

Regulation of Foods Containing Probiotics - Codex Alimentarius, Japan, European Union and India

Aditya Kumar Jain

*National Dairy Development Board, NDDB House, Safdarjung Enclave,
New Delhi-110029, India.*

Corresponding author: Aditya Kumar Jain; aditya@nddb.coop

In 2002, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) published the ‘*Guidelines for the Evaluation of Probiotics in Food*’, and recommended the most widely accepted definition of the term ‘*probiotic*’ as ‘*Live microorganisms which when administered in adequate amounts confer a health benefit to the host*’.⁽¹⁾ This definition encompasses the food as well as the non-food applications of the term.

Increasing use of probiotics in foods has resulted in an array of foods containing such microorganisms, and related claims on their labels, being introduced into the market over the years. Consequently, the competent regulatory agencies around the world have commenced efforts to regulate these claims with a view to protect consumers and ensure fair trade.

This paper attempts to provide an overview of the regulation of foods containing probiotics through information on relevant standards/regulations elaborated by the Codex Alimentarius Commission at the international level and by Japan, European Union and India.

General Regulatory Aspects of Foods Containing Probiotics

Incorporation of probiotics in foods is aimed at imparting some additional beneficial attribute(s) to the foods over and above their normal usefulness. Regulation of foods containing probiotics, thus, is regulation of the claims of such beneficial attributes made, if any, apart from the normal requirements of food safety.

Codex Alimentarius

The Codex Alimentarius Commission (CAC), which elaborates food standards that are recognized as reference standards for international trade in food by the World Trade Organization, does not provide a definition for the term ‘*probiotics*’. However, the **General Standard for the Labelling of Prepackaged Foods (CODEX/STAN 1)**⁽²⁾ includes the following general principle for labeling of foods that applies in respect of the foods containing probiotics as well:

“Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.”

As a corollary, the following Codex guidelines also apply to the foods containing probiotics:

General Guidelines on Claims (CAC/GL 1)⁽³⁾

- Defines ‘Claim’ as any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.
- Prohibited claims include (among others):
 - Claims which cannot be substantiated.
 - Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are in accordance with the provisions of relevant Codex standards or guidelines; or, in the absence of an applicable Codex standard or guideline, are permitted under the laws of the country in which the food is distributed.
- Potentially misleading claims include (among others):
 - Meaningless claims including incomplete comparatives and superlatives.
 - Claims as to good hygienic practice, such as ‘*wholesome*’, ‘*healthful*’, ‘*sound*’.

Guidelines for Use of Nutrition and Health Claims (CAC/GL 23)⁽⁴⁾

- Defines ‘*Health claim*’ as any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.
- States that health claims shall not be permitted for foods for infants and young

children except where specifically provided for in relevant Codex standards or national legislation.

- Includes detailed set of conditions to be met for making a health claim.
- Includes, in an Annex, the ‘*Recommendations on the Scientific Substantiation of Health Claims*’.

All the standards in the Codex Alimentarius are voluntary and the CAC has no enforcement mandate. However, countries are encouraged to harmonize their standards with those established by the CAC. The Codex Alimentarius standards are freely available at the website: <http://www.codexalimentarius.org/standards/en/>.

Countries

Japan

In the context of this subject, the foods in Japan can be divided into two broad categories –unregulated and regulated foods.

The unregulated foods in the context represent all types of processed food, conventional foods including so-called health foods, and dietary supplements. They can be freely sold as any processed food and cannot carry any claim.⁽⁵⁾

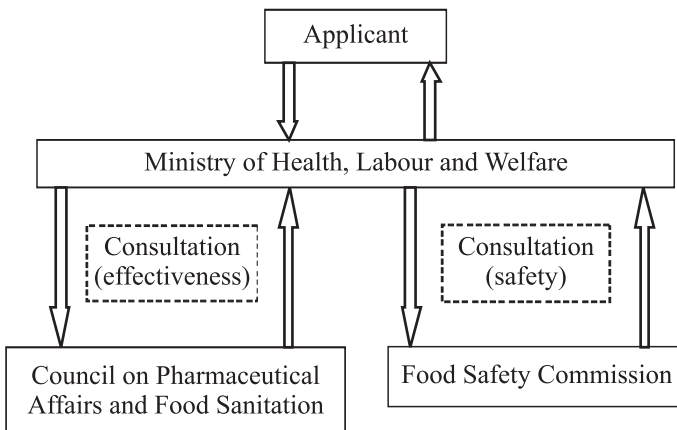


Figure. Flow Chart for FOSHU Approval(7)

In respect of the regulated foods category in the context, which is officially allowed to make health function claims, the system of **Food for Specified Health Uses (FOSHU)** was created under the Nutrition Improvement Law of 1952 in 1991 which labelling is the **world’s first approval system for healthclaim labelling of foods.**^(5, 6) Presently, the FOSHU is covered under the Section ‘*Health Claims and*

Health Foods under the Health Promotion Law administered by the Ministry of Health, Labour and Welfare (MHLW).⁽⁶⁾

Before a FOSHU is placed in the market, it should receive an approval on the contents of labelling from the MHLW, through the examination of scientific evidence(s) on safety, physiological functions and specific health functions claimed (Figure).

Requirements for FOSHU approval include the following⁽⁷⁾:

- Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

FOSHU approval takes strain specific approach based on the concept that each probiotic strain can exhibit its own effect on the host⁽⁵⁾.

In addition to regular FOSHU briefly explained above, following types of FOSHU are available to facilitate FOSHU approvals⁽⁷⁾:

- **Standardized FOSHU:** This type of FOSHU, whose scientific evidences have been accumulated through experiences of the past approvals, is not required to undergo the detailed scientific assessment. It has to only receive the confirmation that it meets the relevant standards and specifications of the MHLW.
- **Qualified FOSHU:** This type of FOSHU, whose beneficial effect(s) to the health have been already confirmed, although the scientific evidence is not complete as required in the previous cases, could be approved with conditions attached.
- **Reduction of disease risk FOSHU:** Reduction of disease risk claim is permitted when reduction of disease risk is clinically and nutritionally established in an ingredient and whose scientific evidence has been widely recognized from the medical and nutritional points of views.

The standardized FOSHU health claims for probiotic products are currently limited to improvement of gastrointestinal conditions. Some examples of such claims are:

- Reaches the intestine alive
- Promotes maintenance of a good intestinal environment
- Reduces harmful bacteria
- Helps balance intestinal flora

FOSHU foods can carry a seal as follows⁽⁷⁾:



Seal for FOSHU Approval

European Union

The specific regulations impacting the foods containing probiotics are:

- Regulation (EC) No. 1924/2006 of 20 December 2006 on nutrition and health claims made on foods
- Regulation (EC) No. 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council
- Regulation (EU) No. 907/2013 of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations)
- Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

Regulation No. 1924/2006⁽⁸⁾ sets out the framework for health claims on foods, which includes the claims related to the foods containing probiotics. Information on key articles is provided below:

Article 13 – Health claims other than those referring to the reduction of disease risk and to children’s development and health
Article 13 (1): It relates to the claims related to the role of a nutrient or other substance in growth, development and functions of the body; or psychological and/or behavioral functions; or slimming, or weight control, reduction in the sense of hunger or increase in the sense of satiety, or to reduction in the available energy from the diet.
Claims are based on generally accepted scientific evidence and the claim may be made without going through the process of applying for authorization and detailed scientific assessment.
The only accepted probiotic claim under Article 13 (1) relates to improved lactose digestion by live yoghurt cultures.
Article 13 (5):It covers the health claims based on emerging science. The process of applying for authorization and detailed scientific assessment needs to be followed. The applicant must produce all the relevant available data/studies and may request protection of proprietary data. The food and constituent must be defined and characterised. The claimed effect must be defined, beneficial physiological effect and be biologically plausible. A cause and effect relationship must be established between the consumption of the food/constituent and the claimed effect.
No probiotic claims have been approved so far under this Article.
Article 14 – Reduction of disease risk claims and claims referring to children’s development and health: The claims pertaining to disease risk reduction claims and claims involving children are assessed in the same way, with the same requirements as Article 13.5 claims.
No probiotic claims have been approved so far under this Article.

Further, as per Article 23, any health claim can only be authorized after a scientific assessment of the highest possible standard. In order to ensure harmonized scientific assessment of these claims, the European Food Safety Authority (EFSA) is identified to carry out such assessments.

Regulation (EC) No. 353/2008⁽⁹⁾ includes a general guide for making an application for authorization of a claim. In its Annex, it also provides technical rules for the preparation and presentation of the application for health claims including general principles for scientific substantiation, food characteristics, organization of pertinent scientific data, summary of pertinent scientific data, and the structure of the application.

Regulation (EU) No. 907/2013⁽¹⁰⁾ concerns the process of application for generic descriptors which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health. It requires that the generic descriptors should correspond to a period of at least 20 years proven usage within the Member State(s) prior to the date of entry into force of the Regulation 1924/2006.

Regulation (EU) No 432/2012⁽¹¹⁾ provides a list of health claims permitted under the provision of Article 13 in the Regulation 1924/2006. It is a dynamic list and is / has been amended from time to time.

Additionally, a guidance document to facilitate implementation of the regulations pertaining to foods containing probiotics is available.⁽¹²⁾

India

The **Food Safety and Standards Act, 2006**⁽¹³⁾, Section 22 pertains to the foods for special dietary uses or functional foods or nutraceuticals or supplements and includes an elaborate collective definition of these foods.

The **Food Safety and Standards (Packaging and Labelling) Regulations, 2011**⁽¹⁴⁾ include a general principle for labeling of foods similar to the one in the '*Codex General Standard for the Labelling of Prepackaged Foods (CODEX/STAN 1)*' indicated before. These Regulations also provide a definition for the term 'health claim' and prohibit a label from containing any statement or claim which is false or misleading in any particular concerning the food contained in the package.

The **Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011**⁽¹⁵⁾ makes a reference to the term '*probiotic*' in relation to yoghurt, *dahi*, *chakka* and *shrikhand*. The term, however, is not defined anywhere in these Regulations.

The specific regulations on foods containing probiotics are still in draft stage—the **Draft Regulations on Labeling (Claims)**⁽¹⁷⁾ developed by the Food Safety and Standards Authority of India for wider consultations in December 2012. These draft Regulations include a detailed section on nutrition and health claims, largely based on relevant Codex standards and guidelines referred before. While not providing a definition for the term '*probiotic*', it envisages that a product claimed to be probiotic should have at least 10^6 colony forming units of the probiotic organism per serve of the product.

While currently there are no specific regulations in force in respect of foods containing probiotics in India, there is a product approval process (mandatory for proprietary products) that appears to regulate health claims on proprietary foods. The format for product approval application seeks information on efficacy in relation to any health claims or risk reduction claims proposed to be made on proprietary products and also requires that the published literature/clinical studies supporting such claims be submitted for assessment.⁽¹⁸⁾

The Indian Council of Medical Research (ICMR) /Department of Biotechnology (DBT) published the *Guidelines for Regulation of Probiotics in Food* in 2011.⁽¹⁶⁾ These deal with the use of probiotics in food and provide requirements for assessment of safety and efficacy of the probiotic strains and health claims including labelling of such products. While largely based on the '*FAO/WHO Guidelines for the Evaluation of Probiotics in Food*', the ICMR/DBT guidelines indicate that while the studies done abroad should be taken into account, the efficacy studies of probiotics (which are of proven benefit in other populations) should also be conducted on Indian subjects.

The International Life Sciences Institute, India has also developed the '*Guidelines and Criteria for Evaluation of Efficacy, Safety and Health Claim of Probiotic in Food Products in India*'.⁽¹⁹⁾

There are several products available in the market that make general or implied health claims.

Conclusion

The term '*probiotic*' is not defined in the Codex Alimentarius and does not appear to be defined in the food legislation in Japan and the European Union. However, there are elaborate regulations specific to the claims on foods containing probiotics in these countries. Relevant food legislation exists also in Australia/ New Zealand, Canada and the United States of America (not covered in this paper). The approved probiotic related claims, however, are limited in number owing to the difficulties associated with availability of conclusive evidence supporting such claims.

In India, there is an urgent need to establish a comprehensive system for regulation of claims in respect of the foods containing probiotics in order to protect interests of the consumer and also to ensure fair trade. It is also necessary to identify/ develop specific expertise within the country to assess the scientific justification supporting such claims.

It can reasonably be envisaged that the competent authorities in India would take into account the guidance available in the relevant standards in the Codex Alimentarius and other countries in this context.

(Views expressed in the paper are of the author and do not necessarily reflect the views of the National Dairy Development Board)

References

1. FAO (2002). Guidelines for the Evaluation of Probiotics in Food. In Report of Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food London Ontario, Canada. Food and Agriculture Organization and World Health Organization.
2. CAC (1985). General Standard for the Labelling of Prepackaged Foods (CODEX/STAN 1). Codex Alimentarius Commission.
3. CAC (1979). General Guidelines on Claims (CAC/GL1). Codex Alimentarius Commission.
4. CAC (1997). Guidelines for Use of Nutrition and Health Claims (CAC/GL 23). Codex Alimentarius Commission.
5. He Fang and Benno Yoshimi (2011). Probiotics and Health Claims – a Japanese Perspective. In Probiotics and Health Claims (Edited by Wolfgang Kneifel and Seppo Salminen), Blackwell Publishing Limited/John Wiley and Sons.
6. Takahashi Teiji (2009). Laws and Regulations on Food Safety and Food Quality in Japan.
7. MHLW (2013). Foods for Specified Health Uses. Ministry of Health, Labour and Welfare, Japan.
8. EC (2006). Regulation (EC) No. 1924/2006 of 20 December 2006 on nutrition and health claims made on foods. European Parliament and the Council.
9. EC (2008). Regulation (EC) No. 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No. 1924/2006. European Commission.
10. EC (2013). Regulation (EU) No. 907/2013 of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations). European Commission.
11. EC (2012). Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. European Commission.
12. EFSA (2011). Scientific and Technical Guidance for the Preparation and Presentation of an Application for Authorization of a Health Claim (revision 1). *EFSA Journal*. 9(5): 2170
13. GOI (2006). Food Safety and Standard Act, 2006 (No. 34 of 2006). Ministry of Law and Justice, Government of India.
14. FSSAI (2011). Food Safety and Standards (Packaging and Labelling) Regulations. Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, India.

15. FSSAI (2011). Food Safety and Standards (Food Products Standards and Food Additives) Regulations. Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, India.
16. ICMR/DBT (2011). Guidelines for Regulation of Probiotics in Food. Indian Council of Medical Research /Department of Biotechnology, India.
17. FSSAI (2012). Draft Regulations on Labelling (Claims). Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, India.
18. FSSAI (2013). Guidelines to be Followed for Product Approval Procedure. Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, India.
19. ILSI. Guidelines and Criteria for Evaluation of Efficacy, Safety and Health Claim of Probiotic in Food Products in India. International Life Sciences Institute – India.