



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

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

(Comments by Burundi, Morocco, Panama, Senegal, Thailand, IPA)

Burundi

Position: Burundi supports further work to establish Guidelines on Probiotics for Use in Foods and Dietary Supplements. There is a need to develop guidelines and a harmonized framework for probiotics, including general specifications and provisions, in order to ensure and sustain the quality of probiotic products globally.

Rationale: According to the WHO and FAO, probiotics are live microorganisms that, when administered in adequate amounts, produce a physiological benefit in the host.

They are resistant to stomach acid and pancreatic juices and have been shown to be effective in boosting immunity, preventing and treating certain types of diarrhea.

In view of the considerable growth in the global market for probiotics, there is a need to develop guidelines and a harmonized framework for probiotics, including general specifications and provisions, in order to ensure and sustain the quality of probiotic products worldwide. This objective is in line with Codex's core values of collaboration, inclusiveness, consensus-building and transparency, and follows the principles set out in the Codex Scientific Foundation, as listed in the Codex Alimentarius Commission's Strategic Plan 2020-2025. The proposed new work will contribute in particular to the following Goals 1, 2 and 3: Strategic Objective 1: "Respond to current, emerging and critical issues in a timely manner". Strategic Objective 2: "To establish standards based on science and Codex risk analysis principles". Strategic Objective 3: "Increasing impact through the recognition and application of Codex standards".

Morocco

Position nationale:

Le Maroc soutient l'élaboration de ces directives afin d'orienter la fabrication de ces produits probiotiques qui sont déjà dans le marché mondial.

Panama

Panama wishes to express its support for the initiative to develop harmonized guidelines for the use of probiotics in foods and food supplements. A global consensus on the regulation and use of probiotics is of utmost importance, not only from a commercial perspective, but also to ensure the health and well-being of our consumers.

The increasing availability and use of probiotic products on the global market has highlighted the lack of a clear and harmonized regulatory framework. Panama believes that the establishment of international guidelines on probiotics will provide countries with a solid basis for regulation, thus protecting the interests of consumers and promoting fair trade.

It is essential that work proposals consider equity in health and nutrition, especially in disadvantaged communities. Probiotics can play an important role in public health, and ensuring that their availability and use are accessible to all is essential. Panama supports and recommends prioritizing initiatives that include these populations in the formulation of policies on probiotics.

Probiotics have been shown to have multiple health benefits, and their consideration in food regulation can contribute to improving public health in Panama and around the world. The adoption of clear standards can facilitate awareness and education campaigns on the proper use of probiotics, benefiting the population.

The lack of a harmonized approach can lead to disagreements and obstacles in international trade. Establishing clear guidelines will help prevent the marketing of mislabeled products and ensure that probiotics marketed in Panama and other nations meet international standards of safety and efficacy.

Spanish:

Panamá desea expresar su apoyo a la iniciativa de desarrollar directrices armonizadas para el uso de probióticos en alimentos y complementos alimenticios. El consenso mundial sobre la regulación y uso de probióticos es de suma importancia, no solo desde la perspectiva comercial, sino también para garantizar la salud y el bienestar de nuestros consumidores.

La creciente disponibilidad y uso de productos probióticos en el mercado mundial ha dejado en evidencia la ausencia de un marco regulador claro y armonizado. Panamá considera que el establecimiento de directrices internacionales sobre probióticos proporcionará a los países una base sólida para la regulación, protegiendo así los intereses de los consumidores y fomentando el comercio justo.

Es esencial que las propuestas de trabajo consideren la equidad en la salud y la nutrición, especialmente en comunidades desfavorecidas. Los probióticos pueden jugar un papel importante en la salud pública, y asegurarse de que su disponibilidad y uso sean accesibles para todos es fundamental. Panamá apoya y recomienda priorizar iniciativas que incluyan a estas poblaciones en la formulación de políticas sobre probióticos.

Se ha demostrado que los probióticos tienen múltiples beneficios para la salud, y su consideración en la regulación alimentaria puede contribuir a la mejora de la salud pública en Panamá y en el resto del mundo. La adopción de normas claras puede facilitar campañas de sensibilización y educación sobre el uso adecuado de probióticos, beneficiando a la población.

La falta de un enfoque armonizado puede llevar a desacuerdos y obstáculos en el comercio internacional. El establecimiento de directrices claras ayudará a evitar la comercialización de productos mal etiquetados y garantizará que los probióticos comercializados en Panamá y otras naciones cumplan con estándares internacionales de inocuidad y eficacia.

Senegal

Contexte: Lors de la 43e session du Comité du Codex sur la Nutrition et les Aliments Diététiques ou de Régime (CCNFSDU43), qui s'est tenue du 7 au 10 mars et le 15 mars 2023, l'Argentine et la Malaisie ont présenté des documents révisés sur les directives harmonisées concernant les probiotiques dans les aliments et les compléments alimentaires. Ces documents ont répondu aux préoccupations soulevées lors du Groupe de travail physique (GTP) du 6 mars 2023. Les délégués ont discuté la proposition révisée, avec des avis partagés entre ceux qui soutiennent et ceux qui s'opposent aux nouveaux travaux. Les avis et discussions sont détaillés dans les paragraphes 104 à 105 du rapport du CCNFSDU43 (REP23/NFSDU).

Le Comité a décidé de créer un Groupe de Travail Électronique (GTE), ouvert à tous les membres et observateurs, sous la présidence de l'Argentine et la coprésidence de la Chine et de la Malaisie. Ce GTE, travaillant en anglais et en espagnol, a pour mandat:

- D'affiner et clarifier la Proposition 2.1 sur les directives harmonisées concernant les probiotiques, en examinant le champ d'application, l'impact sur la sécurité alimentaire, et les besoins en avis scientifiques.
- D'élaborer un document de travail et un document de projet révisés en tenant compte des observations faites lors du CCNFSDU43, avec l'objectif de leur examen lors du CCNFSDU44.

Position: Le Sénégal soutient la conduite de nouveaux travaux pour établir des Directives sur les probiotiques destinés à une utilisation dans les aliments et les compléments alimentaires. Cependant, il met l'accent sur l'importance de l'allaitement maternel.

Justification: Les probiotiques sont des micro-organismes vivants qui, lorsqu'ils sont administrés en quantités adéquates, produisent un bénéfice physiologique chez l'hôte. Ils résistent à l'acidité gastrique et aux sucs

pancréatiques et ont démontré leur efficacité dans la stimulation de l'immunité, ainsi que dans la prévention et le traitement de certains types de diarrhée.

Le lait maternel est reconnu comme la meilleure source de nutrition pour les nourrissons, fournissant non seulement les nutriments nécessaires mais aussi des probiotiques naturels qui jouent un rôle crucial dans le développement du système immunitaire de l'enfant.

Thailand

It appears that probiotics have already been extensively used in food and food supplements and many researches have been conducted to study the use of probiotics in those products. Moreover, study on probiotic's physiological effects and health benefits should be additionally conducted to provide a clearer definition of probiotics.

The elaboration of mentioned above guidelines will ensure the goals of Codex which are consumer health protection and trade facilitation. In principle, we therefore agree with the proposal for new work of Harmonized Probiotic Guidelines for Use in Foods and Food Supplements and an advancement to the 47th CAC for approval.

International Probiotics Association (IPA)

The International Probiotics Association (IPA) wishes to thank Argentina, Malaysia and China for chairing and co-chairing the Electronic Working Group (EWG) to further refine and clarify the Discussion Paper on harmonized probiotic guidelines for use in foods and food supplements for consideration at the CCNFSDU44, under agenda item 6.21.

IPA supports the scope of the new work as proposed in the EWG's revised discussion paper and project document.

In this sense, IPA supports starting new work on Codex Guidelines for Probiotics used as an ingredient in foods and food supplements and the adoption of the Revised Project Document on the New Work Proposal for a Harmonized Probiotic Guidelines for Use in Foods and Food Supplements as presented in Appendix II of the Discussion Paper, which further clarifies, among other aspects that:

- the scope of this work includes the establishment of a harmonized definition, minimum safety and characterization requirements and labelling parameters for probiotics,
- the establishment of a harmonized definition of probiotics as an ingredient category would help to clarify the use of the term probiotic,
- the evaluation of the specific beneficial effects of probiotic microorganisms is excluded from the scope of this work, recognizing that the scientific assessment of efficacy is not within the scope of the Committee,
- 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,
- the scientific guidance as given in FAO/WHO consultations reports of 2001 and 2002 on probiotics shall be referred to. Any expert advice, if needed, may be identified during the course of developing the harmonized guideline.

IPA supports that CCNFSDU44 adopts the new work proposal with highest priority and forwards it to the 47th Session of the Codex Alimentarius Commission (CAC47) for approval as new work, in line with the further comments provided by IPA in the Annex below.

ANNEX

Harmonized guidelines of significant benefit for many countries

Probiotics are live microorganisms increasingly used in a wide variety of food applications. The term "probiotics" is used more and more in several different products, with some products not in line with the commonly referenced FAO/WHO definition. The development of harmonized guidelines could be of significant benefit for many countries using them as a reference for minimal criteria for probiotics, ensuring consumers having access to safe and high quality probiotics, and facilitating international trade and enabling fair and transparent practices. Clarifying the definition of probiotics as an ingredient category would also help to overcome the lack

of harmonisation of regulatory and trade practices and divergent conditions on the use of probiotics in different parts of the world.

High priority

IPA believes that the proposal for new work on Codex Guidelines for Probiotics meets the CCNFSDU prioritization criteria to be ranked as high priority by the Working Group on the Guideline for new work / prioritization mechanism, at its next meeting on 30 September, and by the CCNFSDU44 under agenda item 6.21.

IPA supports the self-assessment of the CCNFSDU prioritization criteria contained in the Discussion Paper prepared by EWG chaired by Argentina and co-chaired by Malaysia and China, moreover, taking into account the criteria that have been subsequently reviewed by the Electronic Working Group on the Prioritization Mechanism as follows:

- Impact on public health¹:

IPA supports that the proposal for new work on Codex Guidelines for Probiotics has a positive impact on the health of the whole population.

The effects of probiotics are broadly acknowledged and scientifically demonstrated to play important roles in several physiological functions e.g. immunological, digestive, respiratory. Probiotic consumption has the potential to significantly support many important health care issues that have a substantial health cost, as seen in various published studies on the health economics of probiotics.

- Impact on food safety

IPA also considers that the proposal for new work on Codex Guidelines for Probiotics has a high positive impact on food safety. Probiotics have a long history of safe use which has been acknowledged already in 2001 by the FAO/WHO Expert Consultation, and by several regulatory organizations, including the European Food Safety Authority, who included typical probiotics species in the list of microorganisms with Qualified Presumption of Safety (QPS) with well-defined generic and specific qualifications.

- Impact on trade practices

IPA supports that the proposal for new work on Codex Guidelines for Probiotics has a High positive impact on trade practices.

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.

- Global Impact

Currently, there is regulatory environment divergence that hinder 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.

IPA believes that the establishment of Codex high-level principles and guidance will have a High global impact:

- for the consistent interpretation and application of the definition of probiotics to help national authorities develop an appropriate regulatory framework to probiotics, and
- to ensure the consumer access to high quality and safe probiotic foods and food supplements.

Scope

IPA supports the scope of the new work as proposed in the EWG's revised discussion paper and the Project Document included in Appendix II.

¹ Health claims on probiotics are excluded from the scope of this work. Codex horizontal guidelines on claims are framed by the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).

IPA therefore supports the establishment of a 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 on aspects not framed by existing Codex standards.

In this sense, IPA supports the adoption of the Revised Project Document on the New Work Proposal for a Harmonized Probiotic Guidelines for Use in Foods and Food Supplements as presented in Appendix II of the EWG's Discussion Paper.

About IPA

The International Probiotics Association (IPA) is a global non-profit organization bringing together through its membership, the probiotic sector's stakeholders including but not limited to academia, scientists, health care professionals, consumers, industry and regulators. The IPA's mission is to promote the safe and efficacious use of probiotics throughout the world. Holding NGO status before Codex Alimentarius, and Observer status at ISO, the IPA is also recognized as the unified "Global Voice of Probiotics" around the world