

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

# E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 7

CX/NFSDU 23/43/7

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

Forty-third Session

Dusseldorf, Germany

7 – 10 March with report adoption by virtual mode on 15 March 2023

### PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS

Prepared by Germany

#### Comments in reply to CL 2020/30/OCS-NFSDU

*Replies by Argentina & Malaysia, Costa Rica, the Dominican Republic, Switzerland, the United States of America & Canada and the European Margarine Association (IMACE)*

#### INTRODUCTION

1. The 41<sup>st</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41) agreed to request the Codex Secretariat to issue a Circular Letter (CL) requesting proposals for new work. The Committee also agreed on a prioritization mechanism and to start it on a pilot basis to assess its usefulness. It also agreed to establish a physical working group chaired by Germany meeting immediately prior to the next session to adjust the draft framework of the prioritization mechanism outlined in the draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU, as necessary, and to conduct a case-by-case review of the proposals submitted by the members in response to the CL.

2. CL 2020/30-NFSDU was sent out to all Members and Observer Organizations in April 2020. Member Governments were invited to propose new work for consideration by the above working group, in accordance with the Criteria for the Establishment of Work Priorities and with the “Draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU”.

3. Due to the COVID-19 pandemic, CCNFSDU42 had to be postponed and then met virtually with an abridged agenda on 19 November to 1 December 2021. As a result, the physical Working Group on the CCNFSDU prioritization mechanism did not meet. However, CCNFSDU42 recognized the need to plan strategically its future work and to start immediately with the work on prioritization. For this reason, the Committee agreed to establish an electronic Working Group chaired by Germany and co-chaired by Canada to revise the draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU and to start using it on a pilot basis at the next session. The report of this EWG and the revised guideline for the preliminary assessment and identification of work priorities for CCNFSDU will be issued as CX/NFSDU 23/43/8.

4. Until 30 September 2022 six new work proposals were received in response to CL 2020/30-NFSDU.

#### CONCLUSION

5. This document presents:

- A comprehensive overview of all new topics that have been proposed to CCNFSDU (prospectively this table will be updated regularly including topics that were considered as priorities but postponed for various reasons as well as topics that have not been supported) (Annex I);
- The proposals for new work and emerging issues received in response to CL 2020/30-NFSDU (Annex II).

#### RECOMMENDATIONS

6. CCNFSDU is invited to consider the new work proposals in light of the prioritization mechanism (see CX/NFSDU 23/43/8).

## OVERVIEW OF ALL NEW TOPICS THAT HAVE BEEN PROPOSED TO CCNFSDU (ALL-TIME LIST)

No.	Year discussed	Title of Work	Prepared by	Result of prioritization process of ad hoc WG	State of Play
<b>PART 1: REQUESTS FOR AMENDMENTS/REVISIONS OF EXISTING CCNFSDU TEXTS</b>					
1.1	2023	Proposed amendment/revision: Standard for Canned Baby Foods (CXS 73-1981)	Dominican Republic	<i>to be completed accordingly</i>	
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 advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children	Switzerland	<i>to be completed accordingly</i>	
<b>PART 2: REQUESTS FOR NEW WORK</b>					
2.1	2023	Harmonized probiotic guidelines for use in foods and food supplements	Argentina and Malaysia	<i>to be completed accordingly</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	Canada and the United States	<i>to be completed accordingly</i>	
2.3	2023	General Guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL)	Costa Rica (co-chaired by Paraguay, EU and the United States)	<i>to be completed accordingly</i>	
2.4	2023	Nutrient reference value (NRV-NCD) for trans-fatty acids	The European Margarine Association (IMACE)	<i>to be completed accordingly</i>	

## Table of Contents

## Part 1: REQUEST FOR AMENDMENTS/REVISIONS OF EXISTING CCFSDU TEXTS

No.*	Title of Work	Prepared by	Page
<b>Proposal 1.1</b>	Proposed amendment/revision: STANDARD FOR CANNED BABY FOODS (cxs 73-1981).	Dominican Republic	<b>4</b>
<b>Proposal 1.2</b>	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 ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN ( <b>CAC/GL 10- 1979</b> )	Switzerland	<b>9</b>

## PART 2: REQUESTS FOR NEW WORK

No.*	Title of Work	Prepared by	Page
<b>Proposal 2.1</b>	DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS <b>AND FOOD SUPPLEMENTS</b>	Argentina and Malaysia	<b>21</b>
<b>Proposal 2.2</b>	Guidelines including General Principles for the Nutritional Composition of foods and beverages made from plant-based and other alternative protein sources	Canada and the United States	<b>34</b>
<b>Proposal 2.3</b>	DISCUSSION PAPER ON GENERAL GUIDELINES TO ESTABLISH NUTRIENT PROFILES FOR FRONT- OF-PACK NUTRITION <b>LABELLING</b> <b>(FOPNL)</b>	Costa Rica (co-chaired by Paraguay, EU and the United States)	<b>47</b>
<b>Proposal 2.4</b>	DISCUSSION PAPER ON ESTABLISHING A NUTRIENT REFERENCE VALUE ( <b>NRV-NCD</b> ) FOR <b>TRANS-FATTY ACIDS</b>	The European Margarine Association (IMACE)	<b>69</b>

\* Proposals listed in alphabetical order of the names of the submitter(s).

## Proposal 1.1

**PROPOSED AMENDMENT/REVISION: STANDARD FOR CANNED BABY FOODS (CXs 73-1981<sup>1</sup>).***Prepared by the Dominican Republic***BACKGROUND****World Health Organisation (WHO).**

1. The 54<sup>th</sup> World Health Assembly, in its Resolution WHA54.2 - Infant and young child nutrition, states the following<sup>2</sup>:

URGES Member States:

4) to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding<sup>3</sup>, and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices.

**Complementary foods<sup>4</sup>**

2. Adequate nutrition during infancy and early childhood is fundamental to the development of each child's full human potential. It is well recognised that the period from birth to two years of age is a "critical window" for the promotion of optimal growth, health and behavioural development. Longitudinal studies have consistently shown that this is the peak age for growth faltering, deficiencies of certain micronutrients, and common childhood illnesses such as diarrhoea. After a child reaches 2 years of age, it is very difficult to reverse stunting that has occurred earlier (Martorell et al., 1994).

3. The optimal age range for complementary feeding is usually between 6 and 24 months of age, although breastfeeding can continue beyond the age of 2 years.

4. The WHO recommends that infants start receiving complementary foods at 6 months, first around two to three times a day between 6 and 8 months, and then between 9 to 11 months and 12 to 24 months, about three to four times a day, with nutritious snacks added once or twice a day as desired.

5. The American Academy of Pediatrics<sup>5</sup> recommends exclusive breastfeeding for about 6 months, followed by continued breastfeeding as other foods and drinks are introduced, with continuation of breastfeeding for one year or longer as mutually desired by mother and infant. While breastfeeding is strongly recommended and many mothers hope to breastfeed their infants, many infants in the U.S. rely on infant formula for some portion of their nutrition.

6. Act 8-95, in the Dominican Republic promotes and encourages Breastfeeding<sup>6</sup>:

- Article 1.- Promotion and Encouragement of Breastfeeding. The promotion, teaching and dissemination of breastfeeding is declared a national priority, as it is essential to ensure the healthy development and growth of children, who receive from their mothers not only the necessary nutrients, but also immunological protection and socio-affective support.

Article 2.- Mother and Child Programmes. Within the programmes aimed at pregnant women and women in labour, as well as in health education programmes for the general population, the State Secretariat of Public Health and Social Assistance (SESPAS) and the Dominican Institute of Social

<sup>1</sup> Previously CAC/RS 73-1976.

<sup>2</sup> <https://apps.who.int/iris/bitstream/handle/10665/260183/WHA54-2001-REC1-eng.pdf?sequence=1&isAllowed=y>

<sup>3</sup> As set out in the conclusions and recommendations of the expert consultation meeting (Geneva, 28-30 March 2001) which carried out the systematic review of information on the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

<sup>4</sup> <https://paho.org/hq/dmdocuments/2012/GuidingPrinciples.pdf>

<sup>5</sup> <https://www.fda.gov/consumers/consumer-updates/infant-formula-safety-dos-and-donts>

<sup>6</sup> <https://repositorio.msp.gob.do/bitstream/handle/123456789/761/LeyNo.8-95.PDF?sequence=1&isAllowed=y#:~:text=Se%20declara%20como%20prioridad%20nacional,tambien%20proteccion%20inmunologica%20y%20apoyo>

## PART 1: PROPOSAL 1 (Dominican Republic)

Security (IDSS), the Medical Corps and Military Health of the State Secretariat of the Armed Forces and the State Sugar Council (CEA) will develop programmes aimed at incentivising:

- a) Exclusive breastfeeding in the first six (6) months after birth.
- b) Breastfeeding up to two (2) years of age, with complementary feeding.

Paragraph - These programmes will be set up according to the organisational structure of the health services, in accordance with regulations to be drawn up for this purpose, ranging from clinics and surgeries in rural and urban areas to district and regional hospitals in urban areas.

7. The Spanish Association of Paediatrics (AEP)<sup>7</sup> recommends introducing pureed vegetables from the age of 6 months, avoiding spinach, cabbage and beetroot in the first months, since they can cause methaemoglobinaemia due to their nitrate content; it recommends introducing these vegetables from the age of 12 months. ([Nutrition Protocols. AEP Protocols, 2002. Chapter 2](#)).

8. The STANDARD FOR CANNED BABY FOODS (CXS 73-1981\* is a standard that encompasses food for infants and young children that are used mainly during the normal weaning period and during the progressive adaptation of infants and children to ordinary food. The foodstuffs covered by this standard do not include the products regulated by the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981) or by the *Standard for processed cereal-based foods for infants and young children* (CXS 74-1981).

9. **Dominican Republic**, in the interest of complying with the Codex principles of ensuring the health of consumers and fairness in the food trade, harmonises and homologates the standards elaborated by Codex and, at the same time, periodically revises Dominican regulations, ensuring that they adapt to the latest amendment or revision of the Codex Alimentarius version.

10. The mirror technical committee of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CT-NFSDU) conducted a revision of the “STANDARD FOR CANNED BABY FOODS” CXS 73-1981\* in its latest 2017 amendment, and during the revision discussions in the technical committee, the breastfeeding medical experts noted that paragraph 9.5.2 of all versions of the standard indicated the following wording:

→ **9.5.2** For canned beets (beetroot) and spinach, the following statement shall appear on the label: “use after the age of **twelve weeks**”.

11. This was a cause for concern, as the country’s guidelines are “*Exclusive breastfeeding for the first six (6) months after birth*”, and yet this paragraph of CXS 73-1981 is promoting the feeding of complementary foods to three-month (12-week) old infants, which poses a serious risk to *the health of the infants*.

• **Data giving rise to the need for amendment/revision of the “STANDARD FOR CANNED BABY FOODS” CXS 73-1981\*.**

12. Dietary intake of nitrates in Spanish infants and children and risk of methaemoglobinaemia<sup>8</sup>. J. Basulto, M. Manera, E. Baladia.

13. Although vegetable consumption is recommended for adults as well as infants and young children, there is a risk that infants and young children may ingest, through these foods, amounts of nitrates that increase the risk of methaemoglobinaemia. Although the average intake of nitrates in the European child population does not exceed safety margins, an analysis carried out by the European Food Safety Authority (EFSA) in 2010 revealed that spinach consumption may be implicated in certain cases of childhood methaemoglobinaemia.

14. In April 2011, after taking into account the abovementioned EFSA report, the Spanish Agency for Food Safety and Nutrition (AESAN) issued a series of recommendations addressed to the Spanish population regarding the presence of nitrates in vegetables. Despite endorsing EFSA’s recommendations, AESAN added

7

[https://www.aesan.gob.es/AECOSAN/web/para\\_el\\_consumidor/ampliacion/nitratos\\_hortalizas.htm#:~:text=La%20Asociaci%C3%B3n%20Espa%C3%B1ola%20de%20Pediatr%C3%ADa,partir%20de%20los%2012%20meses](https://www.aesan.gob.es/AECOSAN/web/para_el_consumidor/ampliacion/nitratos_hortalizas.htm#:~:text=La%20Asociaci%C3%B3n%20Espa%C3%B1ola%20de%20Pediatr%C3%ADa,partir%20de%20los%2012%20meses)

<sup>8</sup> <https://pap.es/articulo/11892/>; Basulto Marset J, Manera M, Baladia E. Ingesta dietética de nitratos en bebés y niños españoles y riesgo de metahemoglobinemia. Rev Pediatr Aten Primaria. 2014;16:65-9. Published on the Internet: 14-11-2013.

## PART 1: PROPOSAL 1 (Dominican Republic)

chard to the list of potentially hazardous vegetables. This vegetable is consumed much more frequently in Spain than in other European countries, and it may have higher nitrate levels than those of spinach.

15. The AESAN recommendations were as follows:
- It is recommended, as a precaution, not to include spinach and chard in purees before the first year of life. If these vegetables are included before the age of one year, care should be taken to ensure that the spinach and/or chard content does not exceed 20% of the total content of the puree.
  - Children between one and three years of age should not be given more than one serving of spinach and/or chard per day.
  - Spinach and/or chard should not be given to children with bacterial gastrointestinal infections.
  - Cooked vegetables (whole or pureed) should not be kept at room temperature. They must be kept in the refrigerator if they are to be consumed on the same day. If they are not to be consumed on the same day, they should be frozen.
16. Therefore, food containing vegetable puree of spinach, cabbage, beetroot or chard is not recommended for consumption by infants and babies under one year of age, as their consumption in this age group could represent a hazard associated with these food products that may have an adverse effect on the health of children under one year of age.
17. Following the provisions of the Codex Procedural Manual,<sup>9</sup> “PROCEDURES FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS”, which indicates in the introduction in Article 8:
- It will be for the Commission itself to keep under review the revision of “Codex standards”. The procedure for revision should, mutatis mutandis, be that laid down for the elaboration of Codex standards, except that the Commission may decide to omit any other step or steps of that Procedure where, in its opinion, an amendment proposed by a Codex Committee is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by the Commission at Step 8.
  - Taking note of the Guide to the Procedure for the Amendment and Revision of Codex Standards and Related Texts:
  - For the purpose of this Guide:
    - Amendment means any addition, change or deletion of text or numerical values in a Codex standard or related text, may be editorial or substantive, and concerns one or a limited number of articles in the Codex text.
  - In particular, amendments of an editorial nature may include but are not limited to:
    - correction of an error;
    - insertion of an explanatory footnote;
    - updating of references consequential to the adoption, amendment or revision of Codex standards and other texts of general applicability, including the provisions in the Procedural Manual.
  - Revision means any changes to a Codex standard or related text other than those covered under “amendment” as defined above.
  - The Commission has the final authority to determine whether a proposal made constitutes an amendment or a revision, and whether an amendment proposed is of an editorial or substantive nature.
18. Therefore, we ask the Codex Committee on Nutrition and Foods for Special Dietary Uses to consider supporting the amendment/revision of the “STANDARD FOR CANNED BABY FOODS” CXS 73-1981\*, so that the Commission approves the correction of paragraph 9.5.2 and modifies it to the following text in all versions:
- 9.5.2** For canned beets (beetroot) and spinach, the following statement shall appear on the label: **“Use after the age of twelve months”**.

<sup>9</sup> <https://www.fao.org/3/ca2329en/CA2329EN.pdf>

---

**PART 1: PROPOSAL 1 (Dominican Republic)**

---

19. Should the CCNFSDU43 consider that further scientific information is needed, we request to consider supporting the sending of the request to JEMNU, to ensure that the recommendation in CXS-73-1981 is correct for the age group comprising infants and young children.
20. **Dominican Republic** thanks the CCNFSDU43 for taking note of and supporting the concern expressed and stated in the Annex to this document, Draft Amendment.

**PROPOSED AMENDMENT TO THE STANDARD FOR CANNED BABY FOODS**

(CXS 73-1981\*)

**(Presented by Dominican Republic)****1. Objective and scope of the Standard**

The objective of the proposed amendment is to promote adequate nutrition for infants and young children under one year of age, since adequate nutrition during infancy and early childhood is fundamental to the development of each child's full human potential.

It is well recognised that the period from birth to two years of age is a "critical window" for the promotion of optimal growth, health and behavioural development. Longitudinal studies have consistently shown that this is the peak age for growth faltering, deficiencies of certain micronutrients, and common childhood illnesses such as diarrhoea. (Martorell et al., 1994).

**2. Relevance.**

In view of the fact that breastfeeding in infants is recommended to be complemented from six months onwards with other foods to cover the nutritional needs of the young child, it is relevant that international regulations ensure that the foods that are added to the infant's menu are those that ensure the health and nutrient intake necessary for his or her development.

It has been proven that the consumption of certain vegetables before the age of one in infants can have harmful effects on their health, and for this reason the Spanish Association of Paediatrics (AEP) recommends introducing pureed vegetables from the age of 6 months, avoiding spinach, cabbage and beetroot in the first months, since they can cause methaemoglobinaemia due to their nitrate content; it recommends introducing these vegetables from the age of 12 months. (Nutrition Protocols. AEP Protocols, 2002. Chapter 2).

**3. Issue raised that needs to be addressed.**

Evaluate the amendment to the standard on container labelling in the Information for Utilization section, in the interest of reducing the danger of vegetable consumption in children up to 12 months of age.

**Draft amendment**

Provision on the labelling of containers in the Information for Utilization section of the Standard for Canned Baby Foods, to be revised.

<b>Title</b>	<b>Reference number</b>	<b>Current section to be reviewed</b>
Standard for canned baby foods	CXS 73-1981*	9.5 Information for utilization  9.5.1 Directions as to the preparation and use of the food and its storage and keeping before and after the container has been opened, shall appear on the label or on the accompanying leaflet.  9.5.2 For canned beets (beetroot) and spinach, the following statement shall appear on the label: "use after the age of twelve weeks".

Options for reviewing the provisions on the labelling of containers in the Information for Utilization section:

**Option 1.**

Replace the provision of article 9.5.2 placed between quotation marks ("use after the age of twelve weeks") with the following text:

**"use after the age of twelve months"**

**Option 2.**

Send the request for change to JEMNU in order to ensure that the recommendation in CXS-73-1981 is revised and scientifically proven to be correct.

## Proposal 1.2

**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 ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (CAC/GL 10-1979)**

*Prepared by Switzerland*

**BACKGROUND**

The Advisory List of nutrient compounds CXG 10-1079 lists calcium-L-methyl-folate as one of two permitted forms of the vitamin folic acid and allows its use for formulas for special medical purposes intended for infants (IF, Sec. B of Codex Standard CXS 72-1981) and generally for foods for special medical purposes for infants and young children. It presently does not allow its use in infant formula (IF, Sec. A of CXS 72-1981), follow-up formula (CXS 156-1987), processed cereal based food for infants and young children (CXS 74-1981) and canned baby food (CXS 73-1981). However, recent science strongly supports that calcium-L-methyl-folate is suitable as a source of folic acid for all foods intended for infants and young children.

The substance L-methyl-folate (synonym: L-5-methyltetrahydrofolate (L-5-MTHF)) is the natural form of the vitamin folic acid/folate. It is an essential B-vitamin, crucial for the synthesis of RNA and DNA, the metabolism of amino acids and for cell division and tissue growth (IOM, EFSA 2014). L-methyl-folate is the active, natural form of folate found in food (Friedrich 1987) and in human plasma. It is the predominant form of folate found in breast milk (Page et al., 2017; EFSA, 2020). It provides one carbon units used for the synthesis of myelin, neurotransmitters and phospholipids, all of which are essential components for normal neurodevelopment [Shane, 2008]. An impaired one-carbon metabolism may limit the availability of docosahexaenoic acid, omega-3 long chain polyunsaturated fatty acid to the brain, which is needed for normal brain development [Troen et al., 2008]. A deficiency impairs DNA replication and cell division which adversely affects rapidly proliferating tissues and results in decreased blood cell production that can lead to megaloblastic anemia, one of the hallmarks of folate deficiency [Carmel 2005].

L-methyl-folate in the form of its calcium salt calcium-L-methyl-folate had been proposed for the first time at the 28<sup>th</sup> CCNFSDU session for listing in the Advisory list (ALINORM 07/30/26- Rev., 2006) and been found suitable at the 29<sup>th</sup> session (ALINORM 08/31/26; 2007) only in foods for special medical purposes and section B of the standard for infant formula. The report did not provide an explanation why its use was not suitable for all foods for infants and young children. However, more recent science including a randomized controlled clinical trial with infants (MEFOLIN study led by B. Koletzko, and published in Troesch et al, 2019) and the latest assessment of the science by the European Food Safety Authority in 2019/2020 (EFSA; 2020) allows to conclude that calcium-L-methyl-folate is suitable for all the food categories in the Advisory list.

It is thus appropriate that the CCNFSDU starts a small piece of new work to extend the uses of this nutrient source from presently two food categories to all six food categories listed in the Advisory list CAC/GL 10-1979, or in other words, align the listing of calcium-L-methyl-folate with the listing of N-pteroyl-L-glutamic acid, which is the other permitted folic acid nutrient source in the Advisory list.

***Procedural requirements***

CL 2020/30-NFSDU specifies that new work proposals should be submitted as a discussion paper together with a project document according to the Procedural manual (Section II: Elaboration of Codex Texts: Proposal to undertake New Work or to Revise a Standard) and address also the additional criteria outlined in Appendix IX REP 20/NFSDU.

This discussion paper consists of three parts:

- Part 1: The project document which follows the Codex Procedural Manual Sec. II Proposal for new work/revision of a standard

While a project document has been submitted, an alternative approach could be followed:

It is noted that the procedure to amend the Advisory is given in the Advisory list itself in section

This procedure does not seem to be connected with the regular step process. If any minor update of the Advisory list such as the update for calcium-L-methyl-folate requires a new work proposal, it may turn out to be detrimental to the objective of achieving results in a timely fashion (see Codex goal 1.2 among others) and may unnecessarily

**PART 1: PROPOSAL 2 (Switzerland)**

bind valuable resources of the CCNFSDU that could be used for more prominent nutritional topics. The CCNFSDU had been requested by the CAC to prioritize its work for accelerated progress of work. It is also noted as an example that the Codex inventory list of food additive specifications (CXA 6-2019) is routinely updated outside the step process.

Part 3 of this reply to CL paper answers (positively) all the questions that need be answered for the amendment of the advisory list as regards Calcium-L-methyl-folate and would thus allow for a straight forward update of the Advisory list regarding this nutrient.

- Part 2: Appendix IX (Guideline for preliminary assessment of work priorities for CCNFSDU) of the CCNSDU report REP20/NFSDU, including a self-assessment against paragraph 2 of the Appendix IX
- Part 3: All information required according to the special procedure in the Advisory list of nutrient compounds (Section 2 in CXG 10-1079)

The first two parts cover the project documents requirements specified in CL 2020/30-NFSDU. The third part covers the procedural requirements according to the Advisory list of nutrient compounds which suggests a simpler, more time and resource efficient approach could possibly be applied to review and implement the change proposed.

References for Parts 1, 2 and 3 are listed in Annex 1.

## PART 1: PROPOSAL 2 (Switzerland)

**Part 1 – The project document: The Procedural manual requirements, Sec II Proposal for new work/revision of a standard*****The purposes and the scope of the standard***

Switzerland proposes to amend the Advisory List of nutrient compounds for use in foods for special dietary uses intended for infants and young children, CXG 10-1979, to align the present listing of calcium-L-methyl-folate as a nutrient source for folic acid with the listing of N-pteroyl-L-glutamic acid as the other folic acid nutrient source. This requires to extend the present listing of this nutrient in Part B of the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children*, CXG 10-1979, for use in all six categories of foods for special dietary uses intended for infants and young children. Presently it is only listed for use in foods covered under Section B of the *Standard for infant formula and formulas for special medical purposes intended for Infants* and for *Food for special medical purposes other than infant formula*.

In addition Switzerland proposes to add to the column named “*purity requirements by international and/or national bodies*” a reference to the United States Pharmacopoeia (USP) in addition to the JECFA (2005) monograph reference as a USP monograph became available in recent years.

The extension of the use calcium-L-methyl-folate is in particular justified on the basis of a new scientific assessment of this nutrient source for infants and young children by the EFSA (2020) the title of which is “*Calcium-L-methyl-folate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based foods*”. This new EFSA safety and bioavailability assessment also included new scientific evidence, in particular evidence from a new intervention study (MEFOLIN study) under the lead of Professor Koletzko, Munich, and which had been published in 2019 (Troesch B, et al, 2019).

The purpose of the Advisory list is to compile nutrient compounds “*which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children*”. Nutrient compounds may be listed when they meet the “*criteria for the inclusion and deletion of nutrient compounds from the advisory list*” in section 2 of the Advisory list. Section 2.2. specifically allows the addition or deletion of a substance from the advisory list and requires that a country, when proposing to add or delete a nutrient compound to/from the list, has to provide the required information according to section 2.1 in the Advisory list. This justification is provided in part 3 of this discussion paper.

As any Codex document, the advisory list is open to reflect scientific progress and be updated accordingly.

***Its relevance and timeliness***

The *Advisory lists of nutrient components for use in food for special dietary uses intended for infants and young children* (CXG 10-1979) was revised in 2008 and amended last time in 2015. Part B of the advisory list contains those nutrient sources of vitamins that meet the criteria for nutrient compounds to be added for nutritional purposes to foods for infants and young children as laydown in section 2.1 of CXG 10-1979.

When discussing the revision of CXG 10-1979 which was adopted in 2008, the Committee agreed to add to part B as an alternative source of folic acid the substance calcium-L-methylfolate. This inclusion was based on a proposal by ISDI presented before the 28<sup>th</sup> session of the committee (CX/NFSDU 06/28/6-Add. 1). The observer’s request referred to the purity criteria laid down in US GRAS notification, and referred to the existing authorization of calcium-L-methyl-folate in the European Union. This initial request was for addition to infant formula (IF) and foods for specific medical purposes (FSMP).

During the 28<sup>th</sup> session of the CCFSDU it was noted that US GRAS was not an appropriate reference for purity criteria (para 123, ALINORM 07/30/26) and calcium-L-methyl-folate was therefore added to an interim *List of nutrient compounds that lack official purity requirements*. There it was listed for use in infant formula (Section A and Section B) and foods for specific medical purposes (ALINORM 07/30/26, page 97).

At the 29<sup>th</sup> session of the CCFSDU the committee agreed to include calcium-L-methyl-folate into part B of the advisory list as suitable purity requirements were available with the respective JECFA monograph of the nutrient from 2005. The committee agreed also to list it for Section B of the infant formula standard but not for section A, and for foods for specific medical purposes. The report of the 29<sup>th</sup> session does not indicate the reasons for this limitation to section B of the instant formula standard. The advisory list that included calcium-L-methyl-folate for use in infant formula (Section B) and FSMP was finally adopted by the Commission in 2008 at the 31<sup>st</sup> session.

As science and manufacturing processes progressed, and relevant new science was published, it appears relevant and right on time to align the use of Calcium-L-methyl-folate with that of N-pteroyl-L-glutamic acid by an extension

## PART 1: PROPOSAL 2 (Switzerland)

of the use of calcium-L-methyl-folate and in addition endorse another internationally recognised specification (United States Pharmacopoeia, USP) for the substance. It should be borne in mind that L-methyl-folate is the most prominent natural source of the vitamin folic acid, and in addition the folic acid form found in human breastmilk.

***The main aspects to be covered***

The new work requires that the entry for the nutrient source 10.2 (Calcium-L-methyl-folate) under the parent nutrient 10. Folic acid, be amended as follows based on the latest science following the assessment procedure as required by Sec.2 of the Advisory list and which is addressed in part 3 of this discussion paper. The specifically required changes for nutrient 10.2 (Calcium-L-methyl-folate) to reflect current science are:

1. Addition of the word "USP" under *Purity requirements by international and/or national bodies*
2. That additional checkmarks be added under *Use in Codex food standards applicable to infants and young children* for use in *IF Sec. A, FUF, PCBF and CBF*.

***An assessment against the Criteria for the Establishment of Work Priorities***

The answers provided here refer to the *Criteria applicable to general subjects*, not to those for commodity standards as the extension of use of calcium-L-methyl-folate concerns the Advisory list of nutrient compounds which is horizontal in its approach by listing nutrient substances suitable for use in certain food categories. The Advisory List is not a Commodity Standard.

***Diversification of national legislations and apparent resultant or potential impediments to international trade.***

With an alignment of the uses for calcium-L-methyl-folate with those of N-pteroyl-glutamic acid by extending its permitted uses to all listed food categories for infants/young children in the Advisory list, manufacturers of those products have an additional choice for choosing a nutrient source for folic acid when formulating their products. Some Codex member countries already permit the use of Calcium-L-methyl-folate as a folic acid source e.g. in infant formula, others are expected in the near future to change their national/regional legislation to allow its use for these other foods, yet others presently do not allow the use of calcium-L-methyl-folate for the Advisory list food categories. Thus, an update of the Advisory list for calcium-L-methyl-folate would help achieve international harmonization and give companies a choice to use the nutrient form of folic acid which is found in breast milk. As many countries globally follow Codex rules when importing/exporting products, the proposed change to the Advisory list will contribute to facilitate, not impede international trade.

***(a) Scope of work and establishment of priorities between the various sections of the work.***

The proposed new work is basically outlined in sec 2.2. of the Advisory list, but can only be started under the umbrella of a new work proposal following the Codex PM. Once the work is approved, it can be accomplished in one step as it is very specific and limited in scope. A division in sub-parts is not needed.

***(b) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).***

The work proposed is a direct result of the assessment of new science by EFSA, a Recognised Authoritative Scientific Body (RASB) for the Codex work of CCNFSDU. It requires locally that the pertinent regulation for infants and young children be amended to be in line with latest science, and implies that Codex members should also follow by amending national regulation after an appropriate adjustment at Codex level (Advisory list). Involvement of other international bodies such as the International Standardisation Organisation (ISO) is not appropriate for the topic.

***(c) Amenability of the subject of the proposal to standardization.***

The Advisory list is already a piece of standardization as it lists acceptable nutrient forms for infants/young children. The new work proposal would only adjust this list to the latest science regarding a folic acid source. While this is as such not separately amenable to standardization, it is nevertheless at the core of a standardization as it part of the Advisory list and keeps it current.

***(d) Consideration of the global magnitude of the problem or issue.***

The Advisory list is a document that reflects international consensus and harmonization of nutrient sources for infants/young children. An update of it concerning a specific nutrient is a request to adjust to current science. This is unlikely to trigger any separate problems which need be addressed. The adjustment for the uses for calcium-L-

**PART 1: PROPOSAL 2 (Switzerland)**

methyl-folate as one of the two nutrient source options for the vitamin folic acid is also appropriate globally as it offers a choice for all manufacturers of these products.

**Relevance to the Codex strategic objectives**

The proposal is consistent with the Strategic Plan 2020-2025 of the Codex Alimentarius Commission and supports goal 1 (*Address current, emerging and critical issues in a timely manner*), and in particular sub-goal 1.1 (*identify need and emerging issues/improved ability of Codex to develop standards relevant to the needs of its members*) and 1.2 (*Prioritize needs and emerging issues. Timely Codex response to emerging issues and the needs of members*). Furthermore, the proposal connects with goal 2 (*Develop standards based on science and Codex risk analysis principles*).

According to the present Codex mission statement, Codex is about protecting consumer health and promoting fair practices in food trade by setting international, science-based food safety and quality standards. The work proposed for calcium-L-methyl-folate provides for a science-based update of a Codex food safety and quality related document and keeps it current with the latest science. This helps to keep this Codex document relevant for international food trade and supports harmonization. Based on the available science, one Codex member country adopted already (Mexico, 2012) their national regulations or are expected to adopt it in the near future (expected for the EU and USA (GRN 915)) the use of this folic acid source for more food categories for infants/young children. Thus, an update for this nutrient source in the Advisory list is both, timely and beneficial with regards to the Codex objectives.

**Information on the relation between the proposal and other existing Codex documents as well as other ongoing work**

The work proposal concerns the Advisory list of nutrient compounds, CXG 10-1979. This Advisory list is relevant for Codex standards for infants and young children as it advises on the permissible nutrient sources for vitamins and minerals. Those concerned standards are:

CXS 72-1981 Standard for infant formula and formulas for special medical purposes

CXS 73-1981 Standard for canned baby foods

CXS 74-1981 Standard for processed cereal-based foods for infants and young children

CXS 156-1987 Standard for follow-up formula

**Identification of any requirement for and availability of expert scientific advice**

The advisory list requires that the addition or a deletion of a substance has to follow the procedure in section 2.1/2.2 within the Advisory list itself. Section 2.1 requires certain scientific information. This information is provided in part 3 of this discussion paper which addresses all points required per Advisory list. Among others an opinion of EFSA on calcium-L-methyl-folate from 2020 is included and presented. As EFSA is an RASB to CCNFSDU, no additional expert scientific advice is needed for this work proposal.

**Identification of any need for technical input to the standard from external bodies so that this can be planned for**

There is no need for additional technical input for this work proposal.

***The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.***

Subject to approval by CAC46 in 2023, the work is expected to be completed by 2024.

## PART 1: PROPOSAL 2 (Switzerland)

**Part 2: Requirements from Appendix IX (Draft Guideline for the preliminary assessment and identification of work priorities for CCFSDU (REP20/NFSDU Appendix IX))****Revision of existing texts**

**Describe the rationale for the proposed revision of an existing CCFSDU text. Is it necessary due to new scientific findings and/or other developments? Can these new findings or developments cause a safety concern to a special group of people?**

Switzerland proposes to align the listing of calcium-L-methyl-folate as a nutrient source for folic acid with that of N-pteroyl-L-glutamic acid. This requires to extend the present listing of this nutrient in Part B of the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children*, CXG 10-1979, for use in all six categories of foods for special dietary uses intended for infants and young children. Presently it is only listed for use in foods covered under Section B of the *Standard for infant formula and formulas for special medical purposes intended for Infants* and for *Food for special medical purposes other than infant formula*. In addition Switzerland proposes to add to the column named “*purity requirements by international and/or national bodies*” a reference to the United States Pharmacopoeia (USP) in addition to the JECFA (2005) monograph reference.

The extension of the use of calcium-L-methyl-folate is in particular justified on the basis of a new scientific assessment of this nutrient source for infants and young children by the EFSA (2020) the title of which is “Calcium-L-methyl-folate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based foods”. This new EFSA safety and bioavailability assessment also included new scientific evidence, in particular evidence from a new intervention study (MEFOLIN study) under the lead of Professor Koletzko, Munich, and which had been published in 2019 (Troesch B. et al, 2019). This clinical study investigated in a randomized, double-blind, parallel, controlled trial the suitability and safety of L-5-methyltetrahydrofolate (L-5-MTHF; synonym name: L-methyl-folate) as a folate source in infant formula. The used nutrient form in this clinical study was calcium-L-methyl-folate.

The new findings support and supplement earlier assessments (EFSA 2004, JECFA 2005) of the substance. This 2020 EFSA opinion concludes that “*calcium-L-methyl-folate is safe under the proposed uses and use levels for infants and young children.*”

Thus, the new scientific findings do not cause a safety concern to special groups of people. It is rather the opposite: the new findings provide for additional safety support. Furthermore, the substance calcium-L-methyl-folate is intended for a substitutional use in relation to the folic acid source N-pteroyl-L-glutamic acid which is the presently permitted form of folic acid acceptable for use in foods for infants and young children and maximum use levels are set in addition in the respective standards for these products.

**Request from CAC.****Has the CAC requested CCFSDU to work on a CCFSDU text or to start new work?**

This proposal for the use extension for calcium-L-methyl-folate in the Advisory List CAC/GL 10-1979 is not a request from the CAC. It is a request from the Codex member country, Switzerland.

**Request from other Codex committees****Has another Codex Committee asked to consider a revision of an existing CCFSDU text or to consider new work?**

No. This is solely a request from the Codex member country, Switzerland.

**Availability of scientific advice****Is scientific advice available or will be provided soon?**

Yes. The latest scientific advice was published in January 2020 and is outlined in the last part of this new work proposal discussion paper, following the requirements in section 2 (Criteria for the inclusion and deletion of nutrient compounds from the advisory list) in the Advisory List of nutrient compounds for use in foods for special dietary uses intended for infants and young children, CXG 10-1979.

## PART 1: PROPOSAL 2 (Switzerland)

**Target group**

**Describe the target group of the proposal. Does the proposal refer to a vulnerable target group (infants, the aged, patients, etc.) or is the target group large (e.g. whole population)?**

The advisory list of nutrient compounds targets food for children aged 0-36 month. This target group of infants and young children is a vulnerable population. It is among others for this reason that this specific advisory list with acceptable nutrient forms exists. As regards the gross size of the target population being principally in scope of the nutrients in the Advisory list, one source of statistical data provided the following numbers for 2015 (in millions):

Region	Number of children (0-4 years) in million
Asia Pacific:	312
Western Europe	27
Eastern Europe	18
North America	23
Latin America	50
Middle East and Africa	192
Australasia	2

The total number of infants/young children amounts to some 600 million. The statistical data shown included children 0-4 years of age; the range of Codex standards is 0-3 years.

**Impact on public health (high/medium/low?)**

The impact on public health is low.

The purpose of this proposal is to allow that the nutrient calcium-L-methyl-folate be also permitted as a suitable nutrient source not only for FSMPs (IF Sec.B and FSMP other than IF Sec.B) but also for infant formula (IF Sec. A), follow-on formula, processed cereal-based foods and for canned baby foods. With that extension of use calcium-L-methyl-folate can be used substitutional for the nutrient source N-pteroyl-L-glutamic acid which is already permitted for all these food categories. As both nutrient sources are safe and bioavailable, and as their use is not additional but substitutional, the impact of the requested extension of use of calcium-L-methyl-folate on public health is low.

**Impact on food safety (high/medium/low?)**

The impact on food safety is low. Food safety is not compromised.

Calcium-L-methyl-folate is an already permitted nutrient source for the target population. The substance permitted by the Advisory list complies with the JECFA (2005) purity criteria. The additional proposal to allow the substance to comply with the purity criteria of its recent USP monograph is equally acceptable and has been confirmed by EFSA (2020). The substance is used substitutional for N-pteroyl-L-glutamic acid and thus does not lead to an increased exposure by the target population to the vitamin folic acid. In addition, the standards for the concerned food categories of the Advisory list set maximum levels for vitamins, including folic acid.

**Impact on fair trade practices (high/medium/low?)**

The impact on fair trade is low.

The extension of use of the already listed nutrient source calcium-L-methyl-folate offers manufacturers an additional choice when selecting a nutrient source for folic acid for use in a food for infants and young children. The presently permitted source of folic acid, N-pteroyl-L-glutamic acid remains listed so that the extension of use for calcium-L-methyl-folate only offers an additional choice. It does not replace the N-pteroyl-L-glutamic acid. However, when a manufacturer decides to use calcium-L-methyl-folate as a folic acid source, its use is substitutional for N-pteroyl-L-glutamic acid. This choice is generic and at the discretion of each manufacturer around the world. Thus, the extension of use of calcium-L-methyl-folate has no negative impact on fair trade practices. It rather helps to maintain global harmonization and fair trade as some Codex members already permit the use of calcium-L-methyl-folate e.g. in infant formula in line with recent science while other will only follow after

## PART 1: PROPOSAL 2 (Switzerland)

an endorsement by Codex via the Advisory list. Thus, this work proposal is not only timely but also beneficial for the international trade and other Codex objectives.

### Part 3: Requirements according to section 2 in the Advisory List of nutrient compounds (CXG 10-1979)

According to Sec. 2.2, a nutrient source may be included in the advisory list only if it meets the criteria laid down in Section 2.1 of CXG 10-1979. The following sections provide for each of the five criteria (a) –(e) in Sec. 2.1 the corresponding evidence which allow inclusion of calcium L-methyl-folate as a source of folic acid for use in all categories of foods for special dietary uses intended for infants and young children. It is recommended that the prioritization physical working group, and subsequently CCNFSDU/CAC, consider whether the application of these criteria do not provide a sound basis for an alternative, more efficient approach to proceed with this proposal than submitting it for prioritization alongside more substantive new work proposals.

#### 2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

##### (a) They are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children

1. Calcium-L-methyl-folate is one of the synonyms for calcium L-5-methyltetrahydrofolate (L-5-MTHF-Ca), the calcium salt of L-5-methyltetrahydrofolic acid (L-5-MTHF). L-5-Methyltetrahydrofolic acid (L-5-MTHF) is the predominant naturally occurring form of folates in food and human breast milk and it is also the essential form in which folates occur and are stored in the human body. During absorption, all natural folates are converted to 5-MTHF which is the only form of folate to enter the human circulation (EFSA, 2004; EFSA, 2020).
2. EFSA evaluated calcium-L-methyl-folate as a source of folate in 2004 and concluded, *“that the use of L-5-MTHF-Ca as a source of folate in foods for specific nutritional uses, food supplements and foods intended for the general population, is not of concern from the safety point of view”*. EFSA noted that a tolerable upper intake level for folic acid would also be applied to the combined intake of folic acid and L-5-MTHF-Ca (expressed as folate).
3. JECFA (65<sup>th</sup> Meeting) evaluated the safety of calcium-L-methyl-folate in 2005, and having at hands an adequate toxicological database and results from clinical studies, the experts concluded that they *“had no concern about the safety of the proposed use of calcium L-5-methyltetrahydrofolate in dry crystalline or microencapsulated form as an alternative to folic acid in dietary supplements, foods for special dietary uses and other foods”*.
4. In 2019/ 2020 EFSA evaluated calcium-L-methyl-folate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food. The evaluation took into account both commercial production processes that are in use and which are covered by the JECFA (2005) and USP (2015) monograph respectively. The EFSA concluded: *“...it was concluded that calcium-L-methyl-folate is non-genotoxic and that sub chronic and embryo toxicity/teratogenicity studies in rats did not reveal any adverse effects up to the highest dose tested. The Panel considered that no additional toxicological studies are required on the nutrient source. The intervention study in healthy infants provided by the applicant did not indicate differences in growth and tolerance parameters in infants who consumed either and infant formula supplemented with calcium-L-methyl-folate or with folic acid, and did not raise concerns regarding safety or tolerability of the infant formula with the proposed nutrient source. The study also provided further supporting evidence for the bioavailability of calcium-L-methyl-folate. The Panel considers that calcium-L-methyl-folate is a source from which folate is bioavailable and concludes that calcium-L-methyl-folate is safe under the proposed uses and use levels for infants and young children.”*

The new intervention study mentioned by EFSA had been conducted by the MEFOLIN Study Group under the lead of Professor Koletzko, Munich, and been published in 2019. This clinical study investigated in a randomized, double-blind, parallel, controlled trial the suitability and safety of L-5-methyltetrahydrofolate (L-5-MTHF) as a folate source in infant formula and had been conducted in conformity with the principles of good clinical practice (GCP).

5. It is noteworthy that in 2004/2005 already both expert bodies (JECFA, EFSA) did not restrict their safety evaluations to specific parts of the population or types of products but rather stated that calcium-L-methyl-folate may safely replace folic acid wherever this is used as a source of folates. In the 2020 scientific opinion of EFSA, the Panel closes the evaluation gap in relation to its 2004 scientific opinion by specifically evaluating

## PART 1: PROPOSAL 2 (Switzerland)

calcium-L-methyl-folate for use by infants (< 12 month) and young children (12 – 35 months) “...to be used as a source of folate in infant formula, follow-on formula, processed cereal-based food and baby food. (para 3.7, page 8 in EFSA (2020))”

6. Being the natural form of folates, L-methyl-folate (more adequately termed by its correct scientific name L-5-methyltetrahydrofolic acid), is also the form of folate found in human breast milk. According to WHO (1981), infant formula is “a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics”. The “gold standard” principle that those nutrients which are present in mother’s milk are expected to be the best candidates for inclusion into infant formula, suggest that the listing of calcium-L-methyl-folate, which provides L-5-methyltetrahydrofolic acid is appropriate and meets this criterion.

***It is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available***

EFSA concluded in 2004 that “the bioavailability of L-5-MTHF-Ca is similar or even slightly higher than that of folic acid.”

JECFA concluded in 2005 that “in humans, the bioavailability of calcium L-5-methyltetrahydrofolate is similar to that of folic acid and that synthetic calcium L-5-methyltetrahydrofolate has the same metabolic fate as other absorbed natural folates.”

In the EFSA opinion of 2020, EFSA in section 4 (page 15) points out that “This opinion deals with the safety and bioavailability of calcium-L-methyl-folate as a new source of folate added for nutritional purposes to infant formula, follow-on formula, and baby food and processed cereal-based foods.” and then continues to discuss the available bioavailability data, including the new data on bioavailability from the aforementioned MEFOLIN study (para 10). In this MEFOLIN study, infants which had been administered calcium-L-methyl-folate and folic acid at equimolar amounts showed that the markers for folate status indicated an at least equivalent bioavailability of L-5-MTHF compared to folic acid. EFSA (2020) concludes its discussion by stating (page 16) “The Panel considers that calcium-L-methyl-folate is a source from which folate is bioavailable”

***The purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered***

The 29<sup>th</sup> session of the CCNFSDU agreed that the purity requirements adopted by JECFA in 2005 were adequate as a reference for calcium-L-methyl-folate. In the meantime, an additional monograph of the United States Pharmacopeia – became available the purity criteria of which were judged as adequate by EFSA (2020) (page 8) for an intended use for foods for infants and young children: “The Panel considers that the information provided on the specifications of the NS is sufficient and does not raise safety concerns”. (The abbreviation NS as used by EFSA means: nutrient source). It is further noted that the advisory list CAC/GL 10-1979 references USP monographs as appropriate purity criteria already for many nutritional substances presently found in the advisory list.

***The stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated***

EFSA reviewed in 2004 a broad range of studies that investigated the stability of calcium-L-methyl-folate in various foods of different matrices. The data presented in the evaluation report confirm that the nutrient is stable when added to food. A comparison of calcium-L-methyl-folate with folic acid in a liquid infant formula as a model food system was examined during heat treatment (100-140°C) for different periods of time (up to 250 min). The stability of calcium-L-methyl-folate was found to be slightly higher than that of folic acid under the applied test conditions.

JECFA (2005) concluded that calcium-L-methyl-folate in crystalline micronized form was stable during food processing and long-term storage under conditions of high temperature and humidity. It is stable in multivitamin tablets and in microencapsulation and food matrix systems. The Committee considered it to be less stable in aqueous solution at elevated temperature.

## PART 1: PROPOSAL 2 (Switzerland)

In 2020 EFSA assessed additional stability data of calcium-L-methyl-folate as such (25 °C, 60 % RH, 24 month test period), in powdered infant formula and follow-on formula (18 month testing period) and in the ready-for-use prepared liquid infant formula (according to the instructions for use of the product). The EFSA Panel (page 7) considered “*that the data provided sufficient information with respect to the stability (...)*”

***The fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.***

The data summarized above were evaluated by EFSA and JECFA applying the generally accepted scientific criteria for the safety assessment of nutrient sources to be added to food. These principles have been refined during the past fifteen years but not changed in their substance, and therefore all three evaluations (EFSA 2004, 2020; JECFA 2005) are considered valid.

Toxicological and clinical studies followed the modern principles of good laboratory and good clinical practice, in particular also the very recent MEFOLIN study (a randomized controlled trial led by B. Koletzko) in infants that compared calcium-L-methyl-folate with folic acid was performed respecting all relevant ethical, medical and scientific standards and which had been evaluated and appraised by the EFSA (2020). This study, and many other studies evaluated by EFSA and JECFA, had been published in peer reviewed journals.

**Annex 1: REFERENCES of relevance for all parts of the reply to CL 2020/30-NFSDU**

Carmel R. Folic acid. In: Shils M, Shike M, Ross A, Caballero B, Cousins RJ, eds. Modern Nutrition in Health and Disease. 11th ed. Baltimore, MD: Lippincott Williams & Wilkins; 2005:470-81

EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. 2004. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium-L-Methylfolate. EFSA Journal 2004; 2(11): 135

EFSA Panel on Dietetic Products, Nutrition and Allergies. 2014. Scientific opinion on Dietary Reference Values for folate. EFSA Journal 2014; 12(11):3893.

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA). 2020. Scientific Opinion, Calcium L-methyl folate as a source of folate added for nutritional purposes to infant and follow on formula, baby food and processed cereal-based food. EFSA Journal 2020;18(1):5947, retrievable at: <http://www.efsa.europa.eu/de/efsajournal/pub/5947>

Institute of Medicine. Dietary reference intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline. Washington, D.C.: The National Academic Press; 1998.

JECFA 65<sup>th</sup> session (2005). TRS report 943 (2016). [https://apps.who.int/iris/bitstream/handle/10665/43408/WHO\\_TRS\\_934\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/43408/WHO_TRS_934_eng.pdf?sequence=1) Mexico: NORMA Oficial Mexicana NOM.131-SSAI-2012, retrievable at: [http://www.dof.gob.mx/nota\\_detalle.php?codigo=5267447&fecha=10/09/2012](http://www.dof.gob.mx/nota_detalle.php?codigo=5267447&fecha=10/09/2012)

Page R, Robichaud A, Arbuckle T, Fraser D, MacFarlane A. 2017. Total folate and unmetabolized folic acid in the breast milk of a crosssection of Canadian women. Am J Clin Nutr. 105(5):1101-1109

Shane B. 2008. Folate and vitamin B12 metabolism: overview and interaction with riboflavin, vitamin B6, and polymorphisms. Food and Nutrition Bulletin. 2008; 29(2 Suppl):S5–16.

Statistical online report prepared by Statista GmbH, Hamburg, Germany, retrievable at: <https://www.statista.com/statistics/249480/infant-and-toddler-population-in-different-regions/>

Troen AM, Chao W-H, Crivello NA, D’Anci KE, Shukitt-Hale B, Smith DE, et al. Cognitive Impairment in Folate-Deficient Rats Corresponds to Depleted Brain Phosphatidylcholine and Is Prevented by Dietary Methionine without Lowering Plasma Homocysteine. The Journal of Nutrition. 138(12):2502–9.

Troesch B, Demmelmair J, Gimpfl M, Hecht C, Lakovic G, et al. MEFOLIN Study Group. Suitability and safety of L-5-methyltetrahydrofolate as a folate source in infant formula: a randomized controlled trial. PLoS One, 14(8), e0216790. <https://doi.org/10.1371/journal.pone.0216790>

USA GRAS Notice Inventory GRN 915 at: <https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices>

WHO International Code of Marketing of Breast-milk Substitutes (1981) [https://www.who.int/nutrition/publications/code\\_english.pdf](https://www.who.int/nutrition/publications/code_english.pdf)

**Proposal 2.1****DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS**

*Prepared by Argentina and Malaysia*

**BACKGROUND**

1. At the thirty-ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU39) in 2017, the Committee adopted the Agenda with the following addition under item 11 - Other business: iii. Harmonized probiotic guidelines for use in foods and dietary supplements (International Probiotics Association).
2. The observer of the International Probiotics Association (IPA) introduced that item and proposed to develop guidelines with a harmonized framework for probiotics (NFSDU/39 CRD/3).
3. Argentina expressed their support to the proposal and their willingness to lead this work. The Committee agreed that Argentina would prepare a discussion paper together with a project document for consideration at its next session.
4. At the fortieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU40) in 2018, Argentina introduced the Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements (CX/NFSDU 18/40/12).
5. The Committee agreed that Argentina should redraft the discussion paper for consideration at its next session elaborating further on the sections on scope, definition as well as health and trade concerns in particular.
6. At the fortieth-first Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41) in 2019, Argentina introduced the Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements (CX/NFSDU 19/41/11).
7. The Committee agreed that the proposal could be submitted in accordance with the prioritization mechanism (Prioritization mechanism to better manage the CCNFSDU) for consideration by the working group on prioritization. The Committee noted the offer of Argentina and Malaysia to prepare a revised proposal.

**INTRODUCTION**

8. Available world scientific literature has indicated that probiotics can play important roles in immunological, digestive and respiratory functions. Around 20,000 papers have been published on the various functional effects of probiotics in peer-review scientific journals in the last 50 years. However, it is really in the last decade that research on probiotics has highly increased.
9. In parallel, with this scientific development, probiotic microorganisms have been used as ingredients in a wide range of foods, beverages and food supplements. Being increasingly accepted by health professionals, the number and type of these products that are available to consumers, have increased considerably.
10. In view of the growing popularity of probiotic-containing foods, beverages and food supplements and the lack of international consensus on the methodology to evaluate probiotics, a joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria was held in 2001 to evaluate many aspects of the use of probiotics in foods.

**SCOPE**

11. The purpose of this proposed work is to establish guidelines for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food.
12. The scope of the proposed guidelines includes establishment of harmonized definition, minimum requirements, for the consistent interpretation and application of the definition of probiotics and guidelines in the FAO/WHO consultation (2001) as well as labelling parameters for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food.

Health claims on probiotics are excluded from the scope of this work.

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

**NEED AND RELEVANCE OF PROBIOTICS GUIDELINE**

13. Today, almost 2 decades after the FAO/WHO consultation in 2001, the status of probiotics as a component in food has not been established on an international basis. There is also no international guideline on probiotic that addresses the minimum safety and characterization criteria, quality and specific labelling requirements for probiotics. As a consequence, there is a lack of harmonized regulation, with countries having different provisions and taking different approaches. These countries recognized the need for regulatory control as probiotic-containing foods, beverages and food supplements are widely available.
14. This lack of harmonization in industry practice and legislation often leads to issues and concerns for the probiotics regulators, industry, and even consumers in regard of quality, safety and labelling. A harmonized guideline addressing these gaps for these international and regionally traded products will facilitate trade and ensure that effective and safe products reach the consumers.
15. Despite the widely recognized definition in the FAO/WHO consultation (2001), as “Live microorganisms which when administered in adequate amounts confer a health benefit on the host”, on a global level, the absence of clear harmonization could lead to misuse of the “probiotic” term and to trade products as probiotics that do not comply with this concept.
16. Recognizing the above, countries accept the need for development of a Codex Alimentarius guidance. The ultimate goal of this discussion paper is for the development of a Codex document which will provide guidance to countries to develop national regulations which are harmonized globally. The establishment of global requirements will satisfy the triumvirate of authorities, consumers and, industry and will certainly lead to better consumer satisfaction, health and well-being.
17. This proposed guideline is relevant and essential as it addresses several aspects not covered by the current Codex standards/guidelines.
  - a. None of the current Codex texts include a definition of probiotics. However, the term “probiotic” is already used in the Codex Regional Standard for Doogh (CXS 332R-2018) adopted for the Near East region. The 44<sup>th</sup> Session of Codex Committee on Food Labelling<sup>10</sup> had indicated that ideally terms used in Codex standards should have a Codex definition. This proposed guideline would address this gap.
  - b. Existing Codex standards do not contain a description with criteria to clarify the meaning of what is a probiotic to ensure a consistent interpretation and application at national and international levels by Codex members of the key aspects of the definition of probiotics, based on the definition of the FAO/WHO (2001) consultation and thereby, of the term probiotic.
  - c. Existing Codex standards do not establish minimum requirements specific for a live microorganism to be qualified as a probiotic or to demonstrate that a strain is a probiotic.
  - d. In addition to the labelling provisions of the General Standard for Labelling of Prepackaged Foods (CXS 1-1985), additional specific labelling requirements for probiotics would be required. CXS 1-1985 does not address aspects such as: the name of the food specific to probiotics, ie: name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients, the declaration of the amount of viable cells of total probiotic microorganisms (CFU/g) or (CFU/ml). These and other labelling requirements specific to probiotics are essential to safe guard interest of consumers.
18. The proposed work is to address the lack of harmonization through the development of a Codex Guidelines. In addition, a CODEX Guideline for probiotics would unleash the potential of innovation while opening new opportunities for scientific development. This proposal for new work meets the general criterion of protecting the health of the consumer and ensuring fair practices in the food trade.

**PROBIOTIC PRODUCTION**

19. At present, according to information provided by the International Probiotics Association (IPA), the ingredients market could be divided as:
  - a) Fermentation and Bacteria Production:

---

<sup>10</sup> REP18/FL, paragraph 17.

**PART 2: PROPOSAL 1 (Argentina and Malaysia)**

Known fermentation capabilities and production facilities are based in many countries across the globe. Some of these are in the following countries: USA, Canada, Pan EU including UK, Brazil, Argentina, Chile, Japan, China, South Korea, India, Australia, South Africa, to name but a few. Fermentation capacity of these facilities range from 20 metric tons to 500 metric tons capacity.

b) Ingredient Market Revenue:

The global probiotics ingredient market was valued at an estimated \$2.25 billion USD in 2019, growing at a rate of 7.9% and is expected to be valued at an estimated \$3.55 billion USD by the year 2025. (Source IPA).

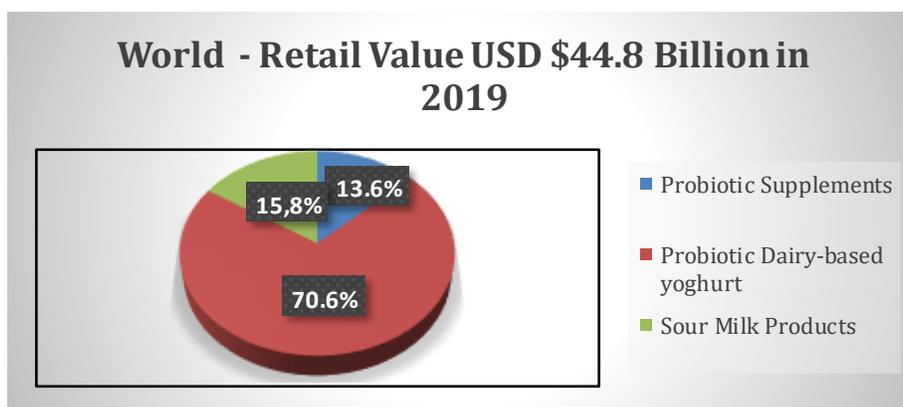
The estimated split of the revenue in 2019 was Functional Food and Beverages 60%, Food Supplements 26%, Other Human Nutrition 2.5%, Animal Feed & Others 11.5%. (Source IPA).

**PROBIOTIC DISTRIBUTION AND TRADE**

20. Probiotics are distributed in 200 countries. (Source IPA).

**PROBIOTIC CONSUMER CONSUMPTION**

21. Probiotics are consumed in foods, beverages and food supplements. Foods include mainly dairy products as yoghurts and other fermented milks as represented in graph 1 and table 1.



**Graph 1:** Global Retail Value, 2019 (Source IPA)

World Retail Value (2019)	\$44,880,000,000.00
Yoghurt	\$31,628,000,000.00
Fermented milks	\$7,078,000,000.00
Supplements	\$6,092,000,000.00

**Table 1:** Global Retail Value, 2019 (Source IPA)

**PROBIOTICS TRADE EXCHANGE**

22. Probiotic Supplements hit \$6.09 Billion USD and Food and Beverage applications hit sales of close to \$40 Billion USD globally, in 2019.

Region	Ingredients for Supplements & Human Nutrition (%)	Ingredients for Food Applications (%)
North America	38	10
Europe, Middle East and Africa	35	34
Latin America	3	7

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

Asia – Pacific Countries	21	46
Australasia	3	3

**Table 2:** Distribution of Ingredients for Supplements and Food Applications, 2019 (Source IPA)

Production of Probiotic Culture for Supplements and Food Applications (2019)	
Supplement totals	1,500,000 Kg
Food and beverage totals	2,700,000 Kg
Totals of Probiotic pure cultures	4,200,000 Kg

**Table 3:** Combined Totals of Pure Bacteria Powder, 2019 (Source IPA)**Colony-Forming Units**

Probiotic ingredients are measured by CFU, or colony-forming units. This is well outlined on the IPA probiotic labelling guidelines published in 2016.

Therefore, the following data is provided to bring importance to what the volume of kilograms represent in CFU as follows:

1.5 million Kgs of culture ingredient for the Food Supplement industry is equivalent to 7.5E+20 or **750,000,000,000,000,000 CFU** of probiotic culture.

2.7 million Kgs of culture ingredient for the Food application industry is equivalent to 4.05E+19 or **40,500,000,000,000,000 CFU** of probiotic culture.

These are estimations based on average yields.

**THE MAIN ASPECTS TO BE CONSIDERED**

23. The requirements that should be considered to demonstrate that a strain is a probiotic should be based on the aspects included in Appendix 3.

**RECOMMENDATIONS**

24. Development of guidelines and a harmonized framework for probiotics, including general specifications and considerations is necessary to ensure and sustain quality probiotic products on a global scale. This objective is in line with the Core Values of Codex, promoting collaboration, inclusiveness, consensus building and transparency, and follows the principles set as the Scientific Basis of Codex, listed within the Codex Alimentarius Commission Strategic Plan 2020-2025. In this regard, the new work proposal will contribute particularly to Goals 1, 2 and 3: Goal 1: *“Address current, emerging and critical issues in a timely manner”*; Goal 2: *“Develop standards based on science and Codex risk-analysis principles”*; Goal 3: *“Increase impact through the recognition and use of Codex Standards”*.
25. Considering the tremendous increase in global market of probiotics, the Committee is invited to consider new work on Guidelines for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food as presented in the project document (Appendix 3). This includes the general specifications and considerations to be considered to demonstrate that a strain is a probiotic.

**PRIORITIZATION OF PROPOSED HARMONIZED GUIDELINES**

26. CCFNSDU41 agreed that the proposed new work on developing a harmonized guideline on probiotics could be submitted in accordance with the prioritization mechanism<sup>11</sup>. This proposal is submitted in response to the CL 2020/30-NFSDU, April 2020, requesting for proposals for new work and emerging issues for consideration by the Physical Working Group on prioritization. This proposal is submitted in accordance with the draft guideline for the preliminary assessment and identification of work priorities for CCFNSDU, which stipulates

<sup>11</sup> REP20/NFSDU, paragraph 185.

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

that new work proposals should be submitted as a discussion paper together with a project document according to the Procedural Manual and address also the additional criteria outlined in the draft guideline as follows<sup>12</sup>. This proposal has met all the said criteria and are summarized in the table below.

Criteria	Further information
Revision of existing texts (See item 17 of the Discussion Paper)	The proposal is to develop new CCNFSDU Guidelines for Probiotics on aspects not framed/covered by existing standards, thereby without re-opening any discussion on the provisions currently included in existing Codex standards.
Request from Codex Alimentarius Commission (CAC)	No request from CAC at this point.
Request from other Codex Committees	No request from other Codex Committees at this point.
Availability of scientific advice	<p>There is scientific advice available by the Codex primary source of nutritional risk assessment advice to Codex Alimentarius, that is, the Food and Agriculture Organization (FAO) and World Health Organization (WHO). FAO and WHO initiated work to evaluate the scientific evidence on the functional and safety aspects of probiotics in food. Two reports are available<sup>13</sup>:</p> <ul style="list-style-type: none"> <li>• Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria. Cordoba, Argentina, 1-4 October 2001.</li> <li>• Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, 30 April-1 May 2002.</li> </ul> <p>These reports can serve as useful references and the recommendations of the experts of the consultations will be taken into account.</p> <p>These reports provide guidelines on how to assess the effect of a probiotic. However, they do not establish minimum characterization criteria specific for a live microorganism to be qualified as a probiotic or to demonstrate that a strain is a probiotic.</p> <p>On the other hand, in the last decade research on probiotics has significantly increased, a large number of papers have been published in peer-review scientific journals, and the most relevant ones will be used as a basis for the drafting of the guidelines.</p>
Target group	Whole population.

<sup>12</sup> REP20/NFSDU, Appendix IX, paragraph 4.

<sup>13</sup> FAO Food and Nutrition Paper 85, Probiotics in food, Health and nutritional properties and guidelines for evaluation.

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

Impact on public health	<p>High impact on public health.</p> <p>Considering: that beneficial effects of probiotics are broadly acknowledged by health professionals, consumers and authorities; that play important roles in immunological, digestive and respiratory functions with potential application for health maintenance and disease prevention; the increasing consumer consumption of probiotic foods, beverages and food supplements that are marketed; that can improve health and quality of life; that probiotic intervention has the potential to significantly benefit many important health care issues that have a substantial health cost.</p> <p>Probiotics are on the regulatory agenda of many countries with national authorities around the world requiring international high-level principles and guidance to develop an appropriate regulatory framework to apply to probiotics.</p>
Impact on food safety	<p>Low impact on food safety.</p> <p>The long history of safe use of probiotics has been acknowledged already in 2001 by FAO/WHO Expert Consultation, who confirmed the absence of established risk associated with the consumption of typical probiotic genera by humans.</p> <p>The long history of safe use of probiotics is also recognized by several regulatory organizations, for example by the European Food Safety Authority, who included typical probiotics species in the list of microorganisms with Qualified Presumption of Safety (QPS)<sup>14</sup> with well-defined generic and specific qualifications.</p> <p>Finally, general food safety of products containing probiotics is addressed by existing Codex standards and guidelines applicable to all food products. In addition, the Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food (2002) is providing general rules to address the safety of probiotics.</p>
Impact on fair trade practices	<p>High impact on fair trade practices.</p> <p>Despite the widely-recognized definition in the FAO/WHO (2001) consultation, and guidelines on probiotics, there is regulatory environment divergence that hinder the marketing and promotion of probiotics in different parts of the world.</p> <p>Harmonized guidelines for these international and regionally traded products will facilitate trade and ensure the consumer access to high quality, functional and safe probiotic foods, beverages and food supplements, avoiding consumers being misled.</p> <p>The development of Codex Guidelines on Probiotics will generate the regulatory harmonization of probiotics across the world, contributing to consistent fair trade practices in this area.</p>

<sup>14</sup> EFSA Journal 2020. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA (2017–2019). 18(2):5966.

**Bibliography**

1. FAO/WHO. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada. 30 April – 1 May 2002.
2. FAO/WHO. Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria. Report of a Joint FAO/WHO Expert Consultation on Evaluation and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid bacteria. Cordoba, Argentina, 1 - 4 October 2001.
3. Commissione Unica per la Dietetica e la Nutrizione. Guidelines on probiotics and prebiotics. Revision May 2013.  
[http://www.salute.gov.it/imgs/C\\_17\\_pubblicazioni\\_1016\\_ulterioriallegati\\_ulterioreallegato\\_0\\_alleg.pdf](http://www.salute.gov.it/imgs/C_17_pubblicazioni_1016_ulterioriallegati_ulterioreallegato_0_alleg.pdf)
4. Guidance Document – The Use of Probiotic Microorganisms in Food. Food Directorate. Health Products and Food Branch. Health Canada. April 2009.  
<https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-use-probiotic-microorganisms-food-2009.html>
5. General scientific guidance for stakeholders on health claim applications EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2016;14(1):4367. <https://www.efsa.europa.eu/efsajournal>.
6. Australia New Zealand Food Standards Code – Standard 1.5.1 – Novel foods.  
<https://www.legislation.gov.au/Details/F2017C00324>
7. International Probiotic Association (IPA). Proposal for New Work on Harmonized Probiotic Guidelines for use in foods and dietary supplements. NFSDU/39 CRD/3
8. CX/NFSDU 15/37/8. Discussion paper on a standard for ready-to use foods.
9. Código Alimentario Argentino. Capítulo XVII. Artículo N° 1389.  
[http://www.anmat.gov.ar/alimentos/codigoa/CAPITULO\\_XVII.pdf](http://www.anmat.gov.ar/alimentos/codigoa/CAPITULO_XVII.pdf)
10. Guidelines on Formulated Complementary Foods for Older Infants and Young Children CAC/GL 8-1991 Adopted in 1991. Amended in 2017. Revised in 2013.
11. Brasil. Resolução Da Diretoria Colegiada RDC N° 241, de 26 de Julho de 2018.  
[http://portal.anvisa.gov.br/documents/10181/3898888/RDC\\_241\\_2018\\_.pdf/941cda52-0657-46dd-af4b-47b4ee4335b7](http://portal.anvisa.gov.br/documents/10181/3898888/RDC_241_2018_.pdf/941cda52-0657-46dd-af4b-47b4ee4335b7)
12. Brasil. Resolução - RES n° 17 de 30/04/1999.  
<http://portal.anvisa.gov.br/legislacao/?inheritRedirect=true#/visualizar/26333>
13. Brasil. Resolução - RES n° 18 de 30/04/1999.  
<http://portal.anvisa.gov.br/legislacao#/visualizar/26339>
14. Colombia. Resolución 333 de 2011.  
[https://docs.supersalud.gov.co/PortalWeb/Juridica/OtraNormativa/R\\_MPS\\_0333\\_2011.pdf](https://docs.supersalud.gov.co/PortalWeb/Juridica/OtraNormativa/R_MPS_0333_2011.pdf)
15. Norma Técnica Ecuatoriana. NTE INEN 1334-3:2011.  
[https://www.controlsanitario.gob.ec/wpcontent/uploads/downloads/2014/07/ec.nte\\_.1334.3.2011.pdf](https://www.controlsanitario.gob.ec/wpcontent/uploads/downloads/2014/07/ec.nte_.1334.3.2011.pdf)
16. Reglamento Técnico Centroamericano (RTCA 67.01.60:10).  
<https://www.sieca.int/index.php/integracion-economica/instrumentos-juridicos/actos-administrativos/consejo-de-ministros-de-integracion-economica/resoluciones/>
17. Chile. Norma Técnica N° 191.  
<http://www.ilsisurandino.cl/wp-content/uploads/2017/09/Resol-860-exenta.pdf>
18. IPA Europe guidelines to qualify a microorganism to be termed as 'probiotic' in foods, beverages and supplements in commercial communications, 2015.  
<http://ipaeurope.org/images/image/pdf/IPA%20Europe%20Guidelines%20to%20qualify%20a%20microorganism%20as%20probiotic.pdf>
19. IPA. Guidance for the Use of the Term “Probiotic” In the Labelling Of Foods, Beverages and Food Supplements. 17 September 2015.
20. IPA. Criteria to Qualify a Microorganism to be termed as 'Probiotic' in Foods, Beverages and Dietary Supplements.  
<http://ipaeurope.org/images/image/pdf/20180524%20IPA%20Europe%20Probiotic%20Criteria%20Document.pdf>
21. ILSI Europe Concise Monograph Series. 2013 ILSI Europe. Probiotics, Prebiotics and the Gut Microbiota by Nino Binns.
22. IPA Europe. What Probiotics Can Do for You. ... A quick guide to probiotics. March 2017.

**Glossary of terms**

Codex Alimentarius Commission	CAC
Codex Committee on Nutrition and Foods for Special Dietary Uses	CCNFSDU
Colony-forming unit	CFU
Conference room document	CRD
Food and Agricultural Organization	FAO
International Probiotics Association	IPA
World Health Organization	WHO

## PROJECT DOCUMENT

### 1. PURPOSES AND SCOPE OF GUIDELINES

The purpose of this work is to establish guidelines for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food.

The scope of the guidelines includes establishment of harmonized definition, minimum requirements, for the consistent interpretation and application of the definition of probiotics and guidelines in the FAO/WHO consultation (2001) as well as labelling parameters for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food.

The scope of this work would be limited to the development on aspects not framed by existing Codex standards without re-opening any discussion on the provisions currently included in the existing horizontal Codex standards (elaborated in Section 6 of this document).

Health claims on probiotics are excluded from the scope of this work.

Drug applications and animal feeds are excluded from the scope of this work.

### 2. RELEVANCE AND TIMELINESS

Probiotics are live microorganisms increasingly used in a wide variety of food, beverages and food supplement applications. There are a number of distinct probiotics strains and consumer demand is driving growing international trade. According to IPA data, probiotics are distributed in 200 countries.

There is growing interest in the concept of probiotics and its role in human nutrition. Probiotics are used in a variety of foods, the main category being dairy products, but they are also present as food supplements. The general population is increasingly interested in maintenance of health and self-care and this may explain the consumers' interest in probiotics. The establishment of a probiotic guideline is supporting the United Nations sustainable development goal 3: "*Good health and well-being*", ensure healthy lives and promote well-being for all at all ages.

The scientific and clinical evidence have progressed rapidly, as has the development of many probiotic products. Unfortunately, misuse of the term probiotic has also become an important issue, with many foods using the term without meeting the criteria of probiotics.

There have traditionally been many products available in the marketplace carrying the label 'probiotic'. However, there are currently no internationally accepted defined criteria or guidelines on what constitutes a 'probiotic' microorganism. The establishment of eligibility criteria will provide proper guidance for global regulatory agencies to develop probiotics specific regulations.

At the same time, probiotic-containing foods, beverages and food supplements have received the legitimate attention of regulatory authorities with an interest in protecting consumers from misleading claims. Regulations on 'probiotics' are now under discussion in some countries while other countries have already established criteria and an organized framework for 'probiotics'. However, these have been developed independently, with some countries having different provisions on probiotics.

Due to the lack of an international guideline, it is essential to establish a Codex guideline for the establishment of requirements, for the consistent interpretation and application of the definition of probiotics and guidelines as well as labelling parameters for probiotics for use as an ingredient in foods, beverages and food supplements where these are regulated as food. Harmonized guidelines would facilitate international trade and enable fair and transparent practices while ensuring that effective and safe products reach the consumers.

Therefore, it is essential that regulatory authorities, industry and consumers have specifications for probiotics for use in foods, beverages and food supplements.

### 3. MAIN ASPECTS TO BE COVERED

The main aspect to be covered includes the establishment of Codex definition of 'probiotics', minimum safety and characterization criteria, and labelling parameters.

#### i. Definition

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

It will be necessary to develop a definition, considering the definition in the FAO/WHO consultation (2001)<sup>15</sup> with criteria that is sufficiently broad to cover both vegetative microorganisms and spores.

ii. Minimum safety and characterization criteria.

Minimum requirements will be required in order to recognize a strain as a probiotic, such as:

a) *Taxonomic characterization of the microorganism.*

b) *Functional characterization of the strain<sup>16</sup> including demonstration of the viability of the microorganism linked to the living character (including in freeze-dried form) in the product throughout shelf-life and hence, when consumed (FAO/WHO, 2002).*

c) *Safety assessment of the microorganism for the intended use.*

iii. Labelling of probiotic-containing foods, beverages and food supplements

In addition to the General Standard for Labelling of Prepackaged Foods (CXS 1-1985), additional specific labelling requirements for probiotic-containing products would be considered so as to provide consumers with information to correctly identify such products.

iv. Reference Methods of Analysis.

Specific methodology for the evaluation of probiotics would be considered so as to recommend methods for the typing of strains and the counting of microorganisms.

#### 4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

##### General criteria

The Codex Alimentarius Commission has a mandate of protecting consumer's health and ensuring fair practices in food trade. The proposed new guidelines will meet this criterion by promoting consumer protection from the point of view of health, food safety and ensuring fair practices in the food trade.

Despite the widely recognized definition of probiotics in the report of the FAO/WHO consultation (2001), which states that "*Live microorganisms which when administered in adequate amounts confer a health benefit on the host*" there is no clear harmonization regarding the use of the term 'probiotic', on a global level, the absence of clear harmonization could lead to misuse of the "probiotic" term and to trade products as probiotics that do not comply with this concept.

In the absence of an internationally accepted standard and guidelines, trading practices can become disordered and non-compliant.

Such practices are also unfair from the consumer perspective as they may not be receiving probiotic-containing foods, beverages and food supplements as expected.

##### Criteria applicable to general subjects

(a) *Diversification of national legislations and apparent result or potential impediments to international trade*

The lack of harmonized provisions for dealing with probiotic-containing food, beverages and food supplements could result in different criteria and conditions to use the term 'probiotic' from one country to another and could result in unnecessary barriers to trade.

Also, the situation could be misused by some manufacturers as well as the misinterpretation of the probiotic concept by consumers.

In addition, this situation could prevent its consistent use on product labels, communications or advertising across the globe.

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

<sup>15</sup> Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1-4 October 2001.

<sup>16</sup>FAO/WHO. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada. 30 April – 1 May 2002.

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

The scope of work will address:

1. The establishment of Codex definition of 'probiotics', considering the definition in the FAO/WHO consultation (2001) report.
2. Minimum requirements and safety criteria for probiotics as an ingredient in foods, beverages and food supplements.
3. Labelling criteria for probiotics.

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

In 2001, scientific community and experts convened by FAO/WHO provided a scientific opinion on 'probiotics' agreed on the following definition (later amended by an expert consensus group): "*live microorganisms which when administered in adequate amounts confer a health benefit on the host*".

This report was followed by the "Guidelines for the Evaluation of Probiotics in Food" where the FAO/WHO experts made several recommendations. One of these was to officially adopt the definition as well as more specific criteria as a prerequisite to qualify a microbial strain as a "probiotic".

While the definition of probiotics has been widely acknowledged by the scientific community and key players in the field of probiotics, the recommendations in the FAO/WHO guidelines have not been implemented.

Only a few countries have regulations on probiotics. Those countries that have developed legislation have different views with diverse criteria regarding the requirements on probiotics in food, beverages and food supplements and their labelling.

These countries have enacted regulations on their own, recognizing that these products are widely available and regulatory control is essential.

In 2011, Argentina incorporated into its food regulatory framework a definition of probiotics, a guide for the evaluation of a probiotic as a food ingredient and a definition of food with probiotics.

Brazil, Colombia, and Ecuador have adopted a definition of probiotics that is aligned with the definition proposed in the FAO/WHO consultation. Besides, Brazil has a protocol for the evaluation of a probiotic as a food ingredient.

The Southern Cone and Caribbean countries include requirements for "probiotic" microorganisms on food labelling.

In Europe, such as Italy, have developed certain requirements for qualifying specific strains as probiotics.

In the US, probiotics can be considered as food or ingredients in food, beverages and food supplements.

Canada has developed a Guidance Document in order to clarify the acceptable use of health claims about microorganisms represented as 'probiotics' on food labels and in advertising.

Australia and New Zealand have neither specific regulations on probiotics nor a definition of probiotics. Microorganisms, including probiotics, are considered "novel food".

In the 10 member country Association of Southeast Asian Nations (ASEAN), only 4 countries (Indonesian, Philippines, Thailand and Malaysia) have enacted clear regulations or guidelines on probiotics in foods and supplements.

The Indonesian regulations on monitoring of claims on processed food labels and advertising in 2016 has included provisions for use of probiotics in foods.

Philippines, in 2004, published a set of guidelines for the use of probiotics in foods.

Thailand has a specific probiotic regulation and a definition of probiotics. This country published a notification in 2012 for the use of probiotics in foods and supplements.

Malaysia in 2017, gazetted a specific regulation on probiotic cultures to be added into foods. The regulation also defines the term "probiotic" which is aligned with the recommendations in the FAO/WHO (2001) consultation. The said regulation also prescribes specific labelling requirements for foods and beverages containing probiotics. These regulations or guidelines were developed independently and have different requirements.

India has a regulatory definition of food with added probiotics.

## PART 2: PROPOSAL 1 (Argentina and Malaysia)

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

Taking into account the existing global references on probiotics, standardization in this area is achievable through harmonization of: a definition, minimum requirements and labelling parameters for probiotics for use as an ingredient in foods, beverages and food supplements.

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

The growing scientific and clinical evidence and the increasing consumer acceptance of probiotics have led to the availability of many products available in the marketplace carrying the label 'probiotic' in many countries worldwide. However, there are currently no defined criteria or guidelines internationally accepted on what constitutes a 'probiotic' microorganism. The term 'probiotic' should only be used to describe microorganisms when certain requirements are met.

The establishment of eligibility criteria and an organized framework to produce probiotic products will provide proper guidance for global regulatory agencies, enabling them to adopt probiotics specific regulations, ensuring a consistent use of the term 'probiotics' which will benefit consumers and industry.

**5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES**

Development of guidelines and a harmonized framework for probiotics, including general specifications and considerations is necessary to ensure and sustain quality probiotic products on a global scale. The development of international standards, guidelines, and other recommendations contributes to protect the health of consumers and to ensure fair practices in food trade.

The objective, as described above, is in line with the Codex Strategic Plan 2020-2025, adopted by the 42.<sup>a</sup> Session of the Codex Alimentarius Commission. In this regard, the new work proposal will contribute particularly to Goals 1, 2 and 3:

Goal 1: *“Address current, emerging and critical issues in a timely manner”.*

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

Goal 3: *“Increase impact through the recognition and use of Codex Standards”.*

**6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS AS WELL AS OTHER ONGOING WORK**

Codex has developed principles and horizontal guidelines on labelling, claims, safety and hygiene covering foods, beverages and food supplements in general, including:

General Principles of Food Hygiene (CXC:1969), General Standard for Food Additives (CXS 192-1995), General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), General Standard for Labelling of Prepackaged Foods (CXS 1-1985), and Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).

However, existing Codex standards and guidelines do not:

- include a definition of probiotics. The term “probiotic” is already used in the Regional Standard for Doogh (CXS 332R-2018) adopted for the Near East region. Ideally terms used in Codex standards should have a Codex definition, as it was noted by the 44.<sup>th</sup> Session of the Codex Committee on Food Labelling<sup>17</sup>.
- contain a description with criteria to clarify the meaning of what is a probiotic to ensure a consistent interpretation and application at national and international levels by Codex members of the key aspects of the definition of probiotics and, thereby, of the term probiotic.
- establish minimum requirements specific for probiotics for a live microorganism to be qualified as a probiotic or to demonstrate that a strain is a probiotic.
- address additional specific labelling requirements for probiotics such as: the name of the food specific to probiotics, i.e: name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients, the declaration of the amount of viable cells of total probiotic microorganisms (CFU/g), and other labelling requirements specific to probiotics.

<sup>17</sup> REP18/FL, paragraph 17.

**PART 2: PROPOSAL 1 (Argentina and Malaysia)****7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

No expert advice other than which is to be found in the CCNFSDU is required at this time. Available scientific guidance as given in FAO/WHO consultation reports of 2001 and 2002 on probiotics shall be referred to.

**8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

No further technical input is required at this time in addition to that provided by CCNFSDU.

**9. PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK**

Subject to approval by CAC46 in 2023, it is expected that the work can be completed by 2025.

## Proposal 2.2

**GUIDELINES INCLUDING GENERAL PRINCIPLES FOR THE NUTRITIONAL COMPOSITION OF FOODS AND BEVERAGES MADE FROM PLANT-BASED AND OTHER ALTERNATIVE PROTEIN SOURCES**

*Prepared by the United States and Canada*

**Discussion Paper****BACKGROUND**

The 41<sup>st</sup> Session of the CCNFSDU considered a paper, CX/NFSDU 19/41/10, prepared by Germany, as host Secretariat of CCNFSDU on a prioritization mechanism to better manage the work of the Committee. The paper put forward proposals for CCNFSDU 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 are submitting this proposal in response to the Circular Letter, CL 2020/30-NFSDU, calling for new work proposals and identification of emerging issues ahead of CCNFSDU43 (March 2023).

**INTRODUCTION**

In the last decade, plant-based diet patterns have become more popular among a wide range of consumers as more plant-based protein foods are being encouraged as part of dietary guidance recommendations. Interest in other non-animal protein products such as foods and beverages made from fungi, insects and fermentation derived proteins is on the rise. In response, innovation in this market sector has led to a large influx of new foods and beverages made from plant-based and other alternative protein sources including products which mimic animal-based products in appearance, representation, and use. The increased presence of these alternative products on the market and the increasing trade of products internationally highlights the need to consider the need for guidance and general principles related to the nutritional composition for such products to protect consumer health.

**Plant-Based Diets and Dietary Guidance**

There has been a recent rise in the adoption of plant-based diets globally. India has had the highest percentage of vegetarians worldwide for quite some time, currently estimated between 20 – 42% of the population<sup>1</sup>, however plant-based diets are now becoming popular in other regions as well. In 2018, the percent of the population following vegetarian/vegan diets in the United Kingdom, Germany, and France reached 8%, 5.6%, and 5.2%, respectively.<sup>2</sup> In the United States, 5% of the population identified as vegetarian in 2018, and among 18–34 year olds that number increased to 8%.<sup>3</sup> In Canada, nearly 10% of the population in 2019 identified as vegetarian or vegan.<sup>4</sup> Regions of South America have similarly experienced significant increases in the adoption of plant-based diets, such as Brazil which saw nearly double the rates of people identifying as vegetarian between 2012 and 2018, jumping from 8% to 14%.<sup>5</sup> There has been an even larger increase globally of 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%.<sup>6</sup> In Europe, the flexitarian trend has also spread, with rates as high as 26% and 23% in Germany and Spain, respectively.<sup>7</sup> In 2019, Canada was estimated to have 25% of its population following a flexitarian diet.<sup>8</sup> Research shows that plant-based diets are also most readily accepted by younger generations<sup>9</sup>, meaning the vegetarian populations is expected to continue to increase over time.

<sup>1</sup> <https://doi.org/10.1016/j.appet.2015.10.018>

<sup>2</sup> [https://www.interbev.fr/wp-content/uploads/2019/10/11\\_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654](https://www.interbev.fr/wp-content/uploads/2019/10/11_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654)

<sup>3</sup> <https://news.gallup.com/poll/267074/percentage-americans-vegetarian.aspx>

<sup>4</sup> [Nourish 2019 Trends Report](#)

<sup>5</sup> <https://www.svb.org.br/2469-pesquisa-do-ibope-aponta-crescimento-historico-no-numero-de-vegetarianos-no-brasil>

<sup>6</sup> <https://time.com/5930095/china-plant-based-meat/>

<sup>7</sup> [https://www.interbev.fr/wp-content/uploads/2019/10/11\\_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654](https://www.interbev.fr/wp-content/uploads/2019/10/11_synthese-panorama-vegetarisme-en-europe.pdf#page=13&zoom=90,-139,654)

<sup>8</sup> [https://reports.mintel.com/display/918746/?fromSearch=%3Ffilters.category%3D155%26last\\_filter%3Dcategory](https://reports.mintel.com/display/918746/?fromSearch=%3Ffilters.category%3D155%26last_filter%3Dcategory)

<sup>9</sup> Charlebois, 2021. Presentation for the Canadian Nutrition Society; *COVID-19 happened. Now what? The pandemic's legacy on our relation with proteins*

## PART 2: PROPOSAL 2 (Canada and the United States)

The recent encouragement to consume more plant foods, as seen in dietary guidance globally, is expected to spur an even 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 Guide<sup>10</sup> 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".<sup>11</sup> 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.<sup>12</sup> South American countries also promote plant foods in dietary guidance; for example, Brazil's dietary guidelines encourage consumption of foods mainly of plant origin.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup>

### **Growth of the Plant and Alternative Protein Market Globally**

With the growing number of plant food consumers, the food industry has quickly developed a wide range of new plant-based food categories and types of products globally. The range of products is even further widened with the emergence of other alternative protein foods, such as dairy beverages made through precision fermentation and mycelium 'meat'.

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. Market research indicates that the global plant-based substitute sector as a whole is expected to reach up to USD \$85 billion by 2030.<sup>16</sup> While the plant-based alternatives 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.<sup>17</sup> Plant-based dairy products, such as soy and nut beverages, currently make up the largest share of the plant-based alternatives market, however plant-based meat and poultry products are experiencing more rapid growth, with an estimated annual growth rate of 14% for the next 5 years.<sup>18</sup> The market for other alternative protein foods and beverages, such as products made from edible insects and fungi, is 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%.<sup>19</sup> The fungal protein market is forecasted to reach USD \$386.6 million globally by 2030, representing an annual growth rate of 9.5%.<sup>20</sup>

<sup>10</sup> [Canada's Food Guide \(2019\)](#)

<sup>11</sup> [Dietary Guidelines for Americans 2020-2025](#)

<sup>12</sup> [Eatwell Guide 2016](#)

<sup>13</sup> [Dietary Guidelines for the Brazilian Population 2014](#)

<sup>14</sup> [https://eatforum.org/content/uploads/2019/07/EAT-Lancet Commission Summary Report.pdf](https://eatforum.org/content/uploads/2019/07/EAT-Lancet_Commission_Summary_Report.pdf)

<sup>15</sup> <http://www.fao.org/3/i5640E/i5640e.pdf>

<sup>16</sup> <https://doi.org/10.3389/fsufs.2020.00134>

<sup>17</sup> [https://www.foodnavigator-usa.com/Article/2021/03/24/Alternative-proteins-will-account-for-11-of-global-protein-market-by-2035-predicts-report?utm\\_source=copyright&utm\\_medium=OnSite&utm\\_campaign=copyright](https://www.foodnavigator-usa.com/Article/2021/03/24/Alternative-proteins-will-account-for-11-of-global-protein-market-by-2035-predicts-report?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)

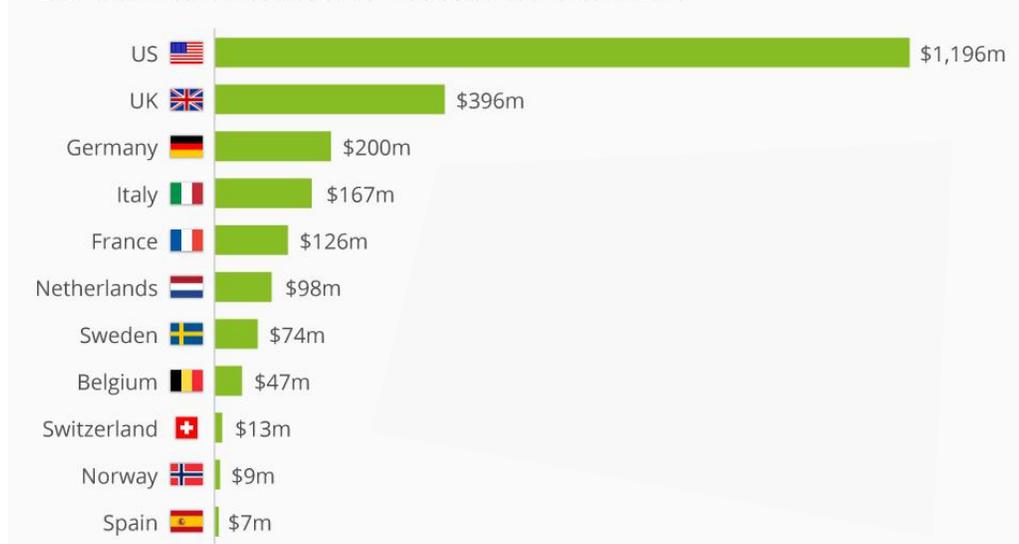
<sup>18</sup> <https://www.globenewswire.com/news-release/2021/03/16/2193792/0/en/At-14-CAGR-Trends-in-The-Plant-based-Meat-Market-Size-Share-Value-Will-Grow-to-USD-9-43-Billion-by-2026-Facts-Factors.html>

<sup>19</sup> 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](https://www.meticulousresearch.com/product/edible-insects-market-5156?utm_source=Globenewswire&utm_medium=Paid&utm_campaign=Product&utm_content=25-05-2022)

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

## PART 2: PROPOSAL 2 (Canada and the United States)

Estimated meat substitute sales in selected countries in 2018



Source: Adapted from Statista<sup>21</sup>

North America and Europe have held the lion's share of the plant-based alternative market to date<sup>22,23</sup> and sales in these regions are expected to grow; however some expect the Asia-Pacific region to soon become the largest plant-based alternative market globally.<sup>24</sup> The plant-based meat substitutes market in China alone was estimated to be worth USD \$910 million in 2018, and is projected to grow 20%-25% annually.<sup>25</sup> Australia is now considered the third-fastest growing vegan market worldwide, behind only China and the United Arab Emirates.<sup>26</sup> 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%.<sup>27</sup> In regions with plant-based alternative markets that are already very strong, such as the United States, growth has been most significant in newer product categories such as plant-based "meats" and 'other dairy products' (plant-based ice cream, yogurt, etc.).<sup>28</sup>

### **Nutritional Composition of Plant-Based and Other Alternative Protein Products and Potential Health Impacts**

The formulations of plant-based and other alternative protein source foods and beverages varies widely between and within product categories, and across countries.

Available composition data shows that some of these products have high concentrations of nutrients of public health concern related to excessive intakes, such as sodium and saturated fat in some meat substitutes, and sugar in some dairy alternatives. These levels are greater than those found in unprocessed plant foods, and are sometimes higher than the animal-based counterparts. For example, a comparison of the nutrient content of four popular plant-based burger alternatives in the United States found that the nutrient composition varies across the plant-based 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).<sup>29</sup> A 2019 review of the ingredients and nutrient profile of meat analogues from the United States, Canada and the United Kingdom found that the nutrient content varied greatly

<sup>21</sup> <https://www.statista.com/chart/18394/meat-substitute-sales-in-selected-countries/>

<sup>22</sup> <https://www.zionmarketresearch.com/market-analysis/plant-based-meat-market>

<sup>23</sup> <https://www.statista.com/statistics/890262/global-meat-substitutes-market-share-by-region/>

<sup>24</sup> <https://www.zionmarketresearch.com/market-analysis/plant-based-meat-market>

<sup>25</sup> <https://time.com/5930095/china-plant-based-meat/>

<sup>26</sup> <https://www.mdpi.com/2072-6643/11/11/2603>

<sup>27</sup> <https://www.mordorintelligence.com/industry-reports/south-america-meat-substitute-market>

<sup>28</sup> <https://bridge2food.com/wp-content/uploads/2019/06/2019-Plant-Based-Foods-Summit-Plenary-Day-1-5-Beena-Goldenberg-Hain-Celestia-B2F-Info.pdf>

<sup>29</sup> <https://www.sciencedirect.com/science/article/pii/S2213453019301144>

**PART 2: PROPOSAL 2 (Canada and the United States)**

across brands and product types (burgers, meatballs, chicken nuggets, etc.), and broad comparison between meat alternatives and their animal-based counterparts is difficult.<sup>30</sup>

The levels of essential nutrients in plant and other alternative protein source foods and beverages also appears to vary greatly. Moving to an almost entirely vegetarian or vegan diet may increase risks of certain nutrient inadequacies. While obtaining recommended intakes of all essential nutrients is possible on an entirely plant-based diet, it requires meal planning and consumption of a wide 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 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.<sup>31,32,33,34</sup> Compositional data available for plant-based dairy alternatives indicates that the majority of plant-based beverages have significantly lower protein content (both total and corrected for quality), and unfortified products have lower calcium, and Vitamin A than cow's milk.<sup>35,36</sup> One study assessing over 100 plant-based beverages in Australia found that roughly half of the dairy alternatives were unfortified, and indiscriminate substitution for cow's milk may lead to significant reductions in intakes of protein, calcium, zinc, Vitamin A, and Vitamin B12.<sup>37</sup>

In addition to plant-based and other alternative protein source products potentially providing lower levels of certain nutrients compared to animal-based products, there is also a health "halo" surrounding plant-based alternatives with consumers often overestimating the nutritional value of these products.<sup>38,39</sup> And beyond the absolute amount of essential nutrients in plant and other alternative protein source foods and beverages, the quality and bioavailability of these nutrients may also be lower compared to the animal-based counterparts.

**Policies and Regulations for the Nutritional Composition of Plant-Based and Other Alternative Protein Source Foods and Beverages**

An initial review of publicly available information on international policies and guidelines shows that most countries regulate plant-based alternatives as general foods, and that few countries have specific regulations for the nutritional composition of these products.<sup>40</sup>

The lack of consistent policies for plant-based and other alternative protein source foods and beverages may have both health and trade implications, and nutritional compositional guidelines for these products may aid in aligning approaches internationally. With the rapid rise in the popularity of these products, harmonized international guidance and general principles on the nutritional composition of these products is very timely.

---

<sup>30</sup> <https://www.sciencedirect.com/science/article/pii/S2213453019301144>

<sup>31</sup> <https://cdnsiencepub.com/doi/pdf/10.1139/apnm-2020-1039>

<sup>32</sup> <https://pubmed.ncbi.nlm.nih.gov/33591857/>

<sup>33</sup> <https://www.mdpi.com/2072-6643/12/7/2034/htm>

<sup>34</sup> <https://pubmed.ncbi.nlm.nih.gov/28532520/>

<sup>35</sup> <https://link.springer.com/article/10.1007/s13197-016-2328-3>

<sup>36</sup> <https://doi.org/10.1016/j.idairyj.2018.07.018>

<sup>37</sup> <https://www.mdpi.com/2072-6643/12/5/1254/htm>

<sup>38</sup> <https://www.mdpi.com/2071-1050/13/3/1478/htm>

<sup>39</sup> <https://d.lib.msu.edu/etd/47846/datastream/OBJ/view>

<sup>40</sup> A summary of the findings from the initial review of international policies and guidelines for the nutritional composition of plant-based and other alternative protein foods and beverages can be found in the Annex.

## PART 2: PROPOSAL 2 (Canada and the United States)

**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 plant-based and other alternative protein source foods and beverages. Many countries and regions do not have specific regulations for the nutritional composition of plant-based and other alternative protein source foods and beverages, however there have been indications in recent years that some countries are looking to develop policies, such as Japan and China.<sup>41,42</sup> In other countries and regions, such as Canada, there are specific regulations for the composition of certain meat and poultry alternatives.

<b>Country/ Region</b>	<b><i>Nutritional Composition of Plant-based and other Alternative Protein Source Foods and Beverages</i></b>
<b>European Union</b>	No specific nutritional composition requirements for plant-based/other alternative protein source products.  Nutrients can be voluntarily added to foods, including plant-based alternatives, to provide a similar nutritional value to foods for which they are intended as alternatives. <sup>43</sup>
<b>United States</b>	No specific nutritional composition requirements for plant-based/other alternative protein source products.  Nutrients can be voluntarily added to plant-based alternatives to replace those nutrients found in the animal-based counterpart. <sup>44</sup>
<b>Canada</b>	Simulated meat and poultry products <sup>45</sup> must meet certain nutritional compositional criteria, <sup>46</sup> and plant-based beverages are permitted to voluntarily add certain vitamins and minerals. <sup>47</sup>
<b>Australia/ New Zealand</b>	No required nutritional composition requirements for plant-based/other alternative protein source products.  Certain vitamins and minerals can be added to both meat analogues and plant-based milk alternatives as long as a certain level of protein is present (12% for meat analogues, 3% for plant-based milk alternatives). <sup>48,49</sup>

<b>Japan</b>	No specific nutritional composition requirements for plant-based/other alternative protein source products.  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. <sup>50</sup>
<b>China</b>	No specific nutritional composition requirements for plant-based/other alternative protein source products.  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. <sup>51</sup> The voluntary standard includes basic composition requirements, including that the formulation shall be

<sup>41</sup> [USDA Report: Japan Begins to Explore Regulations for Alternative Meat Products, 2020.](#)

<sup>42</sup> [USDA, Industry Group Issues Voluntary Standard for Plant Based Meat Alternative Products](#)

<sup>43</sup> [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](#)

<sup>44</sup> [21 CFR 104.20\(e\)](#)

<sup>45</sup> 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

<sup>46</sup> [Food and Drug Regulations, Parts 14 and 22](#)

<sup>47</sup> [Interim Marketing Authorization to permit the optional addition of vitamins and mineral nutrients to plant-based beverages](#)

<sup>48</sup> [Australia New Zealand Food Standards Code – Schedule 17 – Vitamins and minerals](#)

<sup>49</sup> <https://www.foodstandards.gov.au/consumer/nutrition/milkaltern/Pages/default.aspx>

<sup>50</sup> [USDA Report: Japan Begins to Explore Regulations for Alternative Meat Products, 2020.](#)

<sup>51</sup> [USDA, Industry Group Issues Voluntary Standard for Plant Based Meat Alternative Products](#)

PART 2: PROPOSAL 2 (Canada and the United States)

	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.
--	--

## PART 2: PROPOSAL 2 (Canada and the United States)

**Project Document****1. Purpose and Scope of the New Work**

- The purpose of this project is to develop guidance and general principles for the nutritional composition of foods and beverages made from plant-based and other alternative protein sources which are intended to replace animal-based products.
- The scope of this project:
  - includes foods and beverages with protein derived from plants, bacteria, insects, and fungi, which are intended to replace a meat, poultry, fish/seafood, or dairy product; and
  - does not include animal-based or animal cell-based proteins

**2. Relevance and Timeliness**

- In the last decade both dietary guidance and consumer purchasing behaviors have changed, and now include increasing amounts of plant-based foods. As a result, industry has innovated numerous new plant-based food and beverage products, found in both domestic and international markets. There has also been an emergence of foods and beverages made from other alternative protein sources, such as fungi, insects, bacteria and fermentation.
- The nutrient profile of foods and beverages made from plant-based and other alternative protein sources varies widely, and their composition is often very different from the animal-based foods or beverages they resemble and/or are intended to replace. When consumers replace animal-based foods and beverages with alternative protein food/products which are not nutritionally similar to the animal-based food or beverage, nutritional adequacy of diet patterns may be compromised, having both positive and negative public health impacts.
  - 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<sup>52</sup>. 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.
  - Neither of these existing general principles provide guidance specifically for the nutritional composition of plant-based and other alternative protein foods and beverages that are substitutes for animal-based 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 food that are a significant contributor to meeting dietary adequacy of essential nutrients? Should plant-based and other alternative protein replacement foods 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 plant-based and other alternative proteins. Canada, for example, has strict composition requirements for simulated meat and poultry products, and fortified plant-based beverages. Other jurisdictions have exercised limited oversight of alternative protein-based foods and beverages. This has resulted in inconsistent formulations of products globally, which may contribute to consumer confusion and trade barriers.
- In March 2022, the Codex Secretariat requested information (CL 2022/06-EXEC) on new food sources and production systems, 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

---

<sup>52</sup> "A food which resembles a common food in appearance and texture and is intended to be used as a complete replacement or partial replacement for the food it resembles" (Codex General Principles For The Addition Of Essential Nutrients To Foods)

## PART 2: PROPOSAL 2 (Canada and the United States)

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.<sup>53</sup>

Codex guidance and general principles for the nutritional composition of plant-based and other alternative protein foods and beverages 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 contribute towards the broader Codex work related to new food products and production systems, 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, CCEXEC clarified that its review should not impede the initiation of new work by Codex committees under their existing terms of reference.

### 3. Main Aspects to be Considered

- Establish guidance and general principles to guide the development of policies and regulations for the nutritional composition of foods and beverages made from plant-based and other alternative proteins which are substitutes and/or intended as replacements for animal-based products.
- Establish guidance and general principles for nutritional profiles for plant-based or alternative protein replacement foods and beverages based on nutritional equivalence (e.g. protein quality, essential nutrients).
- Establish guidance and general principles for plant-based and other alternative protein substitute foods and beverages which address nutrients of public health concern when consumed in excess of recommendations (e.g. saturated fat, sugars, sodium) and anti-nutritional factors.

### 4. Evaluation of Criteria for the Establishment of New Work Priorities

#### **General Criteria:**

- Clear guidance and general principles for the composition of plant-based and other alternative protein source substitute foods and beverages, can provide:
  - Industry with a clear and consistent direction for nutritional criteria for product formulation; and
  - Consumers with 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 alternative protein food and beverage 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.

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

Develop guidance and general principles for the nutritional composition of plant-based and other alternative protein source foods and beverages which are intended to replace 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 plant-based and other alternative protein source foods. However, there is some internationally relevant work that can be leveraged (e.g. FAO protein work, FAO healthy and sustainable dietary guidelines<sup>54</sup>, etc.). FAO has asked the Codex

<sup>53</sup> CX/EXEC 22/82/4, Agenda Item 4, [CCEXEC sub-committee on new food sources and production systems – interim report](#).

<sup>54</sup> <http://www.fao.org/3/I5640E/I5640e.pdf>

## PART 2: PROPOSAL 2 (Canada and the United States)

Executive Committee (CCEXEC) to consider how Codex could contribute to guidelines and policies related to new food sources and production systems<sup>55</sup>.

(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 of the nutritional composition of plant-based and other alternative protein foods is possible.

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

The rapid increase in availability and use of plant-based and other alternative 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 alternative protein foods and beverages. 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's<sup>56</sup> Goals and Objectives

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

- **Goal 1: Address current, emerging and critical issues in a timely manner**
  - Objective 1.1. To identify needs and emerging issues
  - Objective 1.2. To prioritize needs and emerging issues
    - The plant-based and other alternative protein source food and beverage market is booming globally, and dietary recommendations are now encouraging consumption of more plant-based and alternative protein foods. The need for Codex engagement has already been recognized by the CCEXEC Sub-Committee on new food sources and production systems. Guidance and general principles on the nutritional composition of these products is consistent with consideration in the CCEXEC Sub-Committee.
    - Providing nutrition guidance and general principles for countries who wish to establish science-based guidance, policies, or regulations 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.
    - Therefore, the development of guidance and general principles for plant-based and other alternative protein source foods and beverages 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).

<sup>55</sup> CX/EXEC 22/82/4

<sup>56</sup> For more information, please see the [Codex Strategic Plan 2021-2025](#)

## PART 2: PROPOSAL 2 (Canada and the United States)

- 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 and beverages.
- **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.
    - Plant-based and other alternative protein source foods and beverages 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 plant-based and other alternative protein source foods and beverages.
    - This work is relevant to all Codex regions with respect to both production of raw materials and manufacturing of finished products.
    - Developing guidance and general principles for the nutritional composition for plant-based and other alternative protein source foods and beverages 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 recent CCEXEC interim report on new food sources and production systems (CX/EXEC 22/82/4) as products within scope of this proposal overlap with several of the food categories included in the circular letter<sup>57</sup> (plant-based protein alternatives, fermentation-derived ingredients, edible insects, and microalgae).
- 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).
- The proposal relates to the compositional guidelines for foods using vegetable protein products which 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).
- 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 and beverages, such as the *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.

## 8. Need For Technical Input From External Bodies

- No need identified at this stage.

## 9. Proposed Timeline

Subject to approval by CAC46 in 2023, it is expected that CCNFSDU will require four (4) sessions to complete its work.

<sup>57</sup> CL 2022/06/OCS-CCEXEC

## PART 2: PROPOSAL 2 (Canada and the United States)

**Criteria<sup>58</sup>****1. Revision of existing texts**

*Describe the rationale for the proposed revision of an existing CCNFSDU text. Is it necessary due to new scientific findings and/or other developments? Can these new findings or developments cause a safety concern to a special group of people?*

- The proposal is to develop guidance and general principles for the nutritional composition of foods and beverages made from plant-based and other alternative protein sources which are intended to replace animal-based products. It is not a revision of an existing text.
- No safety concerns for a special group of people expected.

**2. Request from CAC**

*Has the CAC requested CCNFSDU to work on a CCNFSDU text or to start new work?*

- No

**3. Request from other Codex committees**

*Has another Codex Committee asked to consider a revision of an existing CCNFSDU text or to consider new work?*

- No. However the proposal does relate to the recent CCEXEC interim report on new food sources and production systems (CX/EXEC 22/82/4) as products within scope of this proposal overlap with several of the food categories included in the circular letter (CL 2022/06-EXEC) request for information on new food sources and production systems (plant-based protein alternatives, fermentation-derived ingredients, edible insects, and microalgae).

**4. Availability of scientific advice**

*Is scientific advice available or will be provided soon?*

- We may consult the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) on scientific matters regarding nutritional adequacy/equivalence, including protein quality.

**5. Target group**

*Describe the target group of the proposal. Does the proposal refer to a vulnerable target group (infants, the aged, patients, etc.) or is the target group large (e.g. whole population)?*

- The target group is the entire population above the age of 1 year which consumes a mixed diet including foods and beverages made with plant-based and other alternative protein sources which are intended to replace animal-based products.
- In developing nutrition composition guidance and general principles, we may target certain groups which may have an increased consumption of plant-based and other alternative protein source foods and beverages, such as vegetarians and vegans, and vulnerable groups such as young children consuming these products.

**6. Impact on public health**

*Describe the impact on public health (high/medium/low?) Please also include a rationale to justify the response.*

- Medium. As the consumption of plant and other alternative protein source foods and beverages continues to increase, the public health risks related to inadequate or excessive intakes of certain nutrients from these products may be a concern. Establishing international nutrition composition guidance and general principles for these products may result in product formulations that minimize these potential negative public health impacts.

<sup>58</sup> From the [CCNFSDU41 meeting report](#) (2019), Appendix IX, Para. 2.

## PART 2: PROPOSAL 2 (Canada and the United States)

**7. Impact on food safety**

*Describe the impact on food safety (high/medium/low?) Please also include a rationale to justify the response.*

- Low

**8. Impact on fair trade practices**

*Describe the impact on fair trade practices (high/medium/low?) Please also include a rationale to justify the response.*

- Medium.

Establishing global guidance and general principles for the nutritional composition of plant-based and other alternative protein source foods and beverages may lead to more harmonized international regulations and/or standards helping to reduce trade barriers from more consistent policies across countries and regions.

**Proposal 2.3****DISCUSSION PAPER ON GENERAL GUIDELINES TO ESTABLISH NUTRIENT PROFILES FOR FRONT-OF-PACK NUTRITION LABELLING (FOPNL)**

*Prepared by the Electronic Working Group chaired by Costa Rica co-chaired by the European Union, Paraguay and United States of America*

**1. Introduction**

The term “nutrient profiling” has been defined by the World Health Organization (WHO) as “the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health”<sup>1</sup>. The term “nutrient profiling” has also been defined by the European Food Safety Authority (EFSA) as “the classification of foods based on their nutritional composition for specific purposes (e.g., nutrition education, product reformulation, product labelling to help consumers make informed dietary choices, regulation of health claims, restriction of advertisement to children)”<sup>2</sup>.

Nutrient profiling models are being applied to a wide range of risk management policy actions (e.g., FOPNL to help consumers make informed dietary choices, school feeding programs, restriction of advertisement to children and product reformulation (sodium and sugar reduction)). In 2010, the WHO and the International Association for the Study of Obesity (WHO/IASO) held a technical meeting to consider nutrient profiling with the objective of establishing a manual of guiding principles and a framework for establishing and validating nutrient profiling models<sup>3</sup>. Since 2010, there has been significant international experience with establishing nutrient profiling models, particularly with applications to FOPNL and other policy actions. Therefore, the development of Codex guidelines comprising a science-based framework to establish and validate nutrient profiling to be applied to public health policy actions, particularly FOPNL, would be a timely update from 2010 as it would consider new learning from international experiences.

**2. Background**

At the 39<sup>th</sup> session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU39, 2017), the Committee discussed a referral from the 44<sup>th</sup> session of the Codex Committee on Food Labelling (CCFL44, 2017) to consider how nutrient profiling could contribute towards the CCFL’s new work on FOPNL<sup>4</sup>.

During CCNFSDU40 (2018), Costa Rica explained that guidelines for the establishment of nutrient profiling would complement the work being developed in CCFL on FOPNL. The Committee agreed that Costa Rica and Paraguay would undertake an inventory of nutrient profiling and prepare a discussion paper for consideration at CCNFSDU41 (2019).

During CCNFSDU41 (2019), the Committee considered a discussion paper (CX/NFSDU 19/41/12) General Guidelines to Establish Nutrient Profiles for Food Labelling prepared by Costa Rica with the assistance of Paraguay and the United States of America. The discussion paper summarized the inventory results of a stocktake on nutrient profile models and provided a draft project document. The inventory found that 97 nutrient profile models of which 38% were developed for application to FOPNL, 20% were developed for applications to school meals, and 13% were developed for restrictions for marketing to children. When the nutrient profile models developed for application to FOPNL were evaluated, there were two types: (1) thresholds (82%) - based on nutrients and (2) scoring systems (10%) - intended to consider the overall nutritional value of foods. Less than 50%<sup>5</sup> of the nutrient profile models were based on scientific validation or research to evaluate their effectiveness.

<sup>1</sup> Nutrient Profiling: Report of a WHO/IASO Technical Meeting, London, United Kingdom, 4-6 October 2010 (<https://apps.who.int/iris/handle/10665/336447>); Nutrient profiling, World Health Organization (WHO) (<https://web.archive.org/web/20131122184829/http://www.who.int/nutrition/topics/profiling/en/>); WHO Regional Office for Europe. Nutrient Profile Model. 2015.

[https://www.euro.who.int/\\_data/assets/pdf\\_file/0005/270716/Nutrient-children\\_web-new.pdf](https://www.euro.who.int/_data/assets/pdf_file/0005/270716/Nutrient-children_web-new.pdf)

<sup>2</sup> EFSA NDA Panel 2008 and <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.644>

<sup>3</sup> See WHO 2011: <https://apps.who.int/iris/bitstream/handle/10665/336447/9789241502207-eng.pdf?sequence=1&isAllowed=y> Nutrient Profiling: Report of a WHO/IASO Technical Meeting (London, UK, 4-6 October 2010)

<sup>4</sup> See the meeting report of CCFL44 (REP 18/FL, paras 49-50) and the Agenda Item 2 paper prepared for CCNFSDU39 (CX/NFSDU 17/39/2 Rev.1, para. 14).

<sup>5</sup> The figure of 50% in document CX/NFSDU 19/41/12 will be updated after consideration of other existing relevant research studies.

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

The Committee discussed the project document and concluded that the scope was not yet sufficiently clear to take up as new work. The Committee agreed to:

- a. establish an Electronic Working Group (EWG), chaired by Costa Rica and co-chaired by Paraguay, the European Union, and the United States of America, working in Spanish and English, with the following terms of reference:
  - Analyse the discussion paper and document (CX/NFSDU 19/41/12)
  - Develop a discussion paper and project document, which defines the scope for developing general guidelines for the establishment of nutrient profiling for use in FOPNL.
- b. inform CCFL of the ongoing discussion in CCNFSDU and to ask CCFL to what extent the work concerning nutrient profiling in CCNFSDU can support the work of CCFL on FOPNL and to what extent it is taken into account.

At CCFL46 (2021), the Committee finalized the FOPNL guidelines and responded to CCNFSDU41's request (para. b above). CCFL indicated that work on nutrient profiling from CCNFSDU is not necessary for the work of CCFL on FOPNL as that work has been completed (Agenda Item 2 from CCNSDU42 (2021), see CX/NFSDU 21/42/2 para. 23).

At CCNFSDU42 (2021), the Committee did not discuss nutrient profiling because no new work proposals were considered at that meeting due to the virtual nature of the meeting and an abbreviated agenda. The EWG expects that CCNFSDU43 (2023) will discuss new work proposals, including nutrient profiling.

### 3. Work of the EWG: 2020 to present

In February 2020, the CCNFSDU nutrient profiling EWG commenced its first consultation with the objective of obtaining input to better define the purpose and scope of potential work to develop the general guidelines on nutrient profiling for FOPNL. See Annex IV of this document for the CCNFSDU nutrient profile EWG members: 40 Member countries; 1 Member organization; 28 Observers.

The first consultation consisted of 11 targeted questions (see text box directly below) relating to the CCNFSDU41 discussion paper and project document (CX/NFSDU 19/41/12).

**To provide general guidance to assist governments (or other stakeholders) in the development of nutrient profiles for front-of-pack nutrition labeling.**

**Question 1.**

Do you agree with the purpose?

Yes

No

Explain your answer:

**1.2 Other aspects to be considered**

**Question 2.**

Do you have any comments on discussion paper [CX/NFSDU 19/41/12\\*](#) and its Appendixes II and III (in particular regarding the information related to validation)?

\* [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FWD%252Fnf41\\_12e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FWD%252Fnf41_12e.pdf)

Yes

No

Explain your answer:

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

**Question 3.**

Should the WHO work on nutrient profiling contained in the [Nutrient Profiling: Report of a WHO/IASO Technical Meeting, London, United Kingdom, 4-6 October 2010](#) (WHO, 2010)\* be used in the development of this Guidelines? Are there other relevant publications/documents that should be considered? If so, which ones?

\* [https://www.who.int/nutrition/publications/profiling/WHO\\_IASO\\_report2010/en/](https://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010/en/)

Yes

No

Explain your answer:

**Question 4.**

Should defining the components of a nutrient profile model be included in this work (e.g. nutrients, food groups)? If so, which ones?

Yes

No

Explain your answer:

**Question 5.**

Should the Guidelines consider the scientific evidence or sources of scientific evidence that underpins positive or negative public health outcomes associated with these components (e.g., food guides, reports from competent and recognized scientific bodies)?

Yes

No

Explain your answer:

**Question 6.**

What aspects do you think would be relevant to support the work of CCFL on FOPNL?

Explain your answer:

**Question 7.**

Should the Guidelines include approaches or principles how to establish/set recommended ranges or thresholds for the components of a nutrient profile system based on the desired public health outcomes? If so, should the guidelines consider both short term and longer term public health objectives?

Yes

No

Explain your answer:

**Question 8.**

Should the Guidelines consider methodology to validate the nutrient profiles to ensure that the public health objectives are met?

Yes

No

Explain your answer:

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

<b>Question 9.</b>		
Should the guidelines establish a Codex definition of "nutrient profiles" for FOPNL purpose?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Explain your answer:		
<b>Question 10.</b>		
Are there other definitions Codex should establish as part of developing guidelines for nutrient profiles for FOPNL purposes?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Explain your answer:		
<b>Question 11.</b>		
What other aspects should be included with respect to either the scope or framework for establishing guidelines for nutrient profiles for FOPNL purposes?		
Explain your answer:		

#### 4. Conclusions of the EWG based on the replies to the February 2020 consultation (Appendix II of this document):

Based on the 46 responses received in April 2020 from the EWG consultation (30 members (including the EU) and 16 observers), the EWG's feedback can be summarized as follows:

- There was general support for the proposed purpose of this work to develop guidelines for nutrient profiling to be used for the purpose of FOPNL. However, as will be noted below (Appendix II), there were some comments from the EWG consultation that the guidelines should be broader and not limited to only nutrient profiling for FOPNL.
- The purpose of the work should be concise and that the phrase "to assist governments (and other interested parties)" should be deleted because international standards should be applicable to all interested parties and not just governments.
- Purpose and Scope section of the guideline for nutrient profiling, should include applications to other purposes (e.g., public health policies) beyond FOPNL.
- The guidelines should include principles or guidance on the various types of scientific evidence, public health concerns, and/or dietary recommendations used to establish nutrient profiling models.
- The guidelines should include principles for validating and systematically comparing different nutrient profiling models against their public health objective(s).
- The guideline should include principles to evaluate and determine effectiveness after implementation against the intended public health objective(s) for nutrient profiling.
- The guideline should define the nutritional components that can be considered for including in nutrient profiling models and the underlying scientific basis for their role in public health. However, the guideline should not establish specific thresholds for nutritional components.
- The 2010 WHO/IASO technical report could be used as a reference for guideline's development. However, it was noted that this document is more than a decade old and more recent international experiences/learning be considered as a part of guideline development.

**PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)**

- Nutrient profiling should be based on generally-accepted scientific evidence/recommendations on the relationship between diets, dietary patterns, nutrients, NCD risk factors, or other related public health endpoints.
- The guideline should include principles and additional guidance for how to establish thresholds and ranges based on scientific evidence.
- The guidelines should establish an evidence-based definition for nutrient profiling.

**5. Recommendations**

The CCNFSDU is invited to:

- Consider the Project Document proposal presented in Appendix I of this document, in particular the Purpose and Scope sections of the Project Document and general document outline as new work for the committee with the aim of agreeing to the new work and submitting the proposed to the Codex Alimentarius Commission (CAC) for approval.
- Consider a discussion related to identify the need for a broader scope for nutrient profiling, since CCFL46 (2021), finalized the FOPNL guidelines and responded to CCNFSDU41's request (para. 99 iii, REP 21/FL). CCFL indicated that work on nutrient profiling from CCNFSDU is not necessary for the work of CCFL on FOPNL as that work has been completed (Agenda Item 2 from CCNSDU42 (2021), see CX/NFSDU 21/42/2 para. 23).

The EWG Chair and Co-Chairs reiterate that the feedback from CCFL46 (2021) indicated that work on the nutrient profiling to support Codex work on FOPNL was not necessary. Further, some feedback from the April 2020 CCNFSDU nutrient profile EWG consultation indicated that the scope of the guideline on nutrient profiling should be expanded to accommodate objectives beyond FOPNL, that's why further discussion may be needed regarding this point. Therefore, the EWG Chairs and Co-Chairs are proposing that the Purpose and Scope section of the Project Document be expanded to apply not only to FOPNL but also to nutrient profiling intended for other policy actions with nutrition-related objectives such as school feeding, marketing restrictions, and reformulation efforts (e.g. sodium and sugar reductions).

## PROJECT DOCUMENT PROPOSAL

### GUIDELINES FOR DEVELOPMENT OF NUTRIENT<sup>6</sup> PROFILING FOR FRONT-OF-PACK NUTRITION LABELLING (FOPNL)

#### [AND OTHER NUTRITION-RELATED PUBLIC HEALTH OBJECTIVES]

#### 1. PURPOSE AND SCOPE OF THE NEW WORK

Provide general guidelines to assist in the development of evidence-based nutrient profiling for application to front-of-pack nutrition labelling (FOPNL) [and other nutrition-related public health objectives].

Establishing internationally-recognized general guidelines to develop nutrient profiling for use in FOPNL [as well as other nutrition-related public health objectives] can help facilitate the work of governments and other interested parties who seek to establish nutrient profiling models, while also reducing trade barriers. Nutrient profiling models also provide a common framework to support food business operators to reformulate or develop products with a healthier nutritional profile.

#### 2. RELEVANCE AND TIMELINESS

The Codex Alimentarius is a collection of internationally agreed and adopted standards and related texts to protect consumer health and facilitate fair trade practices.

This project is an opportunity for Codex Committee on Nutrition and Foods for Special Dietary Uses (CCFSDU) to support the work of the Commission by ensuring that all Members and observers have harmonized guidelines that will assist in developing nutrient profiling for the purpose of FOPNL [as well as other nutrition-related public health objectives]. These proposed guidelines aim to protect public health and facilitate international trade.

At the 39<sup>th</sup> session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU39, 2017), the Committee discussed a referral from the 44<sup>th</sup> session of the Codex Committee on Food Labelling (CCFL44, 2017) to consider how nutrient profiling could contribute towards the CCFL's new work on FOPNL<sup>7</sup> noting that the Codex *Guidelines on Nutrition Labelling* (CXG 2-1985) do not include guidelines for applying guidelines for nutrient profiling for applications to food labelling.

During CCNFSDU41 (2019), the Committee considered a discussion paper (CX/NFSDU 19/41/12) General Guidelines to Establish Nutrient Profiles for Food Labelling prepared by Costa Rica with the assistance of Paraguay and the United States of America. The CCNFSDU41 discussion paper summarized the inventory results of a stock-take on nutrient profiles and provided a draft project document. The inventory found that 97 nutrient profiles of which 38% were developed for application to FOPNL, 20% were developed for applications to school meals, and 13% were developed for restrictions for marketing to children. When the nutrient profiles developed for application to FOPNL were evaluated, there were two types: (1) thresholds (82%) - based on nutrients and (2) scoring systems (10%) - intended to consider the overall nutritional value of foods. Less than 50%<sup>8</sup> of the nutrient profiles were supported by scientific validation or research to evaluate their effectiveness supporting a need for a harmonized set of international guidelines for both validation and evaluation of nutrient profiles.

Nutrient profile models summarized in the inventory varied in their nutritional components, thresholds, and scientific basis - even when the models had the same (or similar) public health objective(s). This supports the need for a set of guidelines and/or general principles to facilitate a more harmonized approach for establishing science-based nutrient profile models that support national and/or regional dietary patterns and food-based dietary guidelines<sup>9</sup>.

The WHO/IASO Technical Report (2011) can be considered an important reference for this work as this report was an early effort to establish guidelines for establishing nutrient profiling.

<sup>6</sup> For the purposes of this Project Document, the use of the phrase "nutrient profiles" is understood to be a broad term to encompass not only macro- and micro-nutrients but also to encompass food groups and other dietary components.

<sup>7</sup> As agreed at the 44<sup>th</sup> session of the CCFL (REP 18/FL, paras 49-50) and CX/NFSDU 17/39/2 Rev.1, para. 14.

<sup>8</sup> The figure of 50% in document CX/NFSDU 19/41/12 will be updated after consideration of other existing relevant research studies.

<sup>9</sup> See the FAO Food-based dietary guidelines at <https://www.fao.org/nutrition/education/food-based-dietary-guidelines>

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

**3. MAIN ASPECTS TO BE COVERED**

The project objective is to establish a Codex guideline comprised of general principles and other guidance for use by governments, regional authorities, and stakeholders for the development of nutrient profiling for the purpose of FOPNL [as well as other nutrition-related public health objectives]. The guideline is not intended to establish a single harmonized nutrient profiling model; rather, the guideline is intended to articulate general principles to assist in the development of validated science-based nutrient profiling models. The guideline is intended to provide a harmonized approach to establishing nutrient profiling models and, at the same time, to also provide the flexibility to accommodate national and/or regional dietary patterns and food-based dietary guidelines.

Similar to the Guidelines on FOPNL (CXG 2-1985, Annex 2), it is envisioned that the guideline on nutrient profiling would cover the following five aspects:

1. Purpose
2. Scope
3. Definitions
4. Principles

The following aspects can be considered for establishing principles for nutrient profiling models based on the CCNFSDU nutrient profiling EWG consultation (April 2020):

- The guidelines should establish an evidence-based definition for nutrient profiling.
- The guidelines should include principles on establishing the components of nutrient profiling models, which should be based on generally accepted scientific evidence/recommendations on the relationship between diets, dietary patterns, nutrients, NCD risk factors, and/or other related public health endpoints.
- The guideline should include principles and additional guidance for how to establish thresholds and ranges for those components based on scientific evidence. However, the guideline should not establish specific thresholds.
- The principles should include guidance to help establish whether a nutrient profiling model could be applied to all foods equally or whether nutrient profiling models could be specific for different food categories.
- The principles should include guidance to ensure that nutrient profiling models are developed consistent with the information provided in nutrient fact and ingredient declarations.
- The guidelines should include principles for validating nutrient profiling models (e.g. content validity, convergent validity)
- The guideline should include principles to evaluate and determine effectiveness after implementation against the intended public health objective(s) for the nutrient profiling model.

**4. EVALUATION OF CRITERIA FOR THE ESTABLISHMENT OF NEW WORK PRIORITIES****General criteria**

When applied as a tool to improve public health (e.g., FOPNL, school lunch, advertising restrictions, food subsidies, public procurement programs), nutrient profiling models can be applied to initiatives aimed to help consumers develop diet patterns consistent with national or regional food-based dietary guidelines and help reduce the risk of diet-related non-communicable diseases (NCDs). When applied appropriately, nutrient profiling can help provide consumers with information to make informed choices and encourage innovation and reformulation by industry with the view to provide consumers with healthier choices.

**Criteria applicable to general subjects***(a) Diversification of national legislation and apparent resulting or potential impediments to international trade*

Numerous countries/regions have already applied nutrient profiling to underpin voluntary or mandatory regulatory measures to address FOPNL and other public health policies with the aim of reducing NCD risk factors. The absence of harmonized approaches to establishing nutrient profiling has created inconsistencies internationally, which have added complexity to international trade.

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

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

The development of general guidelines for the establishment of nutrient profiling models as a tool to improve public health (e.g., FOPNL, school lunch, advertising restrictions, food subsidies, public procurement programs) can guide public health initiatives to help consumers in developing diet patterns consistent with national or regional food-based dietary guidelines.

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

- Report: "Nutrient Profiling Report of a WHO/International Association for the Study of Obesity (IASO) Technical Meeting". (United Kingdom, 4-6 October 2010). Published in 2011.
- DRAFT FINAL Document: "WHO Guiding Principles and framework manual for front-of-pack labelling for promoting healthy diets" (pre-formatted final draft, May 2019), including Appendix 2 Nutrient Profiling and the Documents included in its Appendix III.

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

The risk factors for diet-related NCDs are generally well understood and recommendations for food-based dietary guidelines are more similar than different around the world, which will enable development of standardized approaches to establish objective, science-based nutrient profiling models for application to FOPNL [and other nutrition-related public health objectives].

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

The public health burden posed by diet-related NCDs is a global problem<sup>10</sup>. Nutrient profiling can be used as a tool for establishing FOPNL [and other nutrition-related public health objectives] aimed at reducing NCD risk factors and establishing healthy food-based dietary patterns.

**5. RELEVANCE TO THE CODEX STRATEGIC PLAN'S GOALS AND OBJECTIVES<sup>11</sup>**

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 document will contribute to the achievement of Strategic Goals 1, 2, and 4, which are described below.

**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.

Worldwide, the incidences of diet-related NCDs continues to increase creating a social and economic burden for all and is a key part of the Sustainable Development Goals (SDGs)<sup>12</sup>. Increasingly, nutrient profiling are being developed and applied internationally as a part of regulatory measures and public health policies with the objective of reducing risk factors of diet-related NCDs and promoting healthy food-based diet patterns.

**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.

Existing science-based information from FAO and WHO expert bodies, as well as other international and national scientific bodies, and scientific input from all countries will be taken into account. Therefore, the development of the nutrient profiling guidelines will be consistent with the use of scientific advice and risk analysis principles in the articulation of control measures.

**Goal 4: Facilitate the participation of all Codex Members throughout 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.

<sup>10</sup> See the WHO NCD Action Plan 2013-2020. [https://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_R10-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf?ua=1)

<sup>11</sup> <http://www.fao.org/fao-who-codexalimentarius/publications/en/>

<sup>12</sup> See: <https://sdgs.un.org/goals>

**PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)**

Increasingly, nutrient profiling models are being developed and applied internationally as a part of regulatory measures and public health policies with the objective of reducing risk factors of diet-related NCDs and promoting healthy food-based diet patterns indicating broad international interest. Therefore, the development of the guidelines for establishing nutrient profiling models would encourage sustainable and active participation of all Codex Members.

**6. RELATIONSHIP BETWEEN THIS PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The proposal relates in part to the Codex *Guidelines on Nutrition Labelling* (CXG 2-1985) and these guidelines are applicable horizontally across all pre-packaged foods.

**7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

FAO and WHO should be considered a primary source of scientific advice but advice from other recognized authoritative scientific bodies will also be consulted. However, at this time, we do not anticipate requesting additional scientific advice from JEMNU.

**8. NEED FOR TECHNICAL INPUT FROM EXTERNAL BODIES**

No need identified at this stage.

**9. PROPOSED TIMELINE**

Subject to approval by CAC46 in November 2023, it is expected that the CCNFSDU will require four (4) sessions to complete its work.

## APPENDIX II

## DISCUSSION PAPER ON GENERAL GUIDELINES TO DEVELOP NUTRIENT PROFILING FOR FRONT-OF-PACK NUTRITION LABELLING (FOPNL)

### 1. Responses to the discussion paper

This discussion paper contains a summary of the responses to the 11 questions included in the questionnaire, provided by the Codex members and observers of the EWG, which were utilized as input to draft the project document proposal.

#### 1.1. Purpose of the proposal

*"Provide general guidance to assist governments (or other stakeholders) in the development of nutrient profiling for front-of-pack nutrition labelling". Do you agree with the purpose of the proposal?*

In response to this question, 25 members and 11 observers agreed with the proposed wording of the "purpose" raised. In addition, 5 members and 4 observers expressed disagreement.

Members who expressed their agreement with the proposal mentioned, among other aspects, that:

- The inventory presented at the CCNFSDU 41 identified a variety of nutrient profile models, created mostly with the goal of developing FOPNL;
- These models have different characteristics and that less than 50% were based on scientific validation or research to assess their effectiveness;
- The guidelines should provide adequate guidance to governments and other stakeholders on how to develop science-based nutrient profile models that will prove effective and suitable for the purpose of FOPNL;
- It should not apply to specific products, alcoholic beverages and foods with low nutritional importance in terms of their composition and quantities (e.g., herbs, spices, tea, etc.), foods in small units.

In addition to the above mentioned comments, several members suggested that the guidelines should make it clear that nutrient profiling for FOPNL are established for prepackaged foods intended for the general population, and that nutrient profiling cover neither groups of the population between 6 and 36 months of age nor those with specific dietary requirements, or following a therapeutic diet.

Several members proposed to eliminate the sentence "to assist the governments (and other stakeholders)" or otherwise clarify the concept, arguing that international standards are relevant for all stakeholders given their voluntary nature, and that each stakeholder shall determine their relevance. Some members suggested retaining the phrase "and other stakeholders".

Some members agreed with the text proposed regarding the purpose of the work. Nevertheless they mentioned it may be appropriate to broad the scope, including in the text conditions for the development of nutrient profiles:

- Solely intended for front-of-pack nutrition labelling.
- For food for healthy/general population.
- For prepacked food products and displayed near the food (e.g. shelf tags or food service, online sales of foods (prepackaged and unpackaged).
- To complement national nutrition guidelines or other relevant policies/programmes.

It is worth noting that 15 members suggested adding the term "science-based", and 8 members suggested adding the term "validated".

Members who did not support the purpose of the proposal mentioned, among other aspects, the following:

- Nutrient profiling could give way to unjustified distinctions between nutrients with similar physiological impact and, therefore, it is impossible to develop 'one-size-fits-all' criteria because of different local food products, dietary guidelines and nutritional needs;
- The WHO has already provided detailed expert guidance to support countries that wish to develop nutrient profile models for FOPNL.

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

For their part, the Observers who did not support the proposal mentioned, among other aspects, that, it is desirable that the responsibility for developing model nutrient profiling remain with national or regional public health authorities, which are best able to take into account regional specificities in meeting the public health goals of their populations when developing front-of-pack nutrition labels:

**1.2. Do you have any comments on discussion paper CX/NFSDU 19/41/12 and its Appendix I (particularly with respect to the information regarding validation)?**

In response to this question, 25 members and 12 observers expressed their desire to make additional comments on document CX/NFSDU 19/41/12 and its Appendix I. In addition, 6 members and 2 observers responded that the content of the document was very clear and had no additional comments; and 1 member did not respond.

The most relevant comments by the members are listed below:

- Some members pointed to potential confusion and inconsistencies in the document CX/NFSDU 19/41/12 as regards the categorization of nutrient profiling models into 'thresholds' and 'scoring' type of models and further noted incomplete information and errors as regards the specific validation approach mentioned for some of the schemes;
- Most members agreed that a validation procedure and a systematic comparison of the different validation approaches are very important (content, convergent and predictive validation), to support the scientific assessment of the nutrient profile model. In this same line, it was stated that further clarity was needed on the purpose of these models and the importance of evidence to provide resources based on scientific research;
- Some members mentioned that it might not be appropriate to define the validation methodology in these guidelines, and that the EWG must consider what level of validation is necessary and feasible;
- Some members proposed that the new document provide clarity on the concept of nutrient profile and cut-off points for front-of-pack nutrition labelling in order to avoid confusions;
- Additionally, some members proposed that it should ensuring an accurate, valid nutritional evaluation of the product, to facilitate an adequate and fair comparison with similar products and help consumers easily assess the nutritional quality of the product and opt for nutrient-dense foods (with a high amount of nutrients per energy unit and low in fat, sugars and salt), in keeping with national public health and nutrition policies;
- Other members proposed soliciting scientific advice from JEMNU regarding validation methods for nutrient profiles, and establishing reference values for non-communicable chronic diseases (NRV-NCD) for all nutrients of concern that need to be limited or else those whose use needs to be promoted. These members argued that it is difficult for governments and other stakeholders to identify the type of validation tests needed, or design the test to be developed for the profile model, and that it is therefore essential to receive guidance in order to adjust them to their specific reality and resources;
- The nutrient profile models should consider the context of mitigating health risks associated to the insufficient or excessive consumption of certain foods with a specific nutritional composition. In addition, a risk assessment based on the epidemiological conditions and prevalent diseases associated with dietary patterns of the population.

**1.3. Should the WHO paper on nutrient profiling, included in "Nutrient Profiling: Report of a WHO/IASO Technical Meeting, London, United Kingdom, 4-6 October 2010 (WHO, 2010)<sup>13</sup>" be used as a reference for the development of these guidelines? Are there other relevant publications/documents that should be considered? If so, which ones?**

- In response to this question, 22 members and 11 observers responded affirmatively; 10 members and 4 observers mentioned that they should not be used and 2 members and 1 observer did not choose any option (yes/no), but provided comments.
- Additionally, in response to the question 'Are there other relevant publications/documents that should be considered? If so, which ones?', 46 members agreed that there are new studies that could complement the work. Most members mentioned that the 2019 WHO guiding principles and framework manual for front-of-pack

<sup>13</sup>[https://www.who.int/nutrition/publications/profiling/WHO\\_IASO\\_report2010/en/](https://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010/en/)

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

labelling for promoting healthy diet, (<https://www.who.int/nutrition/publications/policies/guidingprinciples-labelling-promoting-healthydiet.pdf?ua=1>) should be used as a reference.

Annex II includes a list of studies proposed by the members to be used as a reference for the development of the general guidelines and to establish nutrient profiling for FOPNL.

Countries that did not support the use of the WHO paper on nutrient profiling, contained in the document "Nutrient Profiling: Report of a WHO/IASO Technical Meeting" as reference, argued that the issue of nutritional labelling has evolved significantly since 2010 and that new research has been conducted, which should be taken into account. However, they propose not to exclude it.

#### **1.4. Should this model include the definition of the components of a nutrient profile model (for example, nutrients, food groups)? If so, which ones?**

In response to this question, 27 members and 13 observers supported the inclusion of a definition for the components of a nutrient profile model; 2 members and 3 observers did not support the inclusion of a definition but made some remarks; and one member did not select any option (yes/no), but did issue comments.

When considering which components to include, most members that supported the creation of a definition for the components of nutrient profile models recommended applying the concepts mentioned in the 2019 WHO document, and in other documents listed in Annex II, such as the following:

- Nutrients that must be promoted and limited (within dietary guidelines), specific nutrients of interest to the target population, and mandatory nutritional information;
- Development of a new model or adaptation of an existing one;
- Food groups that must be covered: based on food types or categories;
- Establish the basis of calculation (per 100g/100 ml, 418.9 kJ (100 kcal) or per serving size);
- Profile application criteria according to the utilized FOPNL: threshold scheme or scoring scheme (including the nutritional balance);
- Nutrition policies must be taken into account when deciding on a nutrient profile model, in order to consider dietary patterns and health-related impacts;
- Consider the "list of nutrients" established by the Codex *Guidelines on Nutrition Labelling* (CXG 2-1985).

Additionally, some members deemed it convenient to clarify the meaning of "components", so that while developing the guidelines said components can be identified and the need to define them or not can be more easily assessed. Furthermore, they pointed out that the guidelines should be sufficiently broad, so as not to exclude any currently used model, including its "components", applying the same criteria to all relevant models.

Below are some of the issues highlighted by observers who support the definition of components as part of the guidelines:

- Exclude innovative monosaccharides or disaccharides or functional carbohydrates such as isomaltulose, tagatose, trehalose or ribose from any definition of "sugars" when developing nutritional profiles, since the nutritional properties of these elements are very different from those of traditional sugars;
- While existing schemes are largely voluntary, this result in wide divergences and differences in treatment of the same product depending on the country in which the plan is implemented. It may be useful to reach agreement on the main undisputed nutrients, i.e. nutrients associated with increased risk of NCDs vs. those nutrients that are important for healthy growth and development;
- The nutrient profile scheme should enable consumers to identify the healthiest option within the same product category.

Other additional aspects mentioned by the members who did not support the inclusion were:

- Each country has different approaches and nutrient profile models, which makes it difficult to reach a standard definition that will cover the different needs of each country;
- The definitions included in the *Guidelines on Nutrition Labelling* (CXG 2-1985) are sufficient;

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

- A rigid definition of the components could limit future models that may include other components that may arise with scientific progress.

On the other hand, observers who said they did not support the definition of components mentioned:

- Public health authorities at the national or regional level are better able to define the components of a nutrient profile model in line with situations in member countries and scientific evidence.

**1.5. Should the guidelines consider scientific evidence or the sources of scientific evidence which support positive or negative public health outcomes associated with these components (for example, dietary guidelines, reports from competent, well-recognized scientific organizations)?**

There was consensus (39 members and 16 observers) that scientific evidence or sources of scientific evidence should be taken into account. To increase the robustness of any process to develop nutrient profiling, to assure compliance with the principles of transparency and consensus; It was also stressed that the guidelines should encourage governments to monitor and adapt to new evidence as it emerges.

**1.6 Which aspects do you think could be relevant to support the work of the CCFL on FOPNL?**

29 members and 15 observers responded to this question, 2 members and one observer did not respond. Below is a list of the main aspects considered relevant by the members to support the work of the CCFL on FOPNL:

- Develop clear and effective objectives and for nutrient profiling, to ensure that they complement each other and to avoid the duplication of the CCFL's work;
- Develop a general, harmonized guidance framework to provide the flexibility needed to adopt different profiles and to simplify their implementation;
- Take into account that these guidelines could be included or not in the *Codex Guidelines on Nutrition Labelling (CXG 2-1985)*;
- Analyze how to determine maximum and minimum limits for nutrients, to identify food products that need to apply FOPNL;
- Analyze the need for updates relevant to the FOPNL work, which are not present in current Codex texts and which are specifically within the scope of the CCNFSDU.

Finally, several members agreed that the CCFL must clarify how the CCNFSDU can contribute to the development of FOPNL guidelines.

- Several observers considered relevant to support the work of CCFL in FOPNL and they indicated that it should be objective and non-discriminatory, give due consideration to the role of portions in a balanced diet in accordance with the *Codex General Guidelines on Claims (CXG 1-1979, section 3.5)*<sup>14</sup> and be consistent with national/local nutritional requirements and related public policies;

**1.7. Should the Guidelines include procedures or principles on how to establish/define recommended ranges or thresholds for the components of a nutrient profile system based on the desired public health outcomes? If so, should the guidelines consider short and long term public health outcomes?**

In response to this question, 28 members and 10 observers supported the inclusion of procedures and principles in the guidelines on how to establish or define recommended ranges or thresholds for the components of a nutrient profile system, based on the desired public health outcomes. Two members and 3 observers chose the option NO, but made remarks, and three observers did not choose any option (yes/no). The members who supported the motion justified their response with the following remarks:

- The guidelines should provide general guidance for establishing public health ranges or thresholds, and should not define ranges or thresholds concretely. Some members further recommend that thresholds and ranges be based on scientific evidence, such as the NRVs-R and NRVs-NCD of the Codex and the information provided by RASBs;
- Solicit advice from JEMNU and other expert international organizations to determine NRVs (for example, NRVs-NCD for sugars) for components that will be included in nutrient profiling for FOPNL use;

<sup>14</sup> <http://www.fao.org/3/y2770e/y2770e05.htm>

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

- Provide general and flexible information so that countries can determine how a nutrient profile can contribute to the adoption of an overall healthy diet, which in turn will allow them to measure the impact in terms of compliance with a specific public health objective;
- Consider the short- and long-term public health outcomes in order to measure the impact of the application of nutrient profiling for FOPNL.

For their part, those members who did not support; considered that Governments should remain free to establish their own guidelines, where appropriate, according to their specific public health objectives, which may vary from country to country.

In addition, observers who did not support argued that WHO already provides sufficient orientation in this area, and that this work is not aligned with the CCNFSDU mandate.

### **1.8. Should the Guidelines establish a methodology for validating nutrient profiles, to ensure that they meet public health objectives?**

In response to this question, 27 members and 8 observers considered that the Guidelines should establish a methodology for validating nutrient profiles, to ensure that public health objectives are met, while 3 members and 6 observers chose the option NO, but provided comments. One member did not choose any option (yes/no) but included a comment. The members who supported the motion justified their response with the following remarks:

- Nutrient profiles must be based on scientific evidence. Adequate validation of nutrient profiles is crucial to ensure that they are effective and that they achieve the proposed objectives;
- Given the complexity of nutrient profile validation, the Guidelines should provide references that identify/describe existing methodologies (for instance, content, consistent and predictive validity);
- The Guidelines must clearly state that, prior to conducting the validation process, it is important to define the public health objectives that the nutrient profiles will seek to support. The Guidelines should provide options for assessing impacts, both within the short term (consumption data, for instance) and the long term (public health improvements, e.g. reflected by lower incidence rates for NCDs);
- Analyze the methodologies that could be used to validate nutrient profiles based on the resources available in the countries, the existence of national food-based guides, population-based surveys, etc.);
- Observers who expressed their support consider that: given the limitations of the existing validation criteria and the apparent absence of evaluation criteria, it would be beneficial if the Codex Guidelines addressed how to select the optimal validation approach that would fit the system and the national context and that an adequate validation is essential to ensure that the profiles meet their intended purpose.

Members who do not support, justify their response with some of the following comments:

- Member should remain free to establish their own methodology, where appropriate, according to their specific public health objectives;
- Nutrition labelling of prepackaged foods should be based on scientific evidence and risk analysis as established in the strategic objectives of the Codex Alimentarius. Therefore, their predictive validation is implicit.

Finally, some observers state that since there is no standardized method, the guidelines could include sources of information on existing methodologies so that countries or regions can establish their own validation methods.

### **1.9. Should the guidelines establish a Codex definition for “nutrient profiles” to support FOPNL?**

In response to this question, 27 members and 11 observers agreed that the Guidelines should establish a Codex definition for “nutrient profiles” to support FOPNL. Two members and 3 observers chose the option NO, but provided comments, and one member and 3 observers did not choose any option (yes/no), but also made comments. The members who supported the motion to include a definition justified their response with the following remarks:

- The definition for ‘nutrient profile’ included in the documents ‘Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet by WHO’ (Pre-formatted final draft, May 2019) and “Nutrient Profiling: Report of a WHO/IASO technical meeting, October 2010” could serve as a starting point;
- It is necessary to establish an evidence-based, validated and standardized definition for nutrient profiles, so that it may be utilized by governments and other stakeholders;

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

- The definition should focus specifically on the purpose of FOPNL or health/nutrition claims rather than different objectives;
- The definition must contribute to ensuring that individual nutrient profiles share key aspects for comparability purposes, and that any differences are limited to only those that are strictly necessary to meet their objective;
- The definition must reflect the basic principles; for example, including all relevant nutrients, foods and food groups;

Observers who supported the inclusion of the definition justified their response with the following comments:

- The definition should allow a sufficient level of flexibility to ensure that each Codex member can have the necessary room for manoeuvre to adapt the system to the national and/or regional public health situation and objectives;
- The definition should specify that any nutrient profile should be evidence-based and validated for the intended application.

Some members did not support the establishment of a Codex definition for “nutrient profiles” to support FOPNL because the Codex should adopt the existing WHO definition, instead of proposing a new one that could take years to develop through the Codex process.

In addition, one observer indicated that he did not consider it possible to define nutrient profiles at this stage due to the variety of nutrient profile models in accordance with new scientific evidence.

#### **1.10. Are there other definitions that Codex should establish as part of the development of guidelines for nutrient profiles to support FOPNL?**

In response to this question, 18 members and 4 observers considered that there are other definitions that Codex should establish as part of its development of guidelines for nutrient profiles to support FOPNL. Four members and 3 observers considered that this is not necessary, but some of them justified their responses and 8 members and 9 observers did not select any option (yes/no).

A large number of members who supported the inclusion of other definitions considered that the process of developing guidelines would determine the need to develop other definitions. However, most agreed with the proposal to include the following definitions: food group; scientific validation (including the type or level of evidence that should be considered); nutrient profile models based on scoring, thresholds or others; nutrients of concern; nutrients to be promoted; public health objective/outcome; nutrient profile components; threshold; score; algorithm, total sugars; added sugars; sodium; total fat; saturated fat; trans-fat; food categories; healthy diet; unprocessed/semi-processed/ultra-processed foods; serving size; healthy/unhealthy food.

Some members mentioned that the establishment of a definition for sugar and added sugars would facilitate data interpretation, allow for determining the importance for public health, and facilitate the standardization of nutritional labelling around the world.

On the other hand, some of the members that were not in agreement with the inclusion of other definitions stated that the definitions already included in the *Guidelines on Nutrition Labelling* (CXG 2-1985) are sufficient.

#### **1.11. What other aspects must be included, which relate to the scope or framework for establishing guidelines for nutrient profiles to support FOPNL?**

In response to this question, 24 members and 15 observers mentioned some aspects that should be included, 7 members said they had no comments and 2 members did not respond. Also, 2 observers did not respond to this question; it is worth mentioning that most of the members ratified the answers mentioned in the previous questions. The main aspects are mentioned below:

- Clarify that nutrient profile models for FOPNL are established for general population and for foods in general, and do not include children from 6 to 36 months or population with special dietary needs or therapeutic diets;
- Interested parties must monitor where necessary, in a timely manner, certain aspects of nutrient profiles, in response to regular assessments of the efficiency of the FOPNL scheme with respect to specific indicators; the established nutrient level or threshold should not be static and should be reviewed periodically;
- Ensure that the principles are consistent with the *General Standard for the Labelling of Prepackaged Foods*;

**PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)**

- Should be objective and non-discriminatory, in line with General Guidelines on Claims (CXG 1-1979), section 3.3 “Claims that could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer”;
- It should be monitored and improved, as necessary, to verify long term impact;
- Guidelines should ensure that the nutrient profiles contribute to protecting consumer health and facilitate the elimination of unnecessary barriers to trade;
- Consider an exception list that includes certain foods from the nutrient profile development process (in line with a similar list on FOPNL Guidelines);
- Some members mention that the Committee should examining the feasibility of expanding these principles to apply to non-pre-packaged foods, such as foods sold in restaurants and institutions.

## REFERENCES PROVIDED BY EWG MEMBERS

This Appendix provides a list of studies that members have suggested as reference sources for use in developing general guidelines for establishing nutrient profiling for front-of-pack nutrition labelling (FOPNL).

- WHO (2019). Guiding principles and framework manual for FOPL system development, implementation, monitoring and evaluation. Available: <https://www.who.int/nutrition/publications/policies/guidingprinciples-labelling-promoting-healthydiet.pdf?ua=1>
- WHO (2019). Guiding Principles on Healthy and Sustainable Diets Available: <http://www.fao.org/3/ca6640en/ca6640en.pdf>
- Labonté, M.-È., Poon, T., Gladanac, B., Ahmed, M., Franco-Arellano, B., Rayner, M., & L'abbé, M. R. (2018). Nutrient Profile Models with Applications in Government-Led Nutrition Policies Aimed at Health Promotion and Noncommunicable Disease Prevention: A Systematic Review. *Advances in Nutrition*. <https://doi.org/10.1093/advances/nmy045>
- Poon T, Labonté ME, Mulligan C et al (2018). Comparison of nutrient profiling models for assessing the nutritional quality of foods: a validation study. *2018 Br J Nutr* 120, 567–582 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6137431/>
- Monteiro, C. A., Cannon, G., Lawrence, M., Laura Da Costa Louzada, M., & Machado, P. P. (2019). Ultra-processed foods, diet quality, and health using the NOVA classification system Retrieved from <http://www.fao.org/3/ca5644en/ca5644en.pdf>
- Drewnowski (2005). Concept of a nutritious food: toward a nutrient density score. in *Am. J. Clin. Nutr.* Oct. 2005; 82(4):721-32. See <https://www.ncbi.nlm.nih.gov/pubmed/16210699>
- Drewnowski A, Dwyer J, King JC, et al. A proposed nutrient density score that includes food groups and nutrients to better align with dietary guidance. *Nutr Rev.* 2020;77(6):404-416. doi: 10.1093/nutrit/nuz002.
- Drewnowski A. Uses of nutrient profiling to address public health needs: from regulation to reformulation. *Proc Nutr Soc.* 2017;76, 220–229. doi:10.1017/S0029665117000416. First published online 9 June 2017.
- Drewnowski A and Fulgoni, V. Nutrient profiling of foods: creating a nutrient-rich food index. *Nutr Rev.* 2008;66(1):23–39. doi: 10.1111/j.1753-4887.2007.00003.x.
- Drewnowski, A., Maillot, M., & Darmon, N. (2009). Should nutrient profiles be based on 100g, 100 kcal or serving size? *European Journal of Clinical Nutrition*, 63, 898-904
- Cooper SL, Pelly FE & Lowe JB (2016) Construct and criterion related validation of nutrient profiling models: a systematic review of the literature. *Appetite* 100, 26–40. <https://www.sciencedirect.com/science/article/abs/pii/S0195666316300368?via%3Dihub>
- Cooper SL (2016). An Examination of the Accuracy of Nutrient Profiling Models. Sheri L. Cooper. Faculty of Science, Health, Education and Engineering University of the Sunshine Coast. (Doctoral Thesis) [https://pdfs.semanticscholar.org/9729/9d4027e069924e1a0c1615ae03bf91cc9\\_013.pdf](https://pdfs.semanticscholar.org/9729/9d4027e069924e1a0c1615ae03bf91cc9_013.pdf)
- Global Review of Nutrient Profiling Models, Food Industry Asia study. FIA SECRETARIAT. August 2017 [5a.pdf/comparison\\_of\\_nutrient\\_profiling\\_models\\_for\\_assessing\\_the\\_nutritional\\_quality\\_of\\_foods\\_a\\_validation\\_study.pdf](https://www.fia-secretariat.org/5a.pdf/comparison_of_nutrient_profiling_models_for_assessing_the_nutritional_quality_of_foods_a_validation_study.pdf)
- Propuesta de Criterios y Recomendación de Límites Máximos de Nutrientes Críticos para la Implementación de la Ley de Composición de Alimentos y su Publicidad, Autores: I Zacarías, G Vera, S Olivares, S de Pablo, M Reyes, L Rodríguez, R Uauy y M Araya, INTA, Universidad de Chile, 2011.
- Perfiles nutricionales: Intencionalidad científica versus impacto real en salud pública. Fundación Iberoamericana de Nutrición FINUT 2016. [https://www.finut.org/wp-content/uploads/2016/03/Perfiles\\_Nutricionales\\_18032016\\_conPortadas.pdf](https://www.finut.org/wp-content/uploads/2016/03/Perfiles_Nutricionales_18032016_conPortadas.pdf)

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

- Annex A The 2018 review of the UK Nutrient Profiling Model, 2018, [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/694145/Annex\\_A\\_the\\_2018\\_review\\_of\\_the\\_UK\\_nutrient\\_profiling\\_model.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/694145/Annex_A_the_2018_review_of_the_UK_nutrient_profiling_model.pdf)
- Poon T, Gladanac B, et al. *Advances in Nutrition*, Volume 9, Issue 6, November 2018, Pages 741–788, <https://doi.org/10.1093/advances/nmy045>
- Conference on 'New technology in nutrition research and practice' Nutrient profiling as a tool to respond to public health needs. Nutrient profiling for regulatory purposes. 2017
- Van de Bend et al. (2014). Simple Visual Model to Compare Existing Front-of-pack Nutrient Profiling Schemes. *European Journal of Nutrition & Food Safety* 4(4): 429-534, 2014. Available: <http://journalejnfs.com/index.php/EJNFS/article/view/26877/50432>
- The Preventable Risk Integrated ModEl and Its Use to Estimate the Health Impact of Public Health Policy Scenarios. 2014. <https://www.hindawi.com/journals/scientifica/2014/748750/>
- Nutrient Profiling Technical Guidance, (2011). [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216094/dh\\_123492.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf)
- World Health Organization. Guiding principles and framework manual for the development or adaptation of nutrient profile models. 1st ed. Geneva (Switzerland): WHO. Unedited final draft: 2011. Feb 22. In press.
- The scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (EFSA, 2008): "The Setting Of Nutrient Profiles For Foods Bearing Nutrition And Health Claims Pursuant To Article 4 Of The Regulation (Ec) ° No 1924/2006.
- WHO. (2015). WHO regional office for Europe nutrient profile model. [http://www.euro.who.int/\\_data/assets/pdf\\_file/0005/270716/Nutrient-children\\_web-new.pdf](http://www.euro.who.int/_data/assets/pdf_file/0005/270716/Nutrient-children_web-new.pdf)
- Rayner, M., Scarborough, P., & Stockley, L. (2004). *Nutrient profiles: options for definitions for use in relation to food promotion and children's diets*. London: Food Standards Agency.
- Roodenburg, A. J. C., Popkin, B. M., & Seidell, J. C. (2011). Development of international criteria for a front of package food labelling system: the International Choices Programme. *European journal of clinical nutrition*, 65(11), 1190-1200.
- Scarborough, P., Rayner, M., & Stockley, L. (2007). Developing nutrient profile models: a systematic approach. *Public Health Nutrition*, 10(4), 330-336.
- Lobstein, T., & Davies, S. (2009). Defining and labelling 'healthy' and 'unhealthy' food. *Public health nutrition*, 12(3), 331-340.
- Roberto, C. A., Bragg, M. A., Livingston, K. A., Harris, J. L., Thompson, J. M., Seamans, M. J., & Brownell, K. D. (2012). Choosing front-of-package food labelling nutritional criteria: how smart were 'Smart Choices'?. *Public Health Nutrition*, 15(2), 262-267.
- Feunekes, G. I., Gortemaker, I. A., Willems, A. A., Lion, R., & Van Den Kommer, M. (2008). Front-of-pack nutrition labelling: testing effectiveness of different nutrition labelling formats front-of-pack in four European countries. *Appetite*, 50(1), 57-70.
- Goiana Da Silva et al\_2019\_Nutri-Score a public health tool in Portugal;
- Ares et al\_2018\_Comparative performance of 3 interpretative front of pack nutrition schemes;
- Lawrence et al\_2018\_Do nutrient-based front of pack labelling schemes support or undermine Dietary Guidelines;
- Neal B et al\_2017\_Effects of different front of pack labelling info on the healthiness of food purchases
- EFSA (2008). EFSA's Scientific Opinion: The Setting of Nutrient Profiles for Foods bearing Nutrition and Health Claims Pursuant to Article 4 Of the Regulation (EC)°No. 1924/2006. Available: <https://www.efsa.europa.eu/en/efsajournal/pub/644>

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

- FAO (2016). Plates, pyramids, planet. Developments in national healthy and sustainable dietary guidelines: a state of play assessment. <http://www.fao.org/3/a-i5640e.pdf>
- FAO (2013) Milk and dairy products in human nutrition. Food and Agriculture Organization of the United Nations, Rome. <http://www.fao.org/3/i3396e/i3396e.pdf> .
- Drouin-Chartier J, Brassard D, Tessier-Grenier M, Côté J, Labonté M, Desroches S, Couture P & Lamarche B. Systematic Review of the Association between Dairy Product Consumption and Risk of Cardiovascular-Related Clinical Outcomes. *Adv Nutr.* 2016 Nov 15;7(6):1026-1040. doi: 10.3945/an.115.011403.
- Alvarez-Bueno C, Cavero-Redondo I, Martinez-Vizcaino V, Sotos-Prieto M, Ruiz JR, Gi.I.A. Effects of Milk and Dairy Product Consumption on Type 2 Diabetes: Overview of Systematic Reviews and Meta-Analyses. *Adv Nutr.* 2019 May 1;10(suppl\_2):S154-S163. doi: 10.1093/advances/nmy107
- Visioli, F. & Strata, A. Milk, Dairy Products, and Their Functional Effects in Humans: A Narrative Review of Recent Evidence. *Advances in Nutrition* 5, 131-143, doi:10.3945/an.113.005025 (2014).
- Gil, Á. and Ortega, R.M., (2019). Introduction and Executive Summary of the Supplement, Role of Milk and Dairy Products in Health and Prevention of Noncommunicable Chronic Diseases: A Series of Systematic Reviews. *Advances in Nutrition*, 10(suppl\_2), pp.S67-S73
- Thorning T, Raben A, Tholstrup T, Soedamah-Muthu S, Givens I & Astrup A
- Milk and dairy products: good or bad for human health? An assessment of the totality of scientific evidence. *Food and Nutrition Research* 2016, 60: 32327 <http://dx.doi.org/10.3402/fnr.v60.32527> (2016)
- Thorning, T. K. et al. Whole dairy matrix or single nutrients in assessment of health effects: current evidence and knowledge gaps. *The American Journal of Clinical Nutrition* 105, 1033-1045, doi:10.3945/ajcn.116.151548 (2017).
- The pan-European project FLABEL (Food Labelling to Advance Better Education for Life). Available: [www.flabel.org](http://www.flabel.org)
- Organización Panamericana de la Salud. (2016). Modelo de perfil de nutrientes. Disponible en: [http://iris.paho.org/xmlui/bitstream/handle/123456789/18622/9789275318737\\_spa.pdf?sequence=9&isAllowed=y](http://iris.paho.org/xmlui/bitstream/handle/123456789/18622/9789275318737_spa.pdf?sequence=9&isAllowed=y) .

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

## APPENDIX IV

## LIST OF EWG PARTICIPANTS

NUMBER	MEMBER NAME/ OBSERVER NAME	PARTICIPANT NAME
1	Germany	Alina Steinert Nikolas Roh
2	Argentina	Andrea Moser
3	Australia	Jenny Hazelton Alexandra Jones
4	Austria	Judith Benedics
5	Brazil	Ana Claudia Marquim Firmo de Araújo Ana Paula de R. Peretti Giometti
5	Belgium	Jean Pottier Laurence Doughan
6	Bolivia	Marisol Mamani Nina Yecid Humacayo Morales
7	Canada	Julie Kisch
8	Chile	Cristian Cofré
9	Colombia	Claudia Patricia Moreno Barrera Karen Daza
10	Costa Rica	Amanda Lasso Cruz Alejandra Chaverri Esquivel
11	Egypt	Mohamed M. Abdelhameed
12	European Commission	Heidi Moens Judit Krommer Sabine Pelsser
13	France	Alice Stengel Jean-Christophe Comboroure
14	Guatemala	Sonia Pamela Castillo de Martinez
15	Honduras	Wilfredo Valle Yolubeth Cruz Elsa Barrientos
16	India	G.Bhanuprakash Reddy, M.Raja Sriswan, Priyanka Sharma, Suman Kapur, Vijayalakshmi.
17	Indonesia	Yusra Egayanti
18	Ireland	Mary Flynn Oonagh Lyons
19	Italy	Ciro Impagnatiello
20	Japan	Morita Takeshi
21	Kuwait	Wajd Suliman Al-Othman; Mariam Ahmad Ebrahim; Maha Mohamad AlDalaly; Dana Ahmad AlGhadouri
22	Malaysia	Maizatul Azlina Chee Din Nurul Hidayati binti Mohd Nasir
23	México	Maria Guadalupe Arizmendi Tania Daniela Fosado Soriano
24	Netherlands	Erika Smale
25	New Zealand	Jenny Reid Phillippa Hawthorne Charlotte Channer
26	Nicaragua	Miriam Canda Toledo Zenobia Ochoa

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

27	North Macedonia	Katerina Gerazova Efremova
28	Panama	Joseph Gallardo
29	Paraguay	Alberto Bareiro Arce Marizela López Cattebeke
30	Perú	Juan Carlos Huiza Trujillo Jorge Torres Chocce
31	Poland	Magdalena Kowalska
32	Russian Federation	Alexey Petrenko
33	Saudi Arabia	Fahad AlBadr
34	Singapore	Tan Yi Ling
35	Sweden	Kristina Lagestrand Sjölin Veronica Öhrvik
36	Switzerland	Didier Lusuardi Elodie Fatio
37	South Africa	Malose Daniel Matala Gilbert Tshitauzi Nolene Naicker
38	Vietnam	Nguyen Thi Minh Ha
39	Uganda	Florence Basiimwa Tushemerirwe Ivan Muzira Mukisa, Brian Ssekasamba, Joseph Opit Phiona Namubiru Elizabeth Nyakaisiki Ndahura Ruth Awio Rehema Meeme Hakim Mufumbiro
40	United States	Carolyn Chung Kristen Hendricks Douglas Balentine
41	United Kingdom	Rachel Manners Mary Amy Smulen McNamara
42	BEUC	Emma Calvert
43	Calorie Control Council	Ray DeVirgiliis
44	EU Specialty Food Ingredients (former ELC)	Petr Mensik
45	CEFS	Silvia Tombesi
46	Consumers International	Justin Macmullan
48	FEDIOL	Kalila Hajjar
49	FoodDrinkEurope	Dirk Jacobs
50	Food Industry Asia	Jiang YiFan
51	Helen Keller International	Elizabeth Zehner
52	Institute of Food Technologists (IFT)	Rosetta Newsome
53	International Alliance of Dietary/Food Supplement Associations (IADSA)	Cynthia Rousselot
54	ICA - International Confectionery Association	Eleonora Alquati Allison Graham
55	International Council of Beverages Associations	Simone SooHoo Joanna Skinner
56	ICGA - International Chewing Gum Association	Christophe Leprete
57	International Council of Grocery Makers (ICGMA)	Nancy Wilkins Mark F Nelson
58	International Dairy Federation	Laurence Rycken
59	International Food Additives Council	Robert Rankin

## PART 2: PROPOSAL 3 (Costa Rica, the EU, Paraguay and the United States)

60	International Fruit & Vegetable Juice Association	John Collins
61	The European Margarine Association (IMACE)	Siska Pottie
62	International Special Dietary Foods Industries (ISDI)	Jean Christophe Kremer
63	Institute of Food Technologists (IFT)	Rosetta Newsome
64	FoodDrinkEurope	Dirk Jacobs
65	Specialised Nutrition Europe (SNE)	Aurelie Perrichet
66	The European Consumer Organisation (BEUC)	Camille Perrin Emma Calvert
67	UNICE	Jo Jewell
68	World Federation of Public Health Associations (WFPHA)	Alexandra Jones
69	World Obesity Federation	Prof Mary L'Abbe

**Proposal 2.4****DISCUSSION PAPER ON ESTABLISHING A NUTRIENT REFERENCE VALUE (NRV-NCD) FOR TRANS-FATTY ACIDS**

*Prepared by the European Margarine Association (IMACE)*

**Introduction**

The 41st session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41) agreed to issue a circular letter<sup>1</sup> calling for proposals for new work. The letter invites both members and observers to submit proposals via Codex Contact Points. Proposals should include both a discussion paper and a project document for discussion at the 42nd session.

IMACE, having Observer status at the Codex Alimentarius Commission, representing producers of margarine and spreads thanks the Chair for the invitation to propose new work and respectfully submits this proposal, to establish a Nutrient Reference Value (Non-Communicable Disease) (NRV-NCD) for trans-fatty acids.

**Background**

The negative impact of trans-fatty acids (TFA) on public health has been clearly established. There is a global consensus that intake of trans-fatty acids should be limited as far as reasonably possible. There are no known health benefits associated with consumption of trans-fatty acids. It has been demonstrated by several authors that intake of TFA is associated with increased risk of cardiovascular disease.

At the 41st Session of the Codex Committee on Food Labelling (CCFL), the Committee agreed that CCNFSDU would be asked to develop proposed conditions for a “free of” TFA claim. Subsequently, at CCNFSDU35, Canada was assigned responsibility to develop the proposal. A chronological summary of work on this matter to date is described below<sup>2</sup>.

CCNFSDU36: Canada presented proposed conditions for a “free of” TFA claim (CX/NFSDU 14/36/10). The discussion on this agenda item concluded with a request that Canada seek and take into consideration advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS). Specifically, CCMAS was to be asked for advice on the lowest level of TFA that current analytical methods can accurately detect and consistently reproduce. Further discussion was also deferred to await the outcomes of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) evidence reviews on saturated fatty acids (SFA) and TFA.

CCNFSDU37: The Committee agreed to defer discussion on proposed conditions for a “free of” TFA claim until feedback from CCMAS was received and outcomes of the 6th meeting of the WHO NUGAG were available.

CCNFSDU38: The Delegation of Canada presented revised proposed conditions for a “free of” TFA claim (CX/NFSDU 16/38/10); the proposal took into consideration feedback from CCMAS and the outcome of the NUGAG systematic reviews. In recognition of the importance of analytical methods when establishing quantitative criteria for such a claim, the Committee agreed to defer further discussion so as to request that CCMAS verify whether the new proposed TFA levels would be measurable using the analytical methods identified in the proposal.

CCNFSDU39: The Committee considered an updated proposal from Canada (CX/NFSDU 17/39/9); the proposal took into consideration feedback stemming from a more detailed review of analytical methodology from CCMAS. It was agreed that the proposal would proceed to Step 3 for comments and would be considered at the CCNFSDU’s next session.

CCNFSDU40: Based on comments received at previous sessions, Canada presented two options for consideration by the Committee: 1) setting quantitative conditions for a “free of” TFA claim (as proposed in CX/NFSDU 17/39/9), or 2) discontinuing these efforts and not setting conditions for such a claim. The latter option was put forward to acknowledge some Members’ concerns regarding the use of available methods to accurately assess TFA content in foods at the proposed levels. An almost equal number of Members supported continuing the work on this new claim as did those in support of discontinuing the work. The Committee agreed to suspend further discussion on the development of proposed claims conditions to request that Canada prepare a discussion paper on other risk management options regarding reducing population-level intake of TFA.

The risk management options presented for consideration included (A) Voluntary limits, (B) Regulatory limits, (C) Ban PHO, (D) Prevent in-process formation of TFA, (E) Mandatory labelling, (F) TFA claims, (G) Declare

---

<sup>1</sup> CL 2020/30-NFSDU

<sup>2</sup> From CX/NFSDU 19/41/7-Rev

---

**PART 2: PROPOSAL 4 (IMAGE)**

---

PHO and hydrogenated oils as ingredients. The committee concluded that it would request CCFL to consider (E) and (G), and request CCFO to consider (C).

**Issues**

Lack of an NRV-NCD for TFA means that in countries where labelling actual TFA content is permitted or required, there is no, or no consistent means to provide consumers with context to understand the significance of the amount present. This also means there is no reference point for official nutrition guidance, such as Food-Based Dietary Guidelines, and hence that such guidance may not always adequately account for TFA content of foods. Certain foods may be promoted in nutrition guidelines based on positive NRV-R values, while their TFA content may contribute significantly to, or even exceed the recommended maximum daily intake level.

Legislation currently in place targets only industrial TFA content of individual foods based on their composition while the consensus among leading scientific bodies is that there is no discernible difference in the health impact of TFA from industrial or animal sources and that total dietary intake of TFA from all sources should be reduced.

This Committee decided to suspend work on the claim “Free” from Trans Fatty Acids at the 41<sup>st</sup> session. This means that there is no consistent, fact-based means for consumers to identify foods that do not contain TFA.

**Conclusion**

It is recommended that the Committee consider the issues raised in this discussion paper and agree to initiate new work to establish a nutrient reference value (NRV-NCD) for Trans-fatty acids as set out in the attached Project Document.

**PROJECT DOCUMENT****1. PURPOSE AND SCOPE OF THE NEW WORK**

The purpose of this new work proposal is to establish a nutrient reference value (NRV-NCD) for trans-fatty acids.

**2. RELEVANCE AND TIMELINESS**

The impact of trans fatty acids on public health was established many years ago and is well understood (Willett, Stampfer, Colditz, Spiezer, & Rosner, 1993) (Stender, Dyerberg, Hølmer, Ovesen, & Sandström, 1995). Several high-quality reviews, including (Mozaffarian, Aro, & Willett, 2009) (Brouwer, 2016) have clearly shown that elevated consumption of trans-fatty acids increases risk of CVD morbidity. It is also well-known that trans-fats may occur in foods derived from animals, and industrial sources. So far research has not demonstrated that origin of TFA has a meaningful effect on health impact. There is no demonstrable difference in health impact between trans-fat from ruminant- or industrial-origin based on equal intake levels (SACN, 2007) (Laake, et al., 2012) (Brouwer, Wanders, & Katan, 2015) (Stender S., 2015) (Brouwer, 2016) (EFSA, 2018) and hence intake guidance should not discriminate by source. Expert opinion has long agreed that total intake TFA should be limited to <1% daily energy intake, e.g. (WHO/FAO, 2002) and this is reaffirmed by more recent advice from WHO (NUGAG, 2020).

A recent systematic review of trans fat intakes (Wanders, Zock, & Brouwer, 2017) found that in 22 out of 29 countries studied, total TFA intake was already below the <1%en recommendation, that intake from ruminant sources was higher than industrial sources, and intake from industrial sources has reduced progressively over the last twenty years. From this it may be concluded that manufacturers are heeding calls to eliminate industrial source trans fatty acids, but otherwise consumer habits regarding consumption of sources of ruminant trans fatty acids are not changing. This is not compatible with the goal of reducing trans-fat intake levels to 'as low as possible'.

It has been reported that while average intake has declined, millions of consumers still consume trans-fats at levels that significantly increase their risk for Coronary Heart Disease (CHD) (WHO Regional Office for Europe, 2015). Other studies have suggested that in some countries, population-average, total TFA intake is meeting the recommended 1% maximum daily intake level, but some sub-groups within populations are exceeding the recommended intake level, suggesting that diet and food choices have a significant role to play in addition to food composition (Stender, Astrup, & Dyerberg, 2012). We have shown in Appendix 1, that even when consuming only foods that meet regulatory limits on industrial trans fats, some dietary patterns can still feature significant trans-fat intake.

At the 41<sup>st</sup> Session, this Committee reviewed the discussion paper<sup>3</sup> presented by Canada, on *Risk Management Possibilities for the Reduction of TFA's*. It was concluded<sup>4</sup> that CCNFSDU should recommend to CCFL to amend the Guidelines on Nutrition Labelling (CXG 2-1985) to include declaration of the amount of TFA where nutrition declaration is required and where a claim is made regarding the amount and/or type of fatty acids or the amount of cholesterol. It is noted in the discussion paper that a potential drawback of this measure is that some *consumers who are less knowledgeable about TFA and nutrition labelling may be disadvantaged with regard to identifying pre-packaged and processed foods that are lower in TFA*. To enable consumers to use information on TFA content to make informed food choices, it is therefore necessary to provide context for the declared amount of TFA, which can be achieved by definition of an NRV-NCD that will allow evaluation of TFA content of any food in the context of total dietary intake. Furthermore, definition of an NRV-NCD will enable development of improved nutritional guidance for consumers based on data. A global agreement on such an NRV will ensure that it cannot become a barrier to trade.

This proposal complements action to drive for improving the nutritional properties of specific foods. The WHO REPLACE programme (WHO, 2020) and legislative measures by some member states and organisations currently target elimination or reduction of industrial sources of TFA. However, action to promote improvement of the nutritional properties of specific foods should not be confused with, or seen to be a substitute for, proper recommendations regarding trans-fat in the diet.

**3. MAIN ASPECTS THAT SHOULD BE COVERED**

It is proposed to define an NRV-NCD for trans-fatty acids, in line with the current scientific consensus.

It is proposed that the value for the NRV-NCD for trans-fatty acids should be not more than 1% daily energy intake, in grams adjusted to recommended daily energy requirements for adults and children.

<sup>3</sup> CX/NFSDU 19/41/7-Rev

<sup>4</sup> REP20/NFSDU para131

## PART 2: PROPOSAL 4 (IMACE)

**4. AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES****Guideline for the preliminary assessment and identification of new work priorities for CCNFSDU (REP20/NFSDU Appendix IX, para 2)**

- a) *Revision of existing texts:*** this work will require amendment of the Guidelines on Nutrition Labelling, CXG 2-1985
- b) *Request from CAC:*** this work is not a request from CAC
- c) *Request from other Codex committees:*** this work is not a request from another Codex Committee
- d) *Availability of scientific advice:*** extensive scientific evidence is available in the form of existing publications and reviews and reports from expert bodies such as NUGAG. It is not anticipated that additional scientific advice is needed on this topic.
- e) *Target group:*** this work targets the global population with no specific target sub-groups. Everyone will benefit from this work.
- f) *Impact on Public Health [HIGH]:*** trans-fatty acid intake increases risk of Coronary Heart Disease. Effective measures to reduce trans-fatty acid intake will reduce this risk.
- g) *Impact on Food Safety [LOW]:*** consumption of trans-fatty acids is not linked to food safety.
- h) *Impact on Fair Trade Practices [MEDIUM]:*** establishing an NRV-NCD for trans-fatty acids will enable development of aligned nutrition priorities globally, and thus prevent emergence of unfair trade practices and avoid potential TBT<sup>5</sup> disputes. It would seek to align the recommendations of industrial and ruminant foods, so consumers are not confused.

**Criteria applicable to general subjects:****a) Diversification of national legislation and apparent resultant or potential impediments to international trade:**

Declaration of Trans-fat content of foods is not globally harmonised. In some countries it is mandatory, in others optional, in some it is forbidden. This proposal does not directly address the issue of declaring trans-fat content of foods on labels but establishing an NRV would provide an agreed reference point in case the Commission or national bodies would choose to develop guidance or legislation.

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

- To set a value for an NRV-NCD for trans-fatty acids that is relevant to the general population
- To publish the NRV-NVD in an amendment to CXG 2/1985 (section 3.4.4.2)

**c) Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental body(ies):**

- a. WHO Draft Guidelines (NUGAG, 2020) on saturated fatty acid and trans-fatty acid intake for adults and children, distributed for public consultation May-June 2018 recommend reducing total TFA intake to less than 1% total energy intake.
- b. The European Food Safety Authority presents an overview (EFSA, 2018, p. 11) of recommendations for total trans-fat intake by different national and international bodies:

<sup>5</sup> World Trade Organisation, Agreement on Technical Barriers to Trade [https://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm) accessed 23/06/2020

## PART 2: PROPOSAL 4 (IMAGE)

Country/region	Organisation/institution/ recommendation	Year	TFA	Reference
Belgium	Conseil Supérieur de la Santé	2009	<1 E%	(Conseil Supérieur de la Santé, 2009)
		2016	ALAP	(Conseil Supérieur de la Santé, 2016)
Europe	European Society of Cardiology	2007	-	(Graham et al., 2007)
		2016	ALAP, <1 E%	(Piepoli et al., 2016)
France	EFSA	2010	ALAP	(EFSA NDA Panel, 2004)
	AFSSA, CNERNA and CNRS	2001-2005	<2 E%	(Martin, 2001)
Germany, Austria, Switzerland	D-A-CH	2010	<1 E%	(AFSSA, 2010)
		2000	<1 E%	(D-A-CH, 2002)
Italy	Società Italiana di Nutrizione Umana (SINU)	2015	ALAP, <1 E%	(D-A-CH, 2015)
		2014	ALAP	(SINU, 2014)
Nordic countries	NNR	2004	ALAP	(Becker et al., 2004)
		2012	ALAP	(Norden, 2012)
The Netherlands	Health Council of the Netherlands	2001-2006	<1 E%	(Health Council of the Netherlands, 2002)
		2015	<1 E%	(Health Council of the Netherlands, 2015)
Spain	Sociedad Española de Nutrición Comunitaria (SENC)	2011	<1 E%	(Aranceta, 2011)
		2016	ALAP	(Aranceta Bartrina et al., 2016)
UK	Committee on Nutrition (COMA)	1991	<1 E%	(COMA, 1991)
	Scientific Advisory Committee on Nutrition (SACN)	2007	≤2 E%	(SACN, 2007)
USA	American Heart Association	2006	<1 E%	(Lichtenstein et al., 2006)
		2017	ALAP	(Sacks et al., 2017)
	American Diabetes Association	2008	<1 E%	(Bantle et al., 2008)
		2013	ALAP	(American Diabetes Association, 2013)
USDA Dietary Guidelines for Americans	2010	ALAP; limit industrial TFA	(U.S. Department of Agriculture, 2010)	
	2015	ALAP; limit industrial TFA	(U.S. Department of Agriculture, 2015)	
International	WHO/FAO	2003	≤1 E%	(WHO/FAO, 2003)
		2008	≤1 E%	(WHO/FAO, 2010)

ALAP = as low as possible; E% = % of total energy; TFA = *trans* fatty acids; see glossary for other abbreviations

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

- a. The Annex to the Codex Guidelines on Nutrition Labelling<sup>6</sup> provides in section 3.2.2 criteria for the *Selection of Nutrients and Appropriate Basis for NRVs-NCD*:

<sup>6</sup> CXG 2-1985

## PART 2: PROPOSAL 4 (IMACE)

Requirement	Remarks
<p>Relevant convincing/ generally accepted scientific evidence or the comparable level of evidence under the GRADE classification for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g. adults).</p> <p>Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries.</p> <p>Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.</p>	<p>The link has previously been established with sufficient confidence that it already forms the basis of WHO and national health policies.</p>
<p>Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.</p>	<p>Please refer to “Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental body(ies)”, above.</p>
<p>Where a daily intake reference value is based on a percentage energy intake, the single NRV-NCD should be expressed in grams or milligrams based on a reference intake for the general population of 8370 kilojoules/2000 kilocalories.</p>	<p>WHO and national guidance expresses recommended maximum intake in terms of % daily energy intake, and can be readily expressed in relation to a 2000Kcal diet based on 9Kcal per gram (accepted norm for energy from fat).</p>
<p>Governments may use a Codex NRV-NCD based on the reference energy intake of 8370 kilojoules/2000 kilocalories, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.</p>	<p>The recommended intake in grams can be adjusted to any national variation on recommended daily energy intake for any population group.</p>

- b. The Codex Guidelines on Nutrition Labelling<sup>7</sup> already lists NRVs-NCD for Saturated Fatty Acids and Sodium in section 3.4.4.2:

Intake levels not to exceed

*Saturated fatty acids:* 20 g

*Sodium:* 2000 mg

Saturated Fatty Acids are also a recognised risk factor for cardiovascular disease, and so this may be taken as a precedent supporting the suitability of this proposal to standardization.

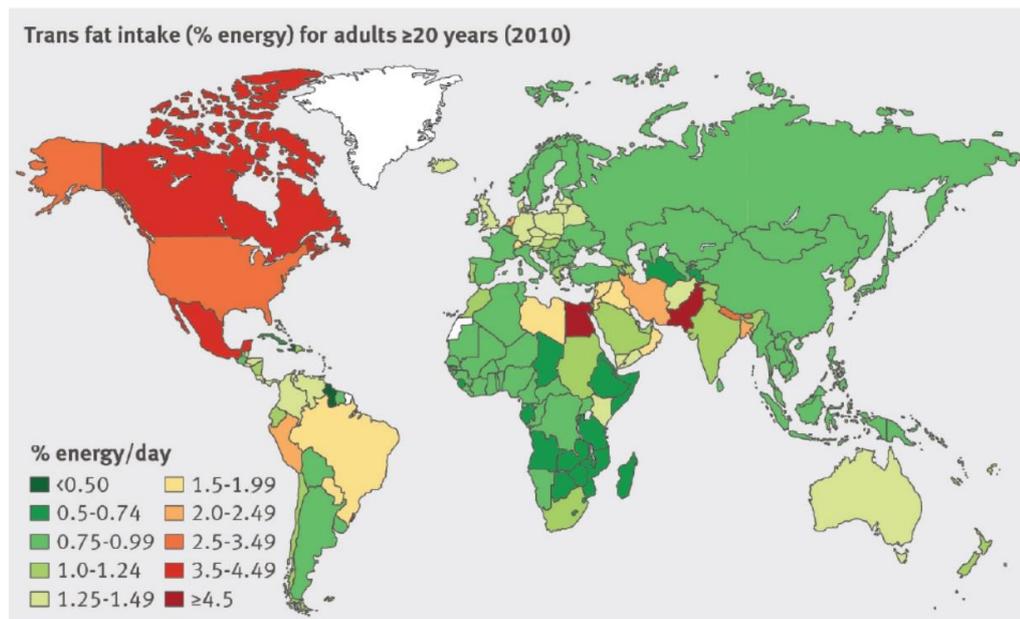
**e) Consideration of the global magnitude of the problem or issue:**

In many countries, the population average intake of total trans-fat exceeds, or is marginally below the 1% energy recommendation (Micha, et al., 2014). As this is an average, some individuals will exceed the recommended maximum intake.

Wanders et al. (Wanders, Zock, & Brouwer, 2017) found that daily TFA intakes varied between 0.3% to 4.2% energy intake in the 29 countries studied, and 7 exceeded the 1%en recommendation in their 2017 systematic review. Furthermore, intake of TFA from animal sources was found to be greater than from industrial sources.

<sup>7</sup> CAC/CL 2-1985

## PART 2: PROPOSAL 4 (IMACE)



## 5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

This proposed revision is fully consistent with the goals of the Codex Strategic Plan 2020-2025<sup>8</sup>:

Goal 1: Address current, emerging and critical issues in a timely manner (objective 1.2)- the need for action on trans-fat intake was established long ago. Up to now most work has focused on improvement of individual products, there has been little attention to improvements to diet. This is long overdue. Adoption of this revision will demonstrate timely response to identified issues.

Goal 2: Develop standards based on science and Codex risk-analysis principles (objectives 2.1 and 2.2)- Scientific advice on this topic is readily available, there is a solid body of evidence already available. Adoption of this proposal will reinforce the role of science in policy-making and demonstrate Codex commitment to use scientific advice and globally representative data in policy-making.

## 6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS AS WELL AS OTHER ONGOING WORK

This proposal is not related to the request from CCFL to establish conditions for use of the claim “free-from” TFAs, work that this committee decided to discontinue at the 41<sup>st</sup> Session. NCD-NRV is a recommendation for dietary intake and is thus unsuitable as a criterion to validate claims on individual foods.

The NRV-NCD would be an additional entry under section 3.4.4.2 of CXG 2 - 1985.

CCMAS reviewed the availability and suitability of analytical methods for the determination of TFA content of foods at their 38<sup>th</sup> Session (May 2017) and reported in REP17/MAS Appendix 2, part 3.

## 7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Several sources have been cited in this project document. If further scientific advice is needed, it is recommended to consult NUGAG.

## 8. IDENTIFICATION OF ANY TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

No technical matters are foreseen that would require advice from external bodies.

## 9. THE PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK; INCLUDING THE START-DATE, THE PROPOSED DATE FOR ADOPTION AT STEP 5, AND THE PROPOSED DATE FOR ADOPTION BY THE COMMISSION

Subject to approval by CAC46 in 2023, it is expected that Committee will require 3 sessions to complete the work.

<sup>8</sup> <http://www.fao.org/3/ca5645en/CA5645EN.pdf>

## References

- Brouwer, I. A. (2016). *World Health Organization & Brouwer, Ingeborg A. (2016). Effect of trans-fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis.* Geneva: World Health Organization.
- Brouwer, I. A., Wanders, A. J., & Katan, M. B. (2015). *Effect of animal and industrial trans fatty acids on HDL and LDL cholesterol levels in humans--a quantitative review.* *PLoS One*, 5(10). doi:10.1371/journal.pone.0009434
- EFSA. (2018). *Scientific and Technical Assistance on Trans Fatty Acids.*
- Laake, I., Pedersen, J. I., Selmer, R., Kirkhus, B., Lindman, A. S., Tverdal, A., & Veierød, M. B. (2012). *A prospective study of intake of trans-fatty acids from ruminant fat, partially hydrogenated vegetable oils, and marine oils and mortality from CVD.* *Br J Nutr.*, 108(4):743-754. doi:doi:10.1017/S0007114511005897
- Micha, R., Khatibzadeh, S., Shi, P., Fahimi, S., Lim, S., Andrews, K. G., . . . Mozaffarian, D. (2014). *Global, regional, and national consumption levels of dietary fats and oils in 1990 and 2010: a systematic analysis including 266 country-specific nutrition surveys.* *BMJ*, 348, g2272. doi:10.1136/bmj.g2272
- Mozaffarian, D., Aro, A., & Willett, W. C. (2009). *Health effects of trans-fatty acids: experimental and observational evidence.* *Eur J Clin Nutr.*, 63 Suppl 2:S5-S21. .
- NUGAG. (2020, June 23). *Call for public comments on the draft WHO Guidelines: Saturated fatty acids and trans-fatty acid intake for adults and children.* Retrieved from WHO, Nutrition: [https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines\\_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)
- Public Health England. (2020, July 7). *Composition of foods integrated dataset (CoFID).* Retrieved from GOV.UK: <https://www.gov.uk/government/publications/composition-of-foods-integrated-dataset-cofid>
- Regulation (EC) 1169/2011 (European Commission 2011).
- SACN, U. K. (2007). *Update on Trans Fatty Acids and Health.* London: TSO (The Stationery Office).
- Stender, S. (2015). *In equal amounts, the major ruminant trans fatty acid is as bad for LDL cholesterol as industrially produced trans fatty acids, but the latter are easier to remove from foods.* *The American Journal of Clinical Nutrition*, 102(6), 1301-1302. doi:doi.org/10.3945/ajcn.115.123646
- Stender, S., Astrup, A., & Dyerberg, J. (2012). *A trans European Union difference in the decline in trans fatty acids in popular foods: a market basket investigation.* *BMJ Open*, e000859. doi:10.1136/bmjopen-2012-000859
- Stender, S., Dyerberg, J., Hølmer, G., Ovesen, L., & Sandström, B. (1995). *The influence of trans fatty acids on health: a report from the Danish Nutrition Council.* *Clin Sci (Lond)*, 88(4), 375-392.
- Wanders, A. J., Zock, P. L., & Brouwer, I. A. (2017). *Trans Fat Intake and Its Dietary Sources in General Populations Worldwide: A Systematic Review.* *Nutrients*, (9) 840. doi:10.3390%2Fnu9080840
- Wanders, A. J., Zock, P. L., & Brouwer, I. A. (2017). *Trans Fat Intake and Its Dietary Sources in General Populations Worldwide: A Systematic Review.* *Nutrients*, (9) 840.
- WHO. (2020, June 23). *Nutrition.* Retrieved from World Health Organisation: <https://www.who.int/nutrition/events/2019-13th-NUGAG-meeting-16to19Dec/en/>
- WHO. (2020, June 20). *REPLACE trans fat.* Retrieved from WHO, Nutrition: <https://www.who.int/nutrition/topics/replace-transfat>
- WHO Regional Office for Europe. (2015). *Eliminating Trans-fats in Europe, A Policy Brief.* Copenhagen: WHO Regional Office for Europe.
- WHO/FAO. (2002). *Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (WHO technical report series 916).* Geneva: World Health Organisation.
- Willett, W. C., Stampfer, M. J., Colditz, G. A., Speizer, F. E., & Rosner, B. A. (1993). *Intake of trans fatty acids and risk of coronary heart disease among women.* *The Lancet*, 341(8845), 581-585.

### Illustrative Daily Intakes

The tables below show predicted trans-fat intake based on three different, illustrative daily menus. The menus are only intended to show the potential range in TFA intakes resulting from different dietary choices. All items selected in these menus meet the limit of 2g industrial TFA per 100g Fat, and limitations on use of partially-hydrogenated vegetable oil implemented by regulation in several countries.

- *Food composition data is taken from the United Kingdom Composition of Foods Integrated Dataset (CoFID) (Public Health England, 2020).*
- *The number appearing in parentheses after the food name is the 'Food code', used to identify the relevant entry in the database.*
- *Trans fat content and energy content (KCal) is taken from table 1.3 (Proximates) "FODTRANS", "KCALs".*
- *Portion data is taken from product information provided by a European retailer*
- *Total trans-fat is the sum of the trans-fat content for the indicated portions.*
- *% energy from trans-fat is calculated<sup>9</sup> as:  $\frac{\text{total trans fat (g)} \times 9}{\text{total energy (KCal)}} \times 100$*

These illustrations show that even when comprising only foods that individually meet limits on industrial trans-fat, total daily intake can significantly exceed the recommended 1%en limit due to the extra intake of TFA from ruminant sources.

MENU "A"	Kcal per 100g	Total TFA g per 100g	Portion size (g) or (ml)	Total TFA per portion	Kcal per portion
<b>Breakfast</b>					
Orange juice (14-329)	36	0,00	200	n/a	72
Black coffee (17-833)	2	0,00	150	n/a	3
Croissant (11-988)	373	0,77	90	0,69	336
Butter (17-685)	744	2,87	10	0,29	74
Jam (17-688)	261	0,00	10	n/a	26
Low-fat yoghurt (12-379)	57	0,02	150	0,03	86
<b>Lunch</b>					
Bread roll (white) (11-1006)	254	0,00	50	n/a	127
Cheddar cheese (12-346)	416	1,44	25	0,36	104
Butter (17-685)	744	2,87	10	0,29	74
Bread roll (white) (11-1006)	254	0,00	50	n/a	127
Ham (19-021)	204	0,03	20	0,01	41
Butter (17-685)	744	2,87	10	0,29	74
Whole milk (12-596)	63	0,13	200	0,26	126
<b>Dinner</b>					
Beef steak (18-073)	257	0,50	140	0,70	360
Broccoli (13-583)	28	0,00	200	n/a	56
Potatoes (13-621)	52	0,00	125	n/a	65
Tiramisu (12-476)	244	1,03	150	1,55	366

<b>Total trans fat (g)</b>	<b>4,43</b>
<b>Total Energy (KCal)</b>	<b>2117</b>
<b>TFA Intake %en</b>	<b>1,9%</b>

<sup>9</sup> CAC/GL 2-1985 3.3.1 Calculation of energy

## PART 2: PROPOSAL 4 (IMAGE)

<b>MENU "B"</b>	<b>Kcal</b>	<b>Total TFA</b>	<b>Portion size</b>	<b>Total TFA</b>	<b>Kcal</b>
	<i>per 100g</i>	<i>g per 100g</i>	<i>(g) or (ml)</i>	<i>per portion</i>	<i>per portion</i>
<b>Breakfast</b>					
Toast (11-1136)	266	0,03	35	0,01	93
Butter (17-685)	744	2,87	10	0,29	74
Scrambled eggs (12-963)	152	0,01	122	0,01	185
Bacon (19-498)	295	0,10	30	0,03	89
Sausage (beef) (19-489)	265	0,53	75	0,40	199
Tea with (whole) milk (17-168)	8	0,13	150	0,20	12
<b>Lunch</b>					
Bread 2 slices (white) (11-1145)	236	0,02	70	0,01	165
Cheddar cheese (12-346)	416	1,44	25	0,36	104
Pickles (17-718)	111	0,00	25	<i>n/a</i>	28
Butter (17-685)	744	2,87	10	0,29	74
<b>Dinner</b>					
Lamb curry (vindaloo) (19-599)	199	0,83	500	4,15	995
Cheesecake (12-562)	325	0,67	125	0,84	406
Single cream (12-332)	193	0,68	10	0,07	19

<b>Total trans fat (g)</b>	<b>6,65</b>
<b>Total Energy (KCal)</b>	<b>2444</b>
<b>TFA Intake %en</b>	<b>2,4%</b>

## PART 2: PROPOSAL 4 (IMAGE)

<b>MENU "C"</b>	<b>Kcal per 100g</b>	<b>Total TFA g per 100g</b>	<b>Portion size (g) or (ml)</b>	<b>Total TFA per portion</b>	<b>Kcal per portion</b>
<b>Breakfast</b>					
Muesli (11-939)	450	0,01	40	0,00	180
Soya-yogurt (12-529)	72	0,00	150	<i>n/a</i>	108
Blueberries (14-325)	40	0,00	21	<i>n/a</i>	8
Honey (17-050)	288	0,00	10	<i>n/a</i>	29
Orange juice (14-329)	36	0,00	200	<i>n/a</i>	72
Black tea (17-167)	0	0,00	150	<i>n/a</i>	0
Toast 2 slices (11-1136)	266	0,03	70	0,02	186
Reduced fat spread (12-503)	533	0,13	20	0,03	107
<b>Snack</b>					
Pear (14-361)	37	0,00	178	<i>n/a</i>	66
<b>Lunch</b>					
Avocado (14-386)	171	0,00	68	<i>n/a</i>	116
Toast 2 slices (11-1136)	266	0,03	70	0,02	186
Reduced fat spread (12-503)	533	0,13	20	0,03	107
Poached egg (12-943)	149	0,02	50	0,01	75
<b>Snack</b>					
2 Crackers (11-1134)	421	0,02	20	0,00	84
Lower-fat cheese (12-549)	190	0,31	28	0,09	53
<b>Dinner</b>					
Brown rice (11-867)	131	0,00	250	<i>n/a</i>	328
Chicken, roasted (18-331)	177	0,10	85	0,09	150
Chilli sauce (17-719)	40	0,00	10	<i>n/a</i>	4
Lime juice (14-279)	9	0,00	10	<i>n/a</i>	1
Mushrooms (13-506)	9	0,00	100	<i>n/a</i>	9
Spinach (13-573)	19	0,00	100	<i>n/a</i>	19
Apple (14-319)	51	0,00	100	<i>n/a</i>	51

<b>Total trans fat (g)</b>	<b>0,28</b>
<b>Total Energy (KCal)</b>	<b>1939</b>
<b>TFA Intake %en</b>	<b>0,1%</b>