



# Regulation On Probiotics: Need For Global Harmonization

**Isha Singh**

M.S. in Food & Nutrition Sciences

# | 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’



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization



International Scientific  
Association for Probiotics  
and Prebiotics

# | 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



# | International Agencies



WHO defines probiotics as a **'Dietary Supplements'**



EFSA evaluates probiotic products, under **'Food & Food Supplements'**  
- *cannot use term 'probiotics'*

# | Country Regulations - Health Canada



Health  
Canada

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<sup>9</sup> CFU** of eligible microorganisms from the ***Bifidobacterium*** or ***Lactobacillus*** genus

# | APAC Country Regulations - Japan

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





# 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



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration



**Ministry for Primary Industries**  
Manatū Ahu Matua

# | 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



# | 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



*Inspiring Trust, Assuring Safe & Nutritious Food*  
Ministry of Health and Family Welfare, Government of India



FOOD SAFETY AND STANDARDS  
AUTHORITY OF INDIA

Reference: FSSAI, 2016

# | APAC country regulations: India (contd..)

## 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 ( $\geq 10^8$  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



*Inspiring Trust, Assuring Safe & Nutritious Food*  
Ministry of Health and Family Welfare, Government of India



FOOD SAFETY AND STANDARDS  
AUTHORITY OF INDIA

Reference: FSSAI, 2016

# | APAC country regulations: India (contd..)

## 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



*Inspiring Trust, Assuring Safe & Nutritious Food*  
Ministry of Health and Family Welfare, Government of India



FOOD SAFETY AND STANDARDS  
AUTHORITY OF INDIA

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* HN019, *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* Shirota, *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\*

## Thailand

**Bacillus** *coagulans*, **Bifidobacterium** *adolescentis*, *B. animalis*, *B. bifidum*, *B. breve*, *B. infantis*, *B. lactis*, *B. longum*, *B. pseudolongum*, **Enterococcus** *durans*, *Enterococcus faecium*, **Lactobacillus** *acidophilus*, *L. crispatus*, *L. gasseri*, *L. johnsonii*, *L. paracasei*, *L. reuteri*, *L. rhamnosus*, *L. salivarius*, *L. zeae*, **Propioni-bacterium** *arabinosum*, **Staphylococcus** *sciuri*, **Saccharomyces** *cerevisiae* subsp. *boulardii*

## Indonesia

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

## Singapore

Species that are acceptable for health products, probiotics (in non-milk based products), **Lactobacillus**, **Streptococcus** *thermophilus*, **Bifidobacteria**

## 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.bulgaricus*, *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.paraplantarum*, **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*

## 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.deibrueckii* 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*.

# 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

## Thailand

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

## Taiwan

Only general probiotic claims for **foods** and **food supplements**

## 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

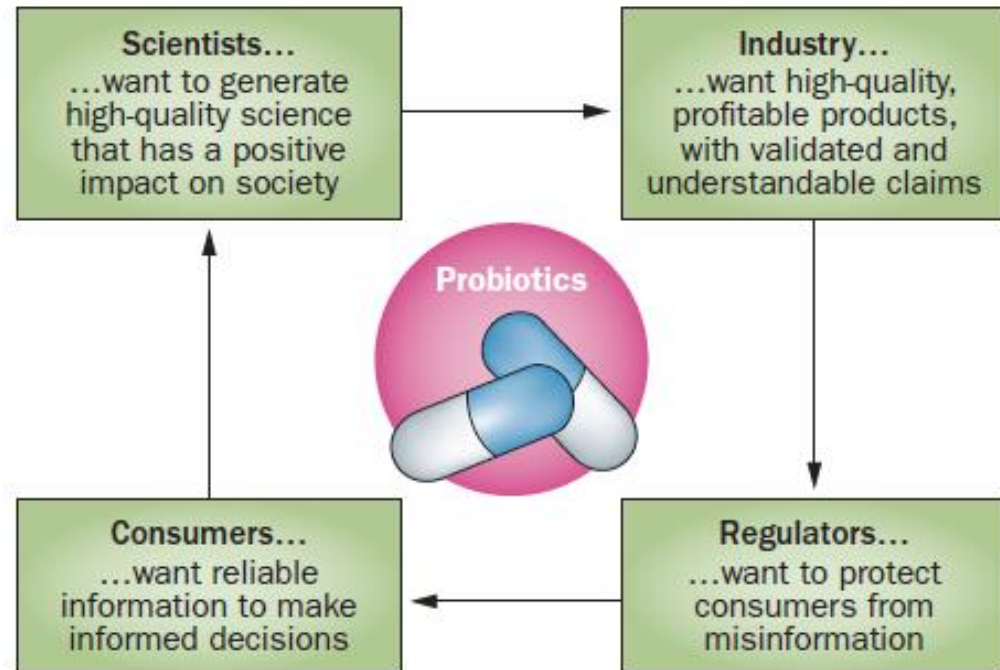


# Way Forward for Probiotic Regulations

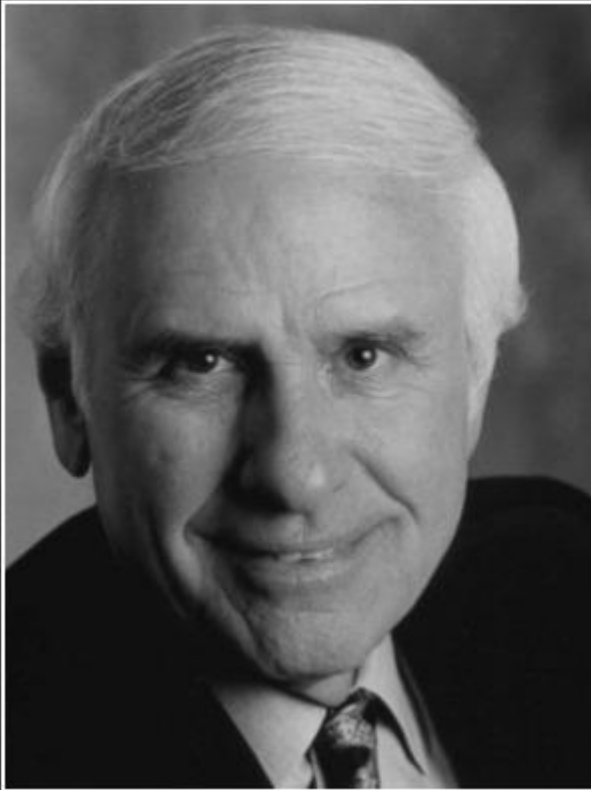


Possible way forward for Probiotics Sector can be:

- **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* —

AZ QUOTES

**Thank you**

# References

- 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)
- Australia New Zealand Therapeutic Goods Administration <https://www.tga.gov.au/>
- Codex Guidelines for Use of Nutrition and Health Claims
- DSHEA of 1994, Amendment to FD&C Act
- EFSA.EFSA Guidelines on the application for authorization of novel foods (2018)  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1381>
- FAO Probiotics in Food Health and nutritional properties and guidelines for evaluation <http://www.fao.org/3/a-a0512e.pdf>
- FSS Nutraceutical Regulation, 2016
- General Classification of Health and Food Products. Classification Tree for Products in the Food-Health Product Interface  
[http://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary\\_Health\\_Products/Overview\\_Framework\\_Policies/Food-Health\\_Product\\_Classification/ClassificationTreeFeb07pdf.pdf](http://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary_Health_Products/Overview_Framework_Policies/Food-Health_Product_Classification/ClassificationTreeFeb07pdf.pdf)
- Health Canada The Use of Probiotic Microorganisms in Food <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-use-probiotic-microorganisms-food-2009.html>
- Health Food Control Act <https://www.fda.gov.tw/EN/lawContent.aspx?cid=16&id=550>
- Hill C et al, 2014 <https://4cau4jsaler1zglkq3wnmje1-wpengine.netdna-ssl.com/wp-content/uploads/2016/01/hill-ISAPP-consensus-panel-probiotic-definition-14.pdf>
- 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>
- Japan Specifications and Standards for Foods, Food Additives, etc. Under the Food Sanitation Act (Abstract) 2010  
[https://www.jetro.go.jp/ext\\_images/en/reports/regulations/pdf/foodext2010e.pdf](https://www.jetro.go.jp/ext_images/en/reports/regulations/pdf/foodext2010e.pdf)
- Korea Health Functional Food Code [http://www.mfds.go.kr/eng/brd/m\\_15/view.do?seq=70011](http://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011)
- Malaysia FOOD REGULATIONS 1985 <http://fsq.moh.gov.my/v5/wp-content/uploads/2018/03/Food-Regulation-1985-update-Jan-2018-latest.pdf>
- NutraIngredients-Asia Report on Probiotics, 2018. [www.nutraingredients-asia.com](http://www.nutraingredients-asia.com)
- Notification of the Ministry of Public Health, Thailand Food and Drug Administration (2011). Use of Probiotic Microorganisms in Foods  
[http://food.fda.moph.go.th/law/data/announ\\_moph/V.English/No.%20339%20Use%20of%20Probiotic%20Microorganisms%20in%20Foods.pdf](http://food.fda.moph.go.th/law/data/announ_moph/V.English/No.%20339%20Use%20of%20Probiotic%20Microorganisms%20in%20Foods.pdf)
- Singapore A Guide to Food Labelling and Advertisements <https://www.ava.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisementsversionjuly2>
- Taiwan Food and Drug Administration. List of Food Raw Material Commodity. <https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160>
- WHO: World Health Organization Guidelines for the Evaluation of Comprobiotics in Food  
[http://www.who.int/foodsafety/fs\\_management/en/probiotic\\_guidelines.pdf](http://www.who.int/foodsafety/fs_management/en/probiotic_guidelines.pdf)