

7 November 2019

CCNFSDU41: Discussion paper on harmonized probiotic guidelines for use in food and dietary supplements¹

ISDI comments on CCNFSDU41: Agenda Item 11

ISDI would like to thank Argentina for their extensive work in preparing this project document and discussion paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements.

ISDI has carefully reviewed the 2019 Discussion Paper and Project Document with consideration of the Conclusions on this topic from CCNFSDU40 (REP 19/NFSDU) which stated that further elaboration on "the sections on scope, definition as well as health and trade concerns in particular" was agreed by the Committee. We note that the document has been streamlined compared to the 2018 document (for example, Draft Guideline has been omitted).

The stated Scope (para 17) focuses on "definition, minimum characterization requirements, safety criteria, quality and labelling criteria", and does propose to reference existing Codex texts for some of these components. However, we note that multiple references to the scope throughout the document are less consistent and result in confusion about the intended scope of the guidance.

ISDI calls attention to the appropriateness of addressing a number of provisions in the future Guidelines against existing texts:

- FAO/WHO Guidelines, 2002,^{1,2} which clearly describe efficacy studies
- In Codex, where safety, manufacturing and labelling requirements of probiotics as a food/food ingredient are elements already covered by several horizontal Standards and Guidelines, including among others:
 - General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)
 - General Principles of Food Hygiene (CXC 1-1969)
 - General Standard for Labelling of Prepackaged Foods (CXS 1-1985)
 - General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CXS 146-1985)
 - Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) along with its annex regarding, "Recommendations on the scientific substantiation of health claims".

In addition, a number of countries have already developed national provisions based on the FAO/WHO Guidelines^{1,2}.

Moreover, ISDI notes that the Discussion Paper also addresses the Codex Standard for Fermented Milks (CXS 243-2003). This is equally true for Codex texts on Foods for Special Dietary Uses (FSDU) whereby the concept of "optional ingredients" covers probiotics used as an ingredient in these foods.

Finally, ISDI notes that, within CCNFSDU41, agenda item 10 addresses "Prioritization mechanism to better manage the work of CCNFSDU" and ISDI is of the view that priority of CCNFSDU should be given to finalizing the current work on Standards/Guidelines for which there are currently no international Guidelines, or that need revision rather than initiating new work for topics which are already covered by existing Codex or FAO/WHO documents.

References

1 Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties in Food including Powder Milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1-4 October 2001.

2 Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food, London, Ontario, Canada, 30 April – 1 May 2002.

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 $^{^{\}rm 1}$ For the background information, please refer to CX/NFSDU 19/41/11.