

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

CRD08

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME FAO/WHO COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN

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Virtual

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Comments of Argentina

CODEX WORK RELEVANT TO THE REGION

Argentina appreciates the document CX/LAC 22/22/6 prepared by the Chair and Secretariat of the CCLAC and, based on the recommendations, presents for information purposes the new work proposal recently sent by our country to the Chair of the Codex Committee on Nutrition and Foods for Special Dietary Uses and to the Codex Secretariat for its treatment in the CCNFSDU43, to be held in March 2023.

The document, which is adjoined to this CRD, is a proposal for the elaboration of Harmonized Probiotic Guidelines for Use in Foods and Food Supplements and was prepared by Argentina and Malaysia.

Member countries of CCLAC are welcomed to analyze the document and consider the possibility of supporting it at the CCNFSDU43 for its inclusion in the work agenda of that committee.

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.

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 44th Session of Codex Committee on Food Labelling¹ 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:

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

¹ REP18/FL, paragraph 17.

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).

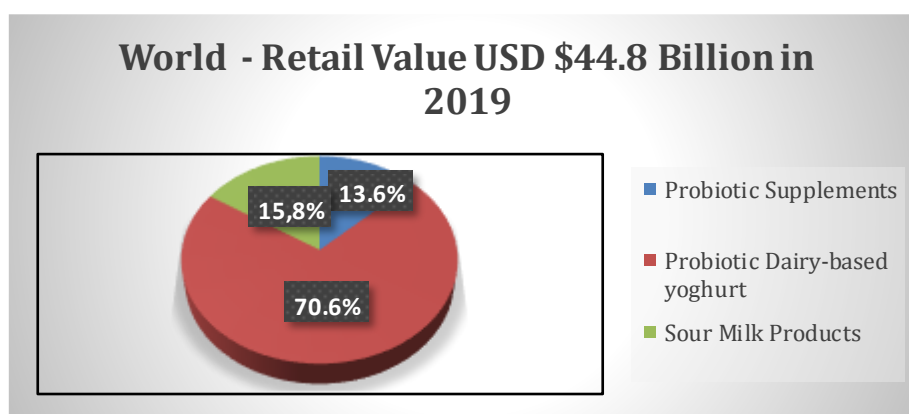
The estimated split of the revenue in 2019 was Functional Food and Beverages 60%, Food Supplements 26%, Other Human Nutrition 2.5%, Animal Feed & Others 11.5%. (Source IPA).

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

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 **40,500,000,000,000,000,000 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

CCNFSDU41 agreed that the proposed new work on developing a harmonized guideline on probiotics could be submitted in accordance with the prioritization mechanism². 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 CCNFSDU, which stipulates that new work proposals should be submitted as a discussion paper together with a project document

² REP20/NFSDU, paragraph 185.

according to the Procedural Manual and address also the additional criteria outlined in the draft guideline as follows³. 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 available⁴:</p> <ul style="list-style-type: none"> • 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. • 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. <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.

³ REP20/NFSDU, Appendix IX, paragraph 4.

⁴ FAO Food and Nutrition Paper 85, Probiotics in food, Health and nutritional properties and guidelines for evaluation.

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)⁵ 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>

⁵ 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.

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Glossary of terms

Codex Alimentarius Commission	CAC
Codex Committee on Nutrition and Foods for Special Dietary Uses CCFNSDU	
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

It will be necessary to develop a definition, considering the definition in the FAO/WHO consultation (2001)⁶ 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 strain⁷ 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*

The scope of work will address:

1. The establishment of Codex definition of 'probiotics', considering the definition in the FAO/WHO consultation (2001) report.

⁶ 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.

⁷FAO/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. 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.–

(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.^a 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 (CAC/RCP1:1969), 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 (CAC/GL 23-1997).

However, existing Codex standards and guidelines do not:

- include a definition of probiotics. The term “probiotic” is already used in the Codex 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.^a Session of the Codex Committee on Food Labelling⁸.
- 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, 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), and other labelling requirements specific to probiotics.

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

En este momento no se requiere ningún otro aporte técnico además del proporcionado por el CCNFSDU.

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

⁸ REP18/FL, paragraph 17.

November 2021	Agreement to undertake new work by the 42. ^a Session of the CCNFSDU
July 2022	Subject to approval of new work by the 44. ^a Session of the CAC
November 2022	The Draft Guidelines will be submitted for consideration–by the 43. ^a Session of the CCNFSDU
July 2024	Final adoption of Draft Guidelines at Step 8 by the 46. ^a Session of the CAC