

Brussels, 7 March 2022

IPA Europe representing the probiotic food and food supplements and the European Dairy Association (EDA) as the voice of the European milk processing industry launch a Joint Statement.

'We ask for an evaluation of the current understanding of the term 'probiotic' within a regulatory EU framework and the conclusive statement that a food containing probiotic microorganisms will be included on the list of nutrition claims'.

A HOLISTIC APPROACH TO PROBIOTIC FOOD & FOOD SUPPLEMENTS IN EUROPE, FOR INFORMED CONSUMERS AND A SUSTAINABLE FOOD INDUSTRY.

The Associations International Probiotic Association - IPA Europe and the European Dairy Association - EDA note the contribution that the probiotic sector can make to deliver on a number of objectives listed by the European Commission in the Farm to Fork in:

- 1 Making relevant and reliable information available to the consumers
- 2 Motivating consumers to make decisions on good and healthy diets in a sustainable perspective
- 3 Using a more flexible approach to regulatory and non-regulatory measures to promote best practices
- 4 Making use of research and innovation.

THE INTEREST IN THIS CATEGORY OF INGREDIENT IS HAMPERED BY A LACK OF KNOWLEDGE AND A LACK OF PRODUCT INFORMATION

The general principle of food labelling is to provide specific and descriptive information to help consumers make appropriate food choices. This principle is currently not applied to probiotics, as the prevailing view of the European Commission is that the term 'probiotic' is considered an implied health claim and is therefore not permitted on the labels and communication of food products and food supplements ¹.

The current situation penalizes European manufacturers of probiotic foods and dietary supplements and does not meet the demand of consumers for appropriate information on food products, which was also the scope of Regulation (EC) N°1924/2006 on Nutrition and Health Claims made on Foods.

We would like to stress the urgent need for a level playing field, allowing EU consumers to make an informed food choice. A consistent EU legal framework will encourage food business operators to

¹ In the EC guidance of 2007 on the interpretation of the nutrition and health claims made on foods, the expression 'contains probiotics' is given as an example of health claim
https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf

further develop and innovate sustainable food production, while providing consumers with the necessary information to make food choices that suit their individual dietary needs².

We, therefore, call for clarification of the definition of the term ‘probiotic’ and a harmonised regulatory framework at EU level, in line with the spirit and the letter of the legal framework for food. A legislative solution should be found within the Nutrition and Health Claims Regulation.

DIFFERENT INTERPRETATIONS IN EUROPE - SOME NATIONAL APPROACHES ARE MORE IN LINE WITH THE ROLE THAT PROBIOTICS PLAY IN THE DIET AND WITH THE CONSUMER EXPECTATION OF BETTER INFORMATION ON LABELLING

Since the implementation of the Nutrition and Health Claims Regulation, there have been several interpretations of the use of the term ‘probiotic’ for food and food supplements.

The lack of clarity at EU level has led Member States to adopt different national approaches to allow the use of the term ‘probiotic’, thereby creating potential adverse effects to the functioning of the European Single Market. It is accepted in some countries but not in others and based on the principle of ‘mutual recognition’, the product legally produced in a country allowing the use of the term probiotic is in free circulation in the EU.

The associations are claiming the opportunity to build a coherent and harmonised approach for the use of the term ‘probiotic’ in Europe. EU food business operators should be able to rely on harmonised rules across the EU to avoid potential barriers within the Single Market.

THERE IS A CLEAR NEED TO LOOK MORE BROADLY THAN THE CURRENT INTERPRETATION OF ‘PROBIOTIC’ GIVEN BY THE EUROPEAN COMMISSION, AND TO ACT ON THE URGENT NEED TO PROVIDE INFORMATION TO CONSUMERS.

The term ‘probiotic’ is an important and specific description of a food category. Both when used to name the category of substances that characterises food and food supplements, or when used to describe the food without mentioning health effects, there is a strong argument that ‘probiotic’ should not be regarded as a health claim. This is confirmed by the EFSA guidance indicating that the term ‘probiotic’ cannot be allowed as a health claim, as it is not sufficiently precise regarding which health benefit it supposedly offers³.

When it comes to a more specific description, the expression ‘contains probiotics’ describes the substance, or category of substances, as factual information. In fact, the Nutrition and Health Claims Regulation allows the statement that a food simply ‘contains’ a certain substance with a nutritional or physiological effect, which is defined as a nutrition claim. To this respect, it is the same as stating ‘contains vitamins and minerals’ or ‘contains fibre’: all these categories of substances may have

² Joint Research Centre (JRC), the EU Science Hub JRC F7 - Knowledge for Health and Consumer Safety, The Human Gut Microbiota: Overview and analysis of the current scientific knowledge and possible impact on healthcare and well-being, EUR 29240 EN, Publications Office of the European Union, Luxembourg, 2018, ISBN 978-92-79-86471-1, doi:10.2760/17381, JRC112042 – https://publications.jrc.ec.europa.eu/repository/bitstream/JRC112042/human_gut_microbiota_online.pdf

³ EFSA Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms. EFSA Journal 2016;14(1):4369, 23 pp. doi:10.2903/j.efsa.2016.4369 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4369>

beneficial effects, but they do not refer to a specific health effect. Similarly, the term ‘probiotic’ as such cannot be considered as a health claim only⁴.

We advocate that the use of the term ‘probiotic’ differs from claiming a specific health effect, as defined by the Nutrition and Health Claims Regulation.

Based on the above, we contend that the European approach should be reviewed to reflect the reality that probiotics are a category of substances that characterises food and food supplements.

The term ‘probiotic’ should be allowed on food labels as voluntary information, according to the Nutrition and Health Claims Regulation, subject to meeting specific criteria and conditions of use.

DISCUSSING THE INTERPLAY BETWEEN SCIENCE, NUTRITION AND REGULATORY ISSUES FOR PROBIOTIC FOOD AND FOOD SUPPLEMENTS: THE TERM SHOULD BE ALLOWED IN EUROPE ON BOTH FOOD PRODUCTS AND FOOD SUPPLEMENTS, WITH CRITERIA AND CONDITIONS OF USE



We stress the importance for consumers to receive appropriate information and fair advertising.



A harmonised approach should be implemented in Europe, with specific criteria for the use of the term ‘probiotic’, in line with the consumer expectations of receiving better information and to avoid disruption of the European Market.



We call for action of the European Commission and relevant stakeholders to build a coherent and consistent framework in Europe, to alleviate an avoidable legal burden, enhance the functioning of our European Single Market. A common EU solution should be found within the Nutrition and Health Claims Regulation, by adding the claim ‘contain probiotic microorganisms’, or similar wording, to the list of nutrition claims.



We count on having political support during further coordination efforts to continuously improve the provision of healthy food products to European consumers.

Rosanna Pecere

Executive Director



The International Probiotic Association – Europe represents the Companies directly engaged in the manufacture of probiotic cultures or probiotic foods, supplements, nutritionals or therapeutic products: BioGaia, Chr. Hansen, Danone, IFF, Lallemand, Lesaffre, Probi and Yakult. With the partner organisation IPA, we reach more than 100 members worldwide.

Alexander Anton

Secretary General



The European Dairy Association is the acknowledged voice of the milk processing industry in the European Union and the benchmark for all sector-specific organisations in the field of agriculture in creating a European forum for both, high-level debates on the future of the European ‘lactosphere’ and in-depth analysis of today’s dairy-related topics.

⁴ The only authorised health claim is for live yoghurt cultures and improved lactose digestion.

<https://www.efsa.europa.eu/fr/efsajournal/pub/1763>

Commission Regulation (EU) No 432/2012