

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 11

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

Forty-first Session

Dusseldorf, Germany  
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### DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOOD AND DIETARY SUPPLEMENTS

*Comments by Indonesia, CRN, IADSA, IPA, YLFA*

#### INDONESIA

Indonesia wishes to express its appreciation to Argentina for preparing Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements. Indonesia would like to provide the following comment:

- Indonesia would like to request clarification on the following items:
  - 1) Para 6 regarding '*... infant foods should be excluded since safety was of concern due to a limited number of studies*' because most probiotic studies have been conducted on infant.
  - 2) Para 19 regarding statement '*traded internationally*' and propose to consider local and regional trade.
- Indonesia proposes to add the following items in the main aspects to be covered:
  - 1) Criteria for establishing positive lists and scientific evidence for their efficacy. The criteria for establishing a positive list should be included in the "Minimum safety and characterization criteria" section.
  - 2) Probiotics clinical trials, because there are currently no guidelines to prove the efficacy of probiotics.
  - 3) The use of multi-strain probiotics, including approaches that must be used and stages that must be passed for multi-strain products.

#### CRN – COUNCIL FOR RESPONSIBLE NUTRITION

CRN appreciates the delegation from Argentina's work invested in preparing the discussion paper on harmonized probiotic guidelines for use in food and dietary supplements; however, we have substantial concerns about the several aspects of the proposed work for the Committee and appreciate the opportunity to raise these issues with the CCNFSDU.

CRN believes that the FAO/WHO definition (2001) "*live microorganisms that, when administered in adequate amounts, confer a health benefit on the host*" is widely used as a basis for regulating probiotics across the globe and does not need to be revised at this time.

CRN further believes that the definition, safety, quality, claims and labeling for probiotics are, and can continue to be, aligned with current general FAO/WHO guidelines. For example, Codex has adopted principles and horizontal guidelines on labeling, claims, contaminants, safety and hygiene covering all foods, including dietary/food supplements. Creating microsegmented categories, each with their own unique Codex Standards, creates significant duplication and exhausts the Committee's resources performing repetitive work. This redundancy can lead to a plethora of unnecessary and unneeded agenda items for CCNFSDU, CCFL, CCMAS and other Codex Committees at a time of heavy workload, compressed or extended meeting days, and delegate confusion and fatigue.

Further, CRN remains confused, just as our members and many of the CCNFSDU delegations, as to whether the new work proposal covers ingredients or finished products—or both. This ambiguity has implications for how the proposed work could impact the global marketplace. Furthermore, we are perplexed regarding the supposed distinction between "benefits" and "claims." With the Codex Claims Guidelines

already in place and being used for every other dietary/food supplement making a claim for a health benefit, the new work proposal tries to indicate that the proposal is intended to address “health effects” and “health benefits,” which are framed to somehow be different from claims as addressed in the Codex Guidelines. They are not. Rather this new terminology is an effort to disguise the re-opening of claims evaluation, already addressed in the Codex Claims Guidelines, as new work, rather than the re-examination of established guidelines; the existing Codex Claim Guidelines have and will continue to provide adequate guidance to the industry for all dietary/food supplements including probiotics.

With tremendous growth in (1) the manufacture and trade in probiotics, and (2) the purchase and use (and re-purchase) by savvy consumers, the proposal fails to identify any significant trade barriers, food safety or public health concerns associated with products that are manufactured in accordance with Codex guidelines and national and regional regulations and standards.

Current national and regional measures (via domestic regulations and standards) are already in place to ensure the safety, efficacy and quality of dietary/food supplement products and ingredients. Setting specific Codex requirements for supplements containing probiotics could destabilize the regulatory landscape for all dietary/food supplements via encouraging the creation of a host of unique microsegmented standards. Indeed, we are already aware that possible category specific standards for protein and prebiotics are being prepared for possible consideration by CCNFSDU, with a watchful eye on the precedent that will be set by the Committee’s consideration of probiotics.

CRN believes that prioritization for new work is needed and very carefully managed, as it is well-known and constantly referred to by CAC and all of the Codex Committees that there are too many unnecessary proposals for new work and the time wasted on addressing, debating and deferring these proposals has been an unacceptable investment of time at Codex Committee meetings. New work of a truly high priority should be agreed upon by CCNFSDU in an objective, consistent and transparent manner.

CRN’s separate comments to the Committee’s discussion paper on prioritization are also relevant to this new work on probiotics as follows. CRN believes that true new work proposals should limit the CCNFSDU’s workload not irresponsibly enlarge it; rationale for new work should contain an estimation of the resources and time frame needed to address the new work; justification as to why CCNFSDU in particular (and/or Codex in general) is the best organization to undertake the new work; and that the likely outcome of embarking on new work does not unfairly or unnecessarily burden individual countries. New work should outline a problem and not offer a pre-determined solution, that is the job of the CCNFSDU physical and/or electronic Working Groups and the CCNFSDU delegates. Yet that is exactly what the Argentinian proposal on probiotics does. All these considerations counsel that the proposal on probiotics should be rejected.

CRN respectfully requests that the Codex CCNFSDU chair and secretariat consider our comments in the spirit in which they are being offered; to reject the addition of new work on probiotics on the above referenced grounds; and to foster relevant new work that is agreed as truly being needed via an independent, objective, consistent, and transparent fashion to manage the workload at the Codex Committee on Nutrition and Foods for Special Dietary Uses.

#### **IADSA - INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS**

The International Alliance of Dietary/Food Supplement Associations (IADSA) represents the global supplement sector. Within our membership are many hundreds of companies who manufacture and/or sell probiotic supplements across the world. Over the past 20 years IADSA has developed many publications and tools to help governments and industry to apply Codex measures to all food supplements, including quality, claims substantiation and product safety (<https://www.iadsa.org/resources>).

IADSA has considered carefully the proposal from Argentina to develop new work relating to probiotics in foods and food supplements. We note that the Discussion Paper and Project Document remain essentially the same as those proposed in 2018.

IADSA still considers that this new work should not be initiated by the Committee.

We note that many of the provisions suggested in the draft Standard/Guidelines are already addressed by other Codex measures. For example, Codex has adopted principles and horizontal guidelines on labelling, claims, contaminants, safety and hygiene covering all foods, including supplements. We therefore consider that the proposal risks creating significant duplication, by repeating in a vertical guideline what has already been agreed. The document also prescribes establishing a definition of probiotics on the basis of the text developed by FAO/WHO as revised by Hill et al., that is “Live microorganisms that, when administered in adequate amounts, confer a health benefit to the host”. This definition is already widely used as a basis for regulating probiotics across the world. In view of the above, we do not consider that it is good use of Codex resources to address these issues again.

In addition, if potential new work will mean deviating from agreed Codex guidelines and standards, IADSA considers that it is essential to be very cautious. Our analysis of the Argentinian submission concludes that deviation from the Codex Claims Guidelines is implied. While the scope of the proposal is stated only as quality, safety and labelling, the substantiation of the probiotic benefits is included as another core objective of the work with multiple references to probiotic benefits in the Discussion Paper and Project Document. For example, the discussion paper contains references to "...probiotics are most effective in conditions related to digestive tract, the immune system, and respiratory functions" (para8), to the health benefits of probiotics (para 9), to their beneficial effects (para 11), "... the importance of probiotic microorganisms to the health of the human population" (para 24), "... for probiotics that contribute protecting the health of consumers, ..." (para 34).

The Codex definition of a health claim states that 'Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health'. We are however confused that the Discussion Paper (footnote page 2) states that health benefits should not be understood as health claims. The project document also refers to functional characterisation that is defined by the Joint FAO/WHO report on drafting guidelines for the evaluation of probiotics in food (30 April-1 May 2002). It should therefore be understood that the proposed new work would address the substantiation of probiotic benefits, differing from or even conflicting with the Codex Claims Guidelines.

Before embarking on this direction, full consideration should therefore be given to the implications of this and, in particular, the precedent this could set for the substantiation of claims for all food ingredients and food products.

Finally, IADSA notes that the Argentinian proposal already addresses detailed elements of any future proposal, covering minimum criteria for the safety and characterisation (taxonomic and functional characterisation). These are subject to multiple interpretations.

Therefore, IADSA has major reservations on the approach and detailed content as set out in the papers and does not consider that this should be agreed as new work by the Committee.

#### **IPA – INTERNATIONAL PROBIOTICS ASSOCIATION**

The International Probiotics Association (IPA) wishes to thank Argentina for redrafting the Discussion Paper on harmonized probiotic guidelines for use in foods and dietary supplements for consideration at CCNFSDU41, under agenda item 11.

IPA believes that the proposal to start new work on probiotic guidelines prepared by Argentina has the potential to be highly significant for the food and food supplement sector.

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 used by the different countries as a reference for minimal criteria for probiotics and will undoubtedly ensure and sustain the quality of probiotic products and facilitate international trade and enable fair and transparent practices. In addition, the term "probiotic" is also used in the Codex Regional Standard for Doogh (CXS 332R-2018) adopted for the Near East region.

IPA therefore supports starting new work to develop Codex guidelines for the use of probiotics in food and food supplements (CX/NFSDU 19/41/11, circulated by the Codex Secretariat), to establish a definition with minimum characterization requirements as well as labelling parameters for probiotics for use as an ingredient in food and dietary supplements on aspects not framed by existing Codex standards.

In this sense, IPA supports the adoption of the Project Document as presented in Appendix 5 of the Discussion Paper on harmonized probiotic guidelines for use in foods and dietary supplements, that is, Codex document CX/NFSDU 19/41/11. However, IPA would like to propose one amendment in Section 3 of the Project Document which deals with the 'Main Aspects to be Covered'. IPA proposes to replace the paragraph in sub-section 'iv. Food Labelling' by a more general text as follows since the identification of the specific labelling parameters under this section would be addressed when drafting the proposed draft guidelines:

#### iv. Food Labelling

In addition to the provisions for labelling in accordance with the General Standard for Labelling of Prepackaged Foods (CXS 1-1985), additional specific labelling requirements for probiotics will be considered. ~~it should be applied the following specific provisions: name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients; amount of viable cells of total probiotic microorganisms (CFU/g); name of the food; serving size and storage conditions.~~

Subject to CCNFSDU's approval to start new work on Codex harmonized guidelines for the use of probiotics in food and food supplements, IPA supports the establishment of an electronic Working Group (eWG) to develop the proposed draft Guidelines for discussion at the next session of the CCNFSDU. Should an eWG be established, IPA is keen to actively contribute for this important work, in order to report best practices of the probiotic sector's stakeholders on the various academic, scientific, regulatory and industry levels from a global perspective.

#### **YLFA - YOGHURT AND LIVE FERMENTED MILKS ASSOCIATION**

The *Yoghurt and Live Fermented Milks association* thanks Argentina for having issued a Discussion Paper on harmonized probiotic guidelines for use in foods and dietary supplements, submitted for consideration to the CCNFSDU41, under agenda item 11.

Together with IPA and IDF, YLFA strongly supports the need for a Codex Standard providing a definition of the term "probiotic", with minimum characterization requirements that comply with the FAO/WHO expert reports published 20 years ago as well as clear rules for labelling.

YLFA is committed to defending the concept of *live microorganisms (in fermented dairy products)* and hence the protection of the definition of live products and their conditions of use. As outlined by Argentina, the beneficial effects of food with added live microorganisms (probiotics) on human health are being increasingly promoted by health professionals. However, the current lack of harmonization or absence of rules on probiotics lead to a clear misuse of the term "probiotic" (especially via e-trade) and doesn't help in consumer protection.

Therefore, the development of harmonized guidelines, used by different countries as a reference for a harmonized definition and minimal criteria for probiotics would undoubtedly ensure and sustain the quality of probiotic products, facilitate international trade and enable fair and transparent practices.

A standard on probiotics would also clarify the significance of another Codex standard, the Codex Regional Standard for Doogh (CXS 332R-2018) that uses the term "probiotic" without defining it.

Finally, when the "new work" on probiotics is accepted by the CCNFSDU, YLFA welcomes the creation of an e-WG where, amongst others, the input of Codex members that already have national probiotic regulation would be highly valuable in assisting Argentina.

YLFA thanks the Committee for taking this comment into consideration.