OPEN ACCESS
Global Journal of Research in Dental Sciences
Volume 01| Issue 02 | Sept - Oct | 2021
Journal homepage: https://gjrpublication.com/journals/

Point of View

Probiotic Regulation in US and Canada

Yi Yang Fei[1], *John Christy Johnson[2], Peter Anto Johnson[3], Noor AL Omran[4] & Austin Mardon[5]

[1 2,4]Antarctic Institute of Canada, Edmonton, Alberta, Canada
[3]Department of Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada
[5]Department of Psychiatry, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada

Submission Date: 09 July 2021 | **Published Date:** 30 Oct. 2021

***Corresponding author:** John Christy Johnson
Antarctic Institute of Canada, Edmonton, Alberta, Canada

Keywords: Probiotic, FAO, WHO, FDA

The definition of probiotic has been continuously refined over the past few decades as its scientific context evolved.[1,2] Despite its relatively recent recognition, probiotics have been used since millennia ago, long before science itself was acknowledged, in fermented products across various ethnic cultures to preventing food spoilage.[1,2] In 2001, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) consolidated a widely accepted basic definition for the term probiotic: "live microorganisms which when administered in adequate amounts confer a health benefit on the host." [3] While kept brief, the wording stresses that a probiotic must be externally introduced with sufficient living amounts in each dosage, and the elicited outcome must be positive for the host's health.[3]

Despite this, the potential misuse of the term and inappropriate health claims are still a concern.[3] In the recent few decades, increased and diverse market demand for different forms of probiotics has become a complex challenge for government authorities across the globe.[4] Although the scientific community has reached a consensus in description guidelines, probiotic products are regulated differently between countries.[4] With varying descriptions and safety standards, categories that include probiotics can range from functional or medical food to dietary supplements or therapeutic drugs.[4] A lack of common terminology makes any probiotic-related discussion among governments, producers, and consumers difficult.[4]

In the US, probiotics in food are considered dietary supplements, and thus only require a pre-marketing demonstration of safety and efficacy which do not require Food and Drug Administration (FDA) approval before being marketed.[5] In addition, the responsibility to ensure adequate and non-misleading evidence is put on the manufacturer, and evidence of efficacy does not need to be presented to the FDA in any form if all ingredients are introduced before October 15,1994.[5] The US government also permits companies to make structural or functional claims without making their supporting data publicly available.[5] Companies will describe their products' ability to maintain normal body functioning, but are required to state that the FDA has not evaluated such claims, nor are the products intended to "diagnose, treat, cure, or prevent any disease."[5] Probiotic use as drugs, however, undergo regulatory processes as a drug under the FDA's regulation for new therapeutic agents.[5] They are associated with health claims, which describe a specific reduction of risk of a disease or a health-related condition.[5] The scientific evidence for these claims must be tailored for the general population, including both healthy and vulnerable subgroups, and all evidence is required to be reviewed by the FDA and made public.[5]

The Canadian regulatory framework has many similarities to the US framework. Namely, probiotics in food and drug use have separate guidelines.[6] Probiotics in food have no specific regulations and instead fall under the general provisions of the *Food and Drug Relations*, which govern both safety and claims of food items.[6] While manufacturers and importers of foods are responsible for the safety and truthfulness of claims, the Canadian Food Inspection Agency (CFIA) is able to enforce these provisions.[6] On the other hand, probiotics are classified as natural health products (NHPs) when a claim for therapeutic purposes is presented.[6] These are regulated under the *Natural Health Products Regulations* and are required to have product licenses in addition to a pre-market assessment by the Food Directorate of Health Canada.[6] The acceptable use of probiotic claims are outlined in Health Canada's guidance document, which lists

several recommendations of the information displayed to consumers: (1) Identification of the Strain, (2) Language Requirements for Probiotic Claims, (3) Quantitative Statements for Probiotic Claims, and (4) Ingredient Lists.[7] A limited number of non-strain-specific claims are made applicable for species under the Table of Acceptable Non-Strain Specific Claims for Probiotics.[7] These claims describe the nature of the probiotics in connection to the gut flora, such as "Probiotics that naturally form part of the gut flora" or "contributes to healthy gut flora."[7] Interestingly, Health Canada states that "at the present time, no strain-specific claims have been accepted."[7]

In summary, regulation on probiotic products largely depends on the type and nature of claims made by the manufacturer, as well as the evidence available to support such claims. In consideration of the complex categorization and extensive review process, regulation for probiotic products may benefit from re-organization to reduce ambiguity in the process of classification.[8] Up-to-date evidence on the effect of probiotics on health and diseases should also be reviewed frequently to ensure the legislation reflects on the best available evidence to maximize the benefit for consumers.

REFERENCES

1. Hume, M. E. (2011). Historic perspective: prebiotics, probiotics, and other alternatives to antibiotics. Poultry science, 90(11), 2663-2669.
2. Fuller, R. (1992). History and development of probiotics. In Probiotics (pp. 1-8). Springer, Dordrecht.
3. Hill, C., Guarner, F., Reid, G., Gibson, G. R., Merenstein, D. J., Pot, B. & Sanders, M. E. (2014). The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nature reviews Gastroenterology & hepatology, 11(8), 506-514.
4. Arora, M., & Baldi, A. (2015). Regulatory categories of probiotics across the globe: a review representing existing and recommended categorization. Indian journal of medical microbiology, 33, S2-S10.
5. Venugopalan, V., Shriner, K. A., & Wong-Beringer, A. (2010). Regulatory oversight and safety of probiotic use. Emerging infectious diseases, 16(11), 1661.
6. Health Canada. Questions and Answers on Probiotics [Internet]. aem. 2009 [cited 2021 Apr 29]. Available from: https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/questions-answers-probiotics.html
7. Health Canada. Guidance Document - The Use of Probiotic Microorganisms in Food [Internet]. aem. 2009 [cited 2021 Apr 29]. Available from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-use-probiotic-microorganisms-food-2009.html
8. White, J., & Reid, G. (2018). A suggestion for evolution of Canada's health regulatory system. Facets, 3(1), 45-60.