CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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

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2 – 6 October 2024

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

prepared by the Electronic Working Group Chaired by Argentina and co-Chaired by Malaysia and China

BACKGROUND

1. During the forty-third session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU43) on 7-10 March and 15 March 2023, Argentina and Malaysia introduced the revised Discussion Paper and Project Document on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements and provided a response to concerns raised in the Physical Working Group (PWG) which took place on 6 March 2023 (as contained in CRD39).

2. Delegates to the CCNFSDU43 discussed the revised proposal. Delegations in favour of the new work proposal expressed the various views and reasons to support the proposal. On the other hand, delegations not in favour of proceeding with the new work expressed their views and concerns. The discussion including the views in favour and not in favour of the new work proposal are contained in paragraphs 104-105 of the Report of the CCNFSDU43 (REP23/NFSDU).

3. In concluding this agenda item, CCNFSDU43 agreed to establish an Electronic Working Group (EWG), open to all Members and Observers, chaired by Argentina and co-chaired by China and Malaysia, working in English and Spanish, with the following terms of reference:

i. Further refine and clarify Proposal 2.1 Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements in document CX/NFSDU 23/43/7, especially with regards to the scope, impact on food safety and need for scientific advice; and

ii. Develop a revised discussion paper and project document, taking into account comments at CCNFSDU43 and with the aim to consider it at CCNFSDU44 as part of the discussions of new work proposals. The revised discussion paper is attached as Appendix I and the project document as Appendix II.

PARTICIPATION AND METHODOLOGY

4. The kick-off message inviting Codex Members and Observers to register to participate in the EWG was issued on 24 April 2023. Thirty-eight (38) Members and fourteen (14) Observers registered to participate in the EWG when registration closed on 30 May 2023. The EWG undertook its work through two rounds of comments via the Codex online platform. The list of participants is attached as Appendix III.

5. The first round of EWG discussion took place from 30 August to 31 October 2023. The Discussion Paper on Harmonized Guidelines for the Use of Probiotics in Foods, Beverages and Food Supplements - revised by Argentina, China and Malaysia, as Chair and co-Chairs, taking into account comments made at CCNFSDU43 - was provided for comments by EWG members in first round. A total of 16 comments were received: 12 from Members and 4 from Observers. The Member Countries and Member Organization that provided comments were Canada, the European Union, Guatemala, Indonesia, Iran, Malaysia, New Zealand, Nigeria, Saudi Arabia, South Africa, Thailand and the United States of America. Regarding the Observers, comments were received from FIA, IDF, IPA and YLFA.

6. The second round of EWG discussion took place from 31 January 2024 to 31 March 2024. A Revised Discussion Paper and Project Document on Harmonized Guidelines for the Use of Probiotics in Foods and

Food Supplements, taking into account the comments received in first round - was provided for comments by EWG members in second round. A total of 13 comments, 8 from Members and 5 from Observers, were received. In this opportunity, the Member Countries and Member Organization were Canada, the European Union, Indonesia, Malaysia, New Zealand, South Africa, Thailand, and the United States of America. With respect to observers, comments were received from FIA, IDF, IFAC, IPA and YLFA.

7. The Chair and co-Chairs of the EWG wish to thank all EWG members for their response and for providing comments and suggestions for improvement of the Discussion Paper and Project Document. All inputs were analyzed by the Chair and co-Chairs and taken into consideration in the preparation of this report and for the updating of and revising the Discussion Paper and Project Document.

GENERAL OVERVIEW OF COMMENTS RECEIVED

A. Summary of Position of Member Countries / Member Organisation and Observers

8. The positions of the EWG members during the two rounds of EWG consultation are summarized in the table below:

	Supporting the work and/or recognising its benefit and/or providing suggestions for improvement of new work proposal	Not supporting and/or sharing concerns	Neutral position
First Round	Canada Guatemala Indonesia Iran Malaysia New Zealand Nigeria Saudi Arabia Thailand United States of America IPA YLFA	European Union South Africa	FIA IDF
Second Round	Canada Indonesia Malaysia New Zealand South Africa Thailand United States of America IFAC IPA YLFA	European Union	FIA IDF

9. The status of support by members of the EWG for the new work proposal to develop a Harmonised Probiotic Guidelines for Use in Foods and Food Supplements is rather similar during both rounds of the consultation.

10. A majority of the EWG members supported the new work proposal. Some indicated either they did not have a pressing need for this work or did not consider it to be high priority, but recognised that there could be a significant benefit for many countries. Several members made several suggestions to provide further clarity to the scope and to address certain aspects of the new work proposal so as to improve the overall discussion paper and project document. Two observers expressed a neutral position in relation to this proposal. The European Union indicated not supporting the proposal, pointing out that providing comments on the discussion paper does not mean that possible future work on probiotics will be supported. Several concerns raised by the EU were addressed in the revised documents.

B. Main aspects raised by EWG members and actions by Chair and Co-Chair

11. The scope of the new work proposal was the focus of discussion of the previous CCNFSDU sessions and the EWG consultations. Taking into account these discussions, the majority of the comments received supported that the scope of this work: includes the developing of a general guidance on adequate minimum characterisation requirements and the safety assessment of probiotic microorganisms, taking into account the work of authoritative scientific bodies, and of labelling requirements specific to probiotic microorganism; and excludes health claims as well as the evaluation of the safety and efficacy of specific strains.

12. One item in the discussion paper and project document brought up by several EWG members is in relation to the definition of probiotics as provided in the FAO/WHO consultation report of 2001. Some members raised concern that the term probiotic in the FAO/WHO definition is in itself a health claim. The definition in the revised discussion paper has provided further clarity that it is only the intention to ensure that a probiotic microorganism does indeed bring about physiological benefits to the consumer. It has been repeatedly made very clear that evaluation of health claims is not within the scope of this proposed guideline.

13. Several members supported the use of the definition of probiotics as provided in the FAO/WHO consultation report and were of the opinion that no revision is needed, other than using the term “physiological effects” instead of “health benefits”. Any expert advice, if needed, may be identified during the course of developing the harmonized guideline.

14. The term “beverages” was removed from the title of the Discussion Paper and Project Document and throughout the document, following the proposals of several EWG members with the understanding that the foods include beverages.

15. There are other points raised by some members, for example on how the characterisation of microorganisms is to be perform, how the safety evaluation is to be carried out, what are the labelling requirements, etc. Some countries have suggested some references that would become useful. The Chair and co-chairs of the EWG feel that these can be adequately addressed once the new work is approved and the development of the guideline proceeds. There will be ample opportunities for members to provide input on some details during the development stage. It is not necessary to debate and resolve all aspects in a discussion paper or project document, as long as the scope and main aspects have been generally agreed upon by members.

CONCLUSION

16. After three sessions of the CCNFSDU and two rounds of consultation among EWG members, the chair and co-chairs are of the opinion that there is general support from many countries of different regions of the world for the proposal to initiate new work to develop a harmonized probiotic guideline by CCNFSDU. Countries have stated very clearly that the products are in their markets and that they require harmonized regulatory guidance for foods and food supplements containing probiotics. The revised discussion paper is attached as Appendix I

RECOMMENDATION

17. CCNFSDU44 is invited to:

i. Consider the discussion paper in Appendix I; and

ii. approve the proposal for new work for a harmonized guideline on probiotics (the project document is as attached in Appendix II), with highest priority and to forward it to the 47th Session of the Codex Alimentarius Commission (CAC47) for approval as new work.

Appendix I

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

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 for 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, further addressing problematic issues related to health and trade.

6. At the forty-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.

8. During the forty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU43) in 2023, in the meeting of the Physical Working Group (PWG) on the Prioritization Mechanism / Emerging Issues or New Work Proposals, the new proposal presented by Argentina and Malaysia was examined in accordance with the provisions of the draft guidelines for the prior evaluation and identification of the priorities of the new proposals. In that regard, the PWG recommended the committee that Argentina/Malaysia continue developing their discussion paper on the proposal for new work for the next session (through the PWG to assess new work proposals).

9. The CCNFSDU, at its forty-third meeting, agreed to establish an EWG open to all members and observers, led by Argentina and co-led by Malaysia and China, using English and Spanish as working languages and with the following terms of reference:

   i. Further refine and clarify Proposal 2.1 Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements in document CX/NFSDU 23/43/7, especially with regards to the scope, impact on food safety and need for scientific advice; and

   ii. Develop a revised discussion paper and project document, taking into account comments at CCNFSDU43 and with the aim to consider it at CCNFSDU44 as part of the discussions of new work proposals.

10. In accordance with the established mandate, the EWG submitted two rounds of comments through the Codex platform:

   i. The First Consultation document published on the platform from August 30 (2023) to October 31 2023).

   ii. The Second Consultation document posted on the platform from January 31 (2024) to March 31 (2024).

   iii. The final report will be due July 2024.

The EWG and co-chairs analyzed the comments received and revised the proposals accordingly for consideration at the 44th CCNFSDU meeting.

INTRODUCTION

11. Available scientific literature throughout the world has indicated that probiotics can play important roles in immunological, digestive and respiratory functions. Over the past 50 years, around 20,000 articles on the various functional effects of probiotics have been published in peer-reviewed scientific journals. However, it is really in the last decade that research on probiotics experienced a great boost.

12. Meanwhile, in parallel with this scientific development, probiotic microorganisms have been used as ingredients in a wide range of foods and food supplements. Being increasingly accepted by health professionals, the number and nature of type of these products that are available to consumers have increased considerably.

13. In view of the growing popularity of probiotic-containing foods 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

14. The purpose of this proposed work is to establish guidelines for probiotics for use as an ingredient in foods and food supplements where these are regulated as food. These guidelines would provide a harmonized framework to regulatory authorities for the evaluation of microorganisms for use as probiotics. It is not the intention for the Committee to actually evaluate each strain in order to generate a positive or negative list of probiotics and continue to update this list.

15. The scope of the proposed guidelines includes establishment of harmonized definition and minimum safety and characterization 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 and food supplements where these are regulated as food. The emphasis to adhere to the definition of the term probiotics is for a harmonized approach to research and development and trade, and for consumer protection, all within the mandate of Codex work.

16. The scope would be limited to the development of aspects not currently existing in any Codex standards/text, and it does not duplicate any part of the existing Codex text, and does not intend to re-open any discussion on the provisions currently included in the existing horizontal Codex standards.

17. The definition of the term “probiotic” in the FAO/WHO consultation report (2001) is widely accepted and will be the basis for establishing the requirements to determine if a microorganism can be accepted as a probiotic. To take into account more recent developments in Codex texts, and in order to minimize the possible confusion that the definition is an implied health claim, a working definition can be proposed as the following:

"*Probiotic" means live microorganisms, when administered in adequate amounts, have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities*".

This definition requires that the microorganism must be able to confer physiological effects of benefit to the individuals consuming it. This is not to be construed as a health claim, but rather to ensure that the microorganism indeed confers physiological effects of benefits to the person, so as to protect the interest of the consumer. This is similar to the requirement in the Codex definition of dietary fibre which requires that the food component must be “shown to have a physiological effect of benefit to health, as demonstrated by generally accepted scientific evidence to competent authorities. This definition is already adopted by Codex (CXG2-1985) and is not considered as a health claim.

18. The evaluation of any intended specific health claim on a food or food supplement that contains the probiotic microorganism, beyond the basic physiological effect, is outside the scope of this guideline.

NEED AND RELEVANCE OF PROBIOTICS GUIDELINE

19. Today, over two decades after the FAO/WHO consultation in 2001, the status of probiotics as an ingredient in food has not been established on an international basis. There is also no international guideline on probiotics that addresses the minimum safety and characterization criteria, quality and specific labelling requirements. As a consequence, there is a lack of harmonized regulation, and countries have different provisions and take different approaches. These countries recognized the need for regulatory control as probiotic-containing foods and food supplements are widely available. In addition, there is an increasing number of research studies on probiotics and discovery of new microorganisms with potential to be recognised as probiotics over the last few decades.

20. This lack of harmonization in industry practice and legislation often leads to issues and concerns for regulators, industry, and even consumers in terms of quality, safety and labelling. A harmonized guideline addressing these gaps for these internationally and regionally traded products will facilitate trade and ensure

that safe products that are adequately characterized, meet the functional characteristics of a probiotic and labelled appropriately reach the consumers.

21. 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 leads to misuse of the “probiotic” term and to trade non-compliant products.

22. Taking the above into account, many countries accept the need for Codex Alimentarius guidelines. The ultimate goal of this discussion paper is the development of a Codex document to 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 more consumer satisfaction, health and well-being.

23. 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 and in the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CXG 46-2003). In its 44th Session, the Codex Committee on Food Labelling indicated that terms used in Codex standards should ideally have a Codex definition. This proposed guideline would address this gap.

b. Existing Codex standards do not establish minimum specific requirements for a microorganism in order to be qualified as a probiotic according to the provisions in the FAO/WHO consultation (2001). The establishment of minimum specific requirements for a probiotic is important to ensure consumers have access to safe and functional probiotics.

c. In addition to the labelling provisions of the General Standard for Labelling of Prepackaged Foods (CXS 1-1985), additional specific labelling requirements for foods and food supplements containing probiotics would be required. CXS 1-1985 does not address aspects such as the name of the probiotic used as an ingredient in food and food supplements as well as the declaration of the amount of viable cells of total probiotic microorganisms. The labelling requirements specific to probiotics are essential to safeguard the interest of consumers.

24. In conclusion, the proposed guideline is therefore relevant and essential as it addresses several aspects not covered by the current Codex standards and guidelines.

25. The proposed new work is clearly within the scope of work of CCNFSDU as the probiotic is to be added to foods and used in food supplements. These can serve as part of the daily diet, similar to many other products discussed under this Committee. This work may require various experts besides nutritionists, for example, microbiologists. These other experts will be invited to contribute to the development of the guideline, similar to work undertaken by other Codex guidelines and standards.

PROBIOTIC PRODUCTION

26. 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, EU, UK, Brazil, Argentina, Chile, Japan, China, South Korea, India, Australia, South Africa, among others. Fermentation capacity of these facilities ranges from 20 to 500 metric tons.

b) Ingredient Market Revenue:

The global probiotic ingredients market was valued at an estimated $4 billion USD in 2023, growing at a rate of 5% and is expected to be valued at an estimated $6.5 billion USD by the year 2028. (Source IPA).

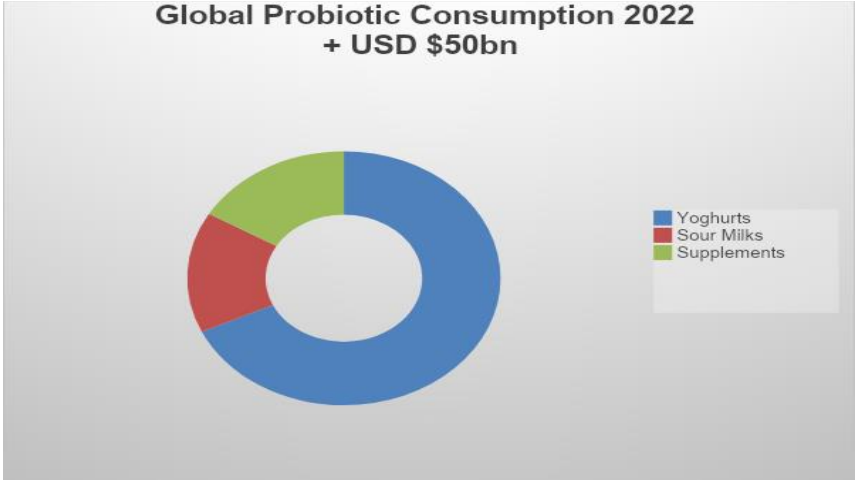
The estimated distribution of the revenue in 2022 was Functional Food and Beverages and fortified yoghurts 77%, Food and/or Dietary Supplements 16%, Other Human Nutrition 7%. (Source IPA).

PROBIOTIC DISTRIBUTION AND TRADE

27. Probiotics are distributed in over 200 countries. (Source IPA).

PROBIOTIC CONSUMER CONSUMPTION

28. Probiotics are consumed in foods 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, 2022 (Source IPA)

World Retail Value (2022)	$50,254,000,000.00
Yoghurt	$34,215,000,000.00
Fermented milks	$7,743,000,000.00
Supplements	$8,296,000,000.00

Table 1: Global Retail Value, 2022 (Source IPA)

PROBIOTICS TRADE EXCHANGE

29. In 2022, Probiotic Supplements hit $8.2 billion USD and Food and Beverage applications hit sales of over $42 billion USD globally.

Region	Ingredients for Supplements & Human Nutrition (%)	Ingredients for Food Applications (%)
North America	31	10
Europe, Middle East and Africa	23	32
Latin America	3	5
Asia – Pacific Countries	40	51
Australasia	3	2

Table 2: Distribution of Ingredients for Supplements and Food Applications, 2022 (Source IPA)

Production of Probiotic Culture for Supplements and Food Applications (2022)	
Supplement totals	2,074,000 Kg
Food and beverage totals	10,489,500 Kg
Totals of Probiotic pure cultures	12,563,500 Kg

Table 3: Combined Totals of Pure Bacteria Powder, 2022 (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 relevance to what the volume of kilograms represent in CFU as follows:

2.074 million Kgs of culture ingredients for the Food Supplement industry is equivalent to 1.03E+21 or **1,037,000,000,000,000,000,000 CFU** of probiotic cultures.

10,489,500 Kgs of culture ingredients for the Food application industry is equivalent to 1.57343E+20 or **157,342,500,000,000,000,000 CFU** of probiotic cultures.

These are estimations based on average yields.

THE MAIN ASPECTS TO BE CONSIDERED

30. 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

31. Development of guidelines and a harmonized framework for probiotics, including general specifications and considerations, is necessary to ensure and maintain the quality of 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".*

32. Considering the tremendous increase in the global market of probiotics, the Committee is invited to consider new work on Guidelines for probiotics for use as an ingredient in foods, and food supplements -when 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

After the initial introduction of the draft Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU, in 2019, two rounds of discussion were held to revise the Guideline, namely in April and September 2022. The overall approach of the prioritization mechanism was not changed. Several amendments were made to the evaluation criteria and the decision tree.

In line with the above development, the four criteria in the revised Guideline of 2022 were used for the self-assessment. The self-assessment of the revised criteria are as given in the table below. Discussions on further refinement to the criteria during CCNFSDU43 are not included here as there was no firm agreement on the proposals.

Criteria	Explanatory descriptions
Impact on health of the target group	Medium positive impact on health of target groups • The target groups are everyone in the life cycle, from infants, children, adolescents, adults and elderly, as probiotic containing foods have been shown to provide health benefits to all age groups. • Around 20,000 papers have been published on the various functional effects and health benefits of probiotics in peer-review scientific journals in the last 50 years. This available scientific literature has indicated that probiotics can play important roles in maintaining immunological, digestive and respiratory functions. Evidence is emerging for their role in several other health conditions. • Probiotics, therefore, have great potential to maintain health, mitigate, prevent or significantly reduce consumer health risks and hence can support health improvements and quality of life. Probiotic intervention has the potential to significantly benefit many important health care issues that have a substantial health cost, as seen in various published studies on the health economics of probiotics. • These beneficial effects of probiotics are broadly acknowledged by health professionals, consumers and authorities.
Impact on food safety	High positive impact on food safety As probiotics products are now being used globally by wide segments of the community of all ages, the development of international guidelines that address

	harmonized characterization and safety criteria is expected to have a high impact on food safety. • One of the main aspects to be included in the proposed harmonized new work is to develop an international guideline that addresses the minimum safety and characterization criteria to recognize a strain as a safe probiotic for use in food and food supplements. • Current Codex text does not adequately cover these. However, the guidelines for the evaluation of probiotics in foods of FAO/WHO, 2002 consultation report can be utilized and would include: - Taxonomic characterization of the microorganism - Functional characterization of the strain - Safety assessment of the microorganism for the intended use. • The long history of safe use of probiotics has been acknowledged already in 2001 by FAO/WHO Expert Consultation, and by several regulatory and scientific organizations, including the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA). EFSA includes typical species which are used as proboiotics in foods and food supplements in the list of microorganisms with Qualified Presumption of Safety (QPS) with well-defined generic and specific qualifications. These expert bodies have confirmed the absence of established risk associated with the consumption of typical probiotic genera by humans. However, because of a lack of clear regulatory requirements, products that may not meet these characterization and safety criteria may be available for consumers. • When these characterisation and safety criteria are included into national regulations, products that do not meet these mandatory screening criteria will not be permitted to be marketed to consumers. • Any products containing potentially harmful microorganisms, e.g., those which may carry transferable antibiotic resistance genes, will not be permitted to be on sale.
Impact on trade practices	High positive impact on trade practices • Despite the widely-recognized definition in the FAO/WHO (2001) consultation and guidelines on probiotics, there is regulatory environment divergence that hinders the marketing and promotion of probiotics in different parts of the world. • Lack of harmonization in industry practices and legislation around probiotics often leads to issues and concerns for regulators, industry, and even consumers in regard of quality, safety and labelling of probiotics. - 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. • As probiotics have to meet specific criteria to be recognized as such, the absence of clear harmonization leads to misuse of the “probiotic” term and to trading products that do not comply with this concept. It has been reported that many products in the market use the term without meeting the criteria for probiotics. • Harmonized guidelines for these international and regionally traded products will facilitate trade and ensure consumer access to high quality, functional and safe probiotic food and food supplements, avoiding consumers being misled. The development of Codex Guidelines on Probiotics will generate the regulatory harmonization of probiotics across the world, thereby facilitating global trade while contributing to consistent fair trade practices in this area.
Global impact	High global impact The development of this harmonized probiotic guideline will have significant global impact on trade and health of consumers, as evidenced from the following: • Probiotic-containing products are distributed globally in some 200 countries. Use of probiotics in foods and supplements is in all continents of the globe, and

	in large amounts. Probiotic supplements hit $6.09 Billion USD and Food an Beverage applications hit sales of close to $40 Billion USD globally, in 2019. • The above trade figures would also mean that probiotics products are produced by manufacturers and consumed by large groups of population in most parts of the world. • The potential health impact is on many population groups in different parts of the world, as the scientific literature has been generated from these different regions. • The new work proposal is, therefore, related to United Nations' Sustainable Development Goals (SDGs), especially on goal 3 on good health and wellbeing. • The establishment of the probiotic guidelines can potentially help resolve or mitigate a major issue of lack of regulations or unclear regulations in many countries in the world, that has brought about trade impediment and confusion to consumers. • This proposal for new work will contribute particularly to Codex Strategic 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". Currently, there is regulatory environment divergence that hinders the marketing and promotion of probiotics in different parts of the world. In addition, probiotics are on the regulatory agenda of many countries around the world. The establishment of Codex high-level principles and guidance will have a high global impact: o for the consistent interpretation and application of the definition of probiotics to help national authorities develop an appropriate regulatory framework to probiotics, and o to ensure the consumer access to high quality, functional and safe probiotic foods and food supplements, avoiding consumers being misled.

Annex 1

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

Annex 2

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Appendix II

PROJECT DOCUMENT

NEW WORK PROPOSAL ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS

1. PURPOSE AND SCOPE OF GUIDELINES

1. The purpose of this proposed work is to establish guidelines for probiotics for use as an ingredient in foods and food supplements where these are regulated as food.
2. These guidelines provide a harmonized framework for regulatory authorities for the evaluation of microorganisms for use as probiotics. It is not the intention for the Committee to actually evaluate each strain in order to generate a positive or negative list of probiotics and continue to update this list.
3. The scope of the proposed guidelines includes establishment of harmonized definition, minimum safety and characterization 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 and food supplements where these are regulated as food. The emphasis to adhere to the definition of the term probiotics is for a harmonized approach to research and development and trade, and for consumer protection, all within the mandate of Codex work.
4. The scope of this work would be limited to the development of aspects not covered by existing Codex standards without re-opening any discussion on the provisions currently included in the existing horizontal Codex standards (Section 6 of this document).
5. The evaluation of the specific beneficial effects of probiotic microorganisms, as well as food and food supplement containing probiotic microorganism, is excluded from the scope of this work, recognising that the scientific assessment of efficacy is not within the scope of the Committee.
6. Drug applications and animal feeds are excluded from the scope of this work

2. RELEVANCE AND TIMELINESS

7. Probiotics are live microorganisms increasingly used in a wide variety of food and food supplement applications. There are a number of different probiotic strains, and consumer demand is driving growing international trade. According to IPA data, probiotics are distributed in 200 countries.
8. There is growing interest in the concept of probiotics and their role in human nutrition and health. Probiotics are used in a variety of foods, mainly dairy products, but they are also present in food supplements. The general population is increasingly interested in health maintenance and self-care, and this may explain the consumers' interest in probiotics. Establishing harmonized guidelines on probiotics contributes to achieving the United Nations' sustainable development goal 3: "Good health and well-being", ensures healthy lives and promote well-being for all at all ages.
9. The scientific and clinical evidence have progressed rapidly, as has the development of many probiotic products. Unfortunately, the misuse of the term "probiotic" has also become an important issue, with many non-compliant foods using the term.
10. There have traditionally been many products available in the marketplace with the term 'probiotic' in their labelling. However, there are currently no internationally accepted defined criteria or guidelines on what constitutes a 'probiotic' microorganism. Establishing eligibility criteria will provide proper guidance for global regulatory agencies to develop probiotic specific regulations.
11. At the same time, probiotic-containing foods and food supplements have received legitimate attention from regulatory authorities concerned with the protection of 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 this topic. However, these have been developed independently, with different provisions in some countries.
12. Due to the lack of international harmonization, it is essential to develop a Codex guideline for the establishment of minimum specific requirements in order to identify a strain as a probiotic for the consistent interpretation and application of the definition of "probiotics" as well as labelling requirements for probiotics for use as an ingredient in foods and food supplements, when 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.

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

3. MAIN ASPECTS TO BE COVERED

14. The main aspects to be covered include the establishment of a Codex definition of 'probiotics', minimum safety and characterization criteria and labelling requirements, as well as the minimum safety criteria for those probiotic microorganisms without a history of safe use.

i. Definition

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

ii. Minimum safety and characterization criteria.

16. Minimum requirements will be specified in order to recognize a strain as a probiotic, such as:

a. Taxonomic identification of the microorganism.

b. Functional characterization of the strain[1]*, including demonstration of the viability of the microorganism (even in freeze-dried form) in the product throughout shelf-life and hence, when consumed (FAO/WHO, 2002).*

c. Safety assessment of the microorganism.

iii. Labelling

17. 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; for example, the term "probiotics", the name of the probiotics microorganism or (genus, species, subspecies, and strain) mentioned in the list of ingredients, the declaration of the number of viable cells of each strain of the total probiotics microorganisms throughout shelf-life (CFU/g or CFU/ml), storage conditions, information on preparation before consumption, etc. These and other specific labelling requirements for probiotic-containing products are essential to safeguard the interests of consumers.

iv. Reference Methods of Analysis

18. Specific harmonized methodologies for the evaluation of probiotics would be considered in order to recommend methods for the typing of strains and the counting of microorganisms as well as evaluating the safety of probiotics.

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

General criteria

19. 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 maintaining health, food safety and ensuring fair practices in the food trade.

20. 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 leads to misuse of the term and to the trading of non-compliant products asprobiotics.

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

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

Criteria applicable to general subjects

[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.
EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (wiley.com)

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

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

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

25. 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*

26. The scope of work will address:

    a. The establishment of a Codex definition of ‘probiotics’, considering the definition in the FAO/WHO consultation (2001) report.

    b. Minimum characterization requirements and safety criteria for probiotics as an ingredient in foods and food supplements, when these are regulated as foods.

    c. Labelling criteria for probiotics.

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

27. 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".

28. 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".

29. 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.

30. Some countries have regulations on probiotics. Those countries that have developed legislation have different views with diverse criteria regarding the requirements on probiotics in food and food supplements and their labelling.

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

32. 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.

33. 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.

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

35. European countries, such as Italy, have developed certain requirements for qualifying specific strains as probiotics.

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

37. 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.

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

39. In China, a voluntary standard of Probiotics for Foods and Beverages Use was developed in 2021 by the Chinese Institute of Food Science and Technology and implemented in June 2022. The voluntary standard includes Basic Requirements, Requirements for Bacterial Strain Levels, Requirements for Production Processes, Technical Requirements, etc.

40. Meanwhile, probiotics have been widely used in the permitted healthy food. China has developed a regulation on the application and review of the probiotic healthy food registration in 2020. The regulation has adopted a definition of probiotics that is aligned with the definition proposed in the FAO/WHO consultation. Besides, the regulation clarified the required data the healthy food applicant needs to provide, including safety data, the strain source, manufacturing technical specification, probiotics preservation method, efficacy study report, related articles and clinical studies to support the health claims, the number of viable cells of each strain of the probiotics throughout shelf-life (no less than 10^6CFU/g or CFU/ml), etc.

41. In the 10-member country Association of Southeast Asian Nations (ASEAN), only four countries (Indonesian, Philippines, Thailand and Malaysia) have enacted clear regulations or guidelines on probiotics in foods and supplements. The regulations in these 4 countries were developed independently and had taken on different approaches.

42. In 2022, Indonesian regulations on processed food labels and advertising have included provisions for the use of microorganisms and probiotics in foods.

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

44. 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.

45. 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 aforementioned regulation also prescribes specific labelling requirements for foods containing probiotics. These regulations or guidelines were developed independently and have different requirements.

46. India has a regulatory definition of food with added probiotics.

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

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

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

48. The growing scientific and clinical evidence and the increasing consumer acceptance of probiotics have led to the availability of many products 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.

49. 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 probiotic specific regulations, ensuring a consistent use of the term ‘probiotics’ which will benefit consumers and industry.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

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

51. 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 AS WELL AS OTHER ONGOING WORK

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

53. General Principles of Food Hygiene (CXC 1-1969), 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), Guidelines on Nutrition Labeling CXG 2–1985 and Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).

54. However, existing Codex standards and guidelines:

55. 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, and it is also mentioned in the Guidelines for the Assessment of the Safety of Foods Produced Using Recombinant DNA Microorganisms (CXG 46-2003).

56. Ideally, terms used in Codex standards should have a Codex definition, as it was noted by the 44thSession of the Codex Committee on Food Labelling[2].

57. Do not contain a description with criteria to clarify the meaning of what is a probiotic, in order 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.

58. Do not establish minimum specific requirements for a live microorganism to be qualified as a probiotic.

59. Do not address additional specific labelling requirements for probiotics such as: the name of the food specific for probiotics (i.e. name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients), the declaration of the viable cell count of total probiotic microorganisms (CFU/g) and other labelling requirements specific for probiotics.

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

60. 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

61. 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

Agreement to undertake new work by the CCNFSDU24. Approval by CAC48. Finalization of work by CCNFSDU46 in 2026 for adoption by CAC50 in 2027

[2] REP18/FL, paragraph 17.

Appendix III

LIST OF PARTICIPANTS

Chair	Argentina	Instituto Nacional de Alimentos – Ministerio de Salud
Co-chair	Malaysia	
Co-chair	China	
Codex Members	USA	US Department of Agriculture-US Codex Office
		US Food and Drug Administration
	India	Codex Contact Point Food Safety Standards and Authority of India
		Central University of Haryana
	Mexico	Codex COFEPRIS
	New Zealand	New Zealand Ministry for Primary Industries
	Norway	Norwegian Food Safety Authority
	Switzerland	Federal Food Safety and Veterinary Office
	France	Government
	Indonesia	Indonesian Food and Drug Authority
	Thailand	Codex Contact Point
	El Salvador	Organismo Salvadoreño de Reglamentación Técnica
	Saudi Arabia	Saudi Food and Drug Authority
	Japan	Consumer Affairs Agency
	Canada	Government of Canada
	Panama	Ministerio de Comercio e Industrias
	Iran	ISIRI
	Uganda	Uganda National Bureau of Standards
	Maroc	ONSSA
	El Salvador	Organismo Salvadoreño de Reglamentación Técnica
	European Union	
	China	CFSA
	Sweden	Swedish Food Agency
	Brazil	ANVISA
	Guatemala	Codex Contact Point - MAGA
	Singapore	Singapore Food Agency
	Germany	BVL
	Australia	Food Standards Australia New Zealand
	Myanmar	Department of Food and Drug Administration
	Grenada	Grenada Food and Nutrition Council
	Nigeria	NAFDAC
	Argentina	Instituto Nacional de Alimentos – Ministerio de Salud
		Punto Focal Codex Alimentarius – Secretaría de Bioeconomía
	Paraguay	Ministerio de Salud Pública y Bienestar Social
	United Kingdom	Department of Health and Social Care

Codex Observers	International Probiotics Association
	International Special Dietary Foods Industry
	Food Industry Asia
	EU Specialty Food Ingredients
	International Food Additives Council
	International Chewig Gum Association
	IADSA
	Cámara de Industria de Guatemala
	Danisco India Pvt. Limited
	IDF – International Dairy Federation
	Asociación de Empresas de Nutrición Infantil - Argentina
	Yoghurt and Live Fermented Milk Association - YLFA International
	Council for Responsible Nutrition
	Danone Argentina S.A.
	Yakult VietNam Co., Ltd
	Infant Nutrition Council of America