CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 11 **CX/NFSDU 19/41/11**

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

Forty-first Session

Dusseldorf, Germany
24 - 29 November 2019

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS

Prepared by Argentina

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 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. Those delegations in support of the work noted that harmonized global guidelines would benefit the Codex community in light of the significant increase in global trade of probiotics for use in foods and dietary supplements in recent years and would assist national authorities in evaluating foods/supplements containing probiotics.

6. Those delegations and an observer not in favour of starting new work at this point, expressed the following view or concerns: there was no perceived need for such work; this work might not have the priority taking into account the current heavy workload of the Committee; the paper needed to be revised to provide more clarity especially on the scope of the work; collection of information and data from Members should be first conducted to identify a globally applicable definition of probiotics; infant foods should be excluded since safety was of concern due to a limited number of studies.

7. 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.

INTRODUCTION

8. The current scientific consensus is that probiotics are most effective in conditions related to the digestive tract, the immune system and respiratory functions. Around 20,000 papers have been published on the topic 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, the number and type of probiotic foods and drinks that are available to consumers, and marketed as having health benefits, has increased considerably.

10. In view of this growing popularity of probiotic foods, and the lack of international consensus on the methodology to assess their efficacy and safety, FAO and WHO initiated work to examine the scientific evidence on the functional and safety aspects of probiotics in food. 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 probiotic foods.

11. The beneficial effects of food with added live microbes (probiotics) on human health are being increasingly promoted by health professionals.

12. Today, more than a decade later, the lack of harmonization in industry practice and legislation remains and often leads to issues and concerns for the probiotics regulators, industry, and even consumers in regard of quality, safety and labelling.

13. Despite the widely recognized FAO/WHO definition (2001), revised by Hill et al. (2014), as "Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host", there is global occurrence of products sold as 'probiotics' that do not meet this definition. The ultimate goal is to establish eligibility criteria to ensure consistent application at national and international levels by Codex member countries, available to promote human health and well-being. As such, the countries recognize the need and opportunity for development of a Codex Alimentarius.

14. Government regulations differ among countries however, the status of probiotics as a component in food is currently not established on an international basis.

15. The development of Codex guidelines for probiotics will provide guidance for global regulatory agencies to build probiotics-focused regulations. 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.

SCOPE

16. The purpose of the work is to establish harmonized guidelines for probiotics for use as an ingredient in foods and dietary supplements.

17. The scope of the proposed guidelines discussion paper includes a definition, minimum characterization requirements, safety criteria, quality and labelling criteria for probiotics for use as an ingredient in foods and dietary supplements.

18. This document refers to live microorganisms recognized to convey a health benefit[1] to humans in appropriate amounts.

19. This discussion paper only refers to probiotics that are produced in food and/or dietary supplement manufacturing facilities and traded internationally.

PROBIOTIC PRODUCTION

20. 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 metric tons capacity.

b) Ingredient Market Revenue:

The global probiotics ingredient market was valued at $1.5 billion USD in 2016 and is expected to be valued at $2.15 billion USD by the year 2021. (Source IPA).

The split of the revenue in 2016 was Functional Food and Beverages 58%, Dietary Supplements 29%, Other Human Nutrition 3%, Animal Feed & Others 10%. (Source IPA).

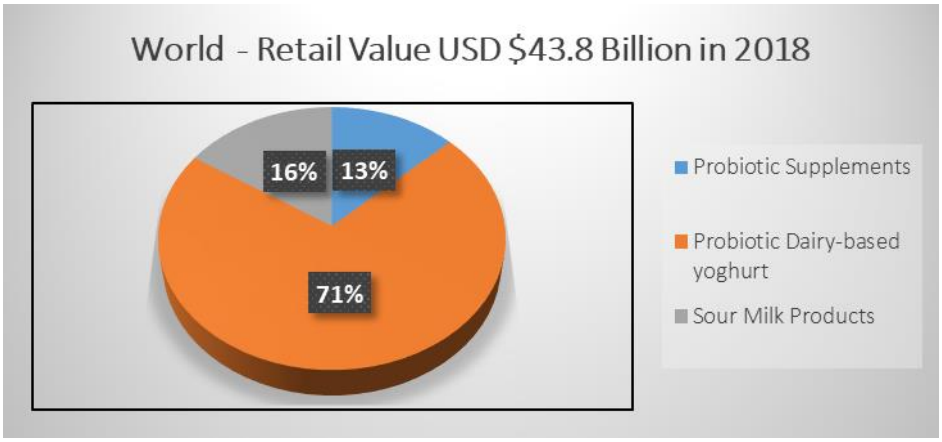
PROBIOTIC DISTRIBUTION AND TRADE

21. Probiotics are distributed in 63 countries. Probiotic dairy-based yoghurts are distributed in 196 countries. (Source IPA).

[1]This does not mean health claim

PROBIOTIC CONSUMER CONSUMPTION

22. Probiotics are consumed in foods, beverages and dietary 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, 2018 (Source IPA)

World Retail Value (2018)	$43,882,000,000.00
Yoghurt	$31,295,000,000.00
Fermented milks	$6,911,000,000.00
Supplements	$5,676000,000.00

Table 1: Global Retail Value, 2018 (Source IPA)

PROBIOTICS TRADE EXCHANGE

23. Probiotic Supplements hit $5.7 Billion USD and Ingredients for Food and Beverage applications hit sales of close to $40 Billion USD globally, in 2018.

Region	Ingredients for Supplements & Human Nutrition (%)	Ingredients for Food Applications (%)
North America	40	12
Europe, Middle East and Africa	31	32
Latin America	3	8
Asia – Pacific Countries	23	45
Australasia	3	3

Table 2: Distribution of Ingredients for Supplements and Food Applications, 2018 (Source IPA)

Production of Probiotic Culture for Supplements and Food Applications (2018)	
Supplement totals	1,400,000 Kg
Food and beverage totals	2,000,000 Kg
Totals of Probiotic pure cultures	3,400,000 Kg

Table 3: Combined Totals of Pure Bacteria Powder, 2018 (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:

1.4 million Kgs of culture ingredient for the Dietary Supplement industry is equivalent to 7E+20 or **700,000,000,000,000,000,000 CFU** of bacterial culture.

2 million Kgs of culture ingredient for the Food application industry is equivalent to 3E+19 or **30,000,000,000,000,000,000 CFU** of bacterial culture.

These are estimations based on average yields.

NEED FOR PROBIOTIC GUIDELINES

24. Given the wide acceptance of the importance of probiotic microorganisms to the health of the human population in addition to the growth of probiotic food and drinks that market health benefits, governments have raised questions about an appropriate regulatory framework to apply to probiotics, to facilitate its appropriate regulation on their national market.

25. There is currently a lack of harmonized regulation, with some countries having different provisions on probiotics. Harmonized guidelines for these international and regionally traded products will facilitate trade and ensure that effective and safe products reach the consumers.

26. The proposed work is to address this lack of harmonization through the development of a Codex Guidelines in order to harmonize framework.

PRODUCTS APPLICABLE FOR THE CODEX GUIDELINES

27. Probiotic microorganisms are used as food ingredients in a wide range of products, including dietary supplements. Both dietary supplements and foods are applicable for the proposed Codex guidelines.

THE MAIN ASPECTS TO BE CONSIDERED

28. The general specifications and considerations that should be considered to demonstrate that a strain is a probiotic should be based on the aspects included in Appendix 5.

29. The aspects that should be considered for probiotics microorganisms once the probiotic is added to food or dietary supplement are included in Appendix 5.

ASPECTS OF PRODUCTION

30. For illustration of an example of a manufacturing process flow, see Appendix 1. That process provides a general overview of the most widely used process for production of viable probiotic strains in a freeze-dried format.

LABELLING

31. The labels of probiotics sold by retail should bear the information included in Appendix 5.

RECOMMENDATIONS

32. 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 2014-2019, Goal 1: *To establish international food standards that address current and emerging food issues and its corresponding objectives*.

33. Adoption of a harmonized definition of probiotics among Codex member countries.

34. Development of Codex guidelines for probiotics to provide agreed essential requirements and specifications for probiotics that contribute to protecting the health of consumers, and ensuring fair practices in food trade.

35. The term probiotic should be used only on products that deliver live microorganisms with adequate viable count of well-defined strains, and the number of viable microorganisms should be correlated with the corresponding probiotic effect.

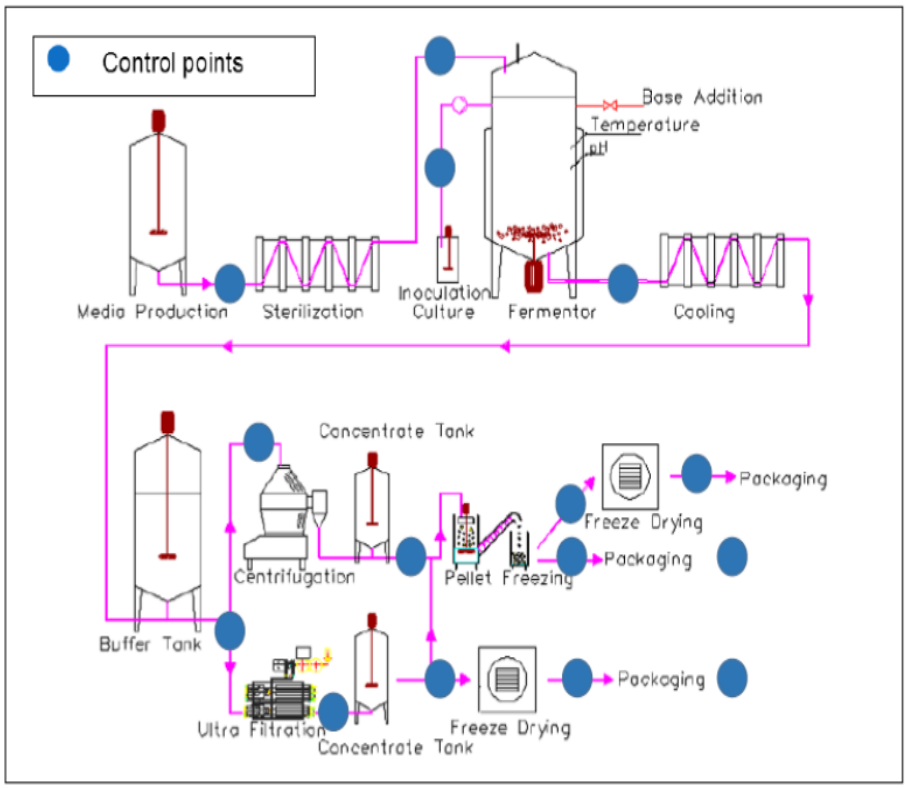
36. A project document is presented in Appendix 5.

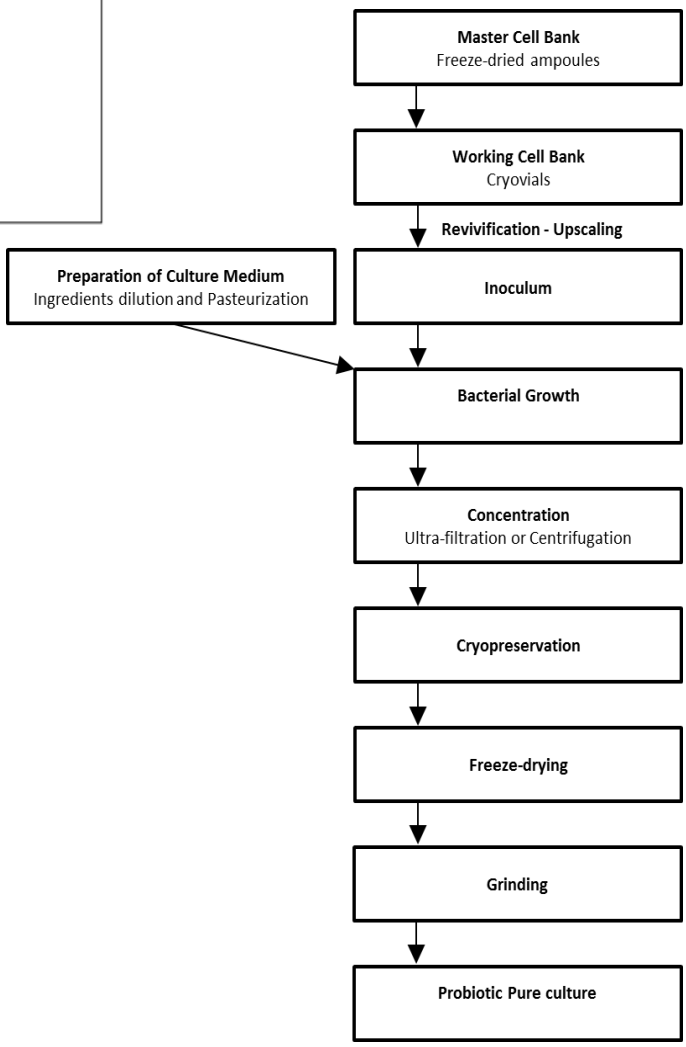
Recommendation

37. The Committee is invited to consider new work on Guidelines for probiotics for use as an ingredient in foods, beverages and dietary supplements as presented in the project document (Appendix 5).

Appendix 1

Bacteria Production Flow Diagram





Appendix 2

Applicable Codex Standards

i. CXC 1:1969: General Principles of Food Hygiene.

ii. CXS 228-2001: General Methods of Analysis for Contaminants.

iii.CXS 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.

iv.CXS 192-1995: General Standard for Food Additives.

v.CXS 1-1985: General Standard for the Labelling of Pre-packaged Foods.

vi.CXG 23-1997. Guidelines for Use of Nutrition and Health Claims.

Appendix 3

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Appendix 4

Glossary of terms

Active Fluorescent Units	AFU
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 Code of Nomenclature	ICNB
International Committee on Systematics of Prokaryotes	ICSP
International Probiotic Association	IPA
List of Prokaryotic Names with Standing in Nomenclature	LPSN
World Health Organization	WHO

Appendix 5

PROJECT DOCUMENT

1. PURPOSES AND SCOPE OF GUIDELINES

The purpose of the work is to establish harmonized guidelines for probiotics for use as an ingredient in foods, beverages and dietary supplements.

The scope of the guidelines includes a definition, minimum characterization requirements, safety criteria, quality and labelling criteria.

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 applications. There are a number of distinct probiotics strains and consumer demand is driving growing international trade.

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 dietary 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.

Currently, probiotics are distributed in 63 countries and probiotic dairy-based yoghurts are distributed in 196 countries. (Source IPA).

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

There have traditionally been many products available in the marketplace carrying the label 'probiotic'. However, there are currently no defined criteria or guidelines internationally accepted 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 foods 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'.

Thereby, harmonized guidelines would facilitate international trade and enable fair and transparent practices.

Due to the lack of an international guideline, standard or reference, it is necessary to establish a Codex guidelines covering the definition, minimum safety and characterization criteria, quality and labelling for probiotics for use as an ingredient in foods and dietary supplements.

Therefore, it is essential that industry have specifications for probiotics in foods and dietary supplements, in order to ensure the proper use of the term all the while respecting national requirements.

Furthermore, Codex guidelines for probiotics would also contribute to the protection of consumers' health.

3. MAIN ASPECTS TO BE COVERED

The main aspect to be covered includes the scope of the guidelines, the establishment of a harmonized definition of 'probiotics', minimum safety and characterization criteria, quality and labelling. Food safety will be addressed through references to relevant Codex standards, guidelines, and codes of practice.

i. Definition

It will be necessary to develop a definition, considering the FAO/WHO definition (2001)[2], revised by Hill et al. (2014), with criteria that is sufficiently broad to cover both vegetative microorganisms and spores.

[2] 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.

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[3].*

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

Furthermore, minimum requirements should also be accomplished for probiotic microorganism once the probiotic is added to food or dietary supplements: the probiotic microorganism(s) should be alive when consumed, should be in adequate amounts of probiotic microorganism(s), and the viability within the food or dietary supplement should be demonstrated.

Additionally, it should be proved that the probiotic strain keeps the viability within the food or dietary supplement where it is added.

iii. Food safety

Food safety aspects will be addressed through references to relevant Codex standards, guidelines, and codes of practice such as:

- Food additive provisions and their maximum limits will be referred to the General Standard for Food Additives (CXS 192-1995).
- Provisions for hygienic practice for production, handling, processing, storage and distribution of probiotics and foods with probiotics with reference to the General Principles of Food Hygiene (CXC 1-1969) and other relevant codex texts.
- Provisions for chemical contaminants with reference to the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

iv. Food Labelling

In addition to the General Standard for Labelling of Prepackaged Foods (CXS 1-1985), it should be applied the following specific provisions: name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients; amount of viable cells of total probiotic microorganisms (CFU/g); name of the food; serving size and storage conditions.

v. Reference Methods of Analysis and Sampling.

a) *Taxonomic characterization of the microorganism.*

The applicable methodology of analysis for the typing of strains and the counting of microorganisms will be considered.

b) *Count of microorganisms.*

Traditionally, plating has been used and endorsed as the "standard way" to evaluate microbial viability and it has been determined through counting “colony-forming units”, CFU. The plate count method is based on the premise that a single bacterium can grow and divide to give an entire colony. This method is historically and currently, the most broadly used method to demonstrate the activity of the microorganisms.

Now, other methods such as flow cytometry (ISO 19344 IDF 232) are coming to be used widely and a standardized method has been developed and used as a way to evaluate total probiotic microorganisms.

All work will be coordinated with the applicable general subject Codex Committee to ensure the appropriate application of Codex expertise and resources.

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 and in particular:

[3]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.

i. *Fair practices in food trade:*

Despite the widely recognized FAO/WHO definition (2001), revised by Hill et al. (2014), which states that "*Live microorganisms that, 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, there are a number of products sold as 'probiotics' that do not comply with this definition.

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

ii. *Food safety:*

It will be proposed to establish safety criteria of probiotics as live microorganisms. Initially, a scientific approach for those genera and species with an established safe history of use in foods, and for those newly recognized as probiotics, an *in-vitro* evidence-based approach, genomic mining and phenotypic analysis shall all be utilized to demonstrate safety.

Criteria applicable to general subjects

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

The lack of a harmonized definition for probiotics could result in many different definitions being developed for the purposes of inclusion in national regulations. The lack of harmonized guidance could also result in unnecessary barriers to trade.

Also, there could be misuse by manufacturers of the "probiotic" denomination and the misinterpretation of the probiotic concept by consumers.

In addition, a harmonized definition for the term 'probiotics' could prevent its misuse on product labels, communications or advertising.

(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 a harmonized definition of 'probiotics'.

2. Minimum safety and characterization criteria for probiotics as an ingredient in foods, beverages and dietary 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 that, 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 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 safety, characterization, quality, and labelling requirements on probiotics in food, beverages and dietary supplements and their labelling.

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 by FAO/WHO. 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, there is neither regulatory status nor guidelines defining the probiotics category nor a commonly acknowledged list of individual probiotic strains and/or species.

Very few EU Member States, such as Italy, have developed certain requirements for qualifying specific strans as probiotics.

In the US, probiotics can be considered as food or ingredients. Safety is demonstrated using the Generally Recognized As Safe (GRAS) process self-determination or through a voluntary notice to the regulatory agency for food ingredients or following the New Dietary Ingredients (NDIs) process for use in food supplements, when applicable.

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".

India has a regulatory definition of food with added probiotics and Thailand has a specific probiotic regulation and a definition of probiotics.

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

There is general support for the harmonization of food and dietary supplement regulations for probiotics to assist in eliminating any impediments to international trade.

Taking into account the existing global references on probiotics, standardization in this area is achievable through harmonization of: a definition, minimum safety and characterization requirements, labelling criteria for probiotics for use as an ingredient in foods and dietary supplements and amount of probiotic microorganism(s)

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

There have traditionally been many products available in the marketplace carrying the label 'probiotic'. 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 for the production of probiotic products will provide proper guidance for global regulatory agencies, enabling them to prepare probiotics specific regulations, and also 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 42nd 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

The proposed work will be used in conjunction with all existing and relevant standards and related texts in particular of the following:

- CXC 1-1969 - General Principles of Food Hygiene.
- CXS 192-1995. General Standard for Food Additives.
- CXS 1-1985. General Standard for Labelling of Prepackaged Foods.
- CXS 193-1995. General Standard for Contaminants and Toxins in Food and Feed.
- CXG 23-1997. Guidelines for Use of Nutrition and Health Claims, which refer to the use of health claims in food labelling and, where required by the authorities having jurisdiction, in advertising of foods. The guidelines are applied with the aim of assisting competent national au-

thorities in their evaluation of health claims in order to determine their acceptability for use by the industry.

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.

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

No technical input other than which is to be found in the CCNFSDU is required at this time.

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

November 2019	Agreement of new work by the 41st Session of the CCNFSDU
July 2020	Subject to approval of new work by the 43rd Session of the CAC
July 2022	CAC Adoption of Draft Guidelines