as dietary fibres would help address this fiber gap and improve public health and nutrition across populations as more products would be available which would contain sources of dietary fibre.

Impact on Food Safety

The proposed work should not have any impact on food safety as carbohydrate polymers with three or more monomeric units are typically approved as food ingredients in countries globally.

Impact on Trade Practices

Most countries recognize dietary fibres as carbohydrate polymers which provide a physiological benefit and have a degree of polymerization of 3 or more.¹² While the current Codex definition does include a footnote which permits national authorities to decide whether to recognize carbohydrate polymers with 3 to 9 monomeric units as dietary fibres, the main Codex definition is for 10 or more monomeric units. Revising the

⁹ Anderson JW, Baird P, Davis RH Jr, Ferreri S, Knudtson M, Koraym A, Waters V, Williams CL. Health benefits of dietary fiber. *Nutr Rev*. 2009 Apr;67(4):188-205. doi: 10.1111/j.1753-4887.

¹⁰ Fu J., Zheng Y, Gao Y, Xu, W. Dietary fiber intake and gut microbiota in human health. *Microorganisms*. 2022; 10: 2507. <https://doi.org/10.3390/microorganisms10122507>.

¹¹ Burke Miller K. Review of whole grain and dietary fiber recommendations and intake levels in different countries. *Nutr Rev*. 2020 Aug; 78(Suppl 1): 29-36. <https://doi.org/10.1093/nutrit/nuz052>.

¹² Wenzel de Menezes E, Giuntini EB, Tanasov Dan MC, Hoffman Sardá FA, Lajolo FM. Codex dietary fibre definition – Justification for inclusion of carbohydrates from 3 to 9 degrees of polymerization. *Food Chem*. 2013 Oct; 140(3): 581-85.

Codex definition to drop the footnote and include 3 or more monomeric units within the main Codex definition will align the Codex definition with what is recognized in most countries as dietary fibre. This alignment will harmonize the Codex definition with international standards and reduce potential barriers to trade. Further, having a more comprehensive definition may increase the availability of products with added dietary fibre, helping to improve intake by consumers globally.

Global Impact

As noted, average intake of dietary fibre is generally low globally, and increasing such intake could aid in addressing a myriad of poor nutrition and health outcomes. Further, permitting carbohydrate polymers with 3 or more monomeric units instead of 10 or more monomeric units to be classified as dietary fibres will likely increase the dietary fibre content of many products available globally. Increasing availability of products with added dietary fibre sources may help encourage greater consumption globally and provide better nutrition to consumers worldwide.

Proposal 2.2

Topic proposal from Canada and the United States of America: General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources

Prepared by Canada and USA

Discussion Paper**BACKGROUND**

The 41st Session of the CCFSDU considered a paper, CX/NFSDU 19/41/10, prepared by Germany, as host Secretariat of CCFSDU on a prioritization mechanism to better manage the work of the Committee. The paper put forward proposals for CCFSDU to better manage its work: a uniform approach on submission of work proposals; additional prioritization criteria besides what is set out in the *Procedural Manual*; use of a Circular Letters to collect new work proposals; and establishing an *ad hoc* working group to review submitted work proposals. We submitted a proposal in response to the Circular Letter, CL 2020/30-NFSDU, calling for new work proposals ahead of CCFSDU43 (March 2023). CCFSDU43 agreed that Canada and USA would refine the scope of the new work proposal. We are submitting this revised proposal in response to the Circular Letter, CL 2024/52-NFSDU, calling for new work proposals and identification of emerging issues ahead of CCFSDU44 (October 2024).

INTRODUCTION

In the last decade dietary guidance globally has evolved to recommend the consumption of more plant-based protein foods, and consumers have become more interested in plant-based dietary patterns. Consumer interest in other non-animal protein products such as foods made from fungi and fermentation derived proteins, as well as insects, is also on the rise. In response, innovation in this market sector has led to a large influx of new foods formulated with protein from non-animal sources¹ globally, including products which mimic animal-based products in appearance, representation, and use. The increased presence of these products on the market and the increasing trade of products internationally highlights the need to establish general guidance and principles related to the nutritional composition for such products, which could support consumer health, improve consistency in global markets, and reduce impediments to trade from more harmonized regulations. As this proposal addresses food products consumed or intended as replacements for animal-based foods, the [General Standard for the use of dairy terms \(GSUDT\) \(CXS 206-1999\)](#) was considered when developing the following discussion paper and project document.

DISCUSSION**Plant-Based Diets and Dietary Guidance**

Diets composed of primarily plant-based foods have been followed by some populations around the world for centuries, however broader consumer interest in plant-based dietary patterns has risen in the past decade. While India continues to have the highest percentage of reported vegetarians worldwide, estimated to be between 20-42% of the population,^{2,3} plant-based diets are becoming increasingly popular in other regions of the world as well. Although estimates vary, a 2018 study found the percent of the population self-reporting as vegetarian/vegan in the United Kingdom, Germany, and France reached 8%, 5.6%, and 5.2%, respectively.⁴ A 2023 survey showed similar vegetarian populations in the United Kingdom and Germany.⁵ In the United States, roughly 5% of the population identified as vegetarian or vegan in polls from 2018 to 2023, and among 18–34 year olds that number increased to 8%.^{6,7,8} In Canada, nearly 10% of the population identified as vegetarian or vegan in a 2019 survey.⁹ Regions of South America have also experienced significant increases in the adoption of plant-based diets, such as Brazil which saw nearly double the rates of people identifying as

¹ For the purposes of this proposal, non-animal means plants, fungi, bacteria, and insect sources.

² <https://doi.org/10.1016/j.appet.2015.10.018>

³ <https://www.statista.com/statistics/1280079/global-country-ranking-vegetarian-share/>

⁴ https://www.interbev.fr/wp-content/uploads/2019/10/11_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654

⁵ <https://www.statista.com/statistics/1280079/global-country-ranking-vegetarian-share/>

⁶ <https://news.gallup.com/poll/267074/percentage-americans-vegetarian.aspx>

⁷ <https://www.statista.com/statistics/1280079/global-country-ranking-vegetarian-share/>

⁸ The Good Food Institute. 2023 State of the Industry Report Plant-based: Meat, seafood, eggs and dairy.

⁹ Nourish 2019 Trends Report. Available at: <https://www.nourish.marketing/wp-content/uploads/2018/11/the2019trendreport-nourish-digital.pdf>

vegetarian between 2012 and 2018, jumping from 8% to 14%.¹⁰ Australia and Nordic countries are also seeing high rates of plant-based diet adoption, with surveys from 2018 to 2021 showing self-reported vegetarianism at roughly 10 - 12%.^{11,12,13} Research shows that plant-based diets are also most readily accepted by younger generations¹⁴, meaning the vegetarian populations is expected to continue to increase over time.

There has been an even larger increase globally in people identifying as flexitarian, those who primarily consume plant foods with the occasional inclusion of meat and fish. In Hong Kong, surveys from 2008 and 2020 found an increase in flexitarianism from 5% to 40%.¹⁵ In Europe, the flexitarian trend has also spread, with rates as high as 26%, 24% and 23% in Germany, France and Spain, respectively.^{16,17} In 2019, Canada was estimated to have 25% of its population following a flexitarian diet.¹⁸ Even among populations who do not identify as vegan, vegetarian or flexitarian, the global trend of reducing or intending to reduce meat consumption is evident. In a 2017 survey, 63% of respondents indicated they want to reduce their meat consumption.¹⁹ Similarly, a 2020 survey reported that 68% of respondents think too much meat is consumed in France.²⁰

The recent encouragement to consume more plant foods, as seen in dietary guidance globally, may also spur greater adoption of vegan, vegetarian and flexitarian diets. In North America, both Canada and the United States have established 'protein food groups' with an emphasis on plant-based proteins in their latest dietary recommendations. Canada's Food Guide²¹ encourages consumers to choose protein foods that come from plants more often, while the Dietary Guidelines for Americans 2020-2025 highlights that a "healthy vegetarian dietary patterns can be achieved through incorporating protein foods from plants".²² In Europe, the United Kingdom's Eatwell Guide 2016 similarly established a food group consisting of both animal and plant-based proteins, with messaging to eat more beans and pulses.²³ South American countries also promote plant foods in dietary guidance; for example, Brazil's dietary guidelines encourage consumption of foods mainly of plant origin.²⁴ On a global scale, dietary guidance from international groups is also beginning to focus on the promotion of plant-based foods, such as the EAT-Lancet Commission's 2019 report recommending increased consumption on plant-based foods for both human and environmental health.²⁵ The FAO, in collaboration with the Food Climate Research Network, also released a report in 2016 evaluating existing dietary guidance world-wide with a focus on sustainability, and found that largely plant-based diets had advantages for both health and environment.²⁶

Growth of the Non-Animal Protein Market Globally

With the growing interest in foods formulated with protein from non-animal sources, the food industry has quickly developed a wide range of new food categories and types of products globally. Plant-based alternatives have increased rapidly in the last decade both in the number of new products reaching the market and the number of units sold annually. Current estimates value the global plant-based food market between 30 to over

¹⁰ <https://www.svb.org.br/2469-pesquisa-do-ibope-aponta-crescimento-historico-no-numero-de-vegetarianos-no-brasil>

¹¹ <https://animalsaustralia.org/our-work/compassionate-living/study-shows-surge-in-aussies-eating-veg/>

¹² <https://www.ipsos.com/sites/default/files/ct/news/documents/2019-11/report-orkla-sustainable-life-barometer-2019-11-november-2019.pdf>

¹³ <https://www.orkla.fi/app/uploads/sites/12/2022/01/Orkla-SLB-2021-Main-Report-Finland.pdf>

¹⁴ Charlebois, 2021. Presentation for the Canadian Nutrition Society; *COVID-19 happened. Now what? The pandemic's legacy on our relation with proteins*

¹⁵ <https://time.com/5930095/china-plant-based-meat/>

¹⁶ https://www.interbev.fr/wp-content/uploads/2019/10/11_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654

¹⁷ <https://www.franceagrimer.fr/Actualite/Etablissement/2021/VEGETARIENS-ET-FLEXITARIENS-EN-FRANCE-EN-2020>

¹⁸ https://reports.mintel.com/display/918746/?fromSearch=%3Ffilters.category%3D155%26last_filter%3Dcategory

¹⁹ <https://www.sciencedirect.com/science/article/abs/pii/S0309174022001619?via%3Dihub>

²⁰ <https://www.franceagrimer.fr/Actualite/Etablissement/2021/VEGETARIENS-ET-FLEXITARIENS-EN-FRANCE-EN-2020>

²¹ Canada's Food Guide (2019). Available at: <https://food-guide.canada.ca/en/>

²² Dietary Guidelines for Americans 2020-2025. Available at: <https://www.dietaryguidelines.gov/>

²³ Eatwell Guide 2016. Available at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/746558/Eatwell_guide_colour_edition.pdf

²⁴ Dietary Guidelines for the Brazilian Population 2014. Available at: <https://www.fao.org/nutrition/education/food-based-dietary-guidelines/regions/countries/brazil/en/>

²⁵ https://eatforum.org/content/uploads/2019/07/EAT-Lancet_Commission_Summary_Report.pdf

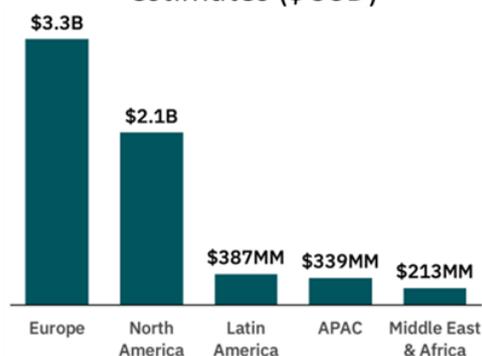
²⁶ <http://www.fao.org/3/I5640E/I5640e.pdf>

40 billion USD in 2023, and market research indicates that the global sector is expected to reach up to USD \$85 billion by 2030.^{27,28,29}

While the plant-based food sector remains relatively small compared to the animal-based products they are replacing, the Boston Consulting Group predicts that by 2035 alternative proteins could account for 11% of the protein market (USD \$290 billion), and more aggressive models estimate it could reach up to 22% in that same timeframe.³⁰ Plant-based alternatives to dairy products continue to make up the largest share of the plant-based alternatives market. In 2023 it was estimated that global sales of plant-based alternatives to dairy products exceeded \$22 billion USD.³¹ Plant-based alternatives to meat and poultry products have also experienced significant growth over the past 10 years, with an estimated annual growth rate between 2019 to 2026 of 14%.³² While sales of plant-based products in mature markets such as the United States declined between 2022 and 2023, this coincided with inflation and changing consumer budgets.³³ During this time there was growth in plant-based food sales in some regions and emerging markets, providing confidence that the plant-based food sector is here to stay.

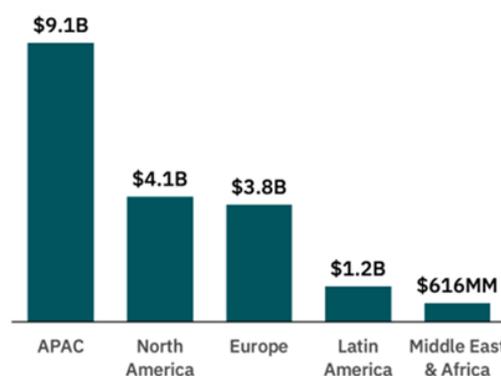
The market for other foods formulated with protein from non-animal sources, such as products made from fungi or bacteria, as well as products made with insect protein, are not as well established as the plant-based market, however significant growth is expected in the next decade. By 2030 edible insects are forecasted to reach USD \$9.6 billion globally, with an annual growth rate of 28.3%.³⁴ The fungal protein market is forecasted to reach USD \$386.6 million globally by 2030, representing an annual growth rate of 9.5%.³⁵

2023 Global plant-based meat and seafood alternatives retail sale estimates (\$USD)



Source: Adapted from Good Food Institute's 2023 State of the Industry Report on Plant-based meat, seafood, eggs and dairy; based on Euromonitor International Inc. staple food data.

2023 Global plant-based beverage retail sale estimates (\$USD)



Source: Adapted from Good Food Institute's 2023 State of the Industry Report on Plant-based meat, seafood, eggs and dairy; based on Euromonitor International Inc. staple food data.

North America and Europe have held the lion's share of the plant-based meat substitute market to date, however other markets are emerging including significant growth in the Asia-Pacific region.^{36,37,38} Based on the Good Food Institute's alternative protein company database, there are currently over 300 plant-based and fermentation derived meat and seafood substitute companies in Europe and over 250 in the United States and

²⁷ <https://www.globenewswire.com/news-release/2024/02/12/2827392/0/en/Plant-Based-Food-Market-Surges-to-USD-85-Billion-by-2030-Reflecting-an-9-95-Growth->

²⁸ <https://doi.org/10.3389/fsufs.2020.00134>

²⁹ The Good Food Institute. 2023 State of the Industry Report Plant-based: Meat, seafood, eggs and dairy

³⁰ <https://www.bcg.com/press/23march2021-alternative-protein-market-reach-290-billion-by-2035>

³¹ The Good Food Institute. 2023 State of the Industry Report Plant-based: Meat, seafood, eggs and dairy

³² <https://www.globenewswire.com/news-release/2021/03/16/2193792/0/en/At-14-CAGR-Trends-in-The-Plant-based-Meat-Market-Size-Share-Value-Will-Grow-to-USD-9-43-Billion-by-2026-Facts-Factors.html>

³³ The Good Food Institute. 2023 State of the Industry Report Plant-based: Meat, seafood, eggs and dairy.

³⁴ Meticulous Research, 2022. https://www.meticulousresearch.com/product/edible-insects-market-5156?utm_source=Globenewswire&utm_medium=Paid&utm_campaign=Product&utm_content=25-05-2022

³⁵ Allied Market Research, 2021. <https://www.alliedmarketresearch.com/fungal-protein-market-A12366#:~:text=The%20global%20fungal%20protein%20market,total%20fungal%20protein%20market%20share>

³⁶ <https://www.zionmarketresearch.com/market-analysis/plant-based-meat-market>

³⁷ <https://www.statista.com/statistics/890262/global-meat-substitutes-market-share-by-region/>

³⁸ <https://www.zionmarketresearch.com/market-analysis/plant-based-meat-market>

Canada, followed closely by nearly 200 in Asia Pacific, Australia and New Zealand.³⁹ The move towards non-animal proteins is also growing in South America, where the meat substitute market is forecasted to reach a value of USD \$328 million by 2025, growing at an annual rate of 12.4%.⁴⁰

Asia-Pacific currently holds that largest share of the global plant-based beverage market, with China alone estimated to have over \$9 billion USD in sales in 2023.⁴¹ The United States currently have the second largest plant-based beverage market at over \$3 billion USD in sales in 2023. From a company standpoint, the European Union and United States and Canada are estimated to have the largest number of companies producing plant and fermentation derived alternatives to dairy products, with close to 250 each.⁴²

Altogether, available sales data highlights the global nature of the non-animal protein source food market, and expected growth of the sector globally in years to come.

Nutritional Composition of Foods Formulated with Protein from Non-Animal Sources

The composition of foods formulated with protein from non-animal sources varies widely between and within product categories, and across countries. This may pose health risks both in exacerbating existing essential nutrient inadequacies and deficiencies globally and in increasing intakes of nutrients to limit such as saturated fat, sodium and sugars. The inconsistent formulations also pose global trade barriers and may impact consumer understanding of these products.

Obtaining recommended intakes of all essential nutrients is possible on an entirely plant-based diet, however it requires meal planning and consumption of a range of plant foods. Studies assessing the nutritional quality of plant-based diets, including those using plant-based alternatives, indicate that while there are health benefits, there are also some health risks. Generally, intakes of fibre, folate, magnesium, fat and saturated fat improve with increased consumption of plant-based foods, however there is also a reduction in the intakes of important essential nutrients such as protein, Vitamin A, Vitamin D, Vitamin B12, heme-iron and zinc.^{43,44,45,46} The reduction in iron, zinc and vitamin A intakes are particularly important as these are three of the most common micronutrient deficiencies globally, most prominent in young children and women of reproductive age.^{47,48}

With the increased interest and popularity of foods formulated with protein from non-animal sources, particularly when used as a partial or total replacement for animal-based foods, the composition of these products is becoming increasingly important. Research and market scans show that the levels of essential nutrients in plant and other non-animal protein source foods varies greatly, and some essential nutrients are lower in these products than in the animal-based foods being replaced. And beyond the absolute amount of essential nutrients in plant and other alternative protein source foods and beverages, in some instances the quality and bioavailability of these nutrients may also be lower compared to the animal-based counterparts.

Compositional data available for plant-based alternatives to animal products indicates that the majority of plant-based beverages have lower protein content than milk (both total and corrected for quality), and unfortified products have lower calcium, and Vitamin A.^{49,50} One study assessing over 100 plant-based beverages in Australia in 2019 found that roughly half of the dairy alternatives were unfortified, and indiscriminate substitution for milk may lead to significant reductions in intakes of protein, calcium, zinc, Vitamin A, and Vitamin B12.⁵¹ Similarly, a study of 132 plant-based meat analogues in Australia collected in 2021 found that only 12% were fortified with iron, zinc and vitamin B12, resulting in significant composition variability across products.⁵² The authors expressed that the low fortification rates are a potential health concern, particularly for

³⁹ <https://gfi.org/resource/alternative-protein-company-database/>

⁴⁰ <https://www.mordorintelligence.com/industry-reports/south-america-meat-substitute-market>

⁴¹ <https://www.statista.com/forecasts/1277967/worldwide-milk-substitute-revenue-by-country>

⁴² <https://gfi.org/resource/alternative-protein-company-database/>

⁴³ <https://cdnsiencepub.com/doi/pdf/10.1139/apnm-2020-1039>

⁴⁴ <https://pubmed.ncbi.nlm.nih.gov/33591857/>

⁴⁵ <https://www.mdpi.com/2072-6643/12/7/2034/htm>

⁴⁶ <https://pubmed.ncbi.nlm.nih.gov/28532520/>

⁴⁷ <https://karger.com/anm/article/66/Suppl.%202/22/40738>

⁴⁸ Stevens, Gretchen A., et al. "Micronutrient deficiencies among preschool-aged children and women of reproductive age worldwide: a pooled analysis of individual-level data from population-representative surveys." *The Lancet Global Health* 10.11 (2022): e1590-e1599

⁴⁹ <https://link.springer.com/article/10.1007/s13197-016-2328-3>

⁵⁰ <https://doi.org/10.1016/j.idairyj.2018.07.018>

⁵¹ <https://www.mdpi.com/2072-6643/12/5/1254/htm>

⁵² <https://onlinelibrary.wiley.com/doi/10.1111/1747-0080.12793>

consumers directly substituting these product for meat and who are not consuming other animal-based products such as milk, yogurt, cheese and eggs. In a recent literature review conducted by the FAO assessing the nutritional composition of foods made from plant-based and other alternative protein sources intended to replace animal-based products, several product categories had significantly lower protein content than the animal-based counterparts.⁵³ 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 3-fold lower protein than milk, with coconut beverages having the lowest protein content (over 8-fold lower than milk). The FAO review also highlighted large nutrient composition variability within plant-based 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.

In addition to the potentially lower levels of certain essential nutrients in foods formulated with protein from non-animal sources compared to animal-based products, there also appears to be a health “halo” surrounding some plant-based alternatives with consumers often overestimating the nutritional value of these products. The United States Food and Drug Administration conducted focus groups which found that although consumers could differentiate plant-based beverages from milk, they do not always understand the nutritional differences between the products and consumers of plant-based beverages frequently claimed these products were healthier than milk.⁵⁴ Similarly, the final report from Australia’s industry working group on the labelling and marketing of plant-based alternatives to meat and meat-based and dairy products highlighted that 36% of respondents to a national survey perceived plant-based alternatives to be nutritionally equivalent to milk.⁵⁵ Some research also indicates that both consumers and health professionals think that non-animal meat substitutes should contain similar levels of certain essential nutrients as the meat products they are replacing.⁵⁶

Available composition data also shows that some of these non-animal protein source products have high concentrations of nutrients of public health concern related to excessive intakes (i.e. sodium, saturated fat and sugars). These levels are greater than those found in unprocessed plant foods, and are sometimes higher than the animal-based counterparts. For example, a 2019 comparison of the nutrient content of four popular plant-based alternatives to burgers in the United States found that the nutrient composition varies across the plant-based alternatives to burgers, but on average they have significantly higher sodium and total fat content, and lower protein, compared to the lean beef burger (per gram basis).⁵⁷ A recent review by the FAO found that some plant-based alternatives had lower levels of nutrients to limit, while others did not.⁵⁸ 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.

Policies and Regulations for the Nutritional Composition of Foods Formulated with Protein from Non-Animal Sources

An initial review of publicly available information on international policies and guidelines shows that most countries regulate foods formulated with protein from non-animal sources as general foods, and that few countries have specific regulations for the nutritional composition of these products.⁵⁹

The lack of consistent policies for foods formulated with protein from non-animal sources has resulted in a lack of consistency in products across global markets, created trade barriers, and impacted consumer understanding. Recommended nutritional compositional guidelines for these products may aid in better aligning products and policies internationally, potentially having positive impacts on both health and trade. Taking steps now to establish base principles for jurisdictions to use in the development of guidance and regulations and for companies to use in product development, while the market is still growing and evolving, will increase international harmonization and help mitigate these issues.

⁵³ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

⁵⁴ 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.

⁵⁵ Industry Working Group Discussion Paper, The Labelling and Marketing of Plant-based Alternatives to Meat and Meat-based and Dairy products. 2021. Available at: <https://www.aph.gov.au/DocumentStore.ashx?id=e8e3f6e4-c348-4cc4-9594-df1f86004c69>

⁵⁶ <https://www.mdpi.com/2071-1050/13/3/1478>

⁵⁷ <https://www.sciencedirect.com/science/article/pii/S2213453019301144>

⁵⁸ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

⁵⁹ A summary of the findings from the initial review of international policies and guidelines for the nutritional composition of foods formulated with protein from non-animal and from insect sources can be found in the Annex.

Initial Review of Policies and Guidelines for the Nutritional Composition of Plant-Based and Other Alternative Protein Foods and Beverages Internationally

The table below provides a summary from an initial scan of publicly available information on international policies and guidelines related to the nutritional composition of foods formulated with protein from non-animal sources. Many countries and regions do not have specific regulations for the nutritional composition of these products, however there have been indications in recent years that some countries are looking to develop policies, such as Japan and China.^{60,61} In other countries, such as Canada, there are specific regulations for the composition of certain meat and poultry alternatives, however they are considered dated.

Country/Region	Nutritional composition of foods formulated with protein from non-animal sources
European Union	No specific nutritional composition requirements for foods formulated with protein from non-animal sources. Nutrients can be voluntarily added to foods, including foods formulated with protein from non-animal sources, to provide a similar nutritional value to foods for which they are intended as alternatives. ⁶²
USA	No specific nutritional composition requirements for foods formulated with protein from non-animal sources. Nutrients can be voluntarily added to foods formulated with protein from non-animal sources to replace those nutrients found in the animal-based counterpart. ⁶³ In 2023 the United States consulted on draft guidance for industry on the labelling of plant-based beverages. ⁶⁴

Canada	Some foods formulated with protein from non-animal sources have regulated composition requirements, while others do not. Simulated meat and poultry products ⁶⁵ must meet certain nutritional compositional criteria, and interpretive guidance for these products was recently updated. ^{66,67} Plant-based beverages and vegetable-based products which resemble cheese are permitted to voluntarily add certain vitamins and minerals. ⁶⁸
Australia/ New Zealand	No required nutritional composition requirements for foods formulated with protein from non-animal sources. Certain vitamins and minerals can be added to both meat analogues and legume-based alternatives to certain dairy products as long as a certain level of protein is

⁶⁰USDA Report: Japan Begins to Explore Regulations for Alternative Meat Products, 2020. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Japan%20Begins%20to%20Explore%20Regulations%20for%20Alternative%20Meat%20Products_Tokyo_Japan_08-12-2020

⁶¹ USDA, Industry Group Issues Voluntary Standard for Plant Based Meat Alternative Products. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Industry%20Group%20Issues%20Voluntary%20Standard%20for%20Plant-Based%20Meat%20Alternative%20Products_Beijing_China%20-%20People%27s%20Republic%20of_01-09-2021

⁶² Regulation (EC) no 1925/2006 of the European parliament and of the council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods

⁶³ Code of Federal Regulations Title 21, volume 2, part 104. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=104.20>

⁶⁴ 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.

⁶⁵ Simulated meat and poultry products are those which do not contain any meat product, poultry product or fish product, but that have the appearance of meat/poultry products

⁶⁶ Food and Drug Regulations, Parts 14 and 22. Available at: https://laws.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/index.html

⁶⁷ <https://inspection.canada.ca/en/food-labels/labelling/industry/meat-and-poultry-products/simulated-products>

⁶⁸ <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/interim-policy-on-use-expired-interim-marketing-authorizations-related-food-fortification.html>

PART 2: PROPOSAL BY CANADA AND USA

	present (12% for meat analogues, 3-15% for plant-based alternatives to certain dairy products). ^{69,70}
Japan	<p>No specific nutritional composition requirements for plant-based/other alternative protein source products.</p> <p>In April 2020 the Japanese Ministry of Agriculture, Forestry and Fisheries established the “Food Tech Study Group” with the goal to establish regulations for a variety of emerging protein sectors including alternative meats.⁷¹</p>
China	<p>No specific nutritional composition requirements for plant-based/other alternative protein source products.</p> <p>A voluntary standard for plant-based meat products was developed in 2020 by the Chinese Institute of Food Science and Technology, and implemented in June 2021.⁷² The voluntary standard includes basic composition requirements, including that the formulation shall be based on the nutrition composition of the animal product it is simulating, and manufacturers are encouraged to improve the protein content and quality, and reduce total fat and sodium content of products.</p>

⁶⁹ Australia New Zealand Food Standards Code – Schedule 17 – Vitamins and minerals. Available at: <https://www.legislation.gov.au/F2015L00449/2017-04-13/text>

⁷⁰ <https://www.foodstandards.gov.au/consumer/nutrition/milkaltern/Pages/default.aspx>

⁷¹ USDA Report: Japan Begins to Explore Regulations for Alternative Meat Products, 2020. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Japan%20Begins%20to%20Explore%20Regulations%20for%20Alternative%20Meat%20Products_Tokyo_Japan_08-12-2020

⁷² USDA, Industry Group Issues Voluntary Standard for Plant Based Meat Alternative Products. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Industry%20Group%20Issues%20Voluntary%20Standard%20for%20Plant-Based%20Meat%20Alternative%20Products_Beijing_China%20-%20People%27s%20Republic%20of_01-09-2021

Examples of varying nutrient composition for products internationals

Comparison: A Simulated Meat Product and a Non-Simulated Meat Product in Canada

Product:	Yves – The Good Veggie Burger		Yves – Garden Vegetable Patties	
Country:	Canada		Canada	
Claims/Statements on front of package	13 g of protein per serving Plant-based Simulated beef burgers Contains no meat		Source of Fibre Plant-based	
Fortified?	Yes		No	
Nutritional Composition	Serving	75 g	Serving	75 g
	Protein	13 g	Protein	9 g
	Vit B12	50%	Vit B12	N/A
	Vit D	N/A	Vit D	N/A
	Calcium	4 %	Calcium	4%
	Iron	25 %	Iron	15%
	Zinc	30 %	Zinc	N/A
	Sodium	320 mg	Sodium	370 mg
	Saturated Fat	0.2 g	Saturated Fat	0 g
	Sugar	1 g	Sugar	2 g
Product Image				

PART 2: PROPOSAL BY CANADA AND USA

Comparison: Beyond Burger Plant-based Patties in Canada and USA

Product:	Beyond Burger Plant-based Burgers		Beyond Burger Plant-based Patties	
Country:	Canada		USA	
Claims/Statements on front of package	45% less saturated fat than regular ground beef 20 grams of protein No soy, gluten Simulated beef burgers Contains no meat		35% less saturated fat than patty of 80/20 ground beef 20 grams of protein	
Fortified?	Yes		Yes	
Nutritional Composition	Serving	113 g	Serving	113 g
	Protein	20 g	Protein	20 g
	Vit B12	2.25 ug / 94%	Vit B12	2.4 ug / 100%
	Vit D	N/A	Vit D	0 ug / 0%
	Calcium	40mg / 3%	Calcium	100 mg / 8%
	Iron	5.5 mg / 31%	Iron	4 mg / 20%
	Zinc	5 mg / 45%	Zinc	4.6 mg / 40%
	Sodium	370 mg / 16%	Sodium	390 mg / 17%
	Saturated Fat	6 g / 31%	Saturated Fat	5 g / 25%
	Sugar	0 g	Sugar	0 g
Product Image				

PART 2: PROPOSAL BY CANADA AND USA

Comparison: Two styles of Beyond Burger Plant-based Patties in USA

Product:	Beyond Cookout Classic Plant-based Patties		Beyond Burger Plant-based Patties	
Country:	USA		USA	
Claims/Statements on front of package	18 g of protein per serving		20 grams of protein per serving 35% less saturated fat than patty of 80/20 ground beef	
Fortified?	No		Yes	
Nutritional Composition	Serving	113 g	Serving	113 g
	Protein	18 g	Protein	20 g
	Vit B12	N/A	Vit B12	2.4 ug / 100%
	Vit D	N/A	Vit D	0 ug / 0%
	Calcium	80mg / 6%	Calcium	100 mg / 8%
	Iron	3.7 mg	Iron	4 mg / 20%
	Zinc	N/A	Zinc	4.6 mg / 40%
	Sodium	340 mg / 15%	Sodium	390 mg / 17%
	Saturated Fat	7 g / 35%	Saturated Fat	5 g / 25%
	Sugar	0 g	Sugar	0 g
Product Image				

PART 2: PROPOSAL BY CANADA AND USA

Comparison: V2 Plant-based Patty in Australia and Beyond Plant-based Patty in USA

Product:	V2 Plant-based Burgers		Beyond Burger Plant-based Patties	
Country:	Australia		USA	
Claims/Statements on front of package	Packed with protein, iron & zinc Added benefit of fibre		35% less saturated fat than patty of 80/20 ground beef 20 grams of protein	
Fortified?	Yes		Yes	
Nutritional Composition	Serving	100 g	Serving	113 g
	Protein	18 g	Protein	20 g
	Vit B12	1.6 ug	Vit B12	2.4 ug / 100%
	Vit D	N/A	Vit D	0 ug / 0%
	Calcium	N/A	Calcium	100 mg / 8%
	Iron	2.8 mg	Iron	4 mg / 20%
	Zinc	3.5 mg	Zinc	4.6 mg / 40%
	Sodium	295 mg	Sodium	390 mg / 17%
	Saturated Fat	6 g	Saturated Fat	5 g / 25%
	Sugar	1 g	Sugar	0 g
Product Image	 <p>The image shows the packaging for V2 Plant Based burgers. It features a large green 'V' logo with a burger inside. Text on the package includes 'Serving suggestion', 'packed with PROTEIN, IRON & ZINC with ADDED BENEFIT OF FIBRE', 'v2 Plant Based burger', '4 PACK 452 g e', and several circular icons: 'EASY TO COOK', 'GOOD FOR YOU', 'ANIMAL-FREE', and 'HEALTHY OIL RATING 4.0/5'.</p>		 <p>The image shows the packaging for Beyond Burger Plant-based Patties. It features a green and white design with two patties visible. Text on the package includes '2 PATTIES', 'BEYOND BURGER PLANT-BASED PATTIES', '35% LESS SATURATED FAT THAN A 4 OZ PATTY OF 80/20 GROUND BEEF (SEE NUTRITION INFORMATION FOR FAT AND SATURATED FAT CONTENT)', '20g OF PROTEIN PER SERVING', and a 'NON-GMO Project VERIFIED' logo.</p>	

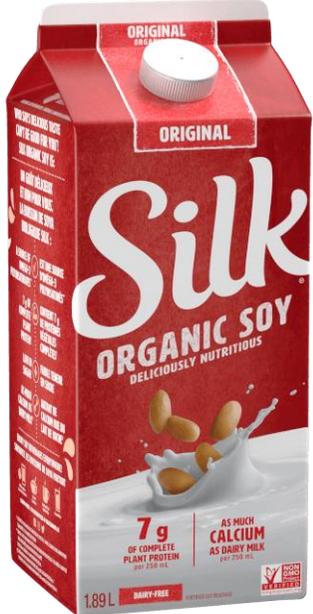
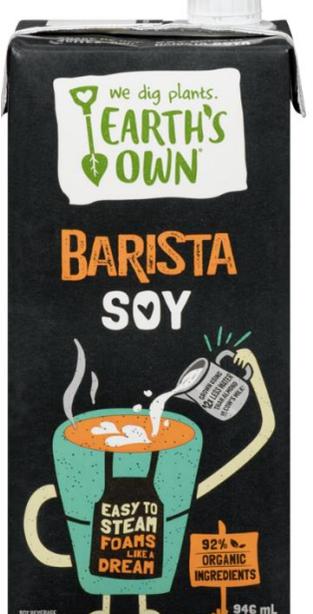
PART 2: PROPOSAL BY CANADA AND USA

Comparison: V2 Plant-based Tenders in Australia and PC Chickenless Breaded Strips in Canada

Product:	V2 Plant-based Tenders		President's Choice Chickenless Breaded Strips	
Country:	Australia		Canada	
Claims/Statements on front of package	3.5 health star rating		Simulated Chicken Contains No Meat	
Fortified?	No		Yes	
Nutritional Composition	Serving	100 g	Serving	90 g
	Protein	11.5 g	Protein	13 g
	Vit B12	N/A	Vit B12	48%
	Vit D	N/A	Vit D	N/A
	Calcium	N/A	Calcium	4%
	Iron	N/A	Iron	25%
	Zinc	N/A	Zinc	23%
	Sodium	627 mg	Sodium	290 mg
	Saturated Fat	3.1 g	Saturated Fat	3 g
	Sugar	3.2 g	Sugar	1 g
Product Image	 <p>The image shows the packaging for V2 Plant Based tenders southern style. It features a large green 'V2' logo and a photograph of the tenders on a plate with dipping sauce. Text on the package includes 'SERVING SUGGESTION', 'AUSTRALIA'S #1 PLANT-BASED MEAT!', 'Plant Based tenders southern style', and '300 g e'. There are also icons for 'EASY TO COOK GREAT TASTE', 'GOOD FOR YOU HEALTHY CHOICE', and 'ANIMAL-FREE SOY-BASED'.</p>		 <p>The image shows the packaging for President's Choice Chickenless Breaded Strips. It features the President's Choice logo and the text 'chickenless BREADED STRIPS • LANIÈRES PANÉES sans poulet'. Below this, it says 'PLANT-BASED À BASE DE PLANTES' and shows a bowl of the breaded strips. The weight is listed as '350 g' and '10' pieces. There are also instructions in French: 'BREADED SIMILATED CHICKEN - CONTAINS NO MEAT / ENVELOPE PANÉE - CONTIENT PAS DE VÉGÉTALE', 'COOK THOROUGHLY BIEN CUIRE', and 'KEEP FROZEN GARDER CONGELÉ'. A note says 'In a 3-grain coating Avec un enrobage de 3 grains'.</p>	

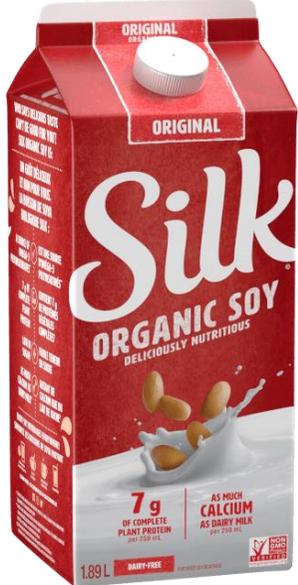
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Comparison: Fortified and Unfortified Soy Beverages in Canada

Product:	Silk Original Fortified Soy Beverage		Earth's Own Barista Soy	
Country:	Canada		Canada	
Claims/Statements on front of package	Fortified Soy Beverage 7 g of complete plant protein As much calcium as dairy milk Dairy-free		Soy Beverage	
Fortified?	Yes		No	
Nutritional Composition	Serving	250 mL	Serving	250 mL
	Protein	7 g	Protein	5 g
	Vit B12	1 ug / 42%	Vit B12	N/A
	Vit D	2 ug / 10%	Vit D	N/A
	Calcium	300 mg / 23%	Calcium	30 mg / 2 %
	Iron	1 mg / 6%	Iron	0.75 mg / 4 %
	Zinc	1 mg / 9%	Zinc	N/A
	Sodium	115 mg	Sodium	190 mg / 8%
	Saturated Fat	0.5 g / 3%	Saturated Fat	0.5 g / 3%
	Sugar	5 g	Sugar	6 g
Product Image				

PART 2: PROPOSAL BY CANADA AND USA

Comparison: Soy Beverages in Canada and USA

Product:	Silk Original Fortified Soy Beverage		West Life Soymilk	
Country:	Canada		USA	
Claims/Statements on front of package	Fortified Soy Beverage 7 g of complete plant protein As much calcium as dairy milk Dairy-free		Soymilk 8 grams protein Plant-based beverage	
Fortified?	Yes		No	
Nutritional Composition	Serving	250 mL	Serving	240 mL
	Protein	7 g	Protein	8 g
	Vit B12	1 ug / 42%	Vit B12	N/A
	Vit D	2 ug / 10%	Vit D	0%
	Calcium	300 mg / 23%	Calcium	30 mg / 2%
	Iron	1 mg / 6%	Iron	1.1 mg / 6%
	Zinc	1 mg / 9%	Zinc	N/A
	Sodium	115 mg	Sodium	100 mg / 4%
	Saturated Fat	0.5 g / 3%	Saturated Fat	0.5 g / 3%
	Sugar	5 g	Sugar	7 g
Product Image				

PART 2: PROPOSAL BY CANADA AND USA

Comparison: Fortified Plant Blend Beverage in Canada and Soy Beverage in USA

Product:	Silk Nextmilk		Silk Original Soymilk	
Country:	Canada		USA	
Claims/Statements on front of package	Fortified Oat and Coconut Beverage Low in sugar Good source of calcium Plant-based Dairy-free Not a source of protein		Soymilk 8 grams protein 50% more calcium Vitamin D	
Fortified?	Yes		Yes	
Nutritional Composition	Serving	250 mL	Serving	240 mL
	Protein	1 g	Protein	8 g
	Vit B12	1 ug / 42%	Vit B12	3 ug / 120%
	Vit D	2 ug / 10%	Vit D	3 ug / 15%
	Calcium	300 mg / 23%	Calcium	450 mg / 30%
	Iron	0.3 mg / 2%	Iron	1.3 mg / 6%
	Zinc	1 mg / 9%	Zinc	N/A
	Sodium	160 mg / 7%	Sodium	90 mg / 4%
	Saturated Fat	4 g / 20%	Saturated Fat	0.5 g / 3%
	Sugar	3 g	Sugar	6 g
Product Image				

Topic proposal from Canada and USA: General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources

Project Document

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 foods¹ formulated with protein from non-animal sources², which are substitute foods³ for animal-based products.
- The scope of products for this project:
 - includes processed foods formulated with protein derived from plants, bacteria, insects, and fungi, 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**; and
 - excludes animal-based protein products (other than insect proteins) and animal cell-based protein products (i.e. cell-cultured foods)

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 food products, found in markets internationally. There has also been an emergence of foods made from other non-animal sources of protein (such as fungi, bacteria and fermentation products) and insects. 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 non-animal 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 non-animal 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.⁴
 - 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

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

² For the purposes of this proposal, non-animal means plants, fungi, bacteria, and insect sources.

³ Substitute foods, per the *General principles for the addition of essential nutrients to foods* (CXG 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/?lnk=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/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B9-1987%252FCXG_009e_2015.pdf)

⁴ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

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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 3-fold lower protein than milk, with coconut beverages⁵ 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.⁶ 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 *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.⁷ 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 *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 non-animal 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 non-animal 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 non-animal sources. Canada, for example, has strict composition requirements for simulated meat

⁵ 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".

⁶ 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.

⁷ "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" (*General Principles for the addition of essential nutrients to foods*)

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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.

- 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.⁸ 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 labelling of plant-based beverages.⁹
- 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.¹⁰ 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.¹¹

Codex general guidance and principles for the recommended nutritional composition of foods formulated with protein from non-animal 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 non-animal 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)

⁸ 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.

⁹ 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.

¹⁰ CX/EXEC 22/82/4, Agenda Item 4, CCEXEC sub-committee on new food sources and production systems – interim report.

¹¹ 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)

- Definitions, if needed and appropriate
- General Principles, to be determined at a later stage. May cover:
 - essential nutrients;
 - protein quality;
 - nutrients of public health concern when consumed in excess of recommendations (e.g., saturated fat, sugars, sodium); and
 - anti-nutritional factors
- Guidelines, to be determined at a later stage. May include guidance for:
 - identifying the foods and beverages within scope of the guidelines and that are considered substitutes foods for animal-based products;
 - recommended composition and nutrient profiles; and
 - labelling considerations
- Roles and Processes

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 non-animal 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 and other non-animal 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 non-animal 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 non-animal sources. However, there is some internationally relevant work that can be leveraged (e.g., FAO protein work, FAO healthy and

sustainable dietary guidelines¹², 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.^{13,14}

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

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 non-animal 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 and other alternative protein diets compared to diets rich in animal products, highlighted by some recent dietary recommendations such as the planetary health diet.¹⁵ 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's¹⁶ 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 non-animal and insect 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

¹² <http://www.fao.org/3/I5640E/i5640e.pdf>

¹³ CX/EXEC 22/82/4

¹⁴ 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

¹⁵ <https://eatforum.org/eat-lancet-commission/eat-lancet-commission-summary-report/>

¹⁶ 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>

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composition of foods made from plant-based and other alternative protein sources internationally.

- Therefore, the development of general guidance and principles for foods formulated with protein from non-animal 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 *Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987) and the *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 *Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987) 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 non-animal 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 non-animal 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 non-animal 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 several of the food categories included in the circular letter¹⁷ (plant-based protein alternatives, fermentation-derived ingredients, edible insects, and microalgae). 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 *General Principles for the addition of essential nutrients to foods* (CXG 9-1987) and the *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 *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.

¹⁷ CL 2022/06/OCS-CCEXEC

- The proposal may also relate to Codex commodity standards for products which would be used as ingredients in plant-based and other alternative protein source foods, such as the *Codex General Standard for Vegetable Protein Products* (CXS 174-1989), the *General Standard for soy protein products* (CXS 175-1989), and the *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 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. This work also established a database of alternative protein foods currently sold in the USA and 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.¹⁸ 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.

¹⁸ 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

Non-animal protein-based alternatives to ground meat:



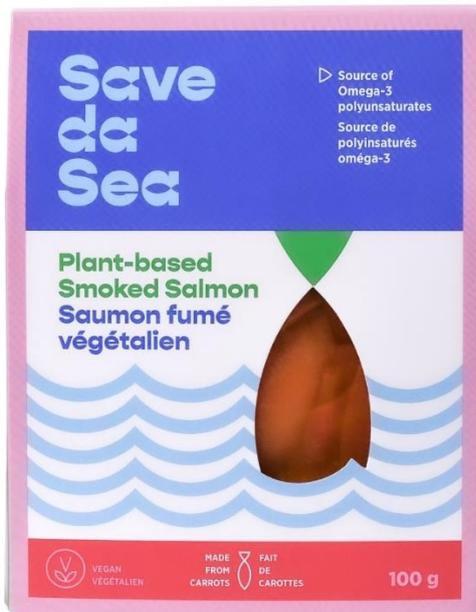
Non-animal protein-based alternatives to meat burgers and meatballs:



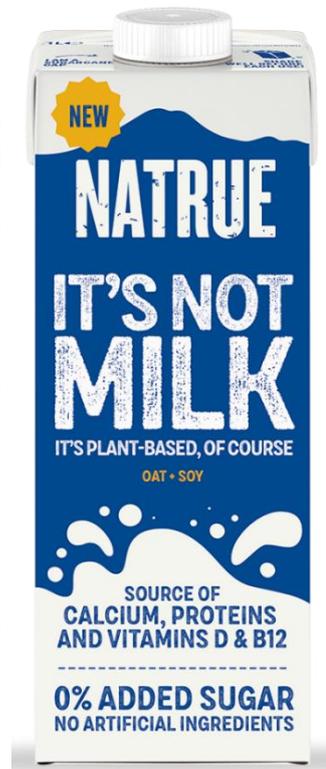
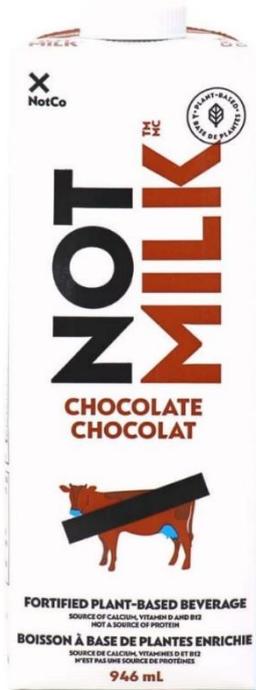
Non-animal protein-based alternatives to chicken:



Non-animal protein-based alternatives to fish and seafood products:



Non-animal protein-based alternatives to milk:



Non-animal protein-based alternatives to dairy products:



Topic proposal from Canada and USA: General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources

Assessment against the explanatory descriptions developed to complement the new work criteria of the Procedural Manual for the specific purposes of CCNFSDU¹

(1) Impact on public health

Describe the target group(s) (e.g. infants, the elderly, patients, whole population) that would be affected by the proposed new work and describe the intended and unintended health impact on the target group(s), and on other groups, if applicable. For example, what is the potential of the proposed work to resolve, prevent, or significantly reduce a public health risk? The impact should be justified and supported by examples and available data, when possible or helpful.

Target group(s):

The target group is the general population four years of age and above who consume a mixed diet, including foods formulated with protein from non-animal protein sources that are intended to replace animal-based products.

In developing general nutrition composition guidance and principles, we may target certain groups who may have an increased consumption of substitute foods formulated with protein from non-animal sources, such as vegetarians and vegans, and vulnerable groups such as children and elderly.

Intended health impact on target group(s):

For the target group, the intended health impact of establishing recommended international nutrition composition guidance for foods formulated with protein from non-animal sources is to reduce the risk of inadequate or excessive intakes of certain nutrients. This would be achieved through industry-led product development aligned with the guidance and/or government regulations and policies related to product formulations.

Background Information and Supporting Evidence:

- Recent dietary guidance and consumer interest have led to a rise in the availability of plant-based and other non-animal protein foods on the global market, including foods formulated with protein from non-animal sources which are intended to replace animal-based products.
 - Dietary guidance globally is increasingly recommending adoption of plant-based diets, and a reduction in the consumption of red and processed meat.^{2,3,4,5} This is based on evidence linking high quality vegetarian and primarily plant-based dietary patterns with reduced risk of a variety of diet-related chronic diseases including obesity, type 2 diabetes, heart disease and certain cancers.^{6,7,8}
 - In response to global consumer interest, foods formulated with protein from non-animal sources have increased rapidly in the last decade, both in the number of new products reaching the market and the number of units sold annually.

¹ Based on the instructions for submitting proposals for new work and the explanatory notes to complement the new work criteria of the Procedural Manual for the specific purposes of CCNFSDU, provided in CL 2024/52-NFSDU. Accessed on May 27, 2024 from https://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FCircular%252520Letters%252FCL%2525202024-52%252Fcl24_52e.pdf

² Canada's Food Guide (2019). Available at: <https://food-guide.canada.ca/en/>

³ Dietary Guidelines for Americans 2020-2025. Available at: <https://www.dietaryguidelines.gov/>

⁴ Eatwell Guide 2016. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/746558/Eatwell_guide_colour_edition.pdf

⁵ Dietary Guidelines for the Brazilian Population 2014. Available at: <https://www.fao.org/nutrition/education/food-based-dietary-guidelines/regions/countries/brazil/en/>

⁶ Satija, Ambika, and Frank B. Hu. "Plant-based diets and cardiovascular health." *Trends in cardiovascular medicine* 28.7 (2018): 437-441.

⁷ McEvoy, Claire T., Norman Temple, and Jayne V. Woodside. "Vegetarian diets, low-meat diets and health: a review." *Public health nutrition* 15.12 (2012): 2287-2294.

⁸ Hemler, Elena C., and Frank B. Hu. "Plant-based diets for personal, population, and planetary health." *Advances in Nutrition* 10 (2019): S275-S283.

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- The global plant-based food sector exceeded \$43 billion USD in 2023, and is projected to exceed \$85 billion USD by 2030.^{9,10}
 - By 2030, the edible insect market is forecasted to reach USD \$9.6 billion globally, and the fungal protein market is forecasted to reach USD \$386.6 million globally.^{11,12}
 - There may be public health risks (both from inadequate or excessive intakes of certain nutrients) associated with foods formulated with protein from non-animal sources. This is due to their variable nutrient composition, consumer assumptions that these products are nutritionally equivalent or superior to the products they are replacing, and a potential increased reliance on these foods as consumers continue to shift dietary patterns. Health risks may be greater in vulnerable populations such as children and elderly, and those following vegetarian and vegan diets.
 - 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.¹³ This work highlights that there is large variability in nutrient composition within product subgroups for these foods, several plant-based alternative categories had significantly lower protein content than their animal-based counterparts (evidence from published research on micronutrient content was limited), and that some plant-based alternatives had higher levels of nutrients to limit such as saturated fat and sodium. For example:
 - the protein content of plant-based products imitating seafood and sausage ranged from 1 - 44g/100g and 8 – 25g/100g, respectively.
 - plant-based products imitating cheese contained an average of 10-fold lower protein than cheese, and apart from soy-beverages, plant-based products intending to replace milk had an average of approximately 3-fold lower protein than milk (with coconut beverages having the lowest protein content, over 8-fold lower than milk).
 - 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.
 - An assessment of 132 plant-based substitutes for meat in Australia found that only 12% were fortified with iron, zinc and vitamin B12, resulting in significant composition variability across products.¹⁴ The authors expressed that the low fortification rates are a potential health concerns, particularly for consumers substituting these product for meat and are not consuming other animal-based products such as milk, yogurt, cheese and eggs.
 - Studies assessing the nutritional quality of plant-based diets, including those using plant-based alternatives, indicate that while there are health benefits, there are also risks of inadequate intakes of certain nutrients. Generally, intakes of fibre, folate, magnesium, fat and saturated fat improve with plant-based diets, however there is also a reduction in the intakes of important essential nutrients such as protein (including reductions in protein quality), Vitamin A, Vitamin D, Vitamin B12, heme-

⁹ <https://www.globenewswire.com/news-release/2024/02/12/2827392/0/en/Plant-Based-Food-Market-Surges-to-USD-85-Billion-by-2030-Reflecting-an-9-95-Growth-MarketDigits.html#:~:text=The%20Global%20Plant%20Based%20Food,forecast%20period%20of%202023%2D2030>

¹⁰ <https://doi.org/10.3389/fsufs.2020.00134>

¹¹ Meticulous Research, 2022. https://www.meticulousresearch.com/product/edible-insects-market-5156?utm_source=Globenewswire&utm_medium=Paid&utm_campaign=Product&utm_content=25-05-2022

¹² Allied Market Research, 2021. <https://www.alliedmarketresearch.com/fungal-protein-market-A12366#:~:text=The%20global%20fungal%20protein%20market,total%20fungal%20protein%20market%20share>

¹³ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

¹⁴ <https://onlinelibrary.wiley.com/doi/10.1111/1747-0080.12793>

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iron and zinc.^{15,16,17,18} The reduction in iron, zinc and vitamin A are particularly important as these are three of the most common micronutrient deficiencies globally, most prominent in young children and women of reproductive age.^{19,20}

- Consumer research also highlights that a “health halo” may exist for some plant and other non-animal protein foods, potentially increasing the risk of nutrient inadequacies in consumers using these products.
 - The United States Food and Drug Administration conducted focus groups which found that although consumers could differentiate plant-based beverages from milk, they do not always understand the nutritional differences between the products and consumers of plant-based alternatives frequently mentioned these products were healthier than milk.²¹
 - An Australian survey in 2020 indicated that over 70% of nutrition professionals and over half of consumers think that meat analogues should have the same iron and vitamin B12 content as traditional meat.²²
 - The final report from Australia’s industry working group on the labelling and marketing of plant-based alternatives to meat and meat-based and dairy products highlighted that 36% of respondents to a national survey perceived plant-based alternatives to be nutritionally equivalent to milk.²³

Unintended health impact on target group(s):

Unintended health impacts on the target group are expected to be very minimal. The establishment of recommended nutrition composition guidance for foods formulated with protein from non-animal sources may create a health halo around these products, particularly if these products qualify for and use nutrient content and health claims. Consumers may shift towards increasing consumption of these processed products, instead of relying on nutrient dense whole plant protein foods which most dietary guidance recommends. However, the proposed general guidance would also include considerations to address nutrients of public health concern commonly found in processed foods (e.g., saturated fat, sugars, sodium), which may actually improve the nutrition quality of these products and minimize any negative, unintended health impacts.

Intended and unintended health impact on other groups:

The target group is the vast majority of the population, and there are no anticipated intended or unintended impacts on the health of other groups.

(2) Impact on food safety

Describe how the proposed new work would impact food safety (i.e. biological, chemical, or physical risks). The impact should be justified and supported by examples and available data, when possible or helpful.

The scope of the proposed guidance is limited to nutrition composition, and is not intending to consider food safety aspects.

(3) Impact on trade practices

Describe how the proposed new work would impact global food trade and how this work might harmonize international standards and reduce barriers to fair trade. Potential impacts on product

¹⁵ <https://cdnsnciencepub.com/doi/pdf/10.1139/apnm-2020-1039>

¹⁶ <https://pubmed.ncbi.nlm.nih.gov/33591857/>

¹⁷ <https://www.mdpi.com/2072-6643/12/7/2034/htm>

¹⁸ <https://pubmed.ncbi.nlm.nih.gov/28532520/>

¹⁹ <https://karger.com/anm/article/66/Suppl.%202/22/40738>

²⁰ Stevens, Gretchen A., et al. "Micronutrient deficiencies among preschool-aged children and women of reproductive age worldwide: a pooled analysis of individual-level data from population-representative surveys." *The Lancet Global Health* 10.11 (2022): e1590-e1599

²¹ 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.

²² <https://www.mdpi.com/2071-1050/13/3/1478>

²³ Industry Working Group Discussion Paper, The Labelling and Marketing of Plant-based Alternatives to Meat and Meat-based and Dairy products. 2021. Available at: <https://www.aph.gov.au/DocumentStore.ashx?id=e8e3f6e4-c348-4cc4-9594-df1f86004c69>

consumption should also be considered. The impact should be justified and supported by examples and available data, when possible or helpful.

Establishing general global guidance and principles for the recommended nutritional composition of foods formulated with protein from non-animal sources, taking into account regional differences in dietary patterns and consumption, is expected to create more consistent policies, regulations and standards for these products across countries and regions. General global guidance may also influence product composition decisions by manufacturers in countries who do not have/are not planning to have policies, regulations or standards for these products. This will ultimately lead to more harmonized nutrient composition across product categories globally, resulting in benefits for both trade and consumer understanding.

Taking steps now to establish general guidelines and principles for jurisdictions to use in the development of guidance and regulations or for industry to use in product development, while the market is still growing and evolving, will maximize the potential impact of this work on harmonizing international standards and mitigating trade issues.

Background Information and Supporting Evidence:

- Currently, international policies and regulations for the nutritional composition of foods formulated with protein from non-animal sources varies greatly. This has resulted in a lack of consistency in product composition across global markets, creates trade barriers, and increases consumer confusion.
 - The majority of jurisdictions globally do not have specific regulations in place for the nutritional composition of foods formulated with protein from non-animal sources which are substitute foods for animal-based products. Canada does have specific regulations in place which require simulated meat and poultry products to meet certain nutritional compositional criteria outlined in the Canadian Food and Drug Regulations, however these are dated.²⁴
 - Several jurisdictions, including the European Union²⁵, the United States²⁶, Australia and New Zealand²⁷, do not have specific composition requirements for foods formulated with protein from non-animal sources but permit the voluntary addition of certain nutrients to these products.
 - There have been indications in recent years that some jurisdictions are looking to develop policies and regulations, or expand upon existing policies, for the composition and labelling of various non-animal protein foods. This highlights the importance and timeliness of developing global guidance for these foods.
 - In April 2020 the Japanese Ministry of Agriculture, Forestry and Fisheries established the “Food Tech Study Group” with the goal to establish regulations for a variety of emerging protein sectors including alternative meats.²⁸
 - A voluntary standard, including basic composition requirements, for plant-based meat products was developed in 2020 by the Chinese Institute of Food Science and Technology, and implemented in June 2021.²⁹

²⁴ Food and Drug Regulations, Parts 14 and 22. Available at:

https://laws.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/index.html

²⁵ Regulation (EC) no 1925/2006 of the European parliament and of the council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods

²⁶ Code of Federal Regulations Title 21, volume 2, part 104. Available at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=104.20>

²⁷ Australia New Zealand Food Standards Code – Schedule 17 – Vitamins and minerals. Available at:

<https://www.legislation.gov.au/F2015L00449/2017-04-13/text>

²⁸ USDA Report: Japan Begins to Explore Regulations for Alternative Meat Products, 2020. Available at:

https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Japan%20Begins%20to%20Explore%20Regulations%20for%20Alternative%20Meat%20Products_Tokyo_Japan_08-12-2020

²⁹ USDA, Industry Group Issues Voluntary Standard for Plant Based Meat Alternative Products. Available at:

https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Industry%20Group%20Issues%20Voluntary%20Standard%20for%20Plant-Based%20Meat%20Alternative%20Products_Beijing_China%20-%20People%27s%20Republic%20of_01-09-2021

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- In 2023 the United States Food and Drug Administration published and consulted on draft guidance for industry on the labelling of plant-based beverages.³⁰
 - In 2023 the Canadian Food Inspection Agency updated their guidelines for simulated meat and poultry products to clarify the application of existing rules and promote market consistency, including summarizing composition requirements for these products.³¹
 - The 2024 Australia Federal Budget committed \$1.5 million to improve existing regulations for the labelling of plant-based and alternative protein products, including funding for independent consumer research to understand the extent of any consumer confusion in relation to plant-based and alternative protein labelling.³²
- The lack of consistency in regulations and policies globally for the composition of foods formulated with protein from non-animal sources has led to huge variability in the nutrient composition of these products, both between and within jurisdictions, and across and within product categories.
 - 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.³³ The data assessed products globally and found that there is significant variation in the composition of plant-based meat and dairy imitations, even within the same food subgroup. For example, the protein content of plant-based imitations of sausage ranged from 8 - 25g/100g and plant-based seafood imitations ranged from 1 - 44g/100g.³⁴
 - An assessment of 132 plant-based substitutes for meat in Australia in 2021 found that only 12% were fortified with iron, zinc and vitamin B12, resulting in significant composition variability across products.³⁵

(4) Global impact

Describe how the proposed new work would be suitable for addressing a worldwide nutrition problem, as per the Codex mandate. The impact should be justified and supported by examples and available data, when possible or helpful.

The rapid increase in availability of foods formulated with protein from non-animal sources is truly 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. Variability in the nutritional composition of foods formulated with protein from non-animal sources, and a lack of current science-based oversight, creates the potential for consumer health impacts on a global scale, from both inadequate and excessive nutrient intakes.

By establishing recommended nutritional composition guidance for these foods based on nutritional equivalence, the proposed work may positively impact health worldwide by minimizing the exacerbation of existing global nutrient inadequacies and deficiencies. This may be particularly impactful in vulnerable populations such as children and elderly, and vegetarians and vegans with limited variety in their diets. The consideration of nutrients of public health concern when consumed in excess of recommendations (e.g., saturated fat, sugars, sodium) in the guidance may also positively

³⁰ 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.

³¹ 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.

³² <https://www.agriculture.gov.au/sites/default/files/documents/2024-25-budget-protecting-and-growing-the-future-of-Australian-agriculture.pdf>

³³ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

³⁴ Food and Agriculture Organization of the United Nations. Proposed Nutrient Profiles for Alternative Protein Foods. Unpublished.

³⁵ <https://onlinelibrary.wiley.com/doi/10.1111/1747-0080.12793>

impact diet-related chronic diseases experienced widely around the world, such as obesity, diabetes and heart disease.

There are also potential global environmental sustainability benefits associated with primarily plant-based and other non-animal protein diets compared to diets rich in animal products, highlighted by some recent dietary recommendations such as the planetary health diet.³⁶ By establishing recommended nutrient composition guidance for foods formulated with protein from non-animal sources, it may support consumers in using these products while still obtaining adequate intakes of essential nutrients, and subsequently reduce consumption of animal-based foods. This may result in positive global impacts on environmental sustainability.

Background Information and Supporting Evidence:

- The non-animal protein food market is growing, globally:
 - Foods formulated with protein from non-animal sources have increased rapidly in the last decade, both in the number of new products reaching the market and the number of units sold annually. The global plant-based food sector exceeded \$43 billion USD in 2023, and is projected to exceed \$85 billion USD by 2030.^{37,38}
 - By 2030, the edible insect market is forecasted to reach USD \$9.6 billion globally, and the fungal protein market is forecasted to reach USD \$386.6 million globally.^{39,40}
 - While Europe and North America have historically held the largest share of the plant-based alternatives market, markets in China, Singapore, India, Australia, the United Arab Emirates and South America are seeing some of the strongest growth and investment.
- Nutrient inadequacies are a global issue:
 - Compared to animal-based foods, plant-based foods often contain less iron, vitamin A and zinc, which are three of the most widespread micronutrient deficiencies worldwide. Globally, the most common micronutrient deficiency is in iron, with an estimated 2 billion people deficient worldwide. This is particularly pronounced in pregnant women.⁴¹
 - It is estimated that globally 56% of pre-school aged children and 69% of non-pregnant women of reproductive age are deficient in at least one of iron, zinc, or vitamin A. These deficiencies were most prominent in south Asia, sub-Saharan Africa, and east Asia and the Pacific.⁴²

³⁶ <https://eatforum.org/eat-lancet-commission/eat-lancet-commission-summary-report/>

³⁷ <https://www.globenewswire.com/news-release/2024/02/12/2827392/0/en/Plant-Based-Food-Market-Surges-to-USD-85-Billion-by-2030-Reflecting-an-9-95-Growth-MarketDigits.html#:~:text=The%20Global%20Plant%20Based%20Food,forecast%20period%20of%202023%2D2030>

³⁸ <https://doi.org/10.3389/fsufs.2020.00134>

³⁹ Meticulous Research, 2022. https://www.meticulousresearch.com/product/edible-insects-market-5156?utm_source=Globenewswire&utm_medium=Paid&utm_campaign=Product&utm_content=25-05-2022

⁴⁰ Allied Market Research, 2021. <https://www.alliedmarketresearch.com/fungal-protein-market-A12366#:~:text=The%20global%20fungal%20protein%20market,total%20fungal%20protein%20market%20share>

⁴¹ <https://karger.com/anm/article/66/Suppl.%202/22/40738>

⁴² Stevens, Gretchen A., et al. "Micronutrient deficiencies among preschool-aged children and women of reproductive age worldwide: a pooled analysis of individual-level data from population-representative surveys." *The Lancet Global Health* 10.11 (2022): e1590-e1599.

Proposal 2.5

DISCUSSION PAPER ON THE DEVELOPMENT OF A CODEX STANDARD FOR FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

Prepared by the United States of America

Introduction

Complementary feeding of older infants and young children is necessary for healthy growth and development. In 2023 the World Health Organization (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 frequent pulses, nuts, and seeds. They also recommend limiting foods high in sugar, salt, and trans-fat.

In December of 2023 an expert consultation of international experts hosted by the Micronutrient Forum (attended by Food and Agriculture Organization (FAO), the World Food Program (WFP) the United Nations International Children's Emergency Fund (UNICEF), and others) 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 the United States Agency for International Development (USAID).² 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 those countries ages 6-23 months are not able to be fed diverse diets needed for healthy growth and development during this critical period of development. Furthermore, recent reports have found that most commercially available fortified complementary foods are not nutritionally adequate.³ 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.⁴

When possible, food systems should be improved to provide affordable locally grown nutrient dense foods. When this is not possible, or it might take years for food system transformation, formulated complementary foods can play an important role in ensuring adequate nutrition. However, science-based international standards to guide composition and labelling for formulated complementary foods are lacking.

Background

CCNFSDU has three texts related to complementary feeding of older infants and young children: the *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991), 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).

The *Guidelines* (CXG 8-1991) provides nutrition targets for complementary foods based on data from the WHO and the Food and Agriculture Organization of the United Nations (FAO) that are two decades old.⁵ The two Codex Standards (CXS 73-1981 and CXS 74-1981) provide requirements for composition of canned baby foods and cereal-based complementary foods based on individual nutrient requirements, emphasize sourcing local ingredients, and have provisions for processing methods, contaminants, hygiene, food additives, packaging, and labelling. The standards only cover canned baby foods (without a designated age range) and cereal-based foods for infants and young children. The standards also do not reflect recent scientific data and findings. The Codex Secretariat's recent review of CCNFSDU standards ([CX/NFSDU 24/4/7](#)) identified both CXS 73-1981 and the CXS 74-1981 as standards in need of revision and/or updating.

Codex standards are lacking for other complementary foods, such as meat, vegetable, fruit or pulses-based products, which market research has shown have increased in volume and diversity in the global trade.⁶ Other related Codex texts include 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*

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

² Micronutrient Forum. Making food systems work for complementary feeding in low- and middle-income countries: Meeting report. Washington, D.C.: Micronutrient Forum; 2024.

³ 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>

⁴ 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.

⁵ World Health Organization. *Vitamin and mineral requirements in human nutrition.* World Health Organization, 2004.

⁶ <https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-food-trends-canada-united-states-mexico-cusma#a>

(CXG 9-1987), and ongoing committee work to establish General Principles and Nutrient Reference Values-Requirements (NRVs-R) for persons aged 6 – 36 months.

Analysis

In light of the new WHO recommendations;⁷ inadequate accessibility, affordability, and availability of nutrient-rich foods from current food systems;⁸ and the lack of standards for formulated complementary foods to meet current recommendations for nutritional adequacy around the world,⁹ there is a strong basis for new work to address the nutritional needs of this age group. Updating the existing standards and implementing new standards for the wide range of formulated complementary foods now commercially available would be a cumbersome, piecemeal approach and would risk not having standards appropriate for meeting the needs of older infants and young children for complementary feeding.¹⁰

Recommendation

To best address current needs, CCNFSDU should consider development of a single standard which reflects the latest global science-based recommendations for complementary feeding and encompasses all the recommended food groups. Rather than update the outdated Codex texts and develop multiple new standards, the United States suggests a more comprehensive approach to meet the needs of today's older infants and young children. The development of a science-based standard for formulated complementary foods for older infants and young children would provide nutritional, quality, and safety parameters applicable to all formulated complementary foods and replace the three outdated relevant Codex texts (CXG 8-1991, CXS 73-1981, and CXS 74-1981). A project document is attached for Committee consideration.

⁷ World Health Organization. "Guideline for complementary feeding of infants and young children 6-23 months of age." (2023): 96-96.

⁸ 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.

⁹ 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>

¹⁰ World Health Organization. "Guideline for complementary feeding of infants and young children 6-23 months of age." (2023): 96-96.

PROJECT DOCUMENT

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

Prepared by the United States of America

I. Purpose and Scope of the New Work

The purpose of this project is to develop a Standard for Formulated 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 formulated complementary food for older Infants and young children, including but not limited to meat, vegetable, fruit or pulses-based products, and includes canned baby foods and processed cereal-based foods.

Breastmilk substitutes are a separate category of products from formulated 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 counties and that two in three children are not able to be fed diverse diets needed for healthy growth and development 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 formulated complementary foods are lacking, outdated, or not followed. A recent report found that most commercially available fortified complementary foods are not nutritionally adequate.⁴

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

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-food-trends-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 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, as well as CXG 8-1991, 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 Formulated 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 (CXS 73-1981 and CXS 74-1981) and update relevant guidance from CXG 8-1991. The main aspects that this proposed standard would consider are as follows:

- Relevant updates to the guidelines contained in CXG 8-1991 in light of current scientific findings and recommendations for complementary feeding for persons aged 6-36 months
- Formulated complementary foods 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

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 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

The lack of a science-based standard to guide the nutritional composition, safety, quality, and labelling for formulated complementary 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,

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

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.

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 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 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 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 formulated complementary foods to ensure they are nutritionally adequate and safe can help address these global issues in a timely manner.

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

⁸ https://cdn.who.int/media/docs/default-source/nutrition-and-food-safety/complementary-feeding/cf-guidelines/dietary-modelling.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.

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-food-trends-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-

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 formulated complementary 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**

Formulated 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 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. It will incorporate and update the relevant aspects of existing texts and replace three Codex texts: CXG 8-1991, 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

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.

PART 2: PROPOSAL BY THE UNITED STATES OF AMERICA

- CAC47, November 2024: Step 1 Approval as new work
- CCNFSDU45, Autumn 2026: Step 2/3/4
- CAC50, Summer 2027: potential interim adoption at Step 5 of key provisions upon which CCNFSDU has reached consensus
- CCNFSDU46, Autumn 2027: Step 4/5
- CAC51, Summer 2028: Adoption at Step 5
- CCNFSDU47, Autumn 2028: Step 6/7
- CAC52, Summer 2029: Final adoption at Step 8

ASSESSMENT AGAINST THE CCFSDU 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.¹⁵
- 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.¹⁶
- Science-based international standards to guide composition and labelling for formulated complementary foods are lacking.
- 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 international standard to guide the composition, safety, and quality of formulated 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 CCFSDU.

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 formulated complementary foods.

The Codex Secretariat's recent review of CCFSDU 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

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

¹⁵ 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.

¹⁶ 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.

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.¹⁷ 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.¹⁸ 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.¹⁹

Science-based international standards to guide composition, safety, and labelling for formulated complementary foods are lacking 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.

¹⁷: 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.

¹⁸ Micronutrient Forum. Making food systems work for complementary feeding in low- and middle-income countries: Meeting report. Washington, D.C.: Micronutrient Forum; 2024.

¹⁹ 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>