

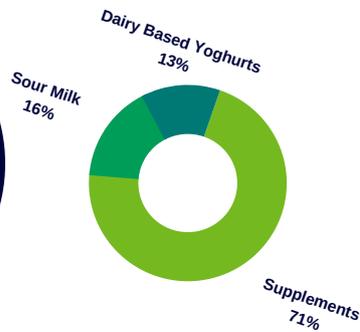
-) PROBIOTIC KEY FACTS AND FIGURES
-) OPENING WORDS BY THE PRESIDENT, ESBEN LAULUND
-) ENGAGING TO DEVELOP BETTER INFORMATION FOR THE USE OF THE TERM "PROBIOTIC"
-) LOOKING AT THE REQUIREMENTS FOR A CATEGORY OF PROBIOTIC FOOD AND FOOD SUPPLEMENTS
-) THE IPA EUROPE VOLUNTARY ENGAGEMENT

IPA Europe - The European Voice of Probiotics

IPA Europe brings together a unique forum of worldwide leading producers of probiotics. IPA Europe is active on all of the following:

- Establish probiotic standards and voluntary guidelines to define the conditions of use of the term "probiotic"
- Establish a harmonized legal status for probiotics in the EU, framing the communication on probiotics towards consumers
- Participate actively in the EFSA consultation process, to ensure an appropriate environment for the establishment of probiotic health claims
- Engage in dialogue with all relevant stakeholders to increase awareness and knowledge on probiotics foods

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.

The global probiotics market, for both foods and supplements, 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 of probiotic yoghurts and fermented milk is projected to increase for the period 2019-2024, with growth driven by Asia Pacific. The forecast for US and Western Europe indicates a decline (respectively of -2,1% for North America and -0,3% for Western Europe).

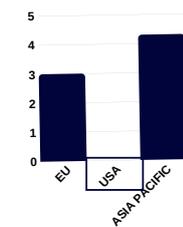
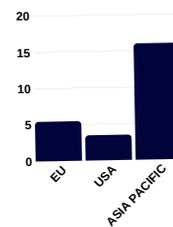
The European probiotic supplement market in 2019 was 1,6 Bn USD- close to a third of the global consumption. As a whole, the expected growth rate for the period 2019-2024 in Europe is lower compared to that of Asia Pacific.



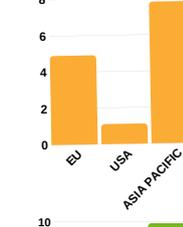
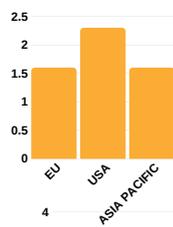
MARKET SHARE 2019 (Bn)

FORECASTED ANNUAL GROWTH RATE 2019-2024 %

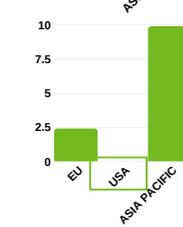
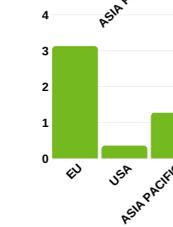
ALL PRODUCTS 4%



GLOBAL 2.4%



GLOBAL 4%



GLOBAL 3,2%

SOURCE EUROMONITOR
ELABORATED BY IPA EUROPE

PROBIOTIC KEY FACTS AND FIGURES

The European probiotic sector needs robust research and innovation, to become again 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 fast 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 on probiotics in food and food supplements [1].

The European voice of 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 for probiotics in the European countries is increasing.

While there is evidence of the effectiveness of probiotics in human wellbeing [2], however 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 an impact on innovation. In fact, the process for claim authorisation provided by the Nutritional and Health Claim Regulation, has proven to be extremely unpredictable, and only 12 claims based on new scientific evidence have been officially approved by the European Commission.

This very low rate of 6% has led to a substantial reduction of the number of applications submitted to EFSA. The implementation of meaningful pre-submission consultations between companies and the European Food Safety Authority (EFSA), in the revised General Food Law Regulation, would certainly encourage the 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_ult_erioreallegato_0_alleg.pdf

The **Czech** Authorities in their National Recommendation Regarding Certain Food Labelling also indicate the conditions for the use of the term probiotics as a nutrition claim and may be used subject to fulfilment of the conditions for use of the claim “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, **Spain, Portugal, France**, it is accepted the use of the term “probiotic” as a non-specific health claim, when accompanied by a specific health claim. **France** has published in April 2020 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

INTRODUCTION NOTE FROM THE PRESIDENT



ESBEN LAULUND
PRESIDENT IPA

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 worldwide. Since then, scientific and clinical evidence have progressed rapidly, as well as the development of a number of robust probiotic products.

Unfortunately, misuse of the term "probiotic" has also become a major issue, with many non-food products like detergents, mattresses, airsprays or even "probiotics allergen free" for the car and for the 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. The current interpretation of the EU Commission, as outlined in a Guidance from 2007 [4], 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 the European consumers can purchase via e-commerce products from outside Europe: 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". It is important, indeed, to underline the fact that some of these products bearing the term "probiotic", even though they are claiming positive effects, do not provide any assessment on the real activity of the probiotic microorganisms.

At the same time, probiotics have received the legitimate attention of regulatory authorities with an interest in protecting consumers from misleading claims. The EU is in the peculiar situation where the use of the term "probiotic" as such is indicated by the European Commission as an example of health claim, and this without any assessment, while an evaluation of EFSA is requested for having a health claim approved.

In order to continue to grow and innovate, we need to create favourable conditions to uphold the competitiveness, quality and sustainability of the probiotic foods and food supplements industry, which is also in line with the Green Deal and Farm to Fork strategy.

As the European Union enters a new and challenging period, EU policy makers will play a decisive role in putting food at the centre of their policies, preparing an EU industrial strategy that aims at safeguarding the world leadership of the European food industry, and continuing to offer high quality products, supporting the health of European consumers.

Now is the time to revisit the concept of the probiotic category, to consider appropriate definitions and to provide useful guidance for stakeholders and for consumers as well.

[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 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 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 an effective personalised nutritional regime, which requires 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 next years [9]
- A healthy behaviour and products able to enhance health, well-being and quality of life can play an important role and will 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 the overall health. Some microorganisms, normally referred to as probiotics and prebiotics can play an important role to sustain 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]

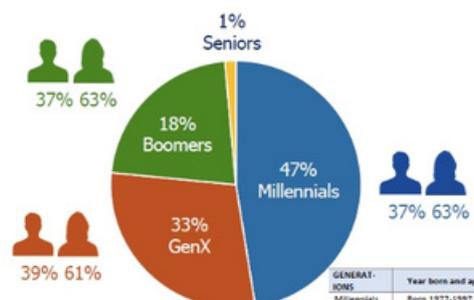
“Probiotic foods and food supplements are a well-studied category of foods which continues to be the subject of leading-edge research.

Consumers of all ages are engaged in a healthy lifestyle, they seek high quality, safe and effective products 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**

E.U. PROBIOTIC USERS



365 million Adults 20+ (Denmark, Germany, France, Italy, 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 will contribute to motivate consumers in making food choices based on a rational understanding of their own interest.**

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”.

This is not happening for probiotic food and food supplements, where the lack of a harmonised approach is not helping responsible players in communicating on probiotics, and is not allowing consumers to make informed choices.

Even if in some EU Countries the term “probiotic” is associated by consumers to the idea of “beneficial food”, this fact does not 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 generalized probiotic consumption in France. The conclusion was that public health and low budget impact due to the probiotics consumption 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, Berdeaux 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 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 upon 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 in further coordinating efforts in continuous improvement to provide healthy food products to the European consumer



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:

- (i) sufficiently characterized;
- (ii) safe for the intended use;
- (iii) 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;
- (iv) alive in the product at an efficacious dose throughout shelf life.

The use of the term would then not require an EFSA health assessment, as long as no reference to 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 scientifically-based criteria as a prerequisite to qualifying “the probiotic category of food and food supplements”.

Every part of the probiotic definition is important and can be transposed into easy-to-use criteria.

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

The wide adoption of these criteria is necessary to ensure the proper use of the word probiotic in scientific publications, on 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 is the European chapter of IPA, the International Probiotics Association; it was established in Brussels in 2015.

IPA Europe, with the 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, nutritionals or therapeutic products BioGaia, Chr. Hansen, Danone, DuPont, IPA, Lallemand, Lesaffre, Probi, Yakult.

The IPA Europe mission is: to gain the 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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IPA Europe issued in April 2017 a brochure
“What Probiotics Can Do For You?”
as a useful tool for a better
understanding of probiotics and the
opportunities they could offer.

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