INTERNATIONAL PROBIOTICS ASSOCIATION EUROPE[1]

10 Key Questions on the Use of the Term 'Probiotic' in Europe

Brussels, 22 January 2025

1. **Q: What is the significance of the word 'probiotic' food and food supplements?**

A: 'Probiotic' food and food supplements refer to products that contain live microorganisms, usually bacteria, that when consumed in adequate amounts and under certain conditions, can positively impact in maintaining or supporting the functions of the body associated with good health or performance. These microorganisms have been integrated into a wide variety of food, food supplement and beverage products. While they are associated with potential benefits, such as enhancing gut health, digestion, and the immune system, it's important to note that the term "probiotic" itself refers to a category of products and does not constitute specific health claim.

2. **Q: How is the term 'probiotic' currently used in Europe and worldwide?**

A: The term 'probiotic' is currently used both in Europe and worldwide to describe a category of products and ingredients that shares certain characteristics. However, there is a lack of formal criteria in the EU for identifying probiotic products and ingredients, leaving room for misuse of the "probiotic" label and misinterpretation of the concept. An increasing number of European countries are implementing national rules allowing the use of the term 'probiotic' on food and food supplements.

3. **Q: On 19 December 2023, the European Ombudsman opened an inquiry, requesting the European Commission to provide further clarifications on why it considers probiotic foods and food supplements should systematically be treated as health claims. However, the Ombudsman ultimately decided to close the case, finding no maladministration by the European Commission. Has anything substantial changed following this conclusion?**

A: No. Despite the fact that over a third of the EU Member States indicate at National level that "probiotics" can be classified as a category of ingredients and/or as nutrition claims, the Ombudsman

[1] IPA Europe is the European chapter of IPA, the International Probiotics Association; it was established in Brussels in 2015. The members of IPA Europe are Companies directly engaged in the manufacture of probiotic cultures or probiotic foods, supplements, nutritionals or therapeutic products. The IPA Europe mission is: to gain acceptance of the term "probiotic" throughout Europe as a defined category and to create a favourable environment for probiotics in Europe.

maintains that there is no legal uncertainty, since the European Commission is confirming the well-known approach, and in practise do not offer any solution.

In an overly caution approach, the Ombudsman estimated that the Commission's interpretation is reasonable, asserting it aligns with the primary goal of European Food Law – consumer protection. This position is based on the EC Guidance of 2007 (Guidance on the implementation of regulation No 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health). However, the EC Guidance of 2007 is outdated and not legally binding, and this stance does not address the current request of better rules and consumer clarity, which prompted the enquiry of the Ombudsman.

4. **Q: What would the EU require in terms of 'scientific evidence' before allowing the use of 'probiotics' as a health claim?**

A: 'Probiotics' is a broad category, which means that the health claims requirements, which are specific to a particular ingredient or strain, cannot be satisfied here. The expression "contains probiotics" merely describes the substance or category of substances as a factual statement. This differs from claiming a specific health effect, which involves describing or implying a function or impact on health. As it stands, the use of the term should not require a health claim assessment by EFSA, as long as no reference to a specific health effect is made.

5. **Q: Does this conclusion of the Ombudsman resolute make it less likely future complaints will be made?**

A: No, quite the opposite. This decision, which fails to offer a way out of this uncertainty in the EU, has opened up more avenues for discussion. Several industry stakeholders have already voiced their confusion about this decision that is leaving business operators without a level playing field to compete fairly and is depriving consumers of the information they are looking for. IPA Europe remains committed to exposing the inconsistencies of this interpretation and addressing the resulting dysfunctions it creates within the European market.

6. **Q: What is the impact of this conclusion on the institutions and on the possibility that the EU will change its mind on the use of 'probiotics' as a health claim?**

A: Within the Institutions, this decision has little to no impact. The role of the Ombudsman is not to make the law, but to identify malfunctions, which he did not find in this case. This means that today there is no pressure on the European Commission, which will maintain its position. Nonetheless, IPA Europe will explore other avenues to raise awareness and advocate for change.

7. **Q: What are the proposal to better regulate the use of the term probiotic in the EU ?**

A: Since the current interpretation the European Commission do not reflect the reality anymore, we believe that the initial step should be to withdraw the outdated EC Guidance of 2007. [2]As this type of document holds no formal legal status, the process should be straightforward.

The expression 'contains probiotics' is a factual information, indicating the name of substances, and complying with the requirements of the Nutrition and health claim regulation (NHCR) n° 1924/2006 "contains "(the name of nutrient or other substance that characterise the product)". Also, according to Directive 2002/46/EC relating to food supplements, Article 6. 2, 'probiotic' should be used on the label of the products as a mandatory category term for food supplements. Compliance with this directive serves as legal reference for several Member States. These legal references for probiotic food and food supplements for widely used bacteria strains, accompanied by some conditions of use, can provide greater clarity.

Unfortunately, the Commission opted to disregard it and maintains the original stance without considering the potential benefits of a more balanced approach.

8. **Q: Why is there a difference of opinion between the EC and the FAO/WHO definition with regards to the health benefits of probiotics?**

A: The European Commission always declared to endorse the WHO/FAO[3] definition but, in practice, altered the conditions, reclassifying 'probiotic' as a health claim only, that require further EFSA assessment. It should be noted that the documentation "Defining and measuring the health benefits of probiotics" in the WHO/FAO 2001 report, item 5.3, already provides examples of the generally accepted scientific data at that time. This was the background for the probiotic definition from WHO/FAO, proving the scientific evidence already in 2001. As such, the European Commission refers to the WHO/FAO definition but does not recognize the scientific data supporting the definition. This makes no sense.

9. **Q: Will the European Commission initiate a formal notice towards the Countries that adopted a national interpretation about the use of the term probiotic? (the European Commission can activate the "EU pilot procedure" which consists in exchange of information; the decision to go to a formal step is very political).**

A: The Commission can opt to issue a formal request for compliance, if it concludes that a country is failing to meet its obligations under EU law. The current situation, as evidenced by numerous initiatives from Member States and diverse legal references, could have already provided sufficient grounds for

[2] Guidance on the implementation of Regulation n. 1924/2006 on Nutrition and Health Claims made on Food https://food.ec.europa.eu/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf

[3] Report of a joint FAO/WHO Expert Consultation on Evaluation if Health and Nutritional Properties of Probiotics, 2001 https://openknowledge.fao.org/server/api/core/bitstreams/382476b3-4d54-4175-803f-2f26f3526256/content

the European Commission. However, presenting detailed arguments for each country within this complex legal landscape is likely to pose a significant challenge.

10. What is the proposed solution to address the lack of criteria for probiotic products/ingredients?

A: To ensure consistency and provide clarity for consumers, it is essential to establish clear criteria for identifying probiotic products and ingredients. In a joint activity, IPA Europe Scientific experts and the International Scientific Association for Probiotics and Prebiotics (ISAPP) have identified 4 science-based criteria as a prerequisite to correctly define "what is a 'probiotic microorganism' in foods and dietary supplements": probiotics must have defined contents, appropriate viable count at end of shelf life, must be safe for their intended use and documented by suitable scientific evidence. These 4 criteria are acknowledged in the open-access paper "Criteria to qualify microorganisms as 'probiotic' in foods and dietary supplements" published on 24th July 2020 in Frontiers in Microbiology.

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