

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 6.21

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

Forty-fourth Session

Dresden, Germany

(Comments by IPA)

### AGENDA ITEM 6.21 DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS

During the Physical Working Group (PWG) discussion on the Harmonized Probiotic Guidelines for Use in Foods and Food Supplements, the PWG Chairperson noted the need for clarification from supporting countries on what they required, considering the FAO/WHO Reports of 2001 and 2002.

The Project Document proposes to develop Codex guidelines on probiotics based on the FAO/WHO Reports of 2001 and 2002. Despite 20 years since the FAO/WHO Reports, there remains regulatory divergence globally on probiotics.

Codex serving as the key international reference for setting food safety standards and regulations, plays a vital role in helping countries adopt the FAO/WHO guidelines into their regulations.

Key recommendations from the 2002 FAO/WHO Report are actually reflected in the scope and main objectives of the Project Document for Codex Guidelines on Probiotics, such as for example:

**Recommendation 1: Adoption of the definition of probiotics as 'Live microorganisms which when administered in adequate amounts confer a health benefit on the host'.**

- This definition would form the basis of the Codex Guidelines. The establishment of a harmonized definition of probiotics as an ingredient category would help to clarify the use of the term probiotic.

**Recommendation 2: The Use and adoption of the guidelines in this report should be a prerequisite for calling a bacterial strain 'probiotic'.**

- The Codex Guidelines would set the general criteria for identifying strains as probiotics, including taxonomic identification, functional characterization, and safety assessment.

**Recommendation 3: Promotion of these guidelines at an international level**

- Codex Guidelines on Probiotics will promote the FAO/WHO recommendations, assisting national and regional authorities in incorporating them into legislation.

**Recommendation 4: Further development of methods (in vitro and in vivo) to evaluate the functionality and safety of probiotics.**

- The Codex Guidelines would recommend methods for the typing of strains and the counting of microorganisms as well as evaluating the safety of probiotics.

In light of all this, it is proposed to adopt this new work:

- to reach a practical consensus on how to apply the FAO/WHO guidance within the Codex framework.
- to focus the scope on the establishment of a harmonised definition, minimum safety and characterisation requirements, which were already indicated as essential criteria for the probiotic in the FAO/WHO 2001/02 guidelines.
- referring to the scientific guidance as given in FAO/WHO consultations reports of 2001 and 2002 on probiotics. Any expert advice, if needed, may be identified during the course of developing the harmonized guideline.