In 2006, the Nutrition and Health Claims Regulation (NHCR, EC 1924/2006) was welcomed by the probiotic industry and other stakeholders alike. However, more than 10 years after the entry into force of NHCR, over 300 individual probiotic health claim submissions have been rejected or withdrawn and no sensible or workable EU framework exists for the use of the term probiotic on labelling and commercial communications.

Individual European Union (EU) countries have different approaches to the labelling of probiotics and probiotic foods. It is accepted in some countries but not others, and some countries do not apply the principle of “mutual recognition”. Deprived of appropriate information on probiotics, consumers are confused and seek out information from the internet and other uncontrolled sources. This is not a good risk management policy and seriously undermines the integrity of the industry.

In a further worrying development, ‘probiotic’ labelling is proliferating to non-food products, using the message of the positive effects of probiotics on gut as a reference for the efficacy of these non-food products. This adds to the confusion of consumers.

**Therefore, the probiotic sector:**

- Urges EU Member States to find a viable solution within the EU Single Market that would allow the probiotic industry to use a generic, traditional denomination that meaningfully expresses the nature of these foodstuffs and is recognised and used widely around the world.

- Calls on the European Commission to adopt a coherent and formal harmonised European approach, consistent with the spirit and the letter of the NHCR, to ensure that this class of ingredients can continue to be produced and effectively marketed within our European Single Market.

Clause 17 of the EU Regulation on the provision of food information to consumers (FIC, EU 1169/2011) states that: “The prime consideration for requiring mandatory food information should be to enable consumers to identify and make appropriate use of a food and to make choices that suit their individual dietary needs.” However, this is not happening in the case of probiotics in food and food supplements.

The industry continues to support the NHCR in its objectives of achieving harmonisation, clarity and consumer protection, but in our view recognising the probiotic category and ensuring consumer protection are not mutually exclusive goals, they are perfectly compatible. This requires acceptance of the distinction between what probiotics ‘are’ – the category –, how probiotics function, and what are the specific health claims that may be associated with different probiotics functions.

The probiotic sector is actively working on obtaining recognition for the probiotic category. IPA Europe has already issued “criteria” in 2015 on what constitutes a probiotic microorganism in food, including food supplements, herewith covering the safety/quality, labelling and efficacy aspects, based on a recognised list of strains. Therefore, the industry recommends that the term ‘probiotic’ should only be used to describe microorganisms when a certain combination of requirements is met. The use of the
term would then not require a specific authorisation, as long as no reference to any specific health effect is made.

**Acceptance of the probiotic category as a nutrition claim would resolve the current impasse for probiotics in the EU, whilst leaving the door open for individual probiotic health claims.** It should be clearly emphasised that there are no safety concerns regarding the inclusion of recognised probiotics in foods or food supplements.

The Nutrition Claim Annex of the NHCR provides for the labelling of substances that mediate a ‘beneficial nutritional or physiological effect, as established by generally accepted scientific evidence’. This applies to the probiotic category and is covered in the section of the Annex titled: ‘CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]’, in this case ‘probiotics’.

**The probiotic sector feels strongly that the time to act is now.** Consumers should be appropriately informed about probiotics, and the current confusion is in contradiction with the scope of the EU Regulation on the provision of food information to consumers (FIC, EU 1169/2011).

The probiotic sector will continue dedicating efforts and resources to improving the environment for probiotics in Europe and we wish to achieve this in collaboration with all relevant stakeholders.

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Rosanna PECERE  
Executive Director

Patrick AHERN  
Director General

Alexander ANTON  
Secretary General