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France Becomes Latest EU Member To Allow 'Probiotic' Label For Dietary Supplements

by [David Ridley](#)

Thanks to work led by consumer healthcare industry association NèreS, France now allows the term “probiotic” on the label of dietary supplements that meet certain conditions, as well as the related health claim “contributes to the balance of the intestinal flora.” The country joins a growing movement away from the European Commission's restrictions on the use of the term.

France has allowed gut-beneficial live organisms in dietary supplements to be sold as “probiotics,” joining a growing movement of countries favoring probiotics liberalization in Europe.

According to a letter sent to stakeholders, including local consumer healthcare industry association NèreS, manufacturers can now use the term “probiotic” on the label of dietary supplements that meet certain conditions, as well as the related health claim “contributes to the balance of the intestinal flora.”

“The French regulating authorities for food supplements have finally accepted the use of ‘probiotics’ on the French market under a set of conditions, recognizing the relevance of this evolution for consumers and retailers,” commented NèreS executive director Luc Besançon.

Probiotic Definitions

France’s General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF): “Microorganismes vivants, qui, lorsqu’ils sont consommés en quantités

Defining probiotics as a category of

product, rather than as a health claim in itself, has allowed France's General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) to negotiate the EU's restrictive rules around use of the term, Besançon noted (see below).

The wording of the associated health claim can be flexible up to a certain point, Besançon explained, for example with equivalent terms for "contributes" such as "participates in" or "maintains" a "normal constitution of the intestinal flora."

However, terms like "enhances" or "augments" are prohibited, he told HBW Insight.

To qualify, probiotic strains must have a history of consumption – to avoid falling under the European Union Novel Food Regulation (EU) 2015/2283 – must be "well-characterized" and must not exhibit antibiotic resistance.

Dietary supplements using the label must also provide a minimum of 10^7 to 10^9 live cells of a strain per day to users, Besançon noted.

Significant Achievement

A significant achievement for France's consumer healthcare industry, the decision follows work by NèreS, Besançon pointed out, in collaboration with partners such as French dietary supplements industry association Synadiet.

Beginning in 2021, this work centered on demonstrating to politicians and regulators via scientific research the understanding of probiotics that consumers, pharmacists and retailers already have.

The associations also pointed to other countries that have allowed the use of the term "probiotics," despite the European Commission's current interpretation of the term – specifically the United Nations/World Health Organisation definition – as an unauthorized health claim.

adéquates, ont un effet bénéfique sur la santé de l'hôte en concourant à l'équilibre de la flore intestinale."

Translated: "Living microorganisms, which, when consumed in adequate amounts, have a beneficial effect on the health of the host by contributing to the balance of the intestinal flora."

Food and Agriculture Organization of the United Nations (FAO)/World Health Organization: "Live microorganisms which when administered in adequate amounts confer a health benefit on the host."

“In the EU at present, there is one health claim approved linking live microorganisms, that is, live cultures in yogurt or fermented milk with improved lactose digestion,” explained probiotics expert David Pineda Ereño.

“However, probiotic strains as such have not received a positive opinion from the European Food Safety Authority (EFSA) on the basis of health benefits claimed as part of submitted applications, therefore no health claim specific to probiotics has been authorised in the EU,” he continued.

“As a result, the European Commission has considered the term ‘probiotic’ to be an unauthorized health claim that cannot be used in food labeling,” added Pineda, who is managing director of DPE International Consulting.

Probiotic Wave

While many EU member states have followed the EC’s interpretation, some have struck out on their own path, beginning with Italy and the Czech Republic.

Based on this precedent, Spain has officially permitted the use of the term probiotics on labels, using the recently introduced mutual recognition procedure for foods and food supplements.

Denmark has also joined this movement for liberalization, allowing the use of probiotic labels for dietary supplements while it waits for the EC to clarify its views.

In 2021, the Netherlands included probiotics in an updated version of the “Nutrition and Health Claims Handbook.”

Others allowing use of probiotics without publishing a formal position include Bulgaria, Malta and Poland.

“As there are no harmonized rules or criteria for probiotics in the EU, the decision remains at national level for EU member states to allow the use of the term probiotic on the label of food and food supplements,” Pineda explained. “The list of EU member states that allow the term probiotics is expanding, which may encourage others to formalize their position in the same direction.”

Over The Counter 28 Feb 2022: The Future Of EU Probiotics Regulation, With David Pineda Ereño

By [David Ridley](#)

28 Feb 2022 In this episode, HBW Insight talks probiotics with David Pineda Ereño, founder of DPE International Consulting and consultant to the International Probiotics Association. Since 2006, no health claims for probiotics have been allowed by harmonized European Union regulations. Even the term "probiotic" is considered an unauthorized health claim by the European Commission. However, as Pineda Ereño explains, many EU member... [Read the full article here](#)

Step Forward

Within this context, France's decision to allow the use of the term "probiotic" is a "very important step forward" for the European probiotics and dietary supplements industry, Pineda argued.

Alongside the formal request to the EC from Denmark for clarification, the International Probiotics Association has been working on new Codex Alimentarius guidelines for the use of probiotics, as a category, in food and food supplements.

The goal of such guidelines, which provide internationally recognized standards relating to food, food production, food labeling, and food safety, would be to provide a basis for regulatory harmonization, for example within the EU.

The IPA's proposals will be discussed by the Codex Committee on Nutrition and Foods for Special Dietary Uses in March this year, Pineda noted.

"In view of this, it is worth monitoring closely the discussions among the EC and EU member states," he suggested.