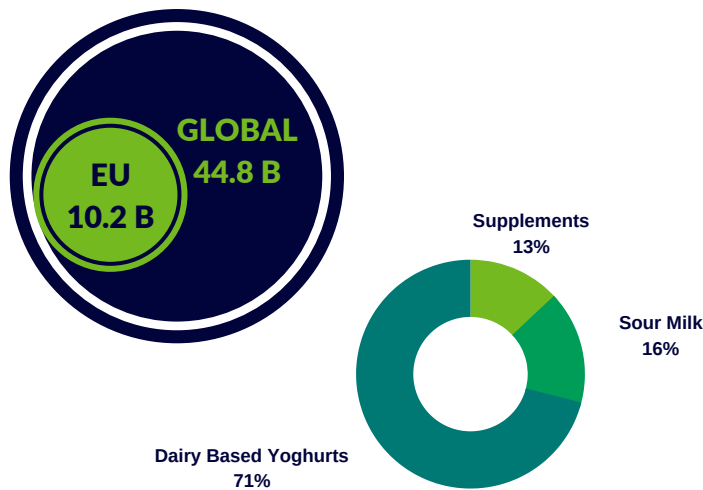




A HOLISTIC APPROACH TO PROBIOTICS IN THE EU FOR INFORMED CONSUMERS AND A SUSTAINABLE FOOD INDUSTRY

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PROBIOTIC KEY FACTS AND FIGURES



SOURCE EUROMONITOR
ELABORATED BY IPA EUROPE

THE GLOBAL PROBIOTICS MARKET 2019 (IN USD)

In 2019 total sales of **probiotic supplements**, **probiotic yoghurts** and **sour-milk products** on the EU market were equal to 10.217,6 Bn USD. The EU was the top global market for probiotic yoghurt and supplement sales until 2009, but now ranks third, after China and the US. For both foods and supplements, the global probiotics market continues to grow from one year to the next, confirming the positive trend. The year 2018 closed at USD 43.8 Bn, in 2019 the market reached USD 44.8 Bn, and forecasts indicate a 4% growth YoY on average for the period 2019-2024.

*Rosanna Pecere, Executive Director
IPA Europe:*

"While there is a high level of uncertainty regarding the use of the term 'probiotic' in the EU market, this promising category is expanding worldwide. The regulatory environment seems to have a major impact on sales in the EU."

The overall market for probiotic yoghurts and fermented milk is projected to increase for the period 2019-2024, with growth driven by Asia Pacific.

The forecast for the US and Western Europe indicates a decline of -2,1% and -0,3% respectively.

The European probiotic supplement market in 2019 was 1,6 Bn USD– close to a third of the global consumption. As a whole, the expected growth rate for the period 2019-2024 in Europe is lower compared to that of Asia Pacific.



SOURCE EUROMONITOR
ELABORATED BY IPA EUROPE

PROBIOTIC KEY FACTS AND FIGURES

The European probiotic sector needs robust research and innovation, to once again become the driving force for innovative products that add value to human wellbeing, and to contribute to the growth of the European economy.

The probiotics industry is growing quickly outside the EU, with significant opportunities for further growth. Within the EU, the uncertainty caused by the regulatory framework, currently considering the term 'probiotic' as a health claim, is impacting this growth. Some EU countries have already developed a national approach to probiotics in food and food supplements [1].

The European voice of the probiotics industry, IPA Europe, is working on the definition, in order to enable the use of the term 'probiotic' as the name of a category. The term "probiotic" is very well established in the minds of consumers, and the interest in probiotics throughout Europe is increasing.

While there is evidence of the positive effect of probiotics on human wellbeing [2], European consumers need reliable information on which probiotics to take, and under which circumstances, to be able to make informed choices [3].

Under the current EU regulatory framework, the uncertainty around the probiotic category has also impacted innovation. In fact, the process for claim authorisation provided by the Nutritional and Health Claim Regulation has proven to be extremely unpredictable. Only 12 claims based on new scientific evidence have been officially approved by the European Commission.

This total approval rate of food health claims of 6% is extremely low. It has led to a substantial reduction in the number of applications submitted to the European Food Safety Authority (EFSA). The implementation of meaningful pre-submission consultations between companies and the EFSA, in the revised General Food Law Regulation, would certainly encourage companies to further invest in innovation.

[1] For example: in **Italy**, the claim "supports the intestinal flora balance" can be used, when certain conditions are fulfilled. Commissione Unica per la Dietetica e la Nutrizione. Guidelines on probiotics and prebiotics. Revision May 2013: http://www.salute.gov.it/imgs/C_17_pubblicazioni_1016_ulterioriallegati_ulteriorioreallegato_0_alleg.pdf

The **Czech** Authorities in their National Recommendation Regarding Certain Food Labelling also indicate the conditions for the use of the term 'probiotic' as a nutrition claim and may be used subject to fulfilment of the conditions for use of the claim, namely that it "contains (name of nutrient or other substance)" listed in the Annex to Regulation (EC) No 1924/2006; same approach of the **Bulgarian** authorities.

In other EU countries, such as **Spain, Portugal, and France**, the use of the term 'probiotic' is accepted as a non-specific health claim, when accompanied by a specific health claim. In April 2020, **France** s published the new national Q&A on nutritional and health claims "Questions/Réponses concernant l'utilisation des allégations nutritionnelles et de santé (Règlement (CE) n°1924/2006) <https://www.economie.gouv.fr/dgccrf/Consommation/Etiquetage-des-produits/Allegations-nutritionnelles-et-de-sante>

[2] Since 2001 there have been more than 500 systematic reviews on probiotics. Findings from systematic reviews are essential to help make recommendations or guidelines for medical and public health policies.

King S, Tancredi D, Lenoir-Wijnkoop I, Gould K, Vann H, Connors G, Sanders ME, Linder JA, Shane AL, Merenstein D. **Does probiotic consumption reduce antibiotic utilization for common acute infections? A systematic review and meta-analysis.** European Journal of Public Health (published 14 September 2018)

Eales J, Lenoir-Wijnkoop I, King S, Wood H et al. **Is consuming yoghurt associated with weight management outcomes? Results from a systematic review.** International Journal of Obesity 2015: 1-16.

King S, Glanville J, Sanders ME, Fitzgerald A, Varley D. **The Effectiveness of Probiotics on Length of Illness in Healthy Children and Adults who Develop Common Acute Respiratory Infectious Conditions: A Systematic Review and Meta-Analysis.** British Journal of Nutrition 2014; 111:1967-1980.

[3] Toscano, M.; De Grandi, R.; Pastorelli, L.; Vecchi, M.; Drago, L.

A consumer's guide for probiotics: 10 golden rules for a correct use. Dig. Liver Dis. 2017 49, 1177-1184 https://pubmed.ncbi.nlm.nih.gov/28830747/?from_term=toscano+2017+guide&from_pos=1

OPENING WORDS BY THE PRESIDENT

ESBEN LAULUND

PRESIDENT IPA EUROPE



The FAO/WHO definition (2001), later amended by an expert consensus group, which defines probiotics as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host" (Hill C 2014) is still relevant and recognised on a global scale. Since then, scientific and clinical evidence has progressed rapidly, as well as the development of a number of robust probiotic products.

Unfortunately, misuse of the term 'probiotic' has also become a significant issue, with many non-food products like detergents, mattresses, or even "probiotic allergen-free" air sprays for the car and home, which are exploiting the term without meeting the definition.

Probiotics are distributed in 80 countries and probiotic dairy-based yoghurts are distributed in 200 countries. As outlined in a Guidance from 2007 [4], the current interpretation of the EU Commission has restricted the use of the word 'probiotic' to be a health claim only.

In recent years, other interpretations have been developed by EU Member States, which are all compliant with the current legal framework [5].

In other regions of the world, public authorities consider probiotics as an ad hoc category of ingredients and acknowledge their specificity [6].

We live in a time when a simple Google search for 'probiotics' produces over 56.8 million hits, meaning that most people have heard about probiotics through various channels. An ever-increasing variety of probiotic products are available in different regions of the world, and European consumers can purchase these products from outside Europe via e-commerce: this represents a loss for the European economy.

However, this also shows that consumers are exposed to any kind of product bearing the term 'probiotic'.

Thus, it is important to emphasise that some products bearing the term 'probiotic', regardless of whether they claim to have positive effects, do not provide any assessment on the real activity of the probiotic microorganisms.

Probiotics have received the legitimate attention of regulatory authorities with an interest in protecting consumers from misleading claims. However, the EU is in the unique situation where the use of the term 'probiotic' is considered a health claim, that still requires an evaluation by the EFSA for approval.

We need to create favourable conditions to uphold the competitiveness, quality and sustainability of the probiotic foods and food supplements industry, in accordance with the Farm to Fork Strategy.

- Work on creating a definition that clearly outlines the probiotic category.
- Develop an EU industrial strategy and continue to offer high-quality products.
- Meet consumer expectations and promote their ability to make informed choices.
- Foster a regulatory environment that provides consistency and promotes innovation within the probiotic industry.

[4] In the EU, Probiotic foods, mainly fermented milks and supplements, fall within the scope of the General Food Law. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 that applies to nutrition claims (such as "low fat", "high fibre") and to health claims made on foods. The expression "contains probiotics" is given as an example of a health claim in the EC Guidance of 2007 on the interpretation of the Regulation. Consequently, there are divergent interpretations in the Member States on the use of the term "probiotic" in the labelling and advertising of food products.
https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf

[5] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims, started to be applied on 1 July 2007.

[6] Authorities worldwide have developed rules to identify the probiotic as a category of ingredients. In 2011, **Argentina** incorporated into its food regulatory framework a definition of probiotics, a guide for the evaluation of a probiotic as a food ingredient.

Brazil, Colombia, and Ecuador have adopted a definition of probiotics that is aligned with the definition proposed by FAO/WHO.

The **Southern Cone and Caribbean** countries include requirements for "probiotic" microorganisms on food labelling. In the **US**, probiotics can be considered as food or ingredients. **Canada** has developed a Guidance Document in order to clarify the acceptable use of health claims about microorganisms represented as 'probiotics' on food labels and in advertising.

India has a regulatory definition of food with added probiotics and **Thailand** has a specific probiotic regulation and a definition of probiotics.

ENGAGING TO DEVELOP BETTER INFORMATION FOR THE USE OF THE TERM 'PROBIOTIC'

Consumers today are increasingly moving towards personalised nutritional regimes, which require access to specific food products with accurate, appropriate and comprehensive information.

This is also confirmed as a priority area by the United Nations in the new development set of goals for the 2030 Agenda for Sustainable Development [7].

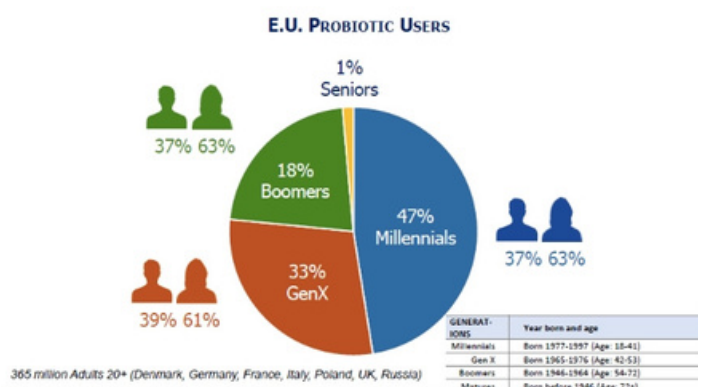
- Consumers seek new ways to manage their health and prevent future health conditions through the use of foods, beverages and supplementation [8]
- Europe's ageing population is expected to increase in the coming years [9]
- Healthy behaviour and products able to enhance overall health, wellbeing and quality of life can play an important role and have a positive impact on keeping the cost of the EU healthcare systems under control [10]
- It is recognised that diet can modify the intestinal microbiome, which in turn has a profound impact on overall health. Some microorganisms, commonly referred to as probiotics and prebiotics can play an important role in sustaining a balanced gut microbiota health [11]. (Publication of the Joint Research Centre (JRC), the EU Science Hub JRC F7)
- Several medical and scientific organisations have highly recommended the use of probiotics to ameliorate gastrointestinal symptoms or diseases in their evidence-based guidelines [12]

"Probiotic foods and food supplements continue to be the subject of cutting-edge research."

"Consumers of all ages are engaged in a healthy lifestyle, and therefore demand proper information on the food products."

(Based on the Natural Marketing Institute's global supplements (SORD), November 2019).

**MORE THAN 36 MILLION PROBIOTIC USERS (20+)
ACROSS DENMARK, FRANCE, GERMANY, POLAND, UK, RUSSIA**



ENGAGING TO DEVELOP BETTER INFORMATION FOR THE USE OF THE TERM 'PROBIOTIC'

IPA Europe is a reliable partner, able to provide accurate information to all the stakeholders and act against the flow of false myths and fake news.

IPA Europe claims that a graded approach should be considered, with different levels of evidence, to encourage the European Commission to further develop the European framework, based also on national good practices and experiences.

Based on the above, we can conclude that **information and education are essential to make a responsible consumer and contribute to motivating consumers to make food choices based on a rational understanding of their own interests.**

The EU Regulation on the provision of food information to consumers (FIC, EU 1169/2011) states that “the prime consideration for requiring mandatory food information should be to enable consumers to identify and make appropriate use of a food and to make choices that suit their individual dietary needs”.

However, this is not the case for probiotic food and food supplements. The lack of a harmonised approach is not helping responsible players to provide information on probiotics and is not allowing consumers to make informed choices.

Although consumers in some EU Countries associate the term 'probiotic' with the notion of “beneficial food”, this does not automatically convert this term into a health claim.

[7] The third goal of the UN plan is “Good health and well-being to ensure healthy lives and promoting well-being for all at all ages”: <https://sustainabledevelopment.un.org/sdg3>

[8] Grant MC, Baker JS. **An overview of the effect of probiotics and exercise on mood and associated health conditions.** Critical Reviews in Food Science and Nutrition. 2017 Dec;57(18):3887-3893. DOI: 10.1080/10408398.2016.1189872.

[9] 2018 Aging Report: **The 2018 Ageing Report Economic and Budgetary Projections for the EU Member States (2016-2070)**. May 2018 European Commission Directorate-General for Economic and Financial Affairs.

[10] A health-economic analysis was undertaken to estimate the public health and budget consequences of a generalised probiotic consumption in France. The conclusion was that public health and low budget impact, due to the consumption of the probiotic, are substantial. Another study was conducted in Canada and the analysis shows that the potential of probiotics to reduce RTI-related events may have a substantial clinical and economic impact.

Lenoir-Wijnkoop I, Gerlier L, Bresson J-L, Le Pen C, Berdeux G (2015) **Public Health and Budget Impact of Probiotics on Common Respiratory Tract Infections: A Modelling Study.** PLoS ONE 10(4): e0122765.

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0122765>
Lenoir-Wijnkoop I, Gerlier L, Roy D, Reid G (2016) **The Clinical and Economic Impact of Probiotics Consumption on Respiratory Tract Infections: Projections for Canada.** PLoS ONE 11(11): e0166232. <https://doi.org/10.1371/journal.pone.0166232>

[11] 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

[12] World Gastroenterology Organisation, **Global Guidelines Probiotics and prebiotics**, February 2017 <https://www.worldgastroenterology.org/guidelines/global-guidelines/probiotics-and-prebiotics/probiotics-and-prebiotics-english>

LOOKING AT THE REQUIREMENTS FOR A CATEGORY OF PROBIOTIC FOOD AND FOOD SUPPLEMENTS

With the help of experts, IPA Europe members gather to discuss issues pertaining to the interplay between science, nutrition and regulatory issues for probiotic food and food supplements, and the challenges which the probiotics manufacturers face.



We share and support the European ambitions in the “Food to Fork strategy”, that are in line with our defined goals



We ask the EU institutions to build a coherent and consistent framework for actions, to alleviate avoidable legal burden, enhance the functioning of our European Single Market and build a better societal foundation with a sound scientific base



We stress the importance for consumers to receive appropriate information and fair advertising: there should be a balance between protecting consumers, allowing innovation and satisfying consumer needs



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



IPA EUROPE & VOLUNTARY ENGAGEMENT

IPA Europe, together with the International Probiotics Association (IPA), is actively working on obtaining recognition for the probiotic category, herewith covering the safety/quality, labelling and efficacy aspects.

IPA Europe recommends that, with respect to commercial communications, the term 'probiotic' should only be used to describe microorganisms when a certain combination of requirements is met (IPA Europe Criteria to qualify a microorganism designated as "probiotic" in food, beverage and dietary supplements
<https://www.ipaeurope.org/documents/position-papers/>).

Still relevant after 19 years, the FAO/WHO definition of probiotics [13] can be translated into four simple and pragmatic criteria allowing one to conclude if specific strains of microorganisms qualify as a probiotic for use in foods and dietary supplements.

Probiotic strains must be:

- sufficiently characterised;
- safe for the intended use;
- supported by at least one positive human clinical trial conducted according to generally accepted scientific standards, or as per the recommendations and provisions of local/national authorities when applicable;
- alive in the product at an efficacious dose throughout shelf-life.

The use of the term would then no longer require an EFSA health assessment, as long as no reference to a specific health effect is made. IPA Europe is working closely with the International Scientific Association for Probiotics and Prebiotics (ISAPP) to provide clarity on each criterion and detail how each of these four criteria can be assessed [14].

IPA Europe supports and encourages responsible production and marketing of probiotic foods and food supplements.

IPA Europe has developed this voluntary approach which consists of science-based criteria as a prerequisite to qualifying "the probiotic category of food and food supplements".

Defining these criteria has been a key objective of different stakeholders in the probiotic field.

The wide adoption of "the probiotic category of food and food supplements" will ensure the proper use of the word 'probiotic' in scientific publications, product labels, and in communications with regulators and the general public.

[13] An expert consultation, convened under the umbrella of the World Health Organization and the Food and Agriculture Organization, proposed a useful definition of probiotics in 2001, which was later refined in 2014 for grammatical reasons to "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host" [1,2]. Hill et al. [2] stipulated that probiotics must have "defined contents, appropriate viable count at end of shelf life and suitable evidence for health benefits", and further stated that all probiotics must be "safe for their intended use". These points were reiterated in 2018 by the International Scientific Association of Probiotics and Prebiotics (ISAPP) in a position statement.
<https://isappscience.org/minimum-criteria-probiotics/>

[14] Founded in 2002, ISAPP brings together global leading scientific experts committed to advancing the science of probiotics and prebiotics, and how probiotics and prebiotics are studied and understood.
<https://isappscience.org/about/>

IPA EUROPE PRIORITIES AND RECOMMENDATIONS FOR A HOLISTIC APPROACH

The European Union is entering a new and challenging period, where policymakers play a decisive role in putting food at the centre of their policies. This necessitates the preparation of a European industrial strategy to uphold the competitiveness, quality and sustainability of the European food industry, including the probiotic foods and food supplements.

IPA Europe is committed to safeguarding the role of the European food industry as a global leader, while continuing to offer high-quality products to European consumers.

IPA Europe priorities to improve the European framework for probiotics are as follows:

- Implement **appropriate criteria and conditions** to frame the term 'probiotic'
- A **graded approach** where, depending on the characteristic of the product, the appropriate rule applies within the EU regulatory framework
- A **clear labelling environment** for probiotics across Europe
- A harmonized and holistic approach which is in line with the **Farm to Fork Strategy objectives**



Framing the use of the term 'probiotic', under appropriate criteria and conditions, is a necessary step towards the interest of European consumers and the functioning of the European Single Market.

Probiotics are currently one of the most topical issues in the field of science and the food industry. An interdisciplinary approach that invokes regulatory, economic, social and scientific means should be adopted by the EU, in order to assess probiotics in a holistic manner.

IPA Europe recommends providing useful guidance for stakeholders and for consumers on the use of the term 'probiotic' in food, beverage, and dietary supplements. This will require reassessment of the EC Guidance of 2007, which indicates that the term 'probiotic' should be regarded as a health claim only. Instead, a graded approach should be developed corresponding to the different level of supporting scientific evidence. This graded approach will make a distinction between the probiotic category and the specific health claim requirements, and will not contradict the spirit of the EU legal framework.

Fostering a favourable environment for probiotics will work to benefit both industry in Europe and European consumers.



Through both regulatory and non-regulatory measures, this graded approach will steer the responsible probiotic industry towards practices that make a healthy, sustainable choice the easy one for consumers.

A category being named 'probiotic' is factual and thus should not be interpreted differently from other nutrients or substances (e.g. dietary fibre). Therefore, there is no reason to apply a very restrictive interpretation only to probiotics.

Currently, the NHCR can be applied differently, depending on the interpretations of the Member States authorities but also on the typology of probiotic food and food supplements. A set of criteria should be used to identify probiotics microorganisms in food and food supplements, covering the safety and quality, labelling and efficacy aspects. With these requirements agreed at European level we can provide clarity to the minimum criteria needed for the proper use of the term probiotic in both food and dietary supplements.

When used in compliance with the definition of the category and within the framework of Regulation (EC) 1924/2006, the use of the term 'probiotic' would not require an EFSA health assessment, as long as no reference to a specific health effect is made



It is crucial to create a labelling environment that the consumers can trust, allowing the consumer to make an informed choice.

Building a comprehensive framework will result in trustworthy and accurate information being featured on labels and in other communications to consumers, pursuant to the Regulation on the provision of food information to consumers (FIC, EU 1169/2011).

This will result in consistent and harmonized information that meets the objective of enabling consumers to identify and make appropriate use of food, as well as making choices that suit their individual dietary needs.

IPA Europe is a strong advocate for, as stated by Commissioner Stella Kyriakides, "having consistent rules in the EU, ensuring that legitimate demands for more information remain compatible with our single market [and] to look into how we can improve consumer information, starting with the possibilities that exist under the current legal framework".



A harmonized response across Member States that invokes comprehensive criteria and conditions for use of the term 'probiotic' and builds a clear labelling environment will contribute towards the objectives of the Farm to Fork Strategy.

Building a sustainable food system requires a holistic approach. Clear and coherent criteria attached to the 'probiotic category of food and food supplements will provide clarity and will contribute towards the overall Farm to Fork Strategy objective of improving information on food, based on good practices and experiences.

This should result in a more consistent framework of regulatory and non-regulatory measures in relation to probiotics that will adequately address the need for better consumer information, will enhance the correct functioning of the European market and will foster an environment that promotes innovation.



IPA Europe maintains that regardless of developments within Europe, it is important to take the global dimension of trade into account.

The development of international guidelines within the Codex Alimentarius and with the WHO are necessary to sustain quality probiotic products on a global scale, and to ensure fair practices in food trade.

Therefore IPA Europe is also a proponent of establishing a definition with minimum characterisation requirements and quality and labelling parameters for probiotics for use as an ingredient in food and dietary supplements on aspects not framed by existing Codex standards.



- **IPA Europe** is the European chapter of IPA, the International Probiotics Association; it was established in Brussels in 2015.
- **IPA Europe**, with their partner organisation IPA, reach together **a platform of more than 100 member companies in 29 countries.**
- The members of IPA Europe are **companies directly engaged in the manufacture of probiotic cultures or probiotic foods, supplements, nutritional or therapeutic products** BioGaia, Chr. Hansen, Danone, IFF, IPA, Lallemand, Lesaffre, Probi, Yakult.
- 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.**

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