INTERNATIONAL PROBIOTICS ASSOCIATION EUROPE[1]

Ombudsman's Conclusion on Probiotics: A Missed Opportunity to Clarify Legal Uncertainty and Meet Consumer Demand

PRESS RELEASE

Brussels, 10 January 2025

The global probiotic market accounts for about US $ 50 Billion in 2023, with forecasts confirming an increasing trend in 2024. The market continues to expand with the globalisation of the online sales, which are driven by Europe, with almost 50% of online probiotic supplements sourced from outside Europe. The EU market was on the top global market until 2009, but now ranks third, after China and US. In Europe, the retail value of probiotics, (sour milk products, yoghurts & dairy based drinking products, food supplements), was around € 10 Billion in 2023.

The European probiotic industry always supported the Nutrition and Health Claims Regulation (NHCR, EC 1924/2006) as an effective regulatory tool to ensure transparent and accurate communication to consumers on the European market. However, the interpretation regarding probiotics, had failed to meet its original objectives and, as a result, has caused significant challenges for both consumers and stakeholders.

Background. On 19th December 2023, following a request of the Association, the Ombudsman opened an inquiry to investigate how the European Commission had addressed certain concerns raised by the complainant. Specifically, the Commission was requested to provide further clarifications on why it considers that the probiotic foods and food supplements should systematically be considered as a health claim. In doing so, the Commission was requested to explain, more specifically, what elements underpin this choice, other than beyond and despite the definition set out in the 2001 Report of a Joint FAO/WHO Expert Consultation on probiotics.

IPA Europe welcomed the Ombudsman's acknowledgment in December 2023 that further clarifications from the European Commission were needed. The Ombudsman's role in cases of divergent legal interpretations is to assess whether the EU administration's interpretation of the relevant legal framework is reasonable and aligns with its guiding administrative principles. However, following the inquiry into the classification of "probiotics" within the EU, the Ombudsman finally decided to close the case, finding no maladministration by the European Commission.

[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, nutritional 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.

While we respect the Ombudsman's role, its conclusions fail to address the main critical concerns raised by stakeholders. Moreover, in absence of definitive evidence that the term "probiotics" misleads consumers, the Commission's decision to adopt a restrictive interpretation to minimize any risk of misunderstanding appears overly cautious.

While this approach may seem prudent from a consumer protection perspective, it carries broader implications:

1. **Chilling Effect on Innovation**: Over-caution can discourage innovation and the development of products or marketing strategies, particularly in industries like food and supplements. This goes on the opposite direction of the establishing a harmonized regulatory framework that supports innovation, reduces administrative burdens, and strengthens the position of the European industry in global markets.
2. **Neglect of Evidence-Based Argumentation**: A cautious stance might ignore robust evidence and consumer data that provide a better understanding of how terms are perceived by consumers. This could result in a one-sided regulatory framework that focuses on hypothetical risks rather than real-world data.
3. **Impact on Consumer Education**: Maintaining a restrictive interpretation may limit consumers' access to valuable information about probiotics and their scientifically validated effects, hindering informed decision-making. Clear and balanced communication is essential for fostering a transparent and consumer-oriented market for probiotics, which supports both public health and economic growth.
4. **Legal uncertainty**: The current interpretation undoubtedly has created legal uncertainty within the European market, reinforced by the National initiatives of 10 Member States that chose to allow the use of the term "probiotics" on their products. Although for the Ombudsman's "there is no legal uncertainty on this matter" these national initiatives underscore a lack of consistency at the EU level, and the need of a revision of the European Commission interpretation, which is only based on a "non-binding guidance".

Conclusion. This development fails to address the longstanding need for clearer guidance and formal recognition of probiotics as a distinct category of products and ingredients. Such recognition is essential for fostering a more consistent and harmonized regulatory framework across Europe. It results in a missed opportunity to enhance legal clarity and consumer protection, and to support innovation within the EU food sector.

IPA Europe remains committed to engaging with policymakers and stakeholders to achieve greater alignment and transparency in the classification and use of "probiotics" across the EU. We will continue to advocate for a balanced, evidence-based regulatory framework that reflects the realities of the market and the views of Member States and stakeholders.

The Decision is available here

For media inquiries or further information, please contact:

Rosanna Pecere
Executive Director IPA Europe
r.pecere@ipaeurope.org