CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 6.21 **CRD24**

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

Forty-fourth Session

Dresden, Germany

(Comments by Malaysia)

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

On behalf of Argentina and China, Chair and Co-chair of the Discussion Paper on Harmonised Probiotic Guidelines, is pleased to inform the Chair and Committee Members of CCNFSDU44 that we have completed the task of organising two rounds of consultations of the EWG to develop a revised Discussion Paper and Project Document on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements, as mandated by the 43rd CCNFSDU. As can be seen from the report in CX/NFSDU 24/44/6 Add. 1, a great majority of the EWG members, that is, 14 of the 17 EWG participating members supported or had no objections to the proposal to approve new work to develop a harmonised probiotic guideline. These members expressed the need for the probiotic guideline for the protection of consumer interest, to improve food safety and to greatly promote fair practices in food trade. We also obtained useful input from members of the EWG on how to further elaborate and refine this proposal, as well as how to address concerns shared by a few members of this Committee.

We are pleased to share with the Committee that the two rounds of consultations of the EWG have responded and addressed the three main aspects of the terms of reference of the EWG. The revised discussion paper and project document have now clearly defined the scope of the proposal, addressed the impact on food safety and clarified with regard to the need for scientific advice.

With regard to the scope of this proposed new work, the majority of the EWG members support the scope as follows:

- development of a general harmonized guidance on adequate minimum characterization and safety requirements of probiotic microorganisms,
- elaboration of labelling requirements specific to probiotic microorganisms; and
- that it **excludes** health claims as well as the evaluation of the safety and efficacy of specific strains.

Establishing the assessment criteria for adequate safety will be a key aspect that the proposed guideline will address as we expect the document would have high positive impact on food safety.

With regard to scientific advice for this new work proposal, most members of the EWG are of the opinion that a key scientific reference would be the FAO/WHO consultation report of 2001. Although the report was published some 20 years ago, much of the basic information are still useful for developing the proposed guideline. In addition, the large number of scientific publications and work of recognized authoritative scientific bodies that have become available can be referred for further scientific advice. Several pertinent references from recognized authoritative organizations are provided in appendix 1. Any other expert advice, if needed, may be identified during the process of development of the guideline, and sourced from the numerous research groups across the globe.

In relation to the definition of probiotics, one of the key point discussed, EWG Members generally supported the use of the definition as provided in the FAO/WHO 2001 consultation report and are of the opinion that no major revision is needed. It can also be noted that the main elements of the definition are cited by many research groups and authorities. However, in order to minimize the potential confusion that the definition is an implied health claim, it was suggested to use the term “physiological effects” instead of “health benefits”, the latter being in the FAO/WHO 2001 report. A working definition is proposed as follows, as contained in paragraph 17 of the discussion paper:

> "*Probiotic" means live microorganisms, when administered in adequate amounts, have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities*".

The chair and co-chairs are of the opinion that after three sessions of the CCNFSDU and two rounds of consultations among EWG members, the discussion paper and project document have addressed the main concerns raised by some members and have incorporated the suggestions of other members. We find this proposed framework ready to proceed to next steps. It is pertinent to take note that, as also the case for other new work proposals, many details, such as the characterization and general safety requirements and

methodologies to be used and labelling requirements are not included in this current document. These details will be adequately developed once the new work is approved and the development of the guideline proceeds. During this process, all members of the Committee will have ample opportunities to provide input.

It is clear that there is general support from many countries from different regions of the world for the proposal and to initiate new work for the development a harmonized probiotic guideline by CCNFSDU. These countries have stated very clearly that the products are in their markets and that they require harmonized regulatory guidance for foods and food supplements containing probiotics. Countries have repeatedly expressed strong support for this new work over the years, recognizing the significant potential of a harmonized Codex guideline to positively impact public health, enhance food safety, and promote fair trade practices.

We therefore respectfully urge CCNFSDU44 to approve, with the highest priority, this proposal for new work for a harmonized guideline on probiotics for use in foods and food supplements, as presented in the Project Document contained in Appendix II of CX/NFSDU 24/44/6 Add. 1.

Appendix 1

Selected key references on **characterisation and safety assessment methodologies** for probiotics.

(listed according to year of publication)

1. Mary Ellen Sanders, Louis M.A. Akkermans, Dirk Haller, Cathy Hammerman, James T. Heimbach, Gabriele Hörmannsperger & Geert Huys (2010). Safety assessment of probiotics for human use, Gut Microbes, 1:3, 164-185. https://doi.org/10.4161/gmic.1.3.12127
2. FAO/WHO (2014) Principles and Guidelines for the Conduct of Microbiological Risk Assessment Cac/Gl 30-1999, And Amendments 2012,2014. Codex Alimentarius Commission. Accessible from: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B30-1999%252FCXG_030e_2014.pdf
3. Siamak Yazdankhah, Ragnhild Halvorsen, Jørgen Lassen and Judith Narvhus (2014). Guidelines for assessment of safety aspects of probiotic (food) products. Opinion of the panel on biological hazards of the Norwegian scientific committee for food safety. VKM Report 2014: 05. https://vkm.no/download/18.13735ab315cffecbb5138800/1499434394387/21d75addae.pdf
4. Binda S, Hill C, Johansen E, Obis D, Pot B, Sanders ME, Tremblay A and Ouwehand AC (2020) Criteria to Qualify Microorganisms as “Probiotic” in Foods and Dietary Supplements. Front. Microbiol. 11:1662. https://doi.org/10.3389/fmicb.2020.01662.
5. Cerk K and Aguilera-Gomez M (2022). Microbiota analysis for risk assessment: evaluation of hazardous dietary substances and its potential role on the gut microbiome variability and dysbiosis. EFSA Journal 2022;20(S1): e200404, 16 pp. https://doi.org/10.2903/j.efsa.2022.e200404.
6. Amy L. Roe, Marie-Eve Boyte, Chris A. Elkins, Virginia S. Goldman, James Heimbach, Emily Madden, Hellen Oketch-Rabah, Mary Ellen Sanders, Jay Sirois, Amy Smith (2022). Considerations for determining the safety of probiotics: A USP perspective. Regul Toxicol Pharmacol . 136: 105266. https://doi.org/10.1016/j.yrtph.2022.105266.
7. Marie-Eve Boyte, Nadeem Akhtar, Binu Koshy & Amy L. Roe (2024). A Review of Probiotic Ingredient Safety Supporting Monograph Development Conducted by the United States Pharmacopeia (USP), Journal of Dietary Supplements, https://doi.org/10.1080/19390211.2024.2314488
8. European Food Safety Authority (EFSA) (2024). EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain. EFSA Journal. https://doi.org/10.2903/j.efsa.2024.8912