ehpm
European Federation of Associations of Health Product Manufacturers

2024

Position Paper for a harmonised EU approach to the use of the term *probiotics*

The probiotics market

The global probiotic supplements market is estimated to have reached nearly 5,9 billion EUR in 2021 and it is expected to grow at a CAGR of 3,7% between 2021 and 2026. The European probiotic supplements market represents nearly 25% of the global market, with a value of over 1,4 billion EUR[1].

In 2020, during the Covid19 crisis, also the probiotic supplements market expanded with e-commerce sales. This trend continued in 2021. With the additional sales generated on e-commerce of 190 million EUR, the European market reached approximately 1,7 billion EUR in 2021[2].

Italy, Germany and France represent the largest markets in Europe. Italy in particular is the largest market in Europe and the third largest market globally, with 560,5 million EUR of sales of probiotic supplements in 2021 and a forecast growth of 5% for the period 2021-2026[3].

1 - Euromonitor International for International Probiotic Association, 2021

2 - IPA on Euromonitor International Data, Lumina on online sales

3 - IPA on Euromonitor International Data, Lumina on online sales

Consumers highly demand probiotic supplements, but do not feel well informed

Several consumer surveys and studies have been undertaken over recent years. These all show that consumers are familiar with the term *probiotics* and are aware of the role of food supplements containing probiotics for their general health, but also that **consumers feel poorly informed due to the fact that the term may not appear on the packaging**.

Moreover, the knowledge on probiotic foods and supplements varies across Europe. Consumers in Poland, Spain and Italy (respectively 78%, 67%, 62%) are most aware of what probiotics are, while Danish consumers are the least aware (32%). Overall, consumers declared to be very or fairly familiar with probiotics[4].

57% of European consumers stated they have purchased a probiotic product in the previous 12 months. 29% of these buy supplements probiotic products. 82% of European probiotic consumers stated they consume probiotic products as part of an everyday balanced diet, while 18% answered they only take probiotics when proving discomfort that a product could address[5].

Out of these surveys, it is clear that consumers do understand the general benefits of probiotics: **consumers take probiotics for the promotion of gut and immune health and to support the microbiome[6]**.

In all surveyed markets, **consumers indicate they would like to see the term *probiotics* indicated on the packaging**. The markets who feel strongest about the appearance of the term on the packaging are Italy and Spain (90%), followed by Belgium (83%) and Germany (82%)[7].

4 - IPA Europe: Probiotics in Europe: consumer survey in 8 EU countries, 8000 consumers 2022

5 - FMCG Gurus, Probiotic Survey, April 2022, 12 countries, 12 000 consumers (Denmark, France, Germany, Italy, Netherlands, Poland, Serbia, Slovenia, Spain, Sweden, Turkey, UK)

6 - Chr. Hansen survey 2022 (New study of consumer understanding of probiotics points to significant opportunities for the food industry)

7 - IPA Europe Probiotic study 2022, Elaboration based on data provided by 3GEM, 1000 responders per country

The European Commission approach

In 2007, the European Commission published the Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[8]. In the document, the term *probiotic* is considered by the European Commission as implying a health benefit and should therefore be classified as a health claim. This guidance though is not legally binding.

This approach continues to have concrete impacts both on the sector and on the consumers' rights to clear and truthful information which is necessary for making informed choices.

In fact, so far, of the almost 400 health claim applications with probiotics that have been submitted for authorisation, only one was authorised[9]. All other probiotics health claim applications have been either rejected or withdrawn due to the uncertainty of the EFSA assessments. The most common reason for rejection was the insufficient characterisation.

Moreover, the lack of information to consumers is in contrast with the requirements laid down in the Food Information for Consumers Regulation (FIC, EU 1169/2011), which 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.[10]

The *2007 approach* to the use of the term *probiotics* is inadvertently causing a lack of a clear information on probiotic products reducing the consumers' ability to make informed choices. This was recently reported by a survey in 8 European Countries, commissioned by IPA Europe, meant to monitor the evolution of European consumers' opinions, trends and behaviours regarding probiotics. The research company found that **"consumers declare that they are better informed in countries where the term 'probiotics' is (partially) allowed by National guidance/ standard: this is the case, for example, in Italy, Spain, and Poland. Very often, the guidance for using probiotics comes from health professionals, which also explains why so many people are aware of this category but find no match when looking at product labels".**[11]

8 - European Commission Guidance Documents

9 - EFSA Scientific Opinion on the substantiation of health claims related to live yoghurt cultures and improved lactose digestion (ID 1143, 2976) pursuant to Article 13(1) of Regulation (EC) No 1924/20061 (2011)

10 - Regulation (EU) No 1169/2011 on the provision of food information to consumers

11 - IPA Europe: Probiotics in Europe: consumer survey in 8 EU countries, 8000 consumers 2022

Member States solutions and lack of harmonisation

The European Commission has not reviewed the *2007 approach*, nevertheless, in recent years, different approaches in favour of the acceptance of the term "probiotics" have been developed by EU Member States.

ITALY

The Italian Guidelines on Probiotics and Prebiotics (2013, 2018) are comprehensive guidelines for probiotics in food, allowing the use of the term *probiotics* if specific conditions are fulfilled. The Italian Guidelines (in EN) are available at the following link: https://www.salute.gov.it/imgs/C_17_pubblicazioni_1016_ulterioriallegati_ulteriореallegato_0_alleg.pdf

CZECH REPUBLIC

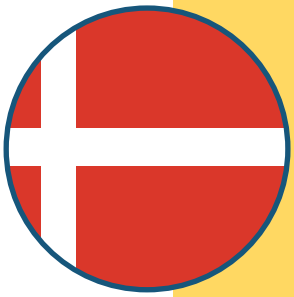
The Czech Authorities have issued national guidelines (2018) allowing the use of the expression "contains probiotics" as a nutritional claim, subject to the fulfilment of the conditions of use for nutrition claims defined in the Nutrition and Health Claims Regulation (NHCR). The same approach is taken also by the Bulgarian Authorities. The Czech Guidelines (in CZ) are available at the following link: https://eagri.cz/public/portal/-q341063---Ss4UXdEz/prirucka-pro-provozovatele

SPAIN

The Spanish Agency for Food Safety and Nutrition (AESAN) issued a National Q&A (2020) indicating that Spanish Authorities will accept the use of the term *probiotics* on the basis of the Mutual Recognition Principle until a *harmonised* approach will be agreed at the EU level. The Spanish Q&A (in ES) is available at the following link: https://www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria/subdetalle/probioticos.htm

THE NETHERLANDS

The Dutch "Nutrition and Health Claims Handbook" (last update 2022) provides clear indication on the use of the term *probiotics* in the Netherlands. The term *probiotics* can be used in mandatory information, to identify the categories of micronutrients or substances that characterise the product in food supplements. The Dutch Handbook (in NL) is available at the following link: https://www.nvwa.nl/documenten/consument/eten-drinken-roken/etikettering/publicaties/handboek-voedings--en-gezondheidsclaims

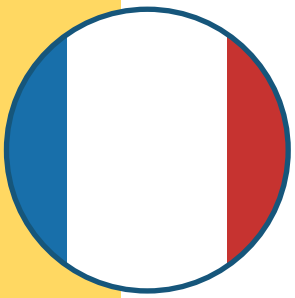


DENMARK

The Danish Authorities have published new guidelines on labelling (last update 2023) which authorise the use of the term *probiotics* on food supplements labels. The term can be used as a mandatory category designation in food supplements. The Danish Guidelines (in DK) are available at the following link: https://en.foedevarestyrelsen.dk/food/labelling-and-marketing-of-food

FRANCE

The French authorities authorise the use of the term *probiotics* to designate the category of food supplements since the beginning of 2023. DGCCRF has updated the Q&A on its website. It provides a good framework for the use of the term. The Q&A is available (in FR) at the following link: https://www.economie.gouv.fr/dgccrf/Consommation/Etiquetage-des-produits/Allegations-nutrionnelles-et-de-sante



EHPM welcomes such developments at national level as a clear sign that also National Authorities acknowledge the impacts of the *2007 approach* and that they are willing to find concrete solutions that will enhance consumers' information. However, the adoption of different approaches within the EU Single Market inadvertently leads to competition distortions, internal barriers to trade, and market access difficulties for European companies.

The category approach – pragmatism prevails

12.a - Dutch "Nutrition and Health Claims Handbook"

12.b - Danish Authorities new guideline on labelling

12.c - French Q&A

Amongst the different developments at national level, the most pragmatic one is the so called *category approach* adopted already by the Dutch, the Polish, the Danish, and most recently by the French Authorities.

The category approach allows the use of the term *probiotics* on the product label **to indicate the mandatory category of the micronutrients or substances that characterise the food supplement, i.e. live lactic acid bacteria and/or bifidobacteria at well-defined conditions**.

For instance, the Danish Authorities require that the category designation *probiotics* must appear on the labelling of the product, but not in the list of ingredients, where, instead, the genera, species and strain of the microorganism in question must be indicated. Substantially, **the term must not be used in such a way that it appears as a health claim of the product**. This is required not only by the Danish Authorities, but also by the Dutch and by the French Authorities.

Notably, the French Authorities, among other requirements, have also defined conditions for the probiotics requiring, for example, that food supplements bearing this term provide a sufficient amount of live cells of a strain per day to allow a significant amount (i.e. in the range of 10^7 to 10^9 live cells of one strain per day) of live microorganisms to reach the gastrointestinal tract and grow.[12]

LEGAL BASIS

The legal basis of the category approach lies in Article 6.3.(a) of the Food Supplements Directive (2002/46/EC) which states that it is mandatory to indicate the category of substances that characterise the product:

Article 6

1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be 'food supplement'.

2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

3. Without prejudice to Directive 2000/13/EC, the labelling shall bear the following particulars: (a) **the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances**;

Mandatory mentions do not fall under the scope of the claims **Regulation (EC) No 1924/2006**. Art 2. 2., point 1 of the claims regulation defines a *claim* as: "any message or representation, which is **not mandatory** under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics".

The use of the term *probiotics* to describe a category, which is mandatory for a food supplement, therefore falls out of the scope of Regulation EC N°1924/2006 and, consequently, also out of the guidance document[13] of the European Commission.

13 - European Commission Guidance on the Implementation of Regulation N° 1924/2006

EHPM believes that the category approach for food supplements is a pragmatic approach, in line with the EU legal requirements, easily applicable by Authorities and food business operators (FBOs) and provides consumers with truthful and easily understandable information on the label. Indeed, it allows FBOs to properly inform consumers in an adequate way in the respect of the claims legislation.

EHPM is in favour of a harmonised European approach to the use of the term *probiotics* for food supplements in line with the *category* approach implemented by a growing number of Member States.

EHPM calls for a European harmonised approach for better consumer information and high quality and safe probiotic food supplements

EHPM is concerned about the lack of information for consumers on probiotic food supplements. Whilst consumer research[14] [15] [16] [17] shows that consumers are familiar with the term *probiotics* and are aware of their general health benefits, the current guidance creates the absence of the use of this term "probiotics", particularly on packaging, and thus is preventing the consumer to make well informed choices when buying such products.

The lack of harmonised approach is a huge hurdle for the development of the probiotic market. EHPM created a working group dedicated to probiotics with the objective to try to find a solution for this unacceptable situation that generates regulatory uncertainties. EHPM is concerned about differing approaches across Member States leading to an unequal treatment between EU consumers in different countries and creating unfair competition for the food supplements operators and putting barriers to the functioning of the EU internal market.

EHPM is in favour of a harmonised, European approach to the use of the term *probiotics*, providing clear information for consumers and offering them high quality and safe probiotic food supplements. Therefore, **EHPM calls the European Commission and the EU Member States to reconsider their approach on probiotic supplements and to align with the pragmatic *category approach* already successfully adopted by several Member States**.

14 - Euromonitor International for International Probiotic Association, 2021

15 - IPA Europe: Probiotics in Europe: consumer survey in 8 EU countries, 8000 consumers 2022

16 - FMCG Gurus, Probiotic Survey, April 2022, 12 countries, 12 000 consumers (Denmark, France, Germany, Italy, Netherlands, Poland, Serbia, Slovenia, Spain, Sweden, Turkey, UK)

17 - Chr. Hansen survey 2022 (New study of consumer understanding of probiotics points to significant opportunities for the food industry)

EHPM PROBIOTICS GUIDELINES

At the same time, EHPM developed probiotic guidelines for a practical, reliable, and safe use of probiotics in food supplements. The guidelines provide recommendations on what constitutes probiotic microorganisms: strain characterisation, safety, viability, manufacturing practices and labelling of food supplements containing probiotics. By all means, the guidelines do not intend to be legal in nature, but consists in recommendations for operators in the food supplement sector for the control of the formulations and manufacturing conditions of their products, supporting them in the marketing of ever safer and higher quality products.

The guidelines have been developed by the EHPM Probiotics Working Group, which gathers experts from the food supplements sector to proactively develop balanced and practical proposals to create a labelling environment that consumers can trust, allowing them to make informed choices about the products they purchase and consume.

About the EHPM

The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975. With its 15 National Associations and its Member Companies, EHPM represents product manufacturers and distributors, the majority of whom are small and medium-sized enterprises (SMEs), in 17 European countries.

EHPM proactively cooperates with the European Institutions and stakeholders to strengthen the overarching strategy for a healthier Europe enshrined in the Farm to Fork and the European Green Deal.

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