

'PROBIOTIC' AS A GENERAL DESCRIPTOR

ARTICLE 1(4) NUTRITION AND HEALTH CLAIMS REGULATION



Probiotics are safe and friendly live microorganisms that are beneficial to human health. The value of the European probiotic market is significant, in terms of the economy, employment and innovation.

Despite the existence of a distinctive probiotics market and the traditional use of the term 'probiotic' as a generic denomination to designate these products, its use has recently come under scrutiny. As of 14 December 2012 the term 'probiotic' will no longer be permitted in labelling, presentation and advertising of food products in the EU, following the implementation of the Nutrition and Health Claims Regulation (NHCR).

Whilst, on the one hand, the term 'probiotic' implies a health benefit (as per its definition), on the other, due to the strain specificity of probiotics, the term 'probiotic' per se cannot be the object of a health claim dossier. The term 'probiotic' should be regarded above all as a generic descriptor of a category of foods, and therefore eligible to fall under the derogation in Article 1(4) of the NHCR, of which the conditions are fulfilled.

The outright prohibition on the use of the term 'probiotic' is disproportionate and goes against the objectives of the Nutrition and Health Claims Regulation.

The industry calls for recognition of probiotics in Europe and, consequently, safeguarding the use of the term 'probiotic' on food products by the granting of an Article 1(4) derogation, in line with the NHCR and its objectives.

Granting the Article 1(4) derogation would not remove probiotics from the scope of the NHCR, nor would it exempt them from its mandatory provisions. Rather, it would ensure the establishment of specific conditions of use for the generic descriptor 'probiotic'.

THE PARADOXICAL PROHIBITION ON THE USE OF THE TERM 'PROBIOTIC' ON FOOD PRODUCTS

Despite its traditional use and recognition by numerous national authorities, the use of the term 'probiotic' in the labelling, presentation and advertising of food products will no longer be permitted in the EU after 14 December 2012, the end of the transition period for health claims not approved under Article 13(3) of the NHCR. This prohibition results from the interpretation of the 2007 European Commission Guidance on the implementation of the NHCR, which considers the phrase "contains probiotics" as a health claim, due to the implied effect on health that the term 'probiotic' may entail. This categorisation seems to be, however, very arbitrary, given that other generic descriptors of food products also implying an effect on human health have been explicitly exempted from the application of the NHCR¹.

The Commission Guidance could lead to a situation in which using the term 'probiotic' anywhere on a food product after 14 December 2012 would require obtaining EFSA approval of such a claim to do so. However, as probiotics' effects are strain-specific, the term 'probiotic' *per se* cannot be the object of a health claim under the NHCR.

As a result, after the ban takes effect, probiotics can continue to be used in food, consumers will continue to want to know whether or not probiotics are in their food, but industry will be prohibited from providing this information in an easily understandable way using the word 'probiotic' (instead, the Latin names of individual probiotic strains will appear in ingredient labelling and many consumers will not understand to what they refer).

'PROBIOTIC' TRADITIONALLY USED AS A LABEL FOR FOODS AND BEVERAGES

The term 'probiotic' has traditionally been used in Europe for the labelling, presentation and advertising of a wide array of foods and beverages to which probiotic bacteria (mainly, but not exclusively, of the *Lactobacillus* and *Bifidobacterium* genera) have been added. The FAO/WHO define probiotics as "live microorganisms which when administered in adequate amounts confer a health benefit on the host".

There is no EU-wide definition of 'probiotic bacteria' or 'probiotics'. Neither is there a harmonised EU legal framework establishing the conditions of use of the term 'probiotic'. In the absence of such a framework, the term 'probiotic' has traditionally been used under general food safety and labelling rules and national provisions, on thousands of foods and beverages in the EU². In some

ABOUT PROBIOTICS

- Probiotics are safe and friendly live microorganisms that can be beneficial to human health.
- Probiotic foods are predominantly dairy products (83.5%), but also include soft drinks, baby foods, pet foods, non-dairy desserts, cereal and cereal bars, baked goods, food supplements and non-food products.
- Probiotics science is constantly developing. Over the last 20 years, more than 7,500 studies have been published on probiotics. The EU itself has invested more than €70m into probiotics research.

¹ Recital 5 of the NHCR explicitly exempts the term 'digestive' and 'cough drops' from the application of the NHCR classifying them as generic descriptors in the understanding of Article 1(4) NHCR. In both cases, to our knowledge, these decisions were not made on the basis of any clear and transparent criteria.

² According to a Mintel study, more than 400 new products with the term 'probiotic' on their label are launched every year in the EU (Mintel, "Global New Product Database", 2012.)

countries, the use of the term 'probiotic' has, in the interest of consumer information, been made mandatory (for instance in Slovakia and Hungary).

The probiotics market has become familiar to and recognised by consumers, yet clear conditions of use for the term 'probiotic' are lacking. Regulating the use of the term, rather than banning it, would better ensure the proper functioning of the internal market and proper information for consumers.

THE POTENTIAL IMPACT OF A PROHIBITION

The lack of a European framework for probiotics and the ban on the use of the term would likely result in the development of *ad hoc* national rules through which EU member states provide for the designation of products containing probiotics. By fragmenting the functioning of the internal market, this would frustrate the objectives of the NHCR. Innovative, science-based companies will not continue to grow in Europe due to the prohibition, but will continue to flourish elsewhere in the world, where use of the term 'probiotic' is permitted.

The food industry would be unfairly harmed in comparison to non-food sectors, like cosmetics, personal care products, pet foods and pharmaceuticals that would continue to use the term 'probiotic' on their products.

A prohibition on the use of the term 'probiotic' would deprive consumers of the ability to make an informed choice on the nature of products, going against the objectives of the NHCR. Using the term 'probiotic' in the name of a product or list of ingredients distinguishes it from other products with which it could be confused (e.g. yoghurt versus probiotic yoghurt) and consumers have become familiar with the terminology.

THE PROBIOTICS SECTOR

- For the last decade, the probiotic foods and beverages sector has seen an average annual growth of 6%. The European probiotic market is significant. In 1996, the retail value of probiotic fermented milks in the EU was €670m (8.4% of the total yoghurt market). By 2011, this figure had increased to €5.4 bn.

- In 2008, the retail value of probiotic supplements in the EU was €380m (26% of the global total).

- The Yoghurt and Live Fermented Milks Association (YLFA) is an independent, non-profit trade association, working to promote the common interests of its members, including probiotics food producers and manufacturers of probiotics. More on www.ylfa.org.

Media fallout from a ban on the use of the term 'probiotic' would also have a considerable negative impact on the image of probiotic products, food and otherwise, to the detriment of this strong and competitive European industry. This would hinder further growth as well as prospects for continued investment in research and innovation, which has already received considerable EU funding.

A WAY FORWARD – 'PROBIOTIC' AS A GENERAL DESCRIPTOR, PURSUANT TO ART. 1(4) NHCR

Given the impossibility of obtaining a claim for the term 'probiotic' under the NHCR, the traditional use of the term, the consumer interest in knowing that probiotics are in certain foods, and the unfair situation this creates compared to other industries that sell probiotic products without such restrictions, a solution to this deadlock, must be found before 14 December 2012 when the term 'probiotic' will be banned from use.

YLFA believes that the derogation pursuant to Article 1(4) NHCR provides a strong legal basis for the use of the term 'probiotic' in the labelling, presentation and advertisement of food and beverages as a generic descriptor throughout the EU. Article 1(4) of the NHCR states that "*for generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, a derogation ...may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), on application by the food business operators concerned.*"

The term 'probiotic' complies with the four cumulative conditions of Article 1(4) of the Claims Regulation, namely:

- It refers to a generic denomination: a common name designating a class of foods and beverages in the EU;
- It has traditionally been used in the EU since the 1960s (and in Japan since 1935);
- It indicates a particularity of a class of foods or beverages, i.e. the presence of probiotic bacteria; and
- The particularity could imply an effect on human health, as acknowledged by the European Commission itself in 2007 and by the FAO/WHO definition.

Using the Article 1(4) provision would not remove probiotics from the scope of the NHCR, nor would it exempt them from its mandatory provisions. Specific health claims on probiotic strains will continue to be assessed under the established authorisation procedures and will only be approved if they meet the rigorous criteria applied by EFSA.

There is a difference between informing the consumer that a *food contains probiotics* (following guidelines such as those adopted by FAO/WHO, or countries such as Canada and Italy), and claiming a *specific health benefit of the microorganism* at hand (claim authorisation required by the NHCR). Accordingly, use of the traditional term 'probiotic' should be allowed as a generic descriptor, provided that certain conditions are met, as long as no references to specific health effects are made.