INTERNATIONAL PROBIOTICS ASSOCIATION EUROPE

Probiotic in Food Q&A 27 October 2020

RP-non official translation

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MINISTERIO DE CONSUMO

agencia española de seguridad alimentaria y nutrición

What are probiotics? There is currently no definition of probiotic in the Food safety law of the European Union. The term "probiotic" is used in general and refers to bacterial species, bacterial strains or live microorganism species such as *Lactobacillus helveticus*, *Lactobacillus rhamnosus*, etc. Probiotics may be part of the composition of different types of foods, including yoghurts, kefir and other foods commonly consumed as part of the diet.

What is microbiota? The microbiota is the set of microorganisms that are usually associated with healthy tissues (skin, mucous membranes, etc.) of the human body. Microorganisms reside in these places more or less permanently and in some cases perform specific functions

Probiotics are authorized in food? There is no specific legislation regulating the use of probiotics in human food, so there are no specific requirements for them, nor a list of authorized probiotics, which does not mean that they cannot be used in food. In fact, for some foods, such as yogurt, they are essential for their manufacture.

The use of probiotics in food is subject to the general requirements laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority.

In particular, for the use of these probiotics it should be taken into account that Article 14 of the Regulation provides, inter alia, that unsafe food shall not be placed on the market.

In the absence of a list of authorized micro-organisms at EU level, the list of QPS of the European Food Safety Authority (EFSA), which is regularly reviewed, is taken as a reference for safe use in food.

Food supplements containing one or more strains of living micro-organisms are currently on the market in the European Union. Infant formulae and follow-on formula are also marketed

which, as an ingredient added on a voluntary basis, contain different strains of living microorganisms. In all cases, these products meet the safety requirement, although none of the micro-organisms normally used have been able to demonstrate a beneficial effect on the general healthy population, in accordance with the standards established by the European Food Safety Authority (EFSA).

On the other hand, and outside the food field, there are products that are marketed as medicines for diarrheal treatment and contain strains of micro-organisms.

What information may appear on the labeling of food? Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods provides that only nutrition and health claims authorized in accordance with the procedures of the Regulation, and provided that they comply with the conditions of use established for each of them, are permitted on the labeling, presentation or advertising of a food of use established for each of them.

The panel on dietetic products, nutrition and allergies (NDA) of the European Food Safety Authority (EFSA) assessed the applications of micro-microorganisms submitted under Article 13 on health claims other than those relating to the reduction of the risk of disease and to the children's development and health, and published the relevant opinions, all of which were unfavorable, except for the live microorganisms *Lactobacillus delbrueckii subsp. bulgaricus and Streptococcus thermophilus* of yogurt or fermented milk containing at least 10^8 colony-forming units per gram, so for these two types of microorganisms, the following statement can be done:

"*live cultures of yogurt or fermented milk improve the digestion of lactose of the product in people with problems digesting lactose"*

There are also a number of EFSA opinions that are not favorable to a wide variety of bacterial species and their possible health benefits, either because of the lack of intervention trials that would allow the statements to be scientifically substantiated, or because they are too general and non-specific statements, or because studies have been carried out on sick persons.

The Commission's Guide to the Implementation of Regulation (EC) No 1924/2006 (adopted by the Standing Committee on the Food Chain and Animal Health of 14 December 2007), which is not legally binding, notes in paragraph III concerning the classification of declarations that, although a declaration using the term "contains" is normally used as a nutritional declaration, in some cases it refers to a substance or group of substances with a specific functional effect. In these cases, statements drafted as "contains" should be considered as a health claim and should be authorized in accordance with the established procedure. More specifically, the Guide clarifies that a claim is a health claim when naming a substance or category of substances, there is a description or indication of its functionality or an implicit effect on health.

From the discussions that have taken place within the European Commission's expert group on nutrition and health claims, it is found that there are different interpretations by the European MMs as regards the use of the term "probiotic", which, in turn, implies a non-harmonized situation on the European Union market.

In this sense, infant formulae and follow-on formulae are marketed which, as an added ingredient on a voluntary basis, contain different living microorganisms. The presence of these live microorganisms is indicated on the product label in the list of ingredients.

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

Therefore, in view of the above, and until there is a uniform approach within the Member States of the European Union, it is considered that the term "probiotic/s" could be accepted on the label of foodstuffs, both domestically manufactured and in other countries of the European Union. In all cases, these products must comply with the safety requirement. However, it should be noted that the use of this term cannot be accompanied by any health claims unless expressly authorized under the European Union Regulation (further information).

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