

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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OTHER BUSINESS AND FUTURE WORK

Comments of International Probiotics Association (IPA)

INTERNATIONAL PROBIOTICS ASSOCIATION (IPA)

Proposal for New Work on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements

Background

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. The importance of probiotic microorganisms to the health of the human population was recognized in addition to the growth of probiotic food and drinks that market health benefits. With a lack of international agreement of the assessment of safety and efficacy, the FAO/WHO Consultation intended to address methodologies for assessment of safety and efficacy and promote general guidelines.¹

Subsequently, an Expert Working Group was assembled to create a methodology for evaluation of probiotics and criteria for substantiating health claims for probiotic foods.²

The outcome of the Consultation and the Working Group both provided very general guidance for a newly growing recognition of the health benefit and consumer demand for probiotic foods, where a global regulatory landscape was lacking. The scope of these meetings did not include bio therapeutic agents nor did it include probiotics not used in food.

With the goal of enhancement of the overall safety and quality of food for consumers, these previous documents laid the groundwork for building guidelines or standards for probiotics. Due to technological advances, the probiotics industry now requires a broader scope that includes advancements in technology and the growing consumer demand for probiotic products used in foods and dietary supplements.

Rationale

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

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. As such, the probiotics industry recognizes the need and opportunity for development of a Codex Alimentarius guidance or standard to more clearly define the required characteristics of safe and efficacious probiotics, and to ensure the same level of quality and manufacturing requirements for all operators on the market. The ultimate goal is establishment of eligibility criteria to ensure consistent application at national and international levels by Codex member countries; available to promote human health and well-being.

Through the International Probiotics Association (IPA and IPA Europe), the Probiotics Industry has developed guidance documents that range from defining basic characteristics of probiotic organisms to Recommended Probiotics Best Practices, designed to provide guidance for industry and uniformity in areas such as stability programs and labelling.

IPA requests initiation of discussion with Codex to review the current situation within the probiotics industry, with the intent to move forward and to make progress towards a harmonized framework that includes essential requirements for probiotics.

We believe that this establishment of eligibility criteria and an organized framework for production of probiotic products will provide a guideline 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.

Recommendation of Proposed Work

We propose to work together as an industry to organize discussions within the Codex framework to build Guidelines and Standards for Probiotics that meet the FAO/WHO definition (2001 & 2002), for use in foods and dietary supplements. The intention is to work toward harmonization on a broader scale, including the many modern aspects of probiotics manufacturing, in addition to establishing unambiguous identification, characterization, safety, and efficacy. Following the scientific basis of Codex, we propose a systematic approach involving an International Risk Assessment, possibly through the Joint Expert Meetings on Nutrition (JEMNU) for initial review.

We propose to initiate discussions to build from the Consultation and Working Group guidance to further develop probiotic criteria that address the following:

1. Definition - The aspects of “live microorganisms”, “adequate amounts” and “a health benefit on the host” must be individually defined and addressed, as they are equally important requirements for all probiotic products.
2. Criteria – Building upon criteria introduced by the FAO/WHO Working Group² for a variety of intended uses in foods and dietary supplements, globally.
3. Safety - Establishment of safety criteria is essential for public health. A safety assessment specific for probiotics as live microorganisms will be proposed, and eliminate the need for unnecessary and non-validated methods, therefore we propose a scientific approach for those Genera and species with an established safe history of use in foods and dietary supplements and those newly established as probiotics, based on *in-vitro* testing, genomic mining and phenotypic analysis.
4. Manufacturing - Manufacturing should be addressed to indicate the most appropriate aspects of probiotic production within a closed, controlled system to provide utmost purity, quality and potency. Quality control and Quality assurance will be addressed in addition to a stability program.
5. Efficacy - The topic of efficacy will be based on the guidance within the Consultation¹. The aspect of combining strains and the resulting efficacy will also be discussed.

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.

For these reasons, IPA decided to initiate a New Work Proposal on probiotics guidelines and/or a Probiotics Standard at the Codex level which will provide agreed essential requirements and specifications for probiotics that contribute to protecting the health of consumers, and ensuring fair practices in food trade.

Scope

The scope of this document will include live microorganisms recognized to convey a health benefit to humans in appropriate, efficacious doses. Only live microorganisms intended to be added to foods or used to supplement the diet where scientific data has demonstrated a clear health benefit will be discussed.

This document is not intended for use in any aspects of production of biologics or pharmaceutical products.

References

¹ 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, October 1-4, 2001.

²Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food
London, Ontario, Canada, April 30 and May 1, 2002 (<ftp://ftp.fao.org/es/esn/food/wgreport2.pdf>)