Understanding Today’s Probiotics Regulations in South East Asia

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Probiotic Foods in South East Asia

• More probiotic foods are being introduced into the SEA region
  - Regulatory agencies are developing regulations and guidelines

• Outline of presentation
  - Current regulatory status
  - Permitted probiotics
  - Permitted claims

• Aim of presentation: Overview of the regulatory requirements
  → Planning of regulatory strategy in the region
Association of South East Asian Nations (ASEAN)

- 10 Countries
- Population 651 million
- 3rd Largest market in the world
- A region of different markets, varying economic development and diverse cultures
## Existing standards/regulations related to probiotics

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<thead>
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<th>Country</th>
<th>Regulations/standards available?</th>
<th>References</th>
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<tbody>
<tr>
<td>Brunei Darussalam</td>
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<td>Brunei Darussalam Public Health (Food) Regulations</td>
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<td>Cambodia</td>
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<td>Indonesia</td>
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<td>BPOM Regulation Number 13 Year of 2016 pertaining Supervision Claims on Labelling and Advertising of Processed Food. (Appendix 7: Guidelines for assessing probiotic uses in processed food)</td>
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<td>Philippines FDA circular No. 16 s. 2004 Guidelines on Probiotics</td>
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<td>Notification of MOPH: Use of Probiotic Microorganisms in Foods</td>
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Indonesia

- **Regulatory Agency**: National Agency of Drug and Food Control (BPOM), Republic of Indonesia
- **Regulation** of Head of Drug and Food Administration Republic of Indonesia Number 13 Year of 2016 pertaining Supervision Claims on Labelling and Advertising of Processed Food.
  - Appendix 7: Guidelines for assessing probiotic uses in processed food
  - Applied to pre-packaged food, It does not include biotherapeutic substances, GMO and other non food products
- **Definition** “Live microorganisms which when administered in adequate amounts confer a health benefits on the host"
- Presentation form:
  - fermented products
  - Dry processed food in the form of granules or powder.
  - Liquid (excluding fermented products)
Indonesia

- Probiotics (with or without health claims) must be assessed and approved for its safety and efficacy before they can be used in food.

- General requirements
  - Probiotic strain must be able to survive and proliferate in digestive tract
  - Assessment is strain and product specific: Effect cannot be extrapolated to other strains or other food products with the same probiotic strain.
  - The dose-response (health benefits) relationship must be clearly demonstrated
  - Scientific evidence must studies results that is relevant/represent Indonesian population
  - Microorganism that have antibiotic resistant genes are not permitted
Indonesia

- Supporting evidence for safety and efficacy assessment
  - Phase 1-3 clinical studies must be conducted
  - Must also include a Double-Blinded Placebo Control trial done on Indonesian population.
  - *In vitro*/animal studies for safety and function characterization

- No positive list of approved probiotic
  - Currently approved probiotics include *Lactobacilli* spp and *Bifidobacteria* spp.
  - *Enterococcus* spp are not permitted due to possible role in the emergence of nosocomial infections
Indonesia

- Currently, no positive list of claims for probiotics.
- The claims must be consistent to the Regulation of Head of Drug and Food Administration Republic of Indonesia Number 13 Year of 2016 pertaining Supervision Claims on Labelling and Advertising of Processed Food
  - Nutrient Function Claims, Other Function Claims and Disease Risk reduction claims are permitted.
Malaysia

- **Regulatory Agency**: Food Safety and Quality Division, Ministry of Health Malaysia
- **Regulation**: Malaysia Food Regulation 1985. Regulation 26A. Probiotic culture
- **Definition**: “live microorganisms which when administered in adequate numbers confer health benefits on the host. “
Malaysia

- Only list of probiotic microorganism listed in the Schedule 12A of the Regulations are permitted
  - Mainly *Bifidobacterium* spp and *Lactobacillus* spp.

- The viable probiotic count must not be less than $10^6$ cfu/ml or cfu/g during the shelf life of the food.

- The probiotic cultures must not contain transmissible antibiotic-resistant genes.

- Companies may apply for inclusion of new probiotic into Schedule 12A
Malaysia

• Permitted Health Claims
  - *Bifidobacterium lactis* helps improve a beneficial intestinal microflora.
  - *Bifidobacterium lactis* may help to reduce the incidence of diarrhea.

(Claim only permitted in infant formula, follow-up formula, formulated milk powder for children and cereal based food for infant and children)

• Companies may apply for new probiotic claims
  - No guidance specific for probiotic microorganisms claims.
  - Follow the general guidelines for new health claims applications
  - Only Nutrient Function claims and Other function claims are allowed
Philippines

• **Regulatory Agency**: Philippines Food and Drug Administration
• **Regulations**: Philippines FDA circular No. 16 s. 2004  Guidelines on Probiotics
• **Definition** “a dietary supplement based on living microorganisms which when administered in sufficient quantity, has a beneficial effect on the host organism, improving the equilibrium of the intestinal microflora. “

• Permitted Probiotics
  - Lactobacilli
  - Bifidobacteria
  - Nonpathogenic strains of Streptococcus
  - Sacchromyces boulardi
  - Bacillus causii

• Companies may apply for inclusion of new probiotic to the permitted list
Philippines

• Permitted claims for Probiotics
  - Enhancement of intestinal ecology
  - Helping improve lactose malabsorption
  - Improving digestion
  - Aid to the enhancement of natural resistance to intestinal infections.

• Companies may seek approval for the use of health claims outside the list, during product registration. The claims must be consistent with the requirements stated in Codex Nutrition labelling and Health Claims requirements
  - Nutrient Function and other function claims
  - Disease risk reduction claims
Singapore

- **Regulatory Agency**: Agri-Food & Veterinary Authority of Singapore

- Probiotics is not defined in the Food Regulations. The use of probiotic microorganisms are include in:
  - Regulation 106: Lactobacillus milk drink or cultured milk drink
  - Regulation 123: Yoghurt

- Probiotics that are acceptable for use in these products include: *Lactobacillus bulgaricus*, *Streptococcus thermophilus*, *Lactobacillus acidophilus* and *Bacterium yoghurtii*
Permitted Health Claims for Probiotics

- 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 digestive system, thereby helping to maintain a healthy digestive system.

Conditions to use these claims

- The exact species of the probiotic present in the product must be declared on the product label.
- The onus lies with the companies to ensure that the viable count of the probiotic present in the product is able to bring about the claimed effect.
Brunei Darussalam

- **Regulatory Agency**: Brunei Darussalam Ministry of Health.
- Brunei’s Food Regulation mirrors Singapore’s’s.
- Probiotics is not defined in the Public Health (Food) Regulations. The used of probiotic microorganisms are include in
  - Regulation 139: Lactobacillus milk drink or cultured milk drink
  - Regulation 162: Yoghurt
- Health claims are currently not permitted
Thailand

- **Regulatory Agency**: Thailand Food and Drug Administration
- **Regulations**: Notification of Ministry of Public Health: Use of Probiotic Microorganisms in Foods
- **Definition**: “Viable microorganisms that are beneficial to body if intake in sufficient amount but excluding:
  1. Biotherapeutic agents;
  2. Beneficial microorganisms not used in food;
  3. Genetically Modified Microorganisms, GMM”
Thailand

- Only probiotic microorganisms listed in the Annex of the Notification are permitted.

- Viable Probiotic microorganisms in such food must be more than $10^6$ cfu/1g food at the end of its shelf life.

- Companies may seek permission to include new probiotic microorganism into the permitted list.
  - Thai FDA will assess the probiotic according to the WHO-FAO “Guidelines for the Evaluation of Probiotics in Food” (2002).

Annex

List of Probiotic Microorganisms in Foods
Attachment of Notification of the Ministry of Public Health

1. Bacillus coagulans
2. Bifidobacterium adolescentis
3. Bifidobacterium animalis
4. Bifidobacterium bifidum
5. Bifidobacterium breve
6. Bifidobacterium infantis
7. Bifidobacterium lactis
8. Bifidobacterium longum
9. Bifidobacterium pseudolongum
10. Enterococcus durans
11. Enterococcus faecium
12. Lactobacillus acidophilus
13. Lactobacillus crispatus
14. Lactobacillus gasseri
15. Lactobacillus johnsonii
16. Lactobacillus paracasei
17. Lactobacillus reuteri
18. Lactobacillus rhamnosus
19. Lactobacillus salivarius
20. Lactobacillus zoeae
21. Propionibacterium acnes
22. Staphylococcus aureus
23. Saccharomyces cerevisiae subsp. Boulardii

Thailand

• Permitted claims for probiotics
  - Currently no list of permitted health claims for probiotics.

• Companies may apply for approval to make Health Claims for the probiotic product.
  - In principle, Thai FDA accept functional claims and disease risk reductions claims that are consistent with the definition in Codex Guidelines
  - Evidence from well designed human intervention studies, systematic reviews and meta analysis, in addition to the in vitro, observational studies should be provided.
# Probiotic regulations in ASEAN

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<tr>
<th>Country</th>
<th>Definition</th>
<th>List of permitted probiotics (positive list)</th>
<th>List of permitted health claims for probiotics (positive list)</th>
<th>Guidance on approval of new probiotic strains and claims</th>
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**Definition**
- Indonesia, Malaysia and Thailand “**Probiotics are live microorganisms which when administered in adequate numbers confer health benefits on the host**” (WHO’s definition of Probiotics)
- Philippines: *a dietary supplement based on living microorganisms which when administered in sufficient quantity, has a beneficial effect on the host organism, improving the equilibrium of the intestinal microflora*

**Permitted Probiotics:** Mainly *Bifidobacterium* and *lactobacillus* spp.

**Assessment of Probiotic**
### General requirements for Health Claims for Food Products

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<th>Other function claims</th>
<th>Disease Risk Reduction claims</th>
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## List of permitted claims for Probiotics

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| Permitted claims | • *Bifidobacterium lactis* helps improve a beneficial intestinal microflora.  
• *Bifidobacterium lactis* may help to reduce the incidence of diarrhea. | • Enhancement of intestinal ecology  
• Helping improve lactose malabsorption  
• Improving digestion  
• Aid to the enhancement of natural resistance to intestinal infections. | • 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 digestive system, thereby helping to maintain a healthy digestive system. |

Approved health claims: Gut health
Check list for marketing probiotics in ASEAN as food

1. Conduct regulatory compliance check
   - Is the probiotic microorganisms and claims on the permitted list?

2. Safety and efficacy supported by robust scientific evidence?
   - Aligned with international standards

3. Are the intended health claims within the scope of the permitted claims for food products?
Diverse regulations - Is there room for convergence?

- Food regulations in ASEAN -> aligned with International practice.
- Development of ASEAN standards for Probiotics?
  - ASEAN Prepared Food Product Working Group
  - Closer collaboration between industry and ASEAN Food Authorities.
Thank you

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