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IPA Rationale for Harmonized Probiotic Guidelines

IPA considers the development of guidelines and a harmonized framework for probiotics is necessary to ensure and sustain quality probiotic products on a global scale.

Why is IPA proposing work in Codex?

IPA is working to ensure that products everywhere in the world that are intended to be marketed as “probiotics” meet a harmonized, science-based definition, and meet basic minimum criteria. As a globally recognized reference for standards on food products, a guidance document or standard in Codex can facilitate the application of the FAO/WHO recommendations that are already a global reference. IPA plans to build upon these existing recommendations, providing substantive guidance on aspects specific to probiotics, such as ingredient identification and manufacturing.

Codex guidelines on probiotics could address the existing recommendations (FAO/WHO, National frameworks) and provide substantive guidance on aspects specific to probiotics, such as:

- a) A clear definition (which does not always exist across national regulations and is not provided at Codex level);
- b) Criteria to be met;
- c) Safety / characterization of probiotics;
- d) Current manufacturing best practices ensuring quality;
- e) Appropriate content labelling;

These guidelines on the use of probiotics in food and food supplement could be used by the different countries as a reference for minimal standards for probiotics. Communications regarding the beneficial effects and/or health claims, remain the competence of national / transnational authorities.

Why is probiotic-specific guidance needed in Codex?

As defined by FAO/WHO, probiotics are live microorganisms that when administered in adequate amounts, confer a health benefit on the host. As dynamic as this definition is, it encompasses three main attributes that an increasing number of products labelled as “probiotics” do not meet.

The term “probiotics” is used more and more in several different products, with few adherence to the commonly referenced FAO/WHO definition. In addition to that, there seems to exist a mix/confusion between the identification of probiotics (factual nature/what probiotics are) and the specific benefits of probiotics (what probiotics do). This is mainly due to the fact that probiotics do not have clear status,

being considered as nutrients or at least acknowledging their specific and inherent characteristics which are the physiological effect attached to probiotics and the health benefits associated to them.

FAO/WHO definition encompasses three main attributes, living condition, Quantity/pattern of consumption and beneficial effect that probiotic must meet to consider a microorganism probiotic.

The goal would be to provide a guidance based on current best practices and learnings, ensuring safe and efficacious products that deliver clear and credible information to consumers.

What is out of scope for the Codex effort on probiotics?

The IPA approach does not seek to list specific requirements to demonstrate efficacy, or to introduce a strain-specific list claiming efficacy. In some cases, this is regulated at national level and Codex would not be the right forum as it could be in conflict with national lists and this is not the objective of the work. Moreover, it would be difficult to manage updates of such a list, as this would imply initiating the lengthy procedures required for updating the Codex standard.

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 promote the safe and efficacious use of probiotics throughout the world. Holding NGO status before Codex Alimentarius, the IPA is also recognized as the unified "Global Voice of Probiotics" around the world.