

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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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

Fortieth Session

Berlin, Germany

26 – 30 November 2018

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS

Comments of Kenya, CRN, IADSA, IDF and IPA

KENYA

General comment:

Kenya comments Argentina for developing this discussion paper. However, upon reviewing the aspects that will be covered by the project view it as possibly being beyond the scope of CCNFSDU. We therefore propose that this work possibly be presented to either food hygiene committee or an Adhoc committee be established to consider this work.

CRN - Council for Responsible Nutrition

The Council for Responsible Nutrition (CRN)¹ is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements, many of which are multinational and market and sell ingredients, finished products and services globally.

CRN in consultation with its member companies examined the “Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements (Prepared by Argentina), CX/NFSDU 18/40/12 with Project Document (Appendix 5) and Proposed Draft Standard (Appendix 6)” and have the following comments.

Duplication of existing Codex Guidelines

CRN notes that the development of probiotic guidelines by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is an unnecessary duplication of work already completed by Codex. As examples, there are principles and guidelines for labeling (General Standard for Labelling of Prepackaged Foods (CODEX STAN 1-1985)²), claims (Nutrition and Health Claims (CAC/GL 23-1997)³), contaminants (Code of Practice Concerning Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

² http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%252FBSTAN%252B1-1985%252FCXS_001e.pdf

³ <http://www.fao.org/ag/humannutrition/32444-09f5545b8abe9a0c3baf01a4502ac36e4.pdf>

49-2001⁴), and safety and hygiene (General Principles of Food Hygiene (CAC/RCP 1-1969)⁵). These principles and guidelines are applicable to all foods/foodstuffs and thus dietary/food supplements, which would include this new work on probiotics. Codex energies need to focus on truly new work and not standards development for micro-segmentation of food categories. Further, the development of a recognized and acceptable definition of probiotics has already been done by WHO in 2003 (“Live microorganisms which when administered in adequate amounts confer a health benefit on the host”⁶), and virtually all relevant regulatory jurisdictions are already comfortable with and utilizing this WHO definition.

Codex Alimentarius Procedures

CRN is curious and dismayed that we never received a “Discussion Paper”, a “Project Document”, or a “proposed Draft Standard.” Rather, these three distinct items arrived as one single co-mingled document. As CRN actively participates in both electronic Working Groups (eWGs) and physical Working Groups (pWGs) on issues of importance to our members, and the overall dietary and food supplement sector, not being offered the step-wise opportunity to participate and provide relevant information and engage in discussion toward a mutually acceptable standard appears to be contrary to the mission of Codex Alimentarius standard development procedures in a “well defined, open and transparent” fashion.

Codex Alimentarius Commission Operations⁷

To summarize the activity to date; (1) an initial proposal was submitted (as done at the 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in early December, 2017 in Berlin by the International Probiotics Association (IPA)). The Argentinian delegation expressed support for this work and offered to lead the development of (2) a discussion paper. CRN along with other countries and non-governmental organizations (NGOs) anticipated an opportunity to review such a (2) discussion paper and offer to engage in an electronic Working Group on this activity and this **did not** occur. The discussion paper is the basis for developing (3) a project proposal which would go to the Codex Alimentarius Commission or Codex Executive Committee for a decision to move forward. At that point, a subsidiary body is selected, i.e., which Codex committee, CCNFSDU, CCFL or some other committee and the possibility of a specialized task force, often an electronic Working Group. To our knowledge, this step was also skipped in the haste to prepare a co-mingled document which has just recently been shared by Argentina. With engagement of all stakeholders, national delegations and NGOs, (4) a proposed draft standard is developed, often by an eWG, and then circulated for comment. Considering the technical and scientific aspects addressed in the initial proposal, there was every expectation that such technical and scientific support and input would be needed to develop an eventual standard reflective of the needs and expectations of both the industry and the regulatory community. CRN and its members stand ready willing and able to offer such expertise via the Codex Step-wise process and eWG model. It appears Codex’s own processes were not observed in this matter.

CONCLUSION:

CRN is concerned that the current “Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements (Prepared by Argentina), CX/NFSDU 18/40/12 with Project Document (Appendix 5) and Proposed Draft Standard (Appendix 6)” sets an unacceptable precedence and that in the future, country delegations and/or NGOs may use the example of an micro-segmented food category to drive political and/or market advantages outside the “well defined, open and transparent” mandate of the Codex Alimentarius process. If there is overt and opaque willingness to bypass these processes when it is seemingly expedient to do so, how can affected stakeholders now and in the future have their voices and concerns be part of the dialog? Codex must address this proposed activity and give ALL of the delegations and observers equal seating at the table.

CRN at this time **DOES NOT SUPPORT** new work on the “Proposed Draft Standard / Guidelines on Probiotics” (Appendix 6 of CX/NFSDU 18/40/12) at the November 26-30, 2018 Codex Committee on Nutrition and Foods for

⁴ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BRCP%2B49-2001%252FCXP_049e.pdf

⁵ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BRCP%2B1-1969%252FCXP_001e.pdf

⁶ FAO/WHO. Probiotics in Food. Health and Nutritional Properties and Guidelines for Evaluation. in FAO Food and Nutrition Paper no. 85 Roma, Italy, 2006.

⁷ THE CODEX SYSTEM: THE CODEX ALIMENTARIUS COMMISSION AND HOW IT WORKS (<http://www.fao.org/docrep/008/y7867e/y7867e05.htm>)

Special Dietary Uses because the document(s) prepared by Argentina are (1) redundant to current Codex Standards that have been developed and (2) the documents received are not per Codex procedures as they are reflective of the proposed draft standard prematurely reaching Codex Step 3 without the intervening Step 1 and Step 2.

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.

IADSA has considered carefully the proposal from Argentina to develop new work relating to probiotics in foods and food supplements. We consider that this new work should not be agreed by the Committee for the following reasons:

1. We note that many of the provisions suggested in the draft Standard/Guidelines are already addressed by other Codex measures. Codex has adopted principles and guidelines on, for example, labelling, claims, contaminants, safety and hygiene covering all foods including supplements. Hence, the proposal would create significant duplication.
2. We also note that WHO has already addressed the definition and characterisation of probiotics in its guidelines of 2003 that is widely used as a reference point.
3. There is confusion about what the new work would cover. What is stated in the Discussion Paper, the Project Document and the draft Standard/Guidelines would appear to be in conflict. For example, the scope of the Discussion Paper applies exclusively to the development of Standards/Guidelines for probiotics used as food ingredients (raw materials). However, in the Project Document and draft Standard/Guidelines, there is a reference to 'foods with probiotics', including labelling requirements such as a definition of 'foods with probiotics' and the name of those foods.

In addition, IADSA has many concerns regarding the specific content of the draft Standard/Guidelines. For example, in relation to point 3) above, if the proposal were to cover both probiotics used as ingredients and finished products by establishing a new food category called 'food with probiotics', this terminology and its interpretation would conflict with existing national and regional provisions and would create a precedent for the creation of other new food categories based on their composition.

Since Codex has not yet taken a decision to move ahead on the new work or not, IADSA understands that it would not be appropriate to provide any specific, detailed comments on the draft Standard/Guidelines for the 40th CCNSFDU meeting.

IDF - International Dairy Federation

In principles, IDF supports the proposal of Argentina to establish guidelines for the use of probiotics in foods and dietary supplements.

Subject to approval by the committee to develop guidelines for the use of probiotics in foods and dietary supplements, IDF would like to offer its participation in the work as it is believed modifications are needed to the proposed document.

It should be more explicit on its scope, purpose, and limits. The definition of a probiotic strain, inactivated or not, a probiotic food product should be established for food and not medical purpose. IDF would like to see the focus on the labelling rules regarding the use of "probiotic".

Safety and health benefit demonstration guidelines should not be detailed in the document but referred to scientific evidence presently available. Of note, a positive list approach such as IDF's one for food culture⁸, does not apply to probiotic strain candidates.

IPA - International Probiotics Association

The International Probiotics Association (IPA) believes that the proposal to start new work on probiotic guidelines led by Argentina has the potential to be highly significant for the food and food supplement sector. IPA therefore

⁸ Bulletin of the IDF 455/ 2012: Safety Demonstration of Microbial Food Cultures (MFC) in Fermented Food Products (accessed on 5 November 2018 <https://store.fil-idf.org/product/safety-demonstration-of-microbial-food-cultures-mfc-in-fermented-food-products-2/>)

supports starting new work to develop Codex⁹ guidelines for the use of probiotics in food and food supplements on the aspects not framed by existing CODEX standards.

IPA wishes to thank Argentina for its initiative in developing the Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements. However, there is still some work to be done in terms of clarifying the scope, purpose and limits. For this purpose, IPA has prepared detailed comments and input. Should a working group be established, either in session or as an eWG, IPA is keen to actively contribute.

IPA also considers that a more global approach is required, focused on setting a definition and providing the parameters for probiotics as a total category, and to develop Codex guidelines which are inclusive of the existing best practices and allow innovation. In this regard, aspects such as a clear definition of probiotics (as there are currently different interpretations in different countries), uniform criteria to be met, characterization of probiotics, expression of count and labelling and content communication related to probiotics are essential and should not be linked to the communication on the beneficial effects of probiotics. The differentiation between the parameters for probiotics as a total category and the conditions for claiming the health benefits of probiotics should be much clearer in that regard.

⁹ CX/NFSDU 18/40/12 circulated by the Codex Secretariat