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Probiotics? Achieving a better regulatory fit: the legal interpretation

11th Probiotics, Prebiotics & New Foods

13 September 2021

Katia Merten-Lentz
Partner
Keller and Heckman LLP
+32 (0) 486.35.65.30
mertenlentz@khlaw.com

Legal foundation

- **European Commission Regulation 1924/2006 on nutrition and health claims made on foods (NHCR) provides the EU legal framework for the use of nutrition and health claims on food labels:**

  Health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health

- There are different types of health claims:
  - Article 13 claims (or function claims) are health claims describing or referring to the role of a nutrient or other substance
  - Article 14 claims are claims referring to children's development and health or the reduction of disease risk claims.

Legal foundation (2)

- **European Commission's guidance on the implementation of Regulation (EC) No 1924/2006:**

  A claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health.

  *Examples: "contains antioxidants" (the function is an antioxidant effect); "**contains probiotics/prebiotics" (the reference to probiotic/prebiotic implies a health benefit).***

  Equally, claims which refer to an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim.

Lack of legal recognition

- As of today, over 400 health claims have been submitted to EFSA and only one was authorized, in 2010, pursuant to article 13(1). This was a claim on lactose digestion for yoghurt or fermented milk containing at least 10^8 CFU/g of the live starter microorganism *L. delbrueckii* subsp. *Bulgaricus* and *Staphylococcus thermophiles.*
- **As such, probiotics and prebiotics is the category of foods that is the most negatively affected by the Regulation on Nutrition and Health Claims.**
- The main reasons for the refusal of claims have generally been that the claim is not sufficiently defined, the food is not sufficiently characterized, that there is a lack of evidence to prove the claim or to establish a cause-effect relationship, or that there are issues with study design, etc.

A revision that is falling through

- Back in 2015, the European Commission had announced that it will conduct an evaluation of Regulation 1924/2006
- The Commission published a roadmap on 8 October 2015 on the evaluation of the EU Nutrition and Health Claims legislation to assess whether nutrient profile and rules concerning health claims were still fit for purposes
- To support the data gathering for this evaluation, the Commission assigned to the Food Chain Evaluation Consortium (FCEC) to carry out an external study. This study was launched in May 2016 and was completed in June 2018. The Commission also launched a Public consultation in 2017
- On 20 May 2020, the European Commission completed its evaluation. Even though it concluded that the Regulation remains fit for purposes, it is clear from the report that it needs a refresh. Since then there has been no evolution.

A cut out positioning

- In 2018, a Member of the European Parliament (Deirdre Clune) asked the European Commission whether it intended to propose a harmonized solution on the legal framework defining probiotic bacteria/micro-organisms or the food category “probiotics”.
- The European Commission, on behalf of then Health Commissioner Mr. Andriukaitis replied that:

  Regulation (EC) No 1924/2006 provides the EU legal framework for the use of nutrition and health claims on foods and, in particular, the procedure for the authorisation of new claims.

  Further to the exchanges with the Member States at the Working Group on health, the term ‘probiotic’ is to be considered as implying a health benefit and indications such as ‘contains probiotics’ should therefore be regarded as health claims when considering new applications.

  The Commission does not have the intention to take action on this specific matter.

EFSA's perceptible evolution

The evolution of the rejection: from weak demands with uncharacterized food constituent to constant rejection of the cause-and-effect relationship

2009
Scientific Opinion on the substantiation of a health claim related to a combination of bifidobacteria (Bifidobacterium bifidum, Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium longum) and decreasing potentially pathogenic intestinal microorganisms

- **The food constituent that is the subject of the proposed claim has not been sufficiently characterized**

2015
Scientific opinion on the substantiation of a health claim related to Bifidobacterium bifidum CNCM I-3426 and defence against pathogens in the upper respiratory tract

- **The food constituent is sufficiently characterised.**
- **Defence against pathogens in the upper respiratory tract is a beneficial physiological effect**
- **A cause and effect relationship has not been established**

2021
XXX

The need for a change

- There is however such an interest and a high demand for probiotics that products with the strain are sold on the market.
- In addition, and despite Europe's firm stand against it, many Member states have officially authorized it, to different extents.
- A harmonised and coherent system would help improve the situation with regard consumer information and the good functioning of the internal market.

→ **It seems that it is time for the European Union to face up to its responsibilities and harmonise the legal framework.**

EFSA ’s interpretation must change

- The first step towards a reform is to change EFSA’s perception of probiotics.
- There is a clear discrepancy between EFSA’s standards for scientific assessment and national rules.
- Unlike what it might have been over a decade ago, the strain object of the claim is now often characterised.
- From the moment the strain is characterised, the demand becomes objective, unlike other unsubstantiated claims such as “detox” or “antioxidant”.

→ EFSA must imperatively move away from this reductive approach and accept to consider the effect of a strain that is sufficiently characterised.

EFSA ’s approach must change

- A specific probiotic strain can produce a specific health effect and needs to bear a health claim
- EFSA was never asked by the EU Commission to provide an opinion about the term probiotic as health claim
- EFSA is not a regulatory authority

→ **EFSA’s standards for its scientific assessments are different from the rationale of the national rules re probiotics.**

→ **EFSA might not be influenced by any softening national approach**

Protecting the consumer

- **According to Regulation 1169/2011 on the provision of food information to consumer:**

  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

- In this case it is the consumer himself who wants the information. One could therefore wonder where the consumer's interest is in refusing him the information?
- Harmonizing the definition and the rules on the use of probiotic would reduce consumer confusion and allow them to make better purchase decision.

→ The lack of a clear communication for the probiotic category, coupled with the various and numerous national applications, are likely to mislead the consumer.

Mutual recognition

- The mutual recognition principle guarantees that any good lawfully sold in one EU country can be sold in another. This is possible even if the good does not fully comply with the technical rules of the other country .
- In a Q&A on probiotics in food published in October 2020, the Spanish Food Safety Agency (ASEAN) said:

  From the discussions that have been held within the European Commission's group of experts on nutrition and health claims, it is found that there are different interpretations by MSEs regarding the use of the term "probiotic", which, in turn, implies a non-harmonized situation in the European Union market.

  In the field of food supplements, it has been found that there are a large number of food supplements on the market, in which the term "probiotic / s" appears. These products come from different EU countries, where they are allowed to be marketed under this name and, therefore, they could not be prevented from being marketed in Spain, in application of the "principle of mutual recognition" established in the Treaty of the European Union.

→ The principle of mutual recognition is another tool for consumer access. This access might as well be informed and transparent.

Where are we headed?

- The recent Spanish Q&A has likely further spurred the debate of the harmonization of the term probiotics in the European Union.
- An engagement of the European Commission to dialogue with national authorities in order to develop a better context for probiotics in food and food supplements in the EU appears both necessary and inevitable.
- An urgent necessity to set a common ground to define probiotic foods and food sup
- An urgent need to remove the 2007 guidance which is obsolete

And out of Europe?

- USA
  - The United States food and drug administration (FDA) regulation of products containing probiotics is complex and depends on the claims that are made on the products: they can be regulated as foods, dietary supplements, cosmetics or drugs biologics.
  - In general, in order to be an ingredient in a food product, the probiotic must be approved by FDA as food additive of be Generally Recognised As Safa (GRAS)
  - With respect to claims, foods containing probiotics cannot claim to treat, cure, mitigate or prevent a disease but they can claim to “affect the structure or any function of the body of man or other animal”
- Asia
  - Asia is a large market for probiotics, although there is little harmonization among countries.
  - For example, Japan was the first country in the world to officially regulate functional foods (including prebiotic products) with the introduction of Foods for Specified Health Use (FOSHU) act in the 1980s. Foods and beverages that claim to provide health benefits to a consumer are permitted through the Japanese Ministry of Health, Labour and Welfare, if valid scientific proof is provided to support such claims
  - Prebiotics are recognized as claims in Indonesia. For instance, in May 2021, Chicory root fibers inulin and oligofructose have been approved for a prebiotic claim for the first time in Indonesia by the country’s National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan).

THANK YOU

Katia Merten-Lentz
Partner
Keller and Heckman LLP
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Washington, DC • Brussels • San Francisco • Shanghai • Paris