



## What Probiotics Can Do for You

... A quick guide to probiotics

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## What are probiotics?

The term probiotic is derived from the Latin preposition “pro,” which means “for” and the Greek word βιωτικός (biōtikos) meaning “bios” or “life”. The idea that micro-organisms could be beneficial for human health was first developed by Elias Metchnikoff in 1900. He proposed that aging is caused by toxic bacteria in the gut and that lactic acid producing good bacteria could prolong life<sup>1</sup>. At the time, Metchnikoff’s theory was ground-breaking.

This later inspired others to begin investigating a causal relationship between intestinal health and micro-organisms such as bacteria and yeasts. This eventually led to the worldwide development, manufacturing, sales and consumption of fermented milk drinks and products. Whilst the definition of probiotics has evolved throughout the years, the most recent and generally accepted definition among the scientific community, states that probiotics are “live [micro-organisms](#) which when administered in adequate amounts confer a health benefit on the host” (From [FAO working group](#) 2001 recommendations)<sup>2</sup>.

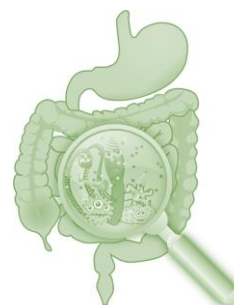
In other words, when consumed in sufficient quantities, these tiny single-celled organisms (mainly bacteria and yeasts) are good for your body and can help you stay healthy.

## Why probiotics are important?

Even though there is growing evidence that probiotics can have beneficial effects beyond gut health, we will start with the latter as it is the most studied up to now. To help you understand the effects of probiotics on our gut, we should first

explain what the **gut microbiota** is and how it works. The gut microbiota, formerly called ‘gut flora’, represents a dynamic community of micro-organisms that live in our intestine. The best way, perhaps, to describe the complex interactions that take place in our gut, is through the following analogy that Stephen O’Keefe, a gastroenterologist from the University of Pittsburgh uses: “*There are hundreds of species of bacteria in the colon, and they’re more like an orchestra ... they play together to come up with a final sound*”<sup>3</sup>.

**Did you know that every person has his/her own unique GUT MICROBIOTA?  
It’s just like an identity card!**

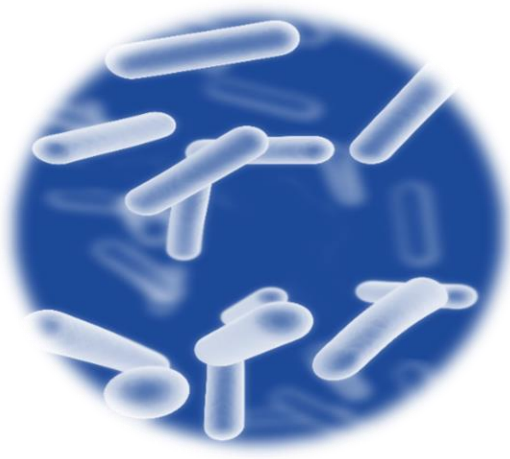


The gut is the main theatre of action for orally ingested probiotics. For centuries, the gut was viewed simply as a biological “food processor”. It is now recognized as a highly complex ecosystem with a surface area of 300 m<sup>2</sup> and is the location of 70% of our immune cells and 100 million neurons.

The gut is the primary interface between the host and the external world, acting first as a barrier but also behaving dynamically to sense and transform ingested substances. Of course, this already complex organ is also home to our microbiota – the community of 10<sup>14</sup> (100 billion) individual microorganisms that have been described as a ‘virtual organ’ within the gut.

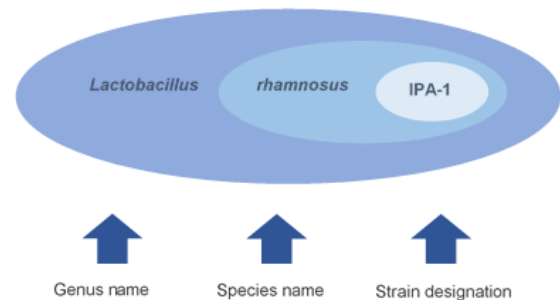
A well-balanced microbiota is essential for the normal functioning of the body, because this is when it can optimally help us digest certain foods, produce vitamins, support our immune system and act as a barrier against other micro-organisms that may be harmful to the structure or function of the body<sup>4</sup>.

Although our gut microbiota is relatively stable, it is prone, throughout our entire life, for variations caused by age, diet, pregnancy, and environment. Illness, stress, travelling or use of medication such as antibiotics can also cause imbalances in our gut microbiota<sup>5,6</sup>.



Probiotics can have effects that are considered beneficial for our gut microbiota as they can help restore and maintain the beneficial micro-organisms in our digestive system. They may also [help the gut microbiota resist](#) to the growth of harmful micro-organisms. A variety of bacteria have been studied to explore their beneficial effects, including various *Lactobacillus* and *Bifidobacterium* strains, as well as the yeast *Saccharomyces cerevisiae* var. *boulardii* and some *Bacillus* species.

Probiotics should be considered as transient micro-organisms that have beneficial effects as they pass through the gut. They are described by their genus, their species and their unique strain designation.



This detailed description is essential as probiotic functions and effects can be *strain-specific*: for example, the effects of *Lactobacillus rhamnosus* IPA-1 can differ from those of *Lactobacillus rhamnosus* IPA-2. For micro-organisms, differences between specific strains can be compared to individual differences between people: we are all human, but each individual may have different skills.

Now that you know a little bit more about how the gut functions and how probiotics work, let's find out what scientists suggest about the benefits that probiotics can confer.

## What does current science say about the benefits of probiotics?

There is no doubt that research on probiotics is a mainstream scientific area: almost 11,000 papers have been published on the topic in peer-review scientific journals in the last 50 years. However, it is really in the last decade that research on probiotics has exploded. This is part due to

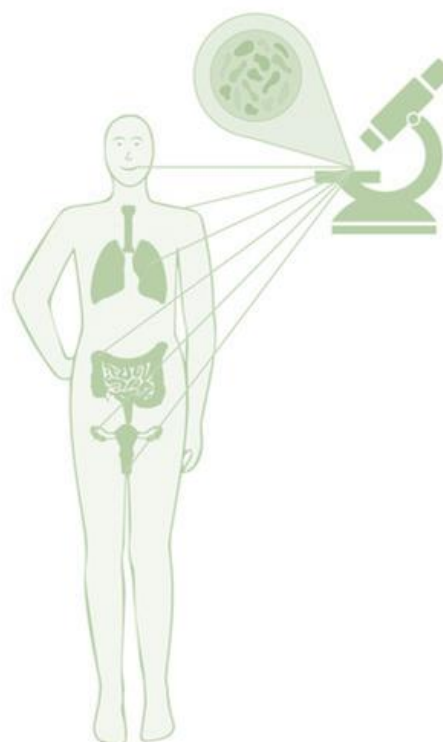
the advent of new scientific technologies, but also because of an increasing interest among consumers and clinicians seeking safe and validated alternatives to pharmaceuticals to assist the general population in maintaining health and wellness.

Taken altogether, these publications convincingly describe different beneficial effects during human interventions. The current scientific consensus is that probiotics are most effective in conditions related to the digestive tract and the immune system. *“When you look at findings from a variety of studies on different end points that look at some aspects of digestive health, the combined evidence suggests that digestive health is a core benefit of many probiotic micro-organisms”* says Mary Ellen Sanders, an internationally recognised scientist in the area of probiotic microbiology<sup>7</sup>.

The quality of evidence is such that several medical and scientific organisations have issued evidence-based guidelines. These organisations highly recommend the use of probiotics in different gastrointestinal symptoms or diseases for children and adults. In addition, international and national clinical guides and scientific research suggest that different types of probiotics can have different positive effects on our health<sup>8-13</sup>.

For instance, the World Gastroenterology Organisation (WGO) concluded in 2011 that probiotics are indicated for prevention of antibiotic associated diarrhoea and for alleviating some symptoms of irritable bowel syndrome.

There is also considerable research underway in additional gut disorders, lactose intolerance, irritable bowel syndrome, inflammatory bowel disease. Beyond the gut, depression, brain function, anxiety, blood cholesterol, urinary/vaginal tract infection, and different types of allergy might be also influenced by the gut microbiota<sup>8-14</sup>.



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Scientists nowadays recognise that the various interactions between food and the gut microbiota have a profound impact on our health. According to the scientific team of the EU-funded project MyNewGut, a large amount of scientific evidence suggests that *“the gut microbiota (and its collective genome) play a key role in the communication and function of the gut and different organs and systems, and thereby, in human development, physiology and health”*<sup>15</sup>.

In our Western diet, the consumption of live microorganisms as part of the daily diet has gradually decreased over the last decades. Earlier sources of living microorganisms were mainly the many different types of fermented foods, in absence of refrigeration and deep freezing.

The reduction of fermented food consumption has been linked to an increased incidence of immune related diseases such as allergy, autoimmunity and even autism spectrum disorder. Probiotics have been proposed as an alternative source of living bacteria.

## What are the differences between:

### a) probiotics and fermented food products

Probiotics are specific micro-organisms with health benefits. Fermented products may be healthy and contain, as a result of fermentation, live micro-organisms that may be related to known probiotic micro-organisms.

However, not all of these microbes from fermentation are considered, by the scientific community, as probiotics.

Furthermore, because the term “probiotics” is often misused, especially in non-food products claiming to contain probiotics, scientists suggest that “*even if a micro-organism has the potential to offer health benefits, it shouldn't be called a probiotic until its effects are demonstrated in good quality studies*”.



The production of yoghurt always needs a combination of two different lactic acid bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*.

Therefore, their recommendation is that if fermented products contain micro-organisms that have been defined, and have been shown to confer some health benefits, then these fermented foods could be considered to contain probiotics<sup>16</sup>.

### b) probiotics and prebiotics

Prebiotics are typically non-digestible [fibre compounds](#) and have distinct functions. Up-to-date research indicates that they can assist specific members of the gut microbiota and also probiotic micro-organisms added from the diet, by helping them grow within the gut environment. The combination of probiotics and prebiotics, commonly known as [synbiotics](#), has been reported to have beneficial effects on our intestinal metabolism and immune function<sup>14, 17</sup>.

### Can I add probiotics to my diet?

Over the years, probiotics have been consumed in different forms, mostly as foods and dietary supplements, and are considered safe for the general population.



If you are healthy and looking to maintain and support your health status, you may want to consider to add probiotics to your daily regime. Moreover, for specific cases, for example when you are given antibiotics, your doctor or pharmacist may also recommend you take a supplement containing probiotics that can help manage or reduce the risk for a particular condition (i.e. perturbations induced by antibiotic courses). People with medical conditions or severely weakened immune systems are advised to consult with their doctor before taking a product containing probiotics.

## Where to find probiotics

You can find probiotics in many different forms such as: yoghurt or drinks containing probiotics available in supermarkets or in retail food shop or in food supplement form in health food shops or pharmacies. Supplements with probiotics vary from types (i.e. strains of micro-organisms), number of live micro-organisms (i.e. Colony Forming Units), and form (i.e. tablets, capsules, sachets).

IPA Europe considers that for any good quality market application, probiotic strains must be alive in the product throughout shelf life, with at least one billion live cells per daily portion<sup>18</sup>.

## How to choose the right probiotic

As mentioned above, not all probiotics are the same as they can have different effects and can function in distinct ways. So, how do you identify which products containing probiotics are good for you?

If you live outside the EU, you should easily find relevant information on the product label as regulators in different parts of the world authorise favourable claims relating to probiotics and their labelling (e.g. Canadian guidelines - see annex).

However, for consumers based in the EU, things are less straightforward as [there is a different approach](#). There is no EU-wide legal framework defining probiotics nor a food category containing probiotics defined. Nor is there a harmonised EU legal framework establishing the conditions for a strain to be considered as probiotic or a positive list of individual strains which have a probiotic status.

According to the [guidelines that IPA Europe](#) recently published on the use of probiotics in food products and supplements, the word probiotic should be used for products provided that certain conditions are met (e.g. being traditionally used in humans, considered safe for human consumption, viable at the time of ingestion, containing strains which are characterised using specified methods and containing at least  $10^9$  live cells per daily portion).

The sufficient amount is at least  $10^9$  live cells per daily portion to guarantee an effect. A different daily dose or quantity per strain may be sufficient, if it is backed up by specific studies that have shown the effects at this dose<sup>11</sup>.

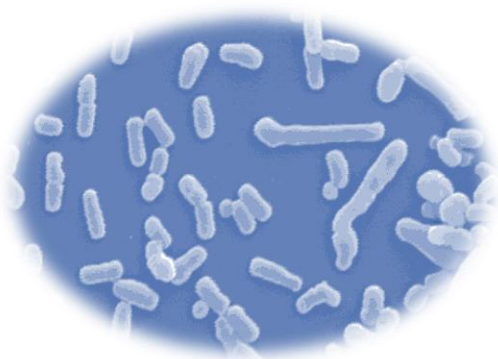
Thus, as a consumer, you cannot easily identify which products do contain probiotic strains and which do not. What makes things even more confusing is an increasing number of non-food products doubtfully claiming to contain probiotics

(i.e. toilet cleaning products, pillows, mattresses, cosmetics, etc.).

Therefore, as a word of caution, make sure you choose reputable manufacturers as the market offers many poor-quality products, particularly through the internet. Trusted companies ensure their products with reliable quality control or third party testing and conduct relevant research to confirm their products' effects. Good quality products will also guarantee a minimum level of live probiotic micro-organisms at the end of shelf-life.

## How to take probiotics

As mentioned above, probiotics are live micro-organisms. Thus, specific products containing probiotic may be sensitive to temperature changes. Therefore, proper storage is vital.



Products containing probiotic work best when taken at the right dose and at the right time. The dose or portion size and frequency of consumption really depend on the product and the strain. Follow the instructions on the packaging to ensure you receive maximum benefits.

Finally, do not forget to always verify the expiration date. This date will only be valid if the product was stored at the advised temperature as well. The storage of the product at higher temperature will generally reduce its shelf life.

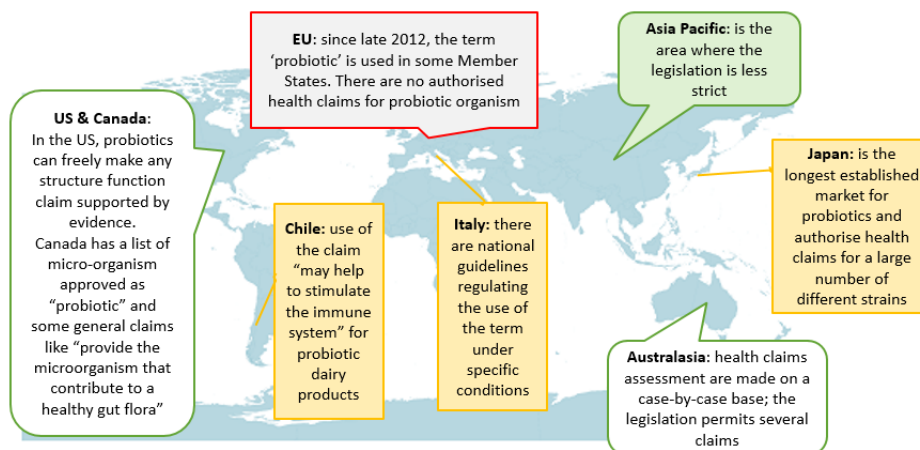
## In summary ...

Hippocrates said more than 2000 years ago, that “all disease begins in the gut”. As scientists today start to unfold the mysteries behind the complex mechanisms in which our body and health can be affected by the gut microbiota, it is becoming clearer (more so now than ever before) that a balanced diet that contains probiotic food or probiotic supplements, is crucial for our well-being. After all, as the saying goes “we are what we eat”!



## ANNEX

Regulators in different parts of the world have differing views on claims relating to probiotics and its labelling<sup>I, III, IV</sup>.



The **Canadian** regulatory scheme on probiotics is deemed as one of the most progressive and well developed schemes globally, allowing probiotics to have health and functional claims whilst being regulated under the food and/or Natural Health Products (NHP) regulatory framework. In this regulation<sup>I</sup>, approved micro-organisms, products, dosage and level of clinical evidence for different indications are listed. Already in 2009, a guidance was published by Health Canada, referring to certain strains as probiotics with approved non-strain-specific claims. This document also explains conditions under which a microorganism can be referred to as "Probiotic"<sup>19</sup>. Later in 2015, in the Annex I of the Canadian Probiotic Monograph, established probiotic bacteria and fungi as well as conditions that must be fulfilled in order to make the pre-cleared claims are listed. Health Canada also allows any evidence-based claims for probiotics whether for use as foods or as Natural Health products, which include, structure-function, disease risk reduction and health claims on a pre-market assessment basis (except for structure function claims on foods that do not fall under the pre-marketing evaluation requirement).

In **United States**, the Food and Drug Administration (FDA) is the main competent agency regulating these product categories. The FDA has no definition of probiotics and regulates them based on their "intended use" under the existing regulation.<sup>20</sup> With respect to microbial ingredients, FDA has stated that "bacteria that have never been consumed as food are unlikely to be dietary ingredients" and instead must be "intentional constituent[s] of food". Further, FDA provides the following example; "bacteria that are used to produce fermented foods that are eaten without a cooking or pasteurization step (e.g. lactic acid bacteria used to produce cheese or yogurt) could be "dietary substances for use by man to supplement the diet by increasing the total dietary intake," which are defined as dietary ingredients in section 201(ff)(1)(E) of the FD&C Act (21 U.S.C. 321(ff)(1)(E)). FDA does not have a separate

regulatory category or definition for dietary ingredients consisting of live or viable microorganisms<sup>21</sup> but such probiotics are within the scope of the food legislation.

In **Japan**, due to their history and cultural acceptance of such products, probiotics defined as functional food must comply with the regulatory scheme set out in either of the Japanese Foods for Special Health Use (FOSHU)<sup>22</sup> or Foods with Nutrient Function Claims (FNFC)<sup>23</sup>. The FOSHU regulatory scheme is the main legislative framework for probiotics with health claims and provides for an authorisation procedure by the Ministry of Health, Labour and Welfare (MHLW), under which functional or physiological health claims are approved<sup>24</sup>. An FOSHU claim is subject to a scientific review by MHLW in order to ensure that the food is safe and efficacious as claimed<sup>22</sup>. Originally, applications were assessed on an individual basis, but in 2005, standards and specifications were established for foods with sufficient FOSHU status and approval on the basis of accumulation of scientific evidence. When an application meets the established standards and specifications, it will be approved as “Standardised FUSHUFOSHU”, without being subject to an individual assessment<sup>25</sup>. The applicant qualifying under the Standardised FUSHUFOSHU procedure is not required to submit any clinical efficacy studies, but only safety studies on the product.

In **Italy**, the use of the word probiotic is allowed for product food and food supplements providing that certain conditions are met (e.g. being traditionally used in humans, considered safe for human consumption, viable in the gut, containing strains which are characterised using specified methods and containing at least 10<sup>9</sup> live cells of at least one strain of bacteria per daily serving of the product). However, the use of different amount of live microorganism may be allowed when its rational has been demonstrated by significant scientific studies (Ministero della Salute, 2013)<sup>III</sup>.

## Examples of national guidelines on probiotics

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