Regulation On Probiotics: Need For Global Harmonization

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What is Probiotic?

- In 2001 FAO/WHO Definition & in 2002 Guidelines on Probiotics:
  - ‘Live microorganisms which when administered in adequate amounts confer a health benefit on the host’

- In 2014, ISAPP consensus statement on the scope and appropriate use of the term probiotic:
  - ‘Live microorganisms that when administered in adequate amounts confer a health benefit on the host’

Current Scenario - Probiotics

Evolution of science on the health benefits of gut microflora in past decades

Research, demands and introduction of new probiotic products across the globe.

In 2017, probiotics ranked as the **fastest growing sector** among food(s) and/or supplement(s) products with a total **global product market value of about 42.5 billion USD**

Out of which, a **17.5 billion USD** contributed by the **APAC market alone**

Reference: Report on Probiotics, 2018
How do countries regulate Probiotics?

• There are different Regulatory approaches across the globe

• Probiotic Regulations in countries vary under these categories:
  • **Foods** – components of regular diet
  • **Supplements** – contains a “Dietary Ingredient” intended to supplement the diet (DSHEA of 1994)
  • **Drugs** - intended to diagnose, treat, cure, mitigate, or prevent any disease (Federal Food, Drug and Cosmetic Act, 1938)
  • **Medical Foods** – For medical conditions

Reference: DSHEA, 1994; FDCA, 1938
Global Regulations: Probiotics
WHO defines probiotics as a ‘Dietary Supplements’

EFSA evaluates probiotic products, under ‘Food & Food Supplements’
- cannot use term ‘probiotics’

In Canada, probiotics can be used in **Food** (food ingredients can be added to foods) and **Natural Health Products** (tablets/capsules).

Probiotic products make **function claims**, which involve support of bodily functions associated with good health or performance. Function claims:

**Cannot claim to cure disease** or reduce risk of disease such as heart disease and cancer

Must be approved if strain specific

Must be strain specific unless the product contains at least $10^9$ CFU of eligible microorganisms from the *Bifidobacterium* or *Lactobacillus* genus

Reference: Health Canada The Use of Probiotic Microorganisms in Food
In Japan, probiotics can be used in Foods, which can make claims under Foods for Specific Health Uses (FOSHU) certification when scientific evidence proves:

• effectiveness on the human body

• the absence of safety issues

• the use of nutritionally appropriate ingredients

• 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

Reference: Japan Information on FOSHU
APAC country regulations: Australia/New Zealand

Food Standards Australia & New Zealand regulate probiotics not only as complementary medicine ingredient but also as food.

Additional regulations for advertisement that prohibit:

- Endorsement from government agencies, healthcare facilities, or healthcare professionals, or incentives for non-healthcare professionals to recommend or supply therapeutic goods
- Testimonials that are inauthentic, not genuine, misleading, or atypical
- Messaging that leads to self-diagnoses or causes fear or distress through consumer ignorance or belief that there are harmful consequences if good is not used
- Encouragement of excessive use
- Promises or guarantees, claims that the product is magical, a miracle, or infallible
- Claims that the product is completely safe or has no side-effects
- Targeting of minors
- Offerings of samples

Reference: Australia New Zealand Therapeutic Goods Administration
Summary of Regulatory Trends - APAC

- Most APAC countries classify probiotics as **health functional foods** or **dietary supplements** (Japan, Korea, Taiwan, Singapore, Malaysia, Philippines)
  - Exception: Australia New Zealand (complementary medicine)
- Claims require scientific substantiation from **human intervention or observational studies**
- Strains from either the **Lactobacillus** or **Bifidobacterium** genus are generally approved for **safety and intestinal health claims** (Japan, Korea, Malaysia, Philippines)
- Claims must be **strain specific** and not overly general or leave room for misinterpretation

Reference(s): Japan Specifications and Standards for Foods, Food Additives, etc. Under the Food Sanitation Act (Abstract) 2010; Korea Health Functional Food Code; Health Food Control Act, Taiwan; Singapore A Guide to Food Labelling and Advertisements; Malaysia Food Regulations 1985; Australia New Zealand Therapeutic Goods Administration, World Health Organization Guidelines for the Evaluation of Probiotics in Food.
APAC country regulations: India

Food Safety and Standards Authority of India regulate probiotics as **Foods with added Probiotic Ingredients**

**Foods containing Probiotic Ingredients** – foods with live microorganisms beneficial to human health, which when ingested in adequate amounts (as a single strain or as a combination of cultures) confer one or more specified/or demonstrated health benefits in human beings

- Microorganism strain used in these foods shall be deemed to possess probiotic property when it is **capable of surviving passage through the digestive tract**, and has the capability to adhere and proliferate in the gut and be able to confer a physiological benefit

Reference: FSSAI, 2016
Labelling:

- Every package of Probiotic Food shall carry:
  - Descriptor: “Probiotic Food”
  - Genus and species including strain designation
  - Viable numbers at the end of the shelf-life of probiotic strain corresponding to the level at which efficacy is claimed ($\geq 10^8 \text{ CFU/g}$)
  - Recommended serving size – delivering viable dose related to health claims
  - An advisory warning “NOT FOR MEDICINAL USE”; any other warning/precaution as applicable

Reference: FSSAI, 2016
Other instructions for Probiotics products:

- Should use additives listed in Schedule VA and VF
- Should use Probiotic cultures listed in Schedule VII or those probiotic microorganisms approved by the Food Authority from time to time
- Probiotic preparations may contain added prebiotics permitted under these regulations

Reference: FSSAI, 2016
### List of Allowable Probiotic Strains

#### Malaysia

**Bifidobacterium** sp. – B.bifidum Bb-02, B.breve strain Yakult, B.breve M-16V, B.animalis subsp. lactis (BB-12), B.lactis HNO19, B.lactis BI-04, B.lactis Bi-07, B.lactis 420, B.lactis CNCM I-3446, **Lactobacillus** sp.– L.acidophilus LA-5, L.acidophilus NCFM, L.acidophilus La-14, L.acidophilus Rosell-52, L.casei Shirato, L.johnsonii La 1/Lj 1, L.johnsonii CNCM I-1225, L.paracasei subsp. paracasei (L.CASEI 01), L.paracasei subsp. paracasei (L.CASEI 431), L.paracasei Lpc-37, L.paracasei CNCM I-2116, L.plantarum Lp-115, L.rhamnosus (LGG), L.rhamnosus Lr-32, L.rhamnosus HN001, L.rhamnosus Rosell-11, L. rhamnosus CGMCC 1.3724, L.salivarius Ls-33, L.reuteri DSM 17938*

#### Taiwan

**Bacillus** coagulans, **Bifidobacterium** bifidum, B.breve, B.infantis, B.lactis, B.animalis subsp. lactis, B.longum, B.adolescentis, **Enterococcus** faecalis, E.faecium, **Lactobacillus** acidophilus, L.bifidus, L.brevis, L.bulgarcus, L.casei, L.casei subsp. rhamnosus, L.cremoris, L.delbrueckii, L.delbrueckii subsp. bulgaricus, L.fermentum, L.gasseri, L.helveticus, L.kefir, L.lactis, L.lactis subsp. lactis, L.paracasei, L.plantarum, L.reuteri, L.rhamnosus, L.salivarius, L.sporogenes, L.pentosus, L.johnsonii, L.paraplanatarum, **Sporolactobacillus** inulinus, **Streptococcus** lactis, Streptococcus salivarius subsp. thermophilus, S.thermophilus, S.faecalis, **Lactococcus** lactis subsp. cremoris, Lactococcus lactis subsp. lactis, Lactococcus lactis subsp. lactis biovar diacetylactis, *Leuconostoc* mesenteroides subsp. cremoris

#### S. Korea

**Lactobacillus** acidophilus, L. casei, L. gasseri, L. delbrueckii ssp. bulgaricus, L. helveticus, L. fermentum, L. paracasei, L. plantarum, L. reuteri, L. rhamnosus, L. salivarius, **Lactococcus** lactis, **Enterococcus** faecium, E. faecalis, **Streptococcus** thermophilus, **Bifidobacteria** bifidum, B. breve, B. longum, B. animalis spp. lactis

#### Indonesia

**Bifidobacterium** breve, B.laktis, B.logum , B.logum NCC 3001, **Lactobacillus** acidophilus, L.bulgarcus, L.casei, L.helveticus, L.paracasei, L.reuteri, L.rhamnosus NCC 4007, **Lactococcus** lactis, **Streptococcus** cremoris, S.lactis, S.thermophilus

#### India

**Bacillus** coagulan, **Bifidobacterium** bifidum, B.lactis, B.breve, B.longum, B.animalis, B.infantis, **Lactobacillus** acidophilus, L.plantarum, L.reuteri, L.rhamnosus, L.salivarius, L.casei, L.brevis, L.johnsonii, L.delbrueckii sub-sp. bulgaricus, L.fermentum, L. caucasicus, L.helveticus, L.lactis, L.amylovorus, L.gallinarum, L.delbrueckii, L.paracasei, L.gasseri, **Streptococcus** thermophilus, **Saccharomyces** cerevisiae, *S.cerevisiae.*

#### Singapore

Species that are acceptable for health products, probiotics (in non-milk based products), **Lactobacillus**, **Streptococcus** thermophilus, **Bifidobacteria**
Probiotic Strains used as Ingredient in Foods

- Malaysia: Yes
- Philippines: Yes
- Thailand: Yes
- Taiwan: Yes
- Indonesia: Yes, but only in milk-based foods
- Singapore: Yes
- India: Yes
List of Allowable Health Claims

Malaysia
Food - Probiotic cultures help in improving intestinal or gut function.*
Health Supplement - Probiotic helps to improve a beneficial intestinal microflora.

Infant formula, follow-up formula, formulated milk powder for children and cereal based food for infant & children
Bifidobacterium Lactis:-
• B. lactis helps improve a beneficial intestinal microflora
• B. lactis may help to reduce the incidence of diarrhea

Singapore
Probiotic can be taken as a supplement of a diet
• Probiotics to help maintain a healthy digestive system
• Probiotics helps in digestion
• Probiotics helps to maintain a desirable balance of beneficial bacterial in the digestive system
• Probiotics helps to suppress/fight against harmful bacteria in the system, thereby helping to maintain a healthy digestive system

Indonesia
Probiotics can be used in foods alone. Live microorganisms which when administered in adequate amounts confer a health benefit on the host
General claim - Helps maintain digestive health

Thailand
No probiotic claims. Health claims approval based on clinical study and scientific substantiation

Taiwan
Only general probiotic claims for foods and food supplements
Possible way forward for Probiotics Sector can be:

- **Live document**: Open to modification as technology and science advances

- **Probiotics quantity** should be labelled in a meaningful way *(CFU not grams)*

- **Robust compliance** to ensure safety and efficacy of the products

**Focus on common GOAL – work the difference!**
If two or three agree on a common purpose, nothing is impossible.

— Jim Rohn —

Thank you
Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Federal Food, Drug and Cosmetic Act, 1938 (USA)
Codex Guidelines for Use of Nutrition and Health Claims
DSHEA of 1994, Amendment to FD&C Act
FSS Nutraceutical Regulation, 2016
IADSA, Probiotics
IPA https://www.nutraingredients-usa.com/Article/2016/12/16/IPA-recommends-expanded-grandfathered-list-for-probiotics
Japan Information on FOSHU https://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html