

# Enforcement of Unified Global Regulatory Guidelines for Probiotic Products: The Framework for Future



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## Abstract

Quality of probiotics, specially having health claims, is a great concern to consumers and regulatory agencies across the globe. The quality of probiotic products mainly depends on regulatory requirements of respective countries. To establish the regulatory parameters and their harmonization as unified legislations for universal acceptance for improvements in quality, safety, and efficacy, existing regulatory framework of different countries on probiotic products was extensively studied by author and his coworkers. Results show that majority of the countries have considered these product under different categories. Increased utilization of probiotics for therapeutic applications has also alarmed the regulatory authorities to reconsider its status and related regulations in alignment with the most stringent category i.e. pharmaceuticals. Like other countries, India has also adopted prudent measures to regulate probiotics on the basis of intended use. However sincere initiatives towards development of harmonized regulations by incorporating different measures for probiotics with nutritive and therapeutic claims are need of the hour. The roadmap for drafting of a comprehensive framework for probiotics is also proposed for future action to ensure safety of consumers.

**Keywords:** Food; Dietary supplements; Health claims; Harmonization Nutraceuticals; Probiotics; Pharmaceuticals; Regulatory guidelines

## Introduction

Probiotics is a broad term, used for friendly bacteria, more appropriately defined as live microorganisms, which upon administration in adequate amounts confer a health benefit on the host. Throughout the world, there has been an upsurge in the usage of probiotic products. Along with their nutritive benefits, these beneficial microorganisms can be used to treat a range of clinical conditions that have been linked to gastrointestinal problems like irritable bowel syndrome, traveler's diarrhea, inflammatory bowel disease, oral diseases like tooth decay and periodontal disease, various other infections including vaginal and infections, and could also be beneficial in preventing autoimmune disorders, cancer, diabetes etc. Despite of having plenty of beneficial effects, both status of the probiotics as a component of food or their therapeutic mechanisms are not clear [1-8].

This has resulted in ambiguity while categorizing them. Despite of having a safe history of prior use, some of the probiotic microbes are known to translocate, resulting in invasive infection

and conferring antibiotic resistance to potential pathogens. Along with it, there are some reports of possible deleterious metabolic activity, immunologic effects and adverse effects especially in immune-compromised, geriatric or pediatric patients. The most serious area of concern is that most of these products are sold over-the-counter as dietary supplements or in food products such as yogurt, as well as in the pharmaceutical preparations too. Furthermore none of the regulating agencies are considering these products as pharmaceuticals despite of ever increasing associated health claims. These situations are posing serious threat to safety of consumers and establishing the credibility of probiotic based products. Currently probiotic based industries are flooding the market with a range of commercial probiotic products and these probiotics are much more preferred over the conventional dosage forms due to their wide therapeutic benefits with negligible side effects but lack of standardization and clinical evidences are also becoming major risk. Therefore stringent legislations related to uniform quality, greater safety of patients, with established scientific evidences

for holistic therapeutic benefits in treatment of various ailments, drafting of comprehensive regulatory guidelines for probiotic products is the need of the hour [1-8].

### Regulations of Probiotics: Critical Review and Methodology

So in this context, already prescribed guidelines from various countries have been collected for common point selection and reviewed critically. It has been observed that presently these products have been classified and regulated under various categories like food products, nutraceuticals, dietary supplements, natural health products, FOSHU and most of the countries have established the guidelines for probiotic food instead of probiotic drugs as their use as food products is well established. Along with this, it has been reviewed that most of the countries have framed the guidelines in accordance to the products manufactured in that country particularly and majority are considering it under functional foods. But therapeutic effect intended by probiotic food articles is beyond the limit of ordinary food articles and hence it is strongly felt that the use of these products must be strictly regulated by establishing all the necessary guidelines in line with the pharmaceuticals.

### Suggestive Regulatory Framework for Probiotics

With respect to probiotics, not even a single country has covered all the aspects including identification, evaluation, manufacturing, approval, identifying and defining data for substantiating health claims, and safety assessment studies. Hence to bring harmonization of standards, a modified appropriate definition, categorization of probiotics based on intended use and separate guidance documents for identification up to genus/species/strain level; evaluation of probiotic formulations; production of the probiotics formulation including GMP aspects; for approval process covering Investigational New Drug approval, New Drug approval and Abbreviated New Drug approval on the basis of GRAS probiotic, live microbes other than GRAS and if new microbe with probiotic potential must be drafted. Other associated guidance documents to be compiled must include identifying & defining data for substantiating health claims for deciding dose and duration of probiotic use, viability at target site and effectiveness, In vitro tests suitable for evaluation of probiotics as well as their safety assessment, labeling and packaging.

The author and his coworkers has proposed guidelines to clear existing ambiguities related to status and approval process for probiotic based products by covering all related aspects like identification and evaluation of microorganisms with probiotic potential up to strain level, good manufacturing processes for production, quality control parameters, dossier development

and related documentations for clinical trials and approval of probiotic products as per their intended use, marketing and labeling requirements etc.

### Conclusion

Some initiatives have already been taken in this arena by several countries and agencies including WHO, USFDA (USA), EFSA (EU), ICMR/DBT/ILSI/FSSAI (India) and so on. In spite of such isolated initiatives, there is a need for global harmonization of the legislation and associated instruments to provide quality, safe, and efficacious probiotics for the benefit of humanity. The proposed draft documents may be adopted as base regulations by regulatory bodies to take lead in current international scenario by framing a comprehensive and harmonized guideline to be accepted universally. The guidelines so developed will result in harmonization of standards for global acceptance, strictly regulated probiotic based products with quality control and assurance, single definition of probiotics and consistent terminology, clear cut demarcation of regulatory probiotic categorization, increased customer acceptance and commercial success of probiotic product.

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