OPEN ACCESS Freely available online

Journal of Probiotics & Health

Editorial

Confusion and Doubts after Approval by the Spanish Food Agency of the Use of the Term 'Probiotic' for Food and Food Supplements

Leticia Bourges*, Cristina Vidreras

Secretary General, CEDR-European Council for Rural Law, Paris, France

INTRODUCTION

In accordance with the "mutual recognition principle", the Agencia Española de Seguridad Alimentaria y Nutrición (AESAN) has announced that the term 'probiotic' must be accepted and can be used on labels for food and food supplements that are sold in Spain.

This unexpected decision is highly controversial as there is no EU-wide legal framework defining the 'probiotic' food category; nor is there a harmonized legal framework in the EU Member States establishing the conditions needed for a microorganism to be considered probiotic. However, the general opinion of European and national authorities is that the term 'probiotic' implies an unauthorized health claim and therefore the use of the term is not authorized in most countries.

However, the AESAN, although previously resistant to lobbyists, has recently published an update on food safety that recognizes the significant presence of probiotics in the Spanish market and indicates that the lack of alignment between countries could go against the principle of mutual recognition (which states that any product legally manufactured or marketed in one Member State should not be prevented from being admitted to the market of any other EU Member State). Many Spanish lawyers though have criticized this polemical argument.

From the discussions that have been held on nutrition and health claims within the European Commission's expert panel, it is confirmed that there are different interpretations by the Member States regarding the use of the term 'probiotic', which, in turn, leads to a non-harmonized situation in the European Union market. Accordingly, infant formulae and follow-on formulae contain different live microorganisms which are subsequently marketed as a voluntarily added ingredient. Consequently, ASEAN states verbatim that until a uniform criterion is generated on the part of the Member States of the European Union, it is considered that it could be accepted that the term probiotic/s on the label of foodstuffs, both of national manufacturing as well as from other countries of the European Union. In all cases, these products must meet the safety requirements. However, it should be noted that the use of this term cannot be accompanied by any health claim, unless expressly authorized under the Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

Many consumer protection experts have criticized this decision as it introduces a new level of confusion in food labeling and advertising: in fact, immediately after its publication, television advertisements for products featuring "thousands of probiotics" have already been disseminated; these television spots are similar to those promoting foods that strengthen immune defenses, etc.

The above mentioned decision completely differs from a previous one (February 2020), which forbade the use of 'probiotic/s' term in food products (surprisingly, both documents are extremely similar in their reasoning); of course, it can be considered a 'small victory' for the microbiome industry: although much remains to be decided about probiotics in Europe, the AESAN decision is explicit, but remains provisional until a uniform criterion is established» at the EU level. This ruling also does not seem to involve the approval of any health claims for probiotics in Spain. However, the very ability to use the term 'probiotic' on product labels is undoubtedly a compromise to the interests of the powerful lobbyists involved.

The AESAN communiqué points out that food supplements containing one or more kinds of live microorganisms are currently being marketed in the European Union. Furthermore, infant formulae and follow-on formulae contain different live microorganisms which are subsequently marketed as a voluntarily added ingredient. In any case, these products must comply with safety requirements, although to date none of the microorganisms typically used has been proven to have any overall beneficial effect on a healthy population, according to the standards established by the European Food Safety Authority (EFSA).

On the other hand, there are products that are marketed outside of the food industry such as medicines for the treatment of diarrheic processes which contain such microorganisms.

Just as there is no legal framework throughout the EU for the use of the term 'probiotic', there is also no uniform requirement

***Corresponding author:** Leticia Bourges, Secretary General, CEDR-European Council for Rural Law, Paris, France; E-mail: bourgesla@yahoo.fr

Received date: March 03, 2021; **Accepted date:** March 17, 2021; **Published date:** March 24, 2021

Citation: Bourges L, Vidreras C (2021) Confusion and Doubts after Approval by the Spanish Food Agency of the Use of the Term 'Probiotic' for Food and Food Supplements. J Prob Health. 9:234.

on the amount of bacteria present in food or food supplements which is needed to yield a presumed beneficial effect. In fact, there are at least three different views on the necessary CFU from different bodies.

ASEAN's decision creates a hazard because it may serve to circumvent the requirement for food business operators to obtain prior authorization from the European Commission in order to be able to state the beneficial effects of their products on the product label or in advertising, i.e. the approval of health claims.

There could also be a new undesirable precedent as several EU Member States, in recent years, have developed different approaches: for instance, the Italian guidelines on probiotics and prebiotics are a comprehensive guideline for probiotics in food, and allow the use of the term 'probiotic' provided certain conditions are met; in addition, the Czech Republic has also issued national guidelines allowing the use of the term 'contains probiotics' as a nutritional claim (?), subject to compliance with the terms of nutritional claims usage as defined in the NHCR (Nutrition and Health Claims Regulations).