

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 7

NFSDU/43 CRD 9

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

Forty-third Session

Düsseldorf, Germany

7 – 10 March with report adoption by virtual mode on 15 March 2023

### PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS

#### Proposal 2.1: Updated Self-assessment of proposed harmonized probiotic guidelines for use in foods and food supplements

*Prepared by Argentina and Malaysia*

#### 1. Impact on health of the target group

- *What is the target group of the proposed work (e.g., infants, the aged, patients, whole population, etc)?*
- *What is the potential of the proposed work to resolve, mitigate, prevent, or significantly reduce a consumer health risk?*
- *Describe the positive impact on health classify it into the high, medium or low*

##### **High 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 world scientific literature has indicated that probiotics can play important roles in immunological, digestive and respiratory functions. Evidence is emerging for their role in several other health conditions
- Probiotics therefore have great potential to resolve, mitigate, prevent or significantly reduce consumer health risks and hence able to improve health and quality of life. Probiotic intervention has the potential to significantly benefit many important health care issues that have a substantial health cost.
- These beneficial effects of probiotics are broadly acknowledged by health professionals, consumers and authorities;

#### 2. Impact on food safety

- *What is the potential of the proposed work to improve food safety?*
- *Describe the positive impact on food safety and classify it into the categories high, medium or low.*

##### **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 guideline that addresses 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 in order to recognize a strain as a safe probiotic
- Current Codex text does not adequately cover these and 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, who 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 do not meet these characterization and safety criteria are on sale to 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 to consumers

### 3. **Impact on trade practices**

- *What is the potential of the proposed work to reduce technical impediments to trade?*
- *Describe the positive impact on trade practices and classify it into high, medium or low.*

#### **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 hinder the marketing and promotion of probiotics in different parts of the world.
- *Lack of harmonization in industry practice and legislation often leads to issues and concerns for the probiotics regulators, industry, and even consumers in regard of quality, safety and labelling.*
  - 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 could lead to misuse of the “probiotic” term and to trade products as probiotics that do not comply with this concept. It has indeed 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 the consumer access to high quality, functional and safe probiotic foods, beverages 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.

### 4. **Global impact**

- *What is the potential of the proposal to resolve, mitigate, prevent, or significantly reduce a global issue?*
- *Describe the global impact of the proposal and classify it into the categories of high, medium or low.*

#### **High global impact**

The development of this harmonised probiotic guideline will have significant global impact on trade and health of consumers, as evidenced from the following:

- Probiotics containing products are distributed globally in some 200 countries. Use of probiotic in foods and beverages and supplement is in all continents of the globe, and in large amounts. Probiotic supplements hit \$6.09 Billion USD and Food and 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 populations 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 Nation’s 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 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*”.