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Humiome®

Harness the power of postbiotics

Trends and innovations reinventing the biotics market



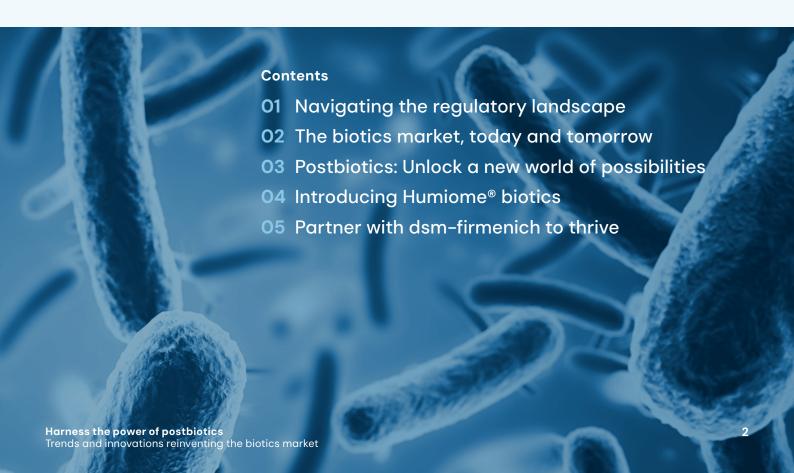
The realm of biotic ingredients — namely probiotics, prebiotics and postbiotics — is undergoing a remarkable evolution.

These ingredients are at the heart of pioneering advancements in the Health from the Gut space and hold significant potential for growth, setting the stage for innovation across a diverse spectrum of products and applications — including functional foods, beverages and nutraceutical solutions.

Within this market, **postbiotics** are emerging as a particularly promising avenue for product development due to their scientifically validated health benefits, high stability profile and possible uses across a wide range of product formats.

However, the biotic ingredients landscape is dynamic and strongly influenced by evolving global regulations. The term "probiotic" is already well–established and authorized in selected regions for instance, whereas "postbiotic" is on the cusp of regulatory recognition. This makes innovation in the postbiotic field more complex.

As an end-to-end partner in the human health, nutrition and care space, dsm-firmenich has the scientific and technical capabilities to help brands navigate the developing biotics market with confidence. We're ready to push the boundaries of biotics innovation with a new way of thinking and cutting-edge solutions that support consumer health more holistically. **Are you?**



O1 Navigating the regulatory landscape

Understanding the innovation opportunities in a category involves examining the characteristics of the market and pathways to access. So, what are the possibilities for biotics-based developments within the current regulatory framework in the European Union (EU)?



Probiotics

Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.¹

In Europe, the term "probiotic" is considered as a general, non-specific health claim under Regulation 1924/2006.² Presently, there is no acceptance of the term as a generic descriptor and individual claims for specific strains have been rejected by the EFSA (European Food Safety Authority).

The only authorized health claim is for food products (Regulation 432/2012)³ — that is "Live cultures in yoghurt or fermented milk improve lactose digestion of the product in individuals who have difficulty digesting lactose". Importantly, this claim mentions the term "live cultures" rather than "probiotics" and is only used for specific strains and quantities, and for yoghurt and fermented milk. For anything outside this field, including all dietary supplements, the strain must be mentioned.

In the absence of harmonization at EU level, some countries, like Spain, the Netherlands, Denmark, Italy and France, are developing their own regulations related to dietary supplements. Some even consider the inclusion of the term "probiotic" as an ingredient name as mandatory.



Prebiotics

Prebiotics are a substrate that is selectively utilized by host microorganisms conferring a health benefit on the host.⁴

There is no authorization at European level for the term "prebiotics". It is also considered a health claim. As prebiotics were established after the term "probiotic" was defined, they are less advanced in terms of regulations.



Postbiotics

Postbiotics are a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host.⁵

They were defined more recently — in 2021 — by the ISAPP (The International Scientific Association of Probiotics and Prebiotics). However, there is still no authorization to use the term and no position is yet taken by regulatory bodies in the EU. The key difference between postbiotics and fermented foods (which also include inanimate microorganisms) is that the microbial composition of a postbiotic must be characterized prior to fermentation — whereas many fermented foods are made from undefined microorganisms.

In summary...

The biotics regulatory landscape is complex. It's likely that all biotics will face similar regulatory hurdles due to their definition, which involves providing "health benefits to the host".

The optimal resolution would involve approving biotics as an ingredient category rather than categorizing them based on health claims.⁶ This approach would promote consistent legislation across Europe, ensuring a level playing field for competition. Additionally, it would enhance transparency for consumers regarding the composition of products and simplify communication.

And in the US?7

Regulation is much more flexible in the US, although it is important to note that US-based medical research center, the NIH (National Institutes of Health), emphasizes that not all probiotics possess scientifically proven effects. FDA (Food and Drug Administration) approval is not required for the marketing of dietary supplements and the strength of evidence behind health claims is the responsibility of the manufacturer. There is strict regulation only in the case of probiotics used to treat or prevent a disease.

O2 The biotics market, today and tomorrow

Crafting health and wellness solutions that resonate with consumers requires a deep understanding of their evolving expectations and preferences, as well as more established trends. Here, we summarize what consumers really want from biotic solutions and where the market is headed.

An evolution of health claims in line with advances in research^{8,9}

Originally, research was focused on digestion, immunity and vaginal health. However, today, science is expanding to investigate the benefits of biotics in cognition, skin, metabolism and more. Thus, even though there is still a strong association between biotics and digestive support, emerging evidence continues to showcase their broader benefits in human health — creating exciting opportunities for innovation in the space.



Favorite consumer health claims

A wide range of health benefits are sought after by consumers in the global dietary supplements market.¹⁰

European consumers are increasing their consumption of probiotics, although usage levels vary from country to country. Digestion and immunity are the most prioritized health areas. But there is growing demand for products that offer mental health support too. 10,13

More specifically, postbiotics are being recognized not only for their impact on gut health and immunity, but also for lowering blood sugar, their role in skin health, reducing appetite, and more.^{8,10} Ultra-segmentation is also on the increase, with health claims becoming more and more precise.^{8,9}

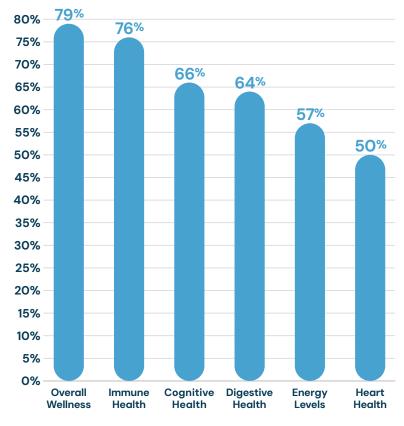


Figure 1. 'What areas of your health do you want to improve/address by using supplements?' (2022)14

A broader awareness of overall health

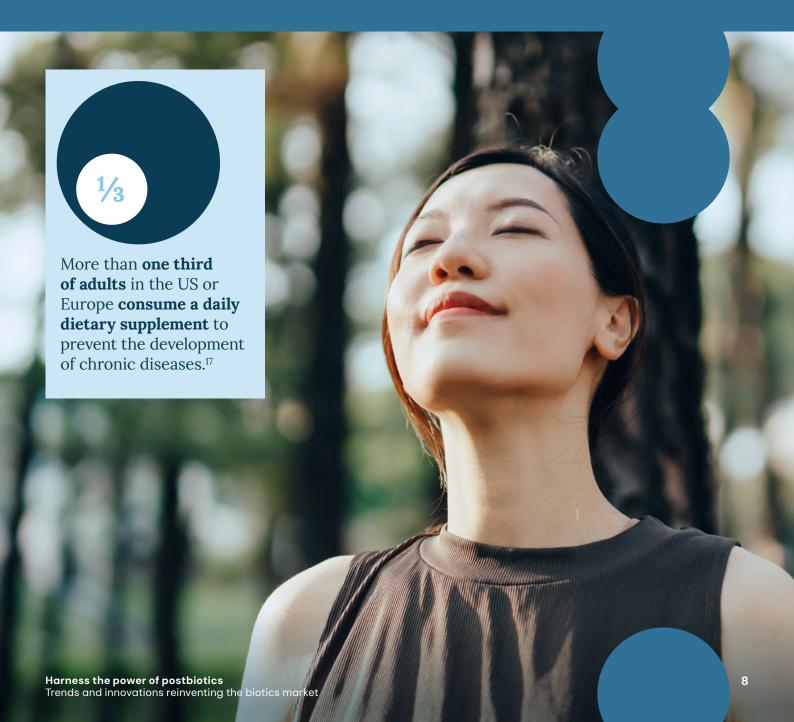
At the same time, there is a growing holistic health mindset. Indeed, there is a rising interest in the microbiome and its impact on overall health, wellness and immunity, especially among younger generations.¹⁵

Preventive health is also developing as a dominant health trend.^{9,16} Governments, as well as consumers, are becoming aware of the importance of prevention, especially in reducing public health expenditure. As evidence of this growing trend, more than one third of adults in the US or Europe consume a daily dietary supplement to prevent the development of chronic diseases.¹⁷ Digestive health, in particular, is expected to be at the forefront of proactive health innovation due to its observed link with overall wellness.

Other consumer preferences

"Naturalness" is increasingly preferred by consumers, who seek more holistic options to support their health. Today, there are high expectations concerning the composition of products, including demands for simplification and the use of natural ingredients.¹⁸

Consumers seek added reassurance too — mostly via scientific research and expert opinions. Certainly, more individuals require comprehensive information and education about a product and its attributes, such as strains included, metabolites, doses and effects *before* they decide to purchase.^{11,12,15}



03 Postbiotics: Unlocka new world of possibilities

A newly defined category of biotics

Clearly defined since 2021, postbiotics are a growing category in the biotics market with significant innovation potential. But *who* is the postbiotic consumer?

The primary consumers of dietary supplements are millennials, followed by baby boomers and Gen X. Individuals in upper socioeconomic brackets also form a significant proportion of the consumer base, while seniors represent a smaller segment of the potential market.

In recent years, consumers have displayed increasing health consciousness, with approximately one in four saying they have used nutritional supplements in the last two years to enhance their wellbeing. Among these individuals, 74% have tried a solution in the last 12 months to improve their digestive health, although only 48% opted for probiotics for this specific health benefit.

Today, dietary supplement consumers place high importance on product safety, effectiveness and quality. Postbiotics, like other biotics, align with consumers' pursuit of digestive health and overall wellness — making them an attractive choice for advancements in the space.



of consumers have tried a supplement solution in the last 12 months¹⁹



of consumers opted for probiotics for digestive health¹⁹

Key advantages of postbiotics^{20,21}



Proven health benefits:

Postbiotics are associated with digestive, metabolic, immune and brain health.



They are safe:

They cannot cause antibiotic resistance, sepsis and fungaemia.



Physiological effects on the host:

Demonstrated to modulate microbiota positively, act against pathogenic bacteria and beneficially regulate the intestinal epithelium.



Convenience:

Postbiotics are easy to standardize, transport and store. They do not require refrigeration and demonstrate high stability batch-to-batch.

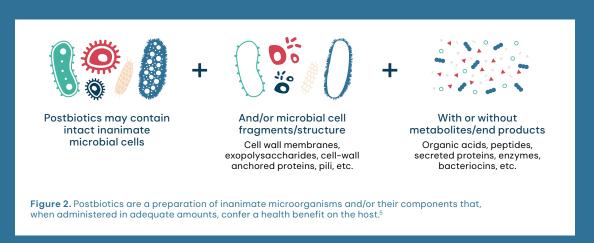
Guaranteeing quality is essential

The 4 criteria for postbiotic classification are to:²⁰

- Include inactivated microbial cells with or without metabolites or cell components
- 2 Have confirmed beneficial effects in humans or animals in a controlled, high-quality trial
- Be administered at a host surface, such as the gastrointestinal tract
- Be assessed for safety in the target host for the intended use.

Variety within the category

As a reminder, postbiotic ingredients contain intact inanimate microbial cells and/or microbial cell fragments or structures, such as cell wall, membranes, exopolysaccharides and pili (Figure 2). Moreover, they can contain metabolites or end products such as organic acids, peptides, secreted proteins, enzymes, vitamins and bacteriocins.



A wide range of possible uses¹⁵

There are many uses for postbiotics. Indeed, they can be combined with probiotics in food and beverages or utilized alone.

Diversity of products:

Today, there is a blurred line between food and nutraceuticals, with trends like "foodification" and "nutraceutization" leading to a variety of product types. Additionally, the use of postbiotics in human health can be extended to pet food products.

Diversity of distribution channels:

Products containing biotics can be found through various distribution channels, such as pharmacies, supermarkets and e-commerce platforms.

Promising market:

The postbiotics market holds significant promise. Already, personalized dietary supplements are on the rise with the development of solutions tailored to individual consumers and their unique microbiota.

Choosing the best product format

In food

Biotics can be found in many foods and drinks (especially dairy products), but probiotic formulation remains a challenge because they are living microorganisms.²² Thanks to their stability properties, viability and efficacy, postbiotics are a viable solution. For the functional drinks market, especially powder mixes, including hot beverages, there is also huge potential for innovation.

In dietary supplements

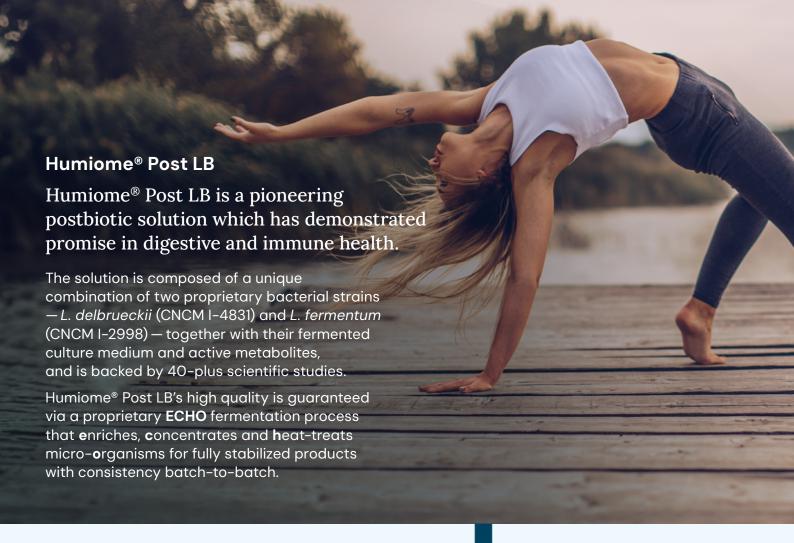
While capsules and pills continue to hold a significant share of the dietary supplement market, the emergence of gummies, constituting 16% of the market, has been notable.¹⁵

Additionally, there is a growing trend towards powder sticks, dispersible tablets, drops and chewable tablets, which offer enhanced taste and practicality. Unlike probiotics — which can be unstable in certain formulations — postbiotics exhibit high stability and can therefore be included in more innovative formats, like gummies, with ease.

Nonetheless, the dietary supplement sector still demands galenic formulations to propel its growth. Recent product innovations encompass a wide range of formats, including chocolate bars, chewing gums, powders, wellness bars and gels — with more exciting developments anticipated in the future!

O4 Introducing Humiome® Postbiotics

The Humiome® Postbiotics portfolio takes innovation to the next level in the dietary supplement space. It forms part of dsm-firmenich's Humiome® biotics brand — a next-generation, multi-ingredient portfolio of prebiotics, probiotics, postbiotics and synbiotics; powered by science and backed by experts.



Our Health from the Gut platform

We understand the complex interactions of a healthy and balanced gut ecosystem; and more importantly, how to restore and maintain balance in the microbiome to support holistic wellbeing. That's why we've developed the Health from the Gut platform.

By selectively supporting and preserving the key pillars of healthy gut ecosystem to maintain its natural balance, our Health from the Gut platform is inspiring purpose-led solutions that unlock the holistic health potential of the gut. The unique offering is supported by dsm-firmenich's proven gut-supporting ingredients, customized solutions and expert services; empowering innovators to bring their next Health from the Gut product to market faster and with enduring success.



Postbiotic innovation starts with dsm-firmenich

We remain at the forefront of innovation and new discoveries in the postbiotics space — and together, we're excited to explore new frontiers in the rapidly expanding Health from the Gut category through biotics innovation.

Unleash the true power of the gut microbiome and bring progress to life with dsm-firmenich.

Partner with us to benefit from our leading-edge Health from the Gut offering.

Partner with us

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