Probiotics used in traditional fermented foods: Traditional or novel?

Probiotics in traditional fermented foods

If you were to ask people to name a microorganism that has traditionally been part of our diet, probiotics and yeasts would most likely top the survey. If people in Europe were then requested to name a food that contains probiotics, yoghurt would most probably win the poll.

However, fewer people would know that probiotics can also be found in sauerkraut, pickles and other fermented foods (e.g. kefir, buttermilk, tempeh, kimchi, miso, etc.) which have all been a common part of people’s diet for years in Europe and in other countries around the world.

What is a probiotic?

Probiotics are defined as live microorganisms which, when administered in adequate amounts, confer a health benefit on the host. It is important to bear in mind, however, that the term “probiotic” is not accepted as a legal term as it infers a health benefit. The term has been ruled to be misleading to consumers and therefore is not accepted by Regulatory Authorities in the European Union (EU).

Probiotics were consumed long before a definition was first put forward by microbiologist Ilya Mechnikov at the beginning of the twentieth century. The future 1908 Nobel laureate proposed that "the dependence of the intestinal microbes on the food makes it possible to adopt measures to modify the flora in our bodies and to replace the harmful microbes by useful microbes."

Although people often think that bacteria and other microorganisms are harmful, many of these microorganisms help our bodies function properly. Bacteria that are naturally present in our intestines help digest food and protect the body against infections caused by other microorganisms by preventing the colonisation of pathogens. Large numbers of microorganisms live inside or on our bodies and they can be identical or similar to many of the microorganisms present in probiotic products.

Mechnikov was spot on. More than a century later, probiotics are now widely investigated and rightly or wrongly promoted for their potential health benefits. However, amongst the several hundred known probiotics which are often described as 'friendly' bacteria, with the Lactobacillus and Bifidobacteria genera being the most popular, not all strains are efficacious or innocuous. It is important to note that the majority of effects of probiotics are strain-specific and cannot be extended to other probiotics of the same genus or species. For example, various species of Lactobacillus are common inhabitants of our intestine, but experiments with Lactobacillus bulgaricus have shown that this species could not survive in the human intestine. The dose at which a probiotic
triggers the targeted effect on the host is another element that could vary from one strain to another. These are only two examples, but the differences can be multiple and call for precise identification of the strain.

So, traditional or novel?

Given their long history of use, can probiotics - intended to be marketed as food in the EU - be considered as traditional and not novel foods?

In short, not exactly, and to answer these questions, there are at least two main aspects to consider, which all determine the level of information required by the European Food and Safety Authority (EFSA) for the evaluation of safety of a novel food prior to entry to the EU market.

‘Novel food’ refers to any food that European consumers have not eaten on a significant level prior to 15 May 1997. A ‘traditional food’ is defined as a novel food derived from primary production, that has been consumed safely for at least 25 years, as part of the customary diet of a significant number of people in at least one country outside the EU. The traditional food route was freshly introduced in the new Novel Food Regulation (EU) 2015/2283, which came into force on 1st January 2018, offering a welcoming and exciting option for the industry. It is therefore essential to understand that, in the context of the novel food regulation, a food may be considered ‘novel’ on the basis that, although it is a ‘traditional’ food in other parts of the world, it is new to the EU market.

A second important aspect is that probiotics typically fall under the category of “(a) food consisting of, isolated from or produced from micro-organisms, fungi or algae” in the novel food regulation. However, the decision of whether a food will be considered traditional or novel will depend on how the food is planned to be made available on the EU market. If it is in a different form from its traditional production process outside of the EU e.g. obtained “from a new source, obtained through the application of new technologies, or by using new substances”, it will be considered a novel food as it does not correspond **stricto sensu** to the original traditional food anymore. For example, if any changes in the production process of the traditional food were made, it would result in the direct change of the identity of the product. In addition, if the intended conditions of use are different of that in the originating country, then most surely the product will not be able to use the traditional food registration route.

If a food is novel or traditional, what next?

A novel food application entails a well-structured dossier, which allows EFSA to conclude whether or not the novel food is safe under the proposed conditions of use in reference to food categories which already exist on the EU market and which may already include necessary data, e.g. information regarding the product’s absorption, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity. The timeline from submission of the dossier to market is approximately 18-21 months.

For traditional food applications, the regulation has introduced a notification procedure and a separate safety assessment for these foods; the European regulatory authorities will assess whether there is a safe history of use in a third country and that this is proven with reliable data submitted by the applicant. Under the traditional food route, there is no need for an applicant to carry out expensive toxicological studies as long as the applicant can provide enough data to support the composition and a product’s safety. The timeline from submission of the dossier to market is approximately 12 months for QPS status and must undergo a full safety assessment. For the assessment of a probiotic, genus, species and/or strain will all be considered.

EFSA has also adopted a system for the safety assessment of microbial species used for food in the EU, which, if favourable, leads to a “Qualified Presumption of Safety (QPS)” status. The QPS status of a strain informs on the safety of a microorganism without prejudice to any other legal requirements. As such, any microorganism that is assigned to that group does not need to undergo the full safety assessment. However, at the moment, no microorganisms have been listed as QPS for use in novel foods. Microorganisms that are not well defined, for which some safety concerns are identified or for which it is not possible to conclude if they pose safety concern to humans, animals or the environment are not considered suitable for QPS status and must undergo a full safety assessment. For the assessment of a probiotic, genus, species and/or strain will all be considered.

Let’s take a few examples:

Buttermilk refers to a range of fermented dairy drinks and there are two main types of buttermilk: traditional and cultured. Traditionally made buttermilk, often referred to as 'grandma's probiotic', is what is left from churning butter, whereas cultured buttermilk is obtained by fermenting pasteurized milk to produce lactic acid. Traditional buttermilk is mainly consumed in Asia, while cultured buttermilk is commonly found in Western countries’ supermarkets and is also very popular in Eastern European countries. Traditionally made or cultured buttermilk will not be considered a traditional food if a change is made to the product, regardless of whether it has been safely consumed for more than 25 years in the country of origin. An application for a product containing buttermilk may therefore have to go through the approval process for a novel food.

Similarly, Kombucha has been traditionally consumed in East Russia and throughout Asia for years. However, it is important to note that if Kombucha is prepared with a novel microorganism, then a novel food application would be required.
Sweet sorghum syrup is another example of food originating from a third country: It has been produced and consumed as an alternative to other sweetening foods (e.g. sugar, honey, molasses) since the mid 1800’s in the USA. Following the notification for traditional food submitted to the European Commission, EFSA concluded that sweet sorghum may be considered as a traditional food and marketed in the EU providing that sweet sorghum is produced in compliance with the requirements of the FDA set in the USA (the country with a history of use and where it originates from).

In conclusion, the use of “probiotics” has dramatically increased over the past fifteen years as they have attracted the interest of consumers due to their perceived health benefits. Traditional foods such as kimchi (a fermented cabbage traditionally eaten in Korea) and kombucha (a fermented tea traditionally consumed in East Russia) have had a large impact on the EU market, paving the way for fermented products containing live microbial strains with a traditional and proven history of safe use outside of the EU. To date, there are no health claims for “probiotics” and they are currently not accepted by EU Regulatory Authorities. If one wants to claim that a “probiotic” has a health benefit (e.g. improves gut health), then a dossier would need to be submitted to the European Commission for a health claim. Yet, the recently published novel food regulation offers a new option to companies wanting to market fermented foods. For example, probiotics that use novel microorganisms and novel production methods will need to undergo a full novel food authorisation. For fermented foods traditionally consumed outside of the EU and which have a safe history of use, the new traditional novel food route should provide a quick route to the market.

References

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