



Event Report | Feb. - Apr. 2023

Probiotics in the EU: A regulatory conundrum

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While the European market for food with beneficial live bacteria known as probiotics is particularly 'alive', the EU regulatory framework on the topic is stuck in 2006 blocking the potential of the sector.

Requests to the European Commission for overcoming the outdated rules are piling up, while some member states even decided to go it alone and tackle the lack of legal clarity – an approach that risks undermining the unity of the Single Market.

In this series of articles, EURACTIV explores the current situation and the next challenges for the probiotics sector in the EU.

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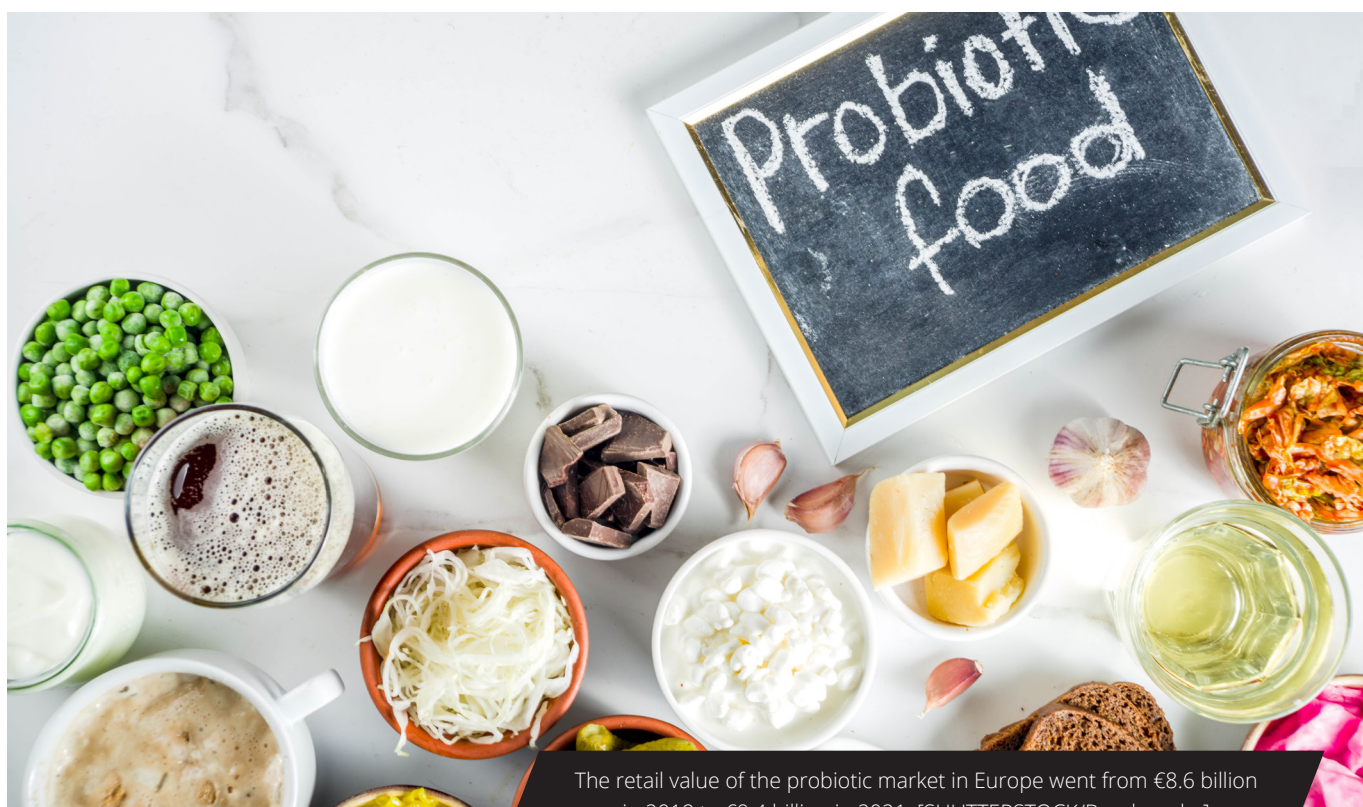
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Probiotics sector ferments amid push to tweak outdated EU framework

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By Gerardo Fortuna | EURACTIV.com



The retail value of the probiotic market in Europe went from €8.6 billion in 2018 to €9.4 billion in 2021. [SHUTTERSTOCK/Bondarenko]

Latest developments on the 'probiotics' term saga suggest that the time is ripe for overcoming the current regulatory framework which, for more than 15 years, has hindered the EU probiotics sector from flourishing as well as restricting consumer information.

Probiotics are live microorganisms thought to provide beneficial effects when consumed, generally by improving or restoring the gut microbiome and the bacterial flora and reinforcing the immune system.

The widely used definition of probiotics comes from [an expert consultation group set up in 2001](#)

by the World Health Organisation (WHO), and the Food and Agriculture Organisation (FAO) which described them as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host".

Much has been made of the potential of probiotics in human health recently, resulting in a boom

in probiotic yoghurt and fermented drinks – including today's popular beverage, kombucha – as well as probiotic food supplements.

Only in Europe, the retail value of the probiotic market (which includes sour milk products, probiotic yoghurts, and probiotic supplements) went from €8.6 billion in 2018 to €9.4 billion in 2021 – with the highest increase recorded in online sales for probiotic supplements worthy €190 million.

However, probiotics suffer from a certain degree of uncertainty at the EU level linked to a restrictive regulatory approach to using the term 'probiotics' itself.

This led to the peculiar situation in which probiotics cannot be advertised as such on food labels in the EU market, whereas the term is broadly used worldwide with no restrictions.

A regulatory bottleneck

Food business operators in the EU have to refer to the so-called '[Claims regulation](#)' if they want to highlight particular beneficial effects or just nutritional facts of their products – for instance, on the product label or in its advertising.

This regulatory framework provides that nutritional and health claims may only be made on foods if they are authorised on a case-by-case basis, following a scientific assessment by the European Food Safety Authority (EFSA).

Problems for probiotics started in 2006 with the Commission's guidance on implementing this regulation. In these non-binding guidelines, the EU executive noted that marketing a product by saying

it 'contains probiotics/prebiotics' should be considered a health claim 'per se'.

However, all the applications submitted for the authorisation of the term probiotic as a health claim have not received a favourable opinion by EFSA "due to the lack of established scientific evidence as to the effects on human health," explained a Commission official to EURACTIV.

"It is therefore prohibited, for the time being, to use health claims on probiotics in the EU market, as none have been authorised," the official said.

The main consequence of this regulatory bottleneck is the impossibility of just informing about the probiotics content of a certain food on labels, even without an actual health claim, such as an additional remark on the benefits for human health.

The only authorised health claim that indicates the presence of probiotics so far is 'live cultures of yoghurt improve lactose digestion', which is how most probiotic yoghurts are currently marketed.

"New applications could be introduced in the future, with updated scientific grounds, for further consideration by EFSA," added the Commission official, maintaining the strong stance from the 2006 guidance.

'What's in a name?'

However, things are slowly changing as pushes to tweak the current obsolete regulatory framework are piling up.

The latest development on the 'probiotic' term saga comes

from the Fit for Future (F4F) platform, an advisor body of the European Commission consisting of representatives from member states, other EU institutions, and stakeholders which delivers opinions for simplification, burden reduction, and modernisation of existing EU laws.

In a set of suggestions to the EU executive [released last December](#), the platform called on the Commission to "consider appropriate actions to provide for a harmonised implementation and enforcement of the rule guiding industry stakeholders to uniformly implement EU rules related to probiotics content of food products."

According to the advisory body, "both consumers and industry will benefit from a harmonised approach," as different national interpretations of the term 'probiotics' might put the internal market at risk of fragmentation.

Since 2018 some EU member states, such as Italy, Czechia, Spain, and most recently France, have, in the meantime, adopted national guidelines developing certain requirements for qualifying specific strains as probiotics as factual information.

"These member states are taking a different position opening a small door to probiotics by distinguishing 'probiotics' as just a category from a real health claim," Katia Merten-Lentz, a lawyer at the Brussels and Paris Bars and expert on the matter, told EURACTIV.

According to the expert, the 2006 Commission guidance is no longer acceptable, particularly compared to the regulatory approaches adopted outside the EU.

In several third countries, like the US and Brazil, probiotics are already considered food or as ingredients, while Canadian authorities even allow the use of health claims about microorganisms represented as 'probiotics' on food labels and in advertising.

Likewise, third countries like India, Argentina, and Thailand have adopted specific probiotic regulations and definitions for probiotics.

What consumer wants

In its suggestions, the Fit for Future (F4F) platform suggests kicking off a comprehensive dialogue about using the word 'probiotic' as it "would ensure better legal certainty and better information to consumers about the products they are interested in."

In a recent survey of 8,000 consumers in eight different European countries conducted by 3GEM on behalf of the International Probiotics Association – Europe (IPA Europe), 57% of those surveyed do not feel informed that a product contains probiotics.

Likewise, 79% of the respondents would like to be informed whether

a product contains probiotics through food labels, either in the list of ingredients or on the packaging.

"We need, at least, to inform consumers as they would like to know that they are buying probiotics," concluded Merten-Lentz.

Contacted by EURACTIV, a Commission official said that the EU executive is aware that one of the suggestions made in the opinion of the F4F platform concerns probiotics but did not comment further.

End of the probiotics term saga can only be 'political', expert says

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By Gerardo Fortuna | EURACTIV.com



The current regulatory brain-teaser on the use of the 'probiotics' term in the EU can only be solved at the political level with an initiative by the European Commission pushed by lawmakers, according to Italian professor Lorenzo Morelli.

Probiotics cannot be advertised as such on food labels in the EU market as the term is considered a 'health claim' and, therefore, may only be made on foods if authorised on a case-by-case basis, following a scientific assessment by

the European Food Safety Authority (EFSA).

However, EFSA has not yet delivered a favourable opinion to all applications submitted for authorising the term probiotic as a health claim.

But for Morelli, director of the Department of Food Science and Technology at the Cattolica University in Milan, "EFSA is, in any case, just an advisory body."

"If the EU policymakers were

to intervene with an explanatory note, that would be the end of the matter," he continued.

Contacted by EURACTIV, an EFSA spokesperson confirmed that the role of the EU agency is to provide scientific advice to EU policymakers

"We're not responsible for setting rules including authorising the use of nutrition and health claims made on food in the EU market – that's for the European Commission and EU Member States," the spokesperson said.

The 'botanicals' solution

Morelli mentioned another peculiar situation occurring with botanicals and derived preparations made from plants, algae, fungi or lichens when used as food supplements.

There is no such centralised authorisation procedure for these food supplements, but they are typically labelled as natural foods with various claims on possible health benefits.

To address the regulatory vacuum, three member states – Belgium, France, and Italy – unified their lists of health claims on botanicals in the so-called BEL-FR-IT protocol, which was then informally accepted as a reference at the EU level.

“One could even start like this for probiotics too. However, if the European Commission intervened, perhaps under pressure from a few parliamentarians [it would be better],” he said.

The ideal solution for Morelli would be to follow a similar pathway to the one adopted for botanicals and recognise that probiotics, as food supplements, traditionally support a balanced composition of the gut microbiota.

“If you advertise for products containing probiotics specific beneficial characterisations such as help in decreasing constipation, or the irritable bowel syndrome, then it is a health claim that needs approval,” he added.

The Italian way

Since 2018, some EU member states have started adopting

national guidelines to face the actual ban on the use of the ‘probiotics’ term for foodstuff. Through the guidelines, these countries have developed certain requirements for qualifying specific strains as probiotics as factual information.

In Italy, for instance, these guidelines rely on the obligation to provide consumers with the reasons behind using a certain food supplement in foodstuff.

The reason for using probiotics is the physiological effect on the balance of intestinal flora – something that is not considered a ‘health claim’ by EFSA in 2009 when the agency evaluated the increasing levels of microflora not carrying in themselves beneficial effects on health.

“If we say that a certain supplement is designed to support balanced intestinal microflora and is, therefore, composed of probiotic bacteria, we are not going against the EU ban on the use of the term probiotic, according to the Italian thinking,” Morelli said.

Although other countries such as Spain and Denmark have followed a similar approach, the solution found by Italy is limited to the national market only, meaning that food producers using probiotics cannot benefit from the free movement of goods across Europe.

Consumer protection

According to Morelli, the rigid position of the EU on the matter is ultimately harming the consumer.

He pointed out that supplements labelled as ‘lactic ferments’ have reappeared in Italian supermarkets, although the term is no longer regulated, these products

could have an ineffective dose of live cultures.

With the guidelines on probiotics, the Italian regulator has, on the contrary, established some standards. For instance, food producers “must guarantee the consumer a minimum viable load of 1,000,000 per bacterial strain for shelf life,” the professor said.

The other worrying trend is using the term ‘probiotics’ in cosmetics, shampoos, and detergents, which are not covered by the ‘health claims’ regulation as they are not foodstuff.

“How can anyone think lactic acid bacteria or bifidobacteria cells can survive in a shampoo with surfactants? It’s a scam, but the term probiotic has acquired a good consumer reputation, so it’s used,” he said, adding that in this way, the food industry, which is the sector that has originally invested in these supplements, is ‘betrayed and beaten’.

PROMOTED CONTENT

DISCLAIMER: All opinions in this column reflect the views of the author(s), not of EURACTIV Media network.

The evolution of European consumers' opinions, trends, and behaviours is shaking up the probiotic market in the EU.

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By IPA Europe | EURACTIV.com



[IPA Europe]

// The evolution of European consumers' opinions, trends, and behaviours shows a strong interest in overall health and well-being. It also highlights that consumers would like to be better informed on the labelling and in communications about probiotic food, and about probiotic microorganisms in food and food supplements".

These were the main results of the online survey carried out to assess people's understanding of the probiotic offer currently on the European market, and their use of probiotic foods and supplements in daily life. [The survey was conducted by the agency 3 Gem in 8 European countries](#) (Italy, Denmark, the Netherlands, Spain, Poland, Belgium, Germany, and Sweden)

on a total of 8000 consumers.

The key findings clearly show that:

Probiotics are popular. Even people who do not use or buy probiotics know the term (56% out of 8.000). Consumers who know what probiotic foods and supplements are, and who also



consume them, mention that their main drive is their overall health and well-being.

Very often, the information 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. Consumers use probiotics and are better informed in countries that have allowed the use of the term for a long time.

The majority of the panel of consumers do not feel well informed that a product contains probiotics (57% out of 8.000); when asked if they want to know more about the packaging and label, the percentage rises to 79% on average.

The survey confirmed the interest in probiotic food and food supplements in Europe. It appears that for the majority

of consumers the answer to “Do you know what probiotics and probiotic foods are?” is “yes” (63%). Women and men seem to consume probiotics almost equally. On average the peak consumption is in the 25-44 age group.

There is quite a substantial amount of people who know the word ‘probiotic’, even though they say that they do not consume them. This is probably due to the large amount of information available on probiotics in online search engines on the web, mainly from commercial and media sources. However, these sites often fail to paint a complete picture, so consumers may miss relevant information.

It is not only “in some third countries” that the use of the term ‘probiotics’ may be regulated differently. Speaking at IPA Probiota World Congress in Barcelona on 8 February 2023,

Rosanna Pecere, Executive Director of IPA Europe, presented an overview of the European market. Since 2018, some EU countries are progressively allowing the use of the term ‘probiotic’ as a ‘commercial practice’, while others are setting national conditions and guidance at the national level. This increased use of the term ‘probiotic’ is also reflected by the market evolution: during the period 2018-2021, the European market of probiotic food and food supplements shows a significant increase in sales of +9,08%. All the ‘probiotic’ products, from European countries and third countries, are in free circulation in the European single market.

In absence of a clear European framework, [European countries are adopting national practices](#) allowing the use of the term ‘probiotic’ on the label and communication, under conditions of use. France, DGCCRF Q&A

published on January 2023 states some criteria of efficacy, the viability of the microorganism, accompanied by the use of a clear statement relating to the 'balance of intestinal flora'. Like the DGCCRF Q&A, the Italian guidelines establish criteria for characterisation, effectiveness, and quantitative viability for probiotics microorganisms in food and food supplements, and the use of the wording for the products that meet these specific criteria. Also, in the Spanish Q&A the term 'probiotic' is used generally, and refers to bacterial species, bacterial strains, or live microorganism species in food and food supplements. Both Spain's and Italy's guidelines cover food and food supplement products containing probiotic micro-organisms. Other EU countries are also having national practices in the use of the term probiotic.

Therefore, it is not only "in some non-EU countries" that

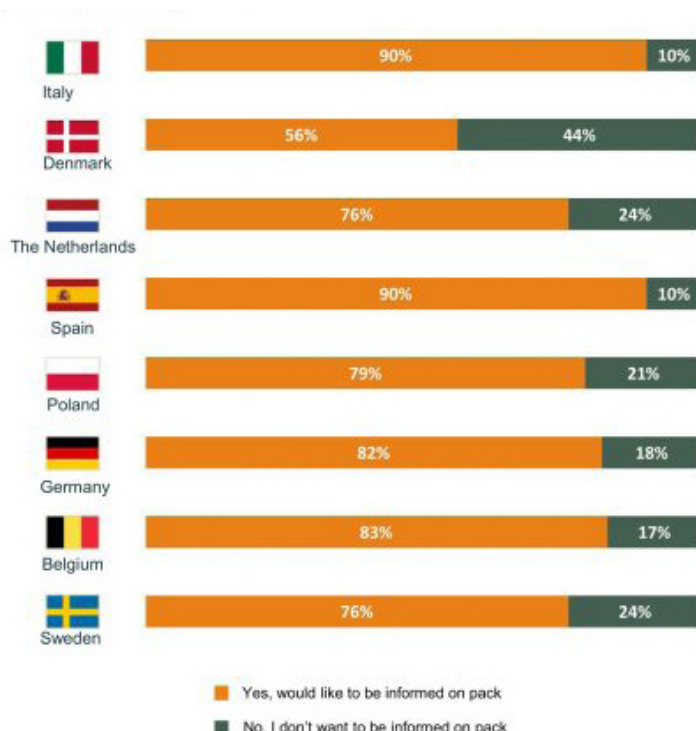
the use of the term 'probiotics' may be regulated differently, and that the different practices can be confusing for European consumers. In March 2023, during the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU 43) in Dusseldorf, there was support by several regions of the world, such as Asia, Africa, the Near East, and Latin America for the proposal to work on harmonized probiotic guidelines. This work will take a long time, but it can be an essential part of the process of harmonising the probiotics framework, but surprisingly the European Commission did not support the proposal.

[‘E-commerce growth is driven by Europe’ by Lumina Intelligence](#), an insight service on the e-commerce retail channel for the probiotics market. The research, based on 25 countries around the world, shows a high increase in the probiotic supplements' e-commerce market size, which was valued US\$ 928

million in 2018 and reached US\$ 1.7 billion in 2021 (+81%). Moreover, we observe that the e-com growth in 2021 for probiotic supplements is driven by Europe, with an increase of +20% in 2020 (versus +15% in America and APAC). Customer reviews grew by 2k% (or 510k) with the growth peaking in H1 2021.

We can conclude that, the lack of agreed criteria and conditions of use to define the probiotic category in the EU expose the manufacturers to a situation of unfair competition and the different practices can create confusion for European consumers who are actively looking for these products. It is probably time to establish certain criteria within the EU and at the international level in order to improve consumer protection against misleading practices and avoid serious disruptions in the European market.

When food and supplements with probiotic microorganisms are available in shops, would you like to see the term 'probiotic' indicated on the product? (e.g in the ingredient list, on the packaging or somewhere else on the label)



"79% of the consumers would like to know more about probiotics through, for example, food labels"

In all tested markets, consumers indicate they would like to see the term 'probiotic' indicated on the packaging.

The markets that feel strongest about the appearance on packaging are Italy and Spain.



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