PROBIOTICS AND THE EU NUTRITION & HEALTH CLAIMS REGULATION: FINDING A WORKABLE SOLUTION

CURRENT STATUS OF PROBIOTICS UNDER THE NUTRITION & HEALTH CLAIMS REGULATION

Based on a questionable categorisation in the 2007 European Commission Guidance on the Implementation of the Nutrition and Health Claims Regulation (NHCR), the use of the term ‘probiotic’, traditionally used and recognised by national authorities, the scientific community and consumers, will be banned in most of the Member States after the 14 December 2012, the end of the transition period for health claims not approved under Article 13(3) of the NHCR.

This ban does not prohibit the use of probiotics in foods and beverages, but prohibits industry from disclosing in a simple manner the presence of probiotics in their product. Such a ban will negatively impact the consumers’ right to be informed about the specific characteristics of certain foods (although the use of the Latin names of individual probiotic strains in ingredient labelling will still be permitted, consumers may not understand to what they refer). It will also unfairly harm the European probiotic food industry’s competitiveness, as well as have a considerable negative impact on the image of probiotic products, to the detriment of this strong and globally competitive European industry.

Despite national and international recognition of probiotics, the systematic rejection of more than 300 probiotic applications submitted to the European Food Safety Authority (EFSA) under the NHCR has led to confusion over the use of the term ‘probiotic’ itself.

The probiotics industry believes in the science and benefits of probiotics and, while continuing its investment in probiotics research, advocates for a uniform and coherent application of the NHCR that provides a workable framework through which industry can communicate the specificity of its foods and ingredients in Europe, and thereby preserve the existence of a well-known and established category of foods and beverages. A means must be found to ensure the proper communication of two distinct cases: firstly, where probiotics are used in a product but do not refer to any specific health benefit, and secondly, where a specific health claim is made on a given probiotic product.

LOOKING TO A WORKABLE AND EFFECTIVE SOLUTION / INDUSTRY’S COMMITMENT TO MAKING THE NHCR WORK

In order to find a workable solution to the current impasse in the implementation of the NHCR to probiotics, various initiatives are currently being undertaken by the probiotic industry. These initiatives, although distinct and with differing end goals, aim to find a way to properly communicate to consumers on the use of probiotics (either their use generally or their claim to have a specific health benefit), and allow industry to continue its investment and research into this exciting field of science.

The initiatives, both regulatory and scientific, reflect the distinction between:

- Informing the consumer about the specificity of this category of product and/or that a food contains probiotics (Article 1(4) should apply); and
- Claiming a specific health benefit of the microorganism at hand (claim authorisation required by the NHCR).

According to this approach, probiotics would therefore be presented in the labelling, presentation and advertisement of food products, either:

- As a generic descriptor, under Article 1(4) NHCR, to designate what is in a product, without making any reference to a specific health benefit (the term ‘probiotic’ per se cannot be subject to authorisation as a health claim); or
- As a general health claim, as defined by Article 10(3) NHCR, subject to the general provisions of the NHCR (Articles 13 and 14), following an EFSA assessment (whether a cluster of strains or individual strains).

YLFAs: ‘Probiotic’ as a generic descriptor – addressing the regulatory contradiction

The probiotics industry, via YLFA, is currently preparing a dossier for the recognition of the denomination ‘probiotic’ as a generic descriptor of a category of foods, under Article 1(4) NHCR. Such a derogation would not remove probiotics from the scope of the NHCR, nor would it exempt them from its mandatory provisions, but would allow for proper communication on an essential characteristic of a class of foods and beverages within the provisions of the NHCR itself.

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3 The probiotic category has in the past been recognised by authorities including Canada, Japan, Brazil, Russia, China, South Korea and Turkey. FAO/WHO has also recognised the category.
4 One generic claim on live yoghurt has received a positive opinion, but in this case it is due to the production of a single enzyme; lactase as the common factor for the whole category (Scientific Opinion on the substantiation of health claims related to live yoghurt cultures and improved lactose digestion (ID 1143, 2976) pursuant to Article 13(1) of Regulation (EC) No 1924/2006).
5 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 fermented milks producers and manufacturers of probiotics. www.ylfa.org
According to Article 1(4) NHCR, “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.” Accordingly, the use of the traditional term ‘probiotic’, which fulfils these conditions, should be allowed as a generic descriptor, provided that certain requirements regarding safety and quality are met (criteria still to be determined) and as long as no references to specific health effects are made.

Global Alliance for Probiotics: Probiotic Cluster Claim (PCC) – exploring the science of probiotics

Some members of the probiotics industry, through the Global Alliance for Probiotics (GAP), are considering submitting a dossier to EFSA for a claim on a cluster of probiotic strains which can be scientifically shown to have the same beneficial effect. Where they can be validly characterised as a cluster, based on their similarities and on the consistency of the health outcome, a submission for a cluster probiotic health claim could be envisaged.

This novel approach, based on assessing the physiological effect of strains, involves a rigorous assessment of the clustered strains’ clinical trials. Should the assessment be deemed positive, and to comply with EFSA’s stringent criteria for health claims, a dossier could be submitted for approval under the NHCR. If approved, the health claim would only apply to the strains in the cluster as defined by the outcome of a systematic review, i.e. those meeting EFSA’s assessment criteria.

Probiotics companies: Individual submissions of probiotic health claims – strain specificity

The probiotics industry also continues working on scientific research with the aim of submitting applications for specific health claims on individual probiotic strains, which would continue to be assessed under the established authorisation procedures and will only be approved if they meet the rigorous criteria applied by EFSA.

Consequently, any health benefit referenced in the labelling, presentation or advertisement of foods and beverages containing probiotics, whether the result of a PCC or an individual application, will remain subject to the EFSA evaluation and official authorisation procedures.

The complementary angles (regulatory and scientific) should help to bring about the recognition of the probiotic category in Europe, which does not contradict the NHCR, yet that at the same time ensures consumers are fully informed. It would also mean legal certainty for a category of food business operators that invest heavily in research, innovation and health in Europe.

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6 The Global Alliance for Probiotics (GAP) is an unincorporated association of seven companies representing the probiotics industry. Its members are manufacturers of probiotics - Chr Hansen, Danisco, Lallemand and Probi – and manufacturers of probiotic food products - Danone, Yakult and Valio.

7 Recent submissions include: Art. 13.5: Probiotic food supplement, and, this probiotic mix improves intestinal comfort (PiLeJe); Art. 13.5: Probiotic food supplement, and, this probiotic mix regulates your intestinal transit (PiLeJe); Art. 13.5: Lactobacillus paracasei LP-33 and, contributes to the body’s resistance to airborne allergens in adult subjects (Merck Médication Familiale & Chr. Hansen A/S); Art. 14: Lactobacillus GG, and, may help to maintain defence against upper respiratory tract viruses in children (Valio Ltd).