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AN OVERVIEW ON HARMONIZING PROBIOTICS CATEGORIES ACROSS THE GLOBE: CURRENT CHALLENGES AND FUTURE ASPECTS

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ABSTRACT

New probiotic strains have been discovered due to their increasing popularity in various countries such as India, Europe, Japan, Brazil, the USA, and Canada, driven by their potential health benefits. Before incorporating probiotics into food products, thorough safety assessments and reliable clinical trials are essential. False claims and improper use of "probiotics" weaken consumer trust and inhibit the industry's growth. There are still challenges in selecting, developing, and utilizing probiotics efficiently. Before employing probiotics as medication, a thorough study of safety aspects, patient risk assessments, and appropriate handling practices is essential. The fragmented worldwide regulatory framework confuses probiotic manufacturers, consumers, regulatory agencies, and scientists. Harmonizing legislation across different nations is necessary by categorizing probiotics according to their claims. Fighting false health claims and ensuring reliable information is crucial. Regulating probiotics according to risk (source, intended use) enables the implementation of suitable measures. Confusion would decrease, and a single regulatory framework would make safe commercialization easier. Future regulations could establish a multi-tiered classification system that meets specific standards. We must resolve these issues to guarantee probiotics' secure and efficient use. Encouraging scientific study, implementing clear labelling, and aiming for global regulatory harmonization will allow us to realize the total health benefits of probiotics.

Keywords: Probiotics, Regulatory bodies, Probiotics categorization, LAB, QPS, GMO

INTRODUCTION:

In recent years, there has been a significant shift in customer preferences for food products due to the growing belief that food directly impacts health. Today's customers seek food that offers more than mere essential nutrition. They desire it to actively advance well-being and wellness. This change has accelerated the growth of dietary supplements and functional foods, with probiotics taking centre stage. These living bacteria are thought to provide a wealth of advantages, including strengthening immunity, enhancing gut health, and possibly even helping to prevent specific illnesses. The market for probiotics is vast, and due to different classifications in various countries, it has become a regulatory maze. Consequently, it is difficult for consumers to know exactly what they buy when purchasing probiotic products. This article aims to explain how probiotic products are categorized globally and proposes an alternative categorization based on features such as target group and health benefits. A harmonized definition of probiotics globally would ensure standardization in information and choice for probiotics concerning consumers and healthcare professionals **[1, 2]**.

History of Probiotics:

- **1857-1864**: Louis Pasteur discovered lactic acid bacteria (LAB) as spoilage organisms in fermented products.
- **1878**: Joseph Lister isolated LAB from milk, furthering the understanding of fermentation processes.
- **1965**: Lilley and Stillwell defined the term probiotics.
- **1989**: Fuller provided a modern definition of probiotics as beneficial microbial supplements.
- **2001**: The FAO/WHO gave a formal definition of probiotics.
- **2003**: The genomic era began with the first genome sequence of a probiotic, *Lactobacillus plantarum*.
- **2005**: Relman used high-throughput 16S amplicon sequencing to catalogue the gut microbiome, advancing the understanding of probiotics.
- **2016**: The FDA/CBER issued guidelines for live biotherapeutics, formalizing the regulatory framework for probiotics **[3]**.

Global probiotic categorization and their regulatory aspects:

Probiotics are classified differently across countries and are recognized by different names. In Japan, China, and Malaysia, they are known as functional foods, while in European nations like Belgium and

Germany, they are categorized as pharmaceuticals and bio-therapeutics. In Canada, they are referred to as natural health products, whereas in the USA, they can be classified as dietary supplements, medications, medical foods, live biotherapeutic agents, or biological agents, depending on their intended use. **Table 1** shows global overview of probiotic categorization and their regulatory bodies. The following section depicts country-specific regulatory status of probiotics:

Table 1: Global Overview of Probiotic Categorization and Their Regulatory Bodies

Country	Regulatory body	Category
India	**Food Safety and Standards Authority of India (FSSAI)**	**Functional foods, drugs**
Europe	**The European Commission Concerted Action on Functional Food Science in Europe (FUFOSE)**	**Functional foods**
Japan	**Ministry of Health and family welfare (MHLW); Food for Specified Health Uses (FOSHU)**	**Functional food and nutraceuticals**
USA	**Dietary Supplement Health and Education Act (DSHEA)**	**Dietary supplements**
Brazil	**The National Health Surveillance Agency (ANVISA)**	**Functional foods**
Canada	**Health Canda, Canadian Food and Drugs Act (CFDA)/ Canadian Food Inspection Agency (CFIA)**	**Natural health products (NHPs)**

India

The FSSAI is responsible for overseeing the regulations related to probiotics. It has established standards and guidelines to ensure the effectiveness, safety, and quality of probiotic products. Manufacturers of probiotics must adhere to strict regulations regarding labelling and health claims as these products are classified as functional foods or dietary supplements. The regulatory framework emphasizes the importance of scientific evidence to support the health benefits that are promoted, aiming to ensure that probiotic products are both safe and effective for consumption.

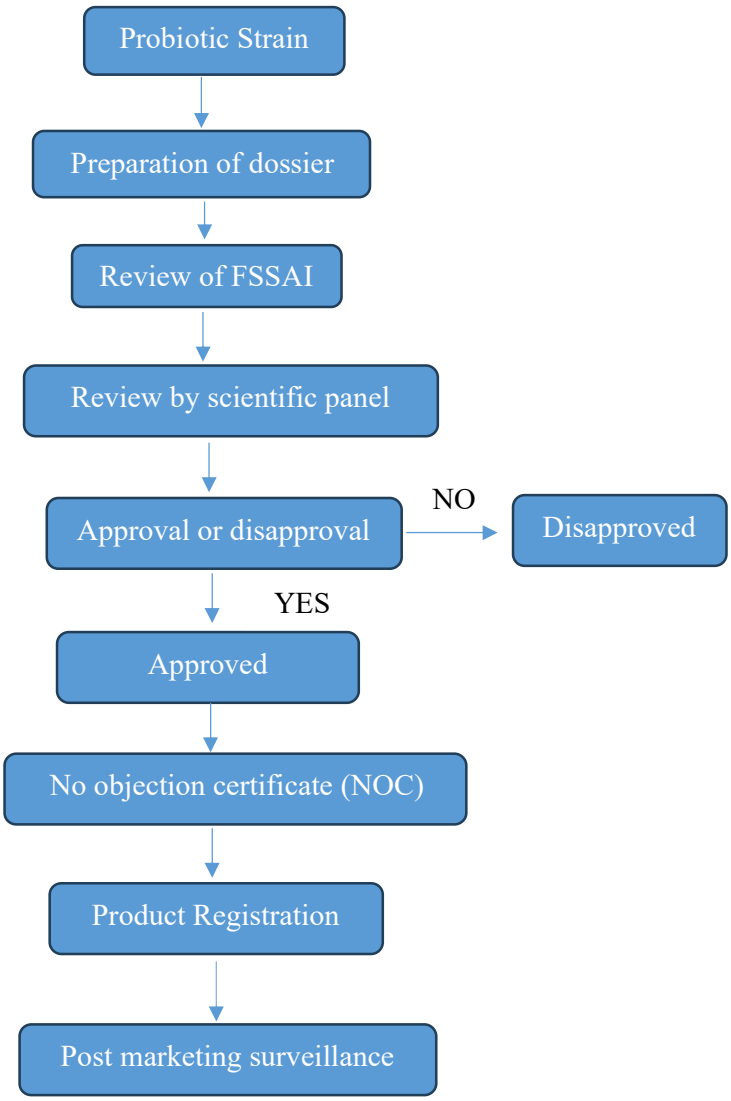

Figure 1: Flowchart of the Approval Process for Probiotics in the India

European Union

Europe is the second region to identify "functional foods" and form a Commission on Functional Food Science in Europe (FUFOSE) in 1995 **[5]**. Due to popularity of functional food items, Europe holds a considerable share of the global probiotic. Dairy products are the main participants in this market, providing customers with easy ways to include probiotics in their diets, especially yogurts and fermented milk. Food safety in Europe adopts a comprehensive strategy. Probiotics and other microbial cultures found in food are subject to stringent regulations. The European Food Safety Authority (EFSA) created the notion of Qualified Presumption of Safety (QPS) [6]. Pre-market safety evaluations of probiotics are ensured by this procedure, protecting consumers. Three scientific committees

involved in the food and food-associated domains within the European Union are Scientific Committee on Plants (SCP); Scientific Committee on Food (SCF) and Scientific Committee on Animal Nutrition (SCAN). **Figure 1** summarizes steps for probiotic approval in European Union.

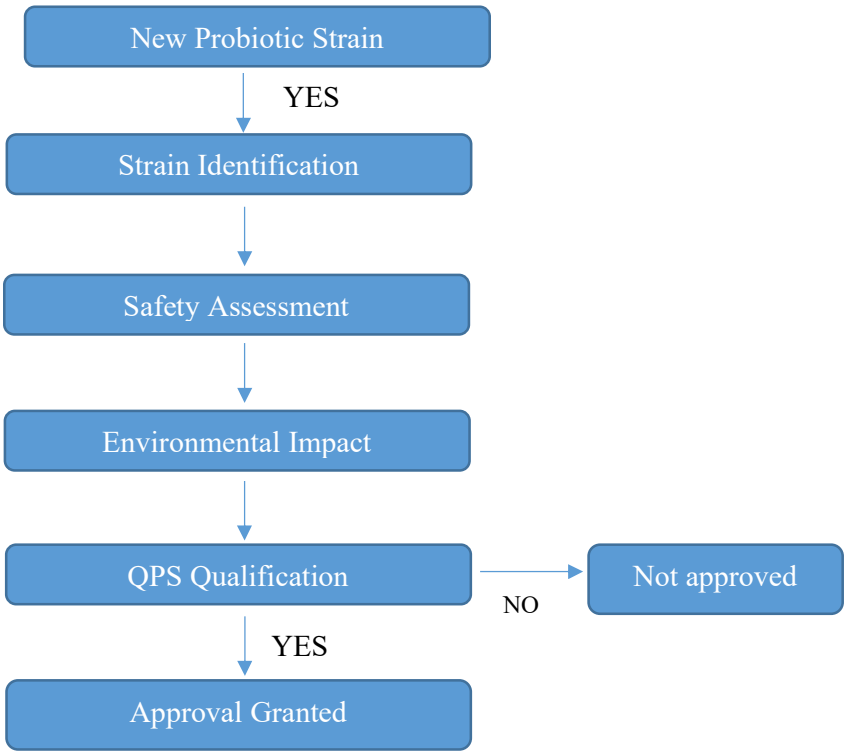

Figure 2: Flowchart of Steps for Probiotic Approval in European Union

Japan

Japan continues to lead the world market for probiotics purchased as foods and medications. Japan was the first country in the world to implement a regulatory framework for nutraceuticals and functional foods in 1991 **[7]**. In contrast to many other nations struggling with a single probiotic system, Japan has a two-tiered system that separates probiotic products with general health claims from those with more targeted ones **[8]**.

Table 2: Categorization and Regulation of Probiotic Products in Japan

Tier	Category	Description	Health Claims	Regulatory Body	Health Claim Grading
Tier 1	Food products with probiotics	Standard probiotic beverages, capsules, or dairy products containing live bacterial cultures	Cannot declare any health benefits on the label	N/A	N/A
Tier 2	Foods for specific health use (FOSHU)	Functional foods with verified health benefits requires comprehensive assessment	Can declare health benefits	MHLW	Grade A: Highest grade for claims with solid nutritional and medical data Grade B: Moderate level for claims with verified supporting documentation Grade C: Lowest grade for claims with insufficient data but hints of support

USA

The regulatory landscape surrounding probiotics might be complex in the United States of America (USA). Compared to other nations with a single, straightforward approach, the US uses a multi-layered method based on the format and intended use of the probiotic product. The guidelines for dietary supplements, which may include some probiotics, are established by the Dietary Supplement Health and Education Act (DSHEA), and the Food and Drug Administration (FDA) regulates several goods, including probiotics, for efficacy and safety **[9, 10]**.

Brazil

In South America, Brazil is considered a leader in establishing regulations for functional foods. Probiotics are classified as a unique functional food in Brazil, separate from other dietary groups. These are distinct from regular food groups. This distinction acknowledges their potential health benefits beyond essential nutrition. The regulatory agency responsible for regulating the functional foods containing probiotics is the National Health Surveillance Agency (ANVISA) **[11]**.

Canada

In Canada, probiotics are categorized as natural health products (NHPs). All Canadian laws about food and drugs are based on the Canadian Food and Drugs Act (CFDA), and the regulatory framework for probiotics is governed primarily by Health Canada, which ensures that products are safe, effective, and of high quality **[12, 13]**.

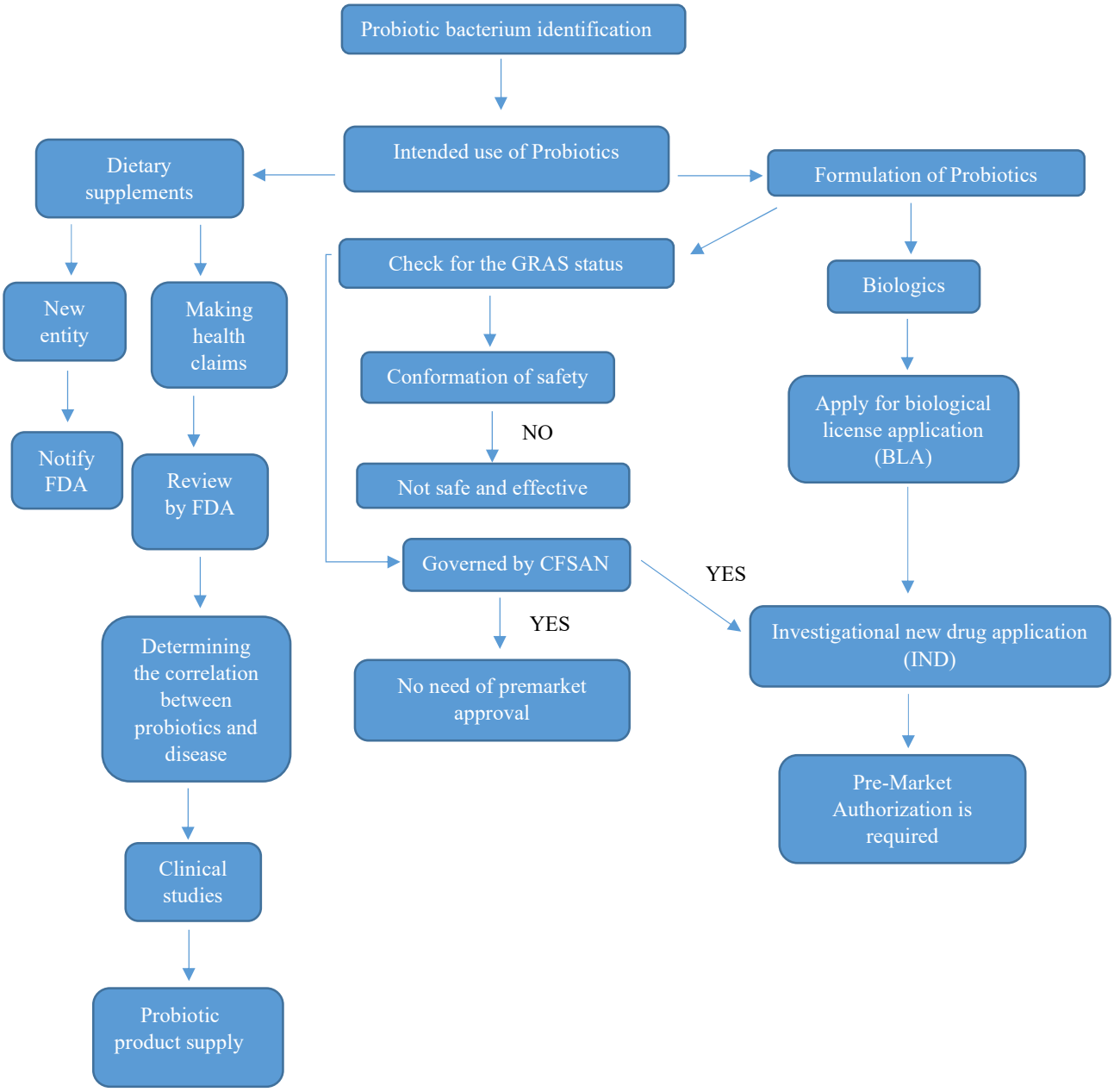

Figure 2: Flowchart of Steps for Probiotic Approval in USA

Challenges with the Current Categorization:

- Confusion arises because there is no single, globally accepted definition of probiotics. Different countries and regulatory agencies may have varying interpretations, leading to inconsistencies in safety assessments, marketing strategies, and product labelling.
- It can be challenging to identify which particular bacteria meet the criteria for being considered "probiotics" with potential health

benefits without a precise definition. This ambiguity may impede future advancements in the realm of science **[14]**.

- Probiotics can be found in various products, including nutritional supplements, yogurts, and even specific makeup items. However, the regulations surrounding these products differ based on their classification as food, supplements, or cosmetics. This situation can be confusing for both consumers and manufacturers **[15]**.
- Manufacturers may find it difficult to navigate the complex network of regulations based on product classification, as different categories can have varying standards for labelling, approval procedures, and safety evaluations.
- Functional foods may have subcategories that still need to be defined despite their definition in some nations. Some countries, like India's Food Safety and Standards Authority (FSSA), define functional food categories but leave out specific subcategories like nutraceuticals and bio-therapeutic agents (which may include some probiotics). A clear definition of subcategory is needed to establish precise regulations for these functional foods.
- Live microorganisms are considered a crucial component of probiotics in many classifications. However, several studies indicate that some heat-treated or non-living bacterial strains may also have health benefits. These alternatives may need to be adequately considered by the current categorization scheme.
- Although a specific type of bacteria may be classified as a probiotic, the health benefits can vary by strain. Current classification systems may not always account for this strain specificity, making it challenging to definitively prove the effectiveness of specific probiotic products **[16]**.
- Making educated decisions concerning probiotic goods can be challenging for customers without precise classification and labelling guidelines. They may be unaware of these products' hazards, advantages, and proper applications.
- Inaccurate classification might provide opportunities for deceptive advertising claims. It is possible to mislead consumers about the actual health advantages of some probiotic supplements.

The benefits of probiotics are that they are safe, natural, and advantageous for both humans and animals, regardless of their

name. We need to monitor the facts about probiotics more effectively to fully harness their potential. Otherwise, there could be significant issues with the categorization of probiotics, which is concerning.".

Future Recommendation for Probiotic Categorization:

- Establishing a globally recognized definition for probiotics would be a huge step forward. Crucial elements, including the strain's specificity, viability, and the minimal standards a microorganism must meet to be called a "probiotic," should be considered in this interpretation **[17]**.
- International cooperation among scientific communities, regulatory agencies, and industry participants can help to create a unified classification and definition system.
- Defining precise regulatory categories for probiotics is necessary to minimize confusion. Regulatory routes for probiotic products could decrease while maintaining thorough safety assessments to promote innovation and accelerate the development of novel probiotic strains with well-defined advantages **[18]**.
- Probiotic product labelling needs to be harmonized and made explicit by regulations. This contains details about the particular strain of probiotics, how much to take, any possible adverse effects, and whether or not to combine certain drugs. Initiatives to inform customers about probiotics, their possible advantages, and how to select high-quality products depending on their needs would be helpful in addition to clear labeling.
- Maintaining awareness is crucial for long-term clinical studies. While most research focuses on the short-term effects of probiotics, it is vital to understand their safety and utility over an extended period thoroughly.
- The classification scheme must be flexible enough to consider new scientific findings and developments in the study and production of probiotics.
- Examining Genetically Modified Probiotics (GMO) probiotics more thoroughly is critical. Since many of these items are genetically modified, a more thorough safety evaluation procedure is necessary. Identifying any possible genetic change risks may require lengthy clinical trials and thorough pre-clinical testing **[19, 20]**.

CONCLUSION:

New probiotic strains have been discovered due to their increasing popularity in various

countries such as India, Europe, Japan, Brazil, the USA, and Canada, driven by their potential health benefits. Before incorporating probiotics into food products, thorough safety assessments and reliable clinical trials are essential. False claims and improper use of "probiotics" weaken consumer trust and inhibit the industry's growth. There are still challenges in selecting, developing, and utilizing probiotics efficiently. Before employing probiotics as medication, a thorough study of safety aspects, patient risk assessments, and appropriate handling practices is essential. The fragmented worldwide regulatory framework confuses probiotic manufacturers, consumers, regulatory agencies, and scientists. Harmonizing legislation across different countries is necessary by categorizing probiotics according to their claims. Fighting false health claims and ensuring reliable information is crucial. Regulating probiotics according to risk (source, intended use) enables the implementation of suitable measures. Confusion would decrease, and a single regulatory framework would make safe commercialization easier. Future regulations could establish a multi-tiered classification system that meets specific standards. We must resolve these issues to guarantee probiotics' secure and efficient use. Encouraging scientific study, implementing clear labelling, and aiming for global regulatory harmonization will allow us to realize the total health benefits of probiotics.

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