



Council for Responsible Nutrition

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VIA ELECTRONIC SUBMISSION

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Re: Discussion paper on harmonized probiotic guidelines for use in food and dietary supplements – Prepared by Argentina (CX/NFSDU 19/41/11)

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

¹ The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter [@CRN_Supplements](https://twitter.com/CRN_Supplements), [Facebook](https://www.facebook.com/CRNUSA), and [LinkedIn](https://www.linkedin.com/company/crnusa).

are multinational and already actively selling ingredients, finished products and services globally. CRN has been an active participant at Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) meetings and on relevant electronic Working Groups (eWGs) regarding a number of industry-specific issues and concerns. CRN has championed current scientific-thinking and organized and helped promote scientific conferences and symposia focused on public health objectives.

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 CCFNSDU.

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 CCFNSDU 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 CCFNSDU, 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 CCFNSDU 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 CCFNSDU'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 CCFNSDU 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 CCFNSDU physical and/or electronic Working Groups and the CCFNSDU 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 CCFNSDU 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.

CRN will also submit these comments directly to the US Codex delegation.

Respectfully submitted,



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