

Regulatory Framework for Health & Functional Claims in Singapore

Prepared for the Regional Think Tank Committee

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Regulatory Authority: HPB

- Health Promotion Board (HPB) is the regulatory body.
- Ensures responsible use of health claims.
- Evaluates new claims based on scientific evidence.
- Coordinates expert panel reviews.

INDUSTRY GUIDE FOR APPLICATION OF NEW HEALTH CLAIMS ON FOOD PRODUCTS (SINGAPORE)

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Types of Claims

- Nutrient Function Claims: Describe physiological roles of nutrients (e.g., 'Calcium helps build strong bones').
- Other Function Claims: Describe effects of food constituents on body functions (e.g., 'Probiotics help digestion').
- Disease Risk Reduction Claims: Link food consumption to reduced disease risk (e.g., 'Fibre may reduce cancer risk').

Definition and Examples of Health Claims

| | Nutrient Function Claims | Other Function Claims | Reduction of Disease Risk Claims |
|------------|--|--|---|
| Definition | Nutrition claims that describe the <u>physiological role</u> of the nutrient in growth, development, and normal functions of the body. | Claims about the specific beneficial effects of consuming foods or their food constituents, as part of the total diet, on the body's normal functions or biological activities that <u>positively contribute to health</u> , improve the function, or modify or preserve health. | Claims relating to the consumption of a food or food constituent, in the context of the total diet, which is associated with the <u>reduced risk of developing a disease or health-related condition</u> . |
| Examples | <ul style="list-style-type: none">✓ Protein helps in tissue building and growth. ✓ Vitamin B2 contributes to the maintenance of normal vision | <ul style="list-style-type: none">✓ Inulin helps support the growth of beneficial bacteria/good intestinal flora in the gut.✓ Prebiotics promote the growth of good Bifidus bacteria to help maintain a healthy digestive system. | <ul style="list-style-type: none">✓ A healthy diet rich in whole grains, fruits and vegetables that contain dietary fibre may reduce the risk of heart disease. (Name of food) is low in/free of fat and high in dietary fibre. |

General Principles

- Claims must comply with Singapore Food Regulations.
- Must not be misleading, false, or prohibited.
- Nutrition Information Panel (NIP) required for substantiation.
- Claims must be consistent across all marketing materials.

International Reference & Harmonization

- Codex Alimentarius (FAO/WHO) - CAC/GL 23-1997. Singapore adopts Codex principles to ensure claims are truthful, scientifically substantiated, and not misleading.
- ASEAN Harmonization - Singapore participates in ASEAN Food Safety and Standards harmonization, ensuring regional consistency.

Prohibited Claims

- Claims that food prevents, alleviates, or cures diseases.
- Claims implying medical advice or professional endorsement.
- Unverifiable scientific data or exaggerated claims.

Application Process Overview

- Complete application form.
- Attach supporting studies and documents.
- Submit to HPB via email.
- HPB reviews and forwards to expert panel.
- Decision within 6-9 months.

APPLICATION FORM FOR USE OF HEALTH CLAIMS FOR FOOD INTENDED FOR SALE IN SINGAPORE

Part A: Applicant Information

| | |
|-----------------|--|
| Company Details | |
| Company Name | |
| Company Address | |

| | |
|---|--|
| Contact Person Details | |
| <i>*Note: HPB should be informed if there are any changes in the contact person's details</i> | |
| Full Name | |
| Job Title / Position | |
| Company Name (if different from above) | |
| Company Address (if different from above) | |
| E-mail | |
| Contact Number | |

Part B: Summary of Proposed Claim

Type of claim (please tick):

| | |
|--------------------------|---|
| <input type="checkbox"/> | Nutrient function claim ¹ |
| <input type="checkbox"/> | Other function claim ² |
| <input type="checkbox"/> | Disease risk reduction claim ³ |

Proposed wording of the claim:

| |
|--|
| |
|--|

Application Form: Part A

- Company Details: Name, address.
- Contact Person: Name, title, email, phone.
- Notify HPB of any changes in contact details.

Application Form: Part B

- Type of Claim: Tick appropriate category.
- Proposed Claim Wording.
- Ingredient Details: Name, characteristics, target group.
- Health-Benefit Relationship.
- Usage Conditions.
- Summary of Scientific Evidence.

Proposed Claim Wording

4.1 HOW TO WORD PROPOSED CLAIM

✓ Do's

Example

Use clear and factual language

- ✓ "Vitamin A helps to maintain normal skin and mucous membranes."
- ✓ "Vitamin B2 contributes to the maintenance of normal vision."
- ✓ "Folic acid is essential/important for the growth and division of cells."

Clearly specify the food constituent that the claim is based on (should correspond with supporting studies)

- ✓ "Inulin helps to support the growth of beneficial bacteria/good intestinal flora in the gut."
- × "Fibre helps to support the growth of beneficial bacteria/good intestinal flora in the gut."

✗ Don'ts

Example

Don't use medical or absolute terms

Avoid absolute terms like "cures", "prevents", or "ensures", as well as terms that suggest endorsement by healthcare professionals, such as "doctor-approved formula" or "recommended by dietitians".

Don't exaggerate the effects of food constituents that are not supported by the evidence provided

If your supporting studies show that "vitamin C helps support normal immune function", do not extrapolate to claim that "vitamin C prevents the common cold".

Don't use vague terms

Avoid generic phrases such as "good for you" or "supports health".

Application Form: Annex

- Summary of Supporting Studies.
- Minimum two independent human intervention studies.
- Include study design, population, outcomes, results, limitations.

Supporting Studies

Simplified 3-step evidence-based framework to evaluate studies:

- **Step 1: Assess the study design and quality**
 - Identify type of study design
 - How reliable are these studies in terms of their design and execution?

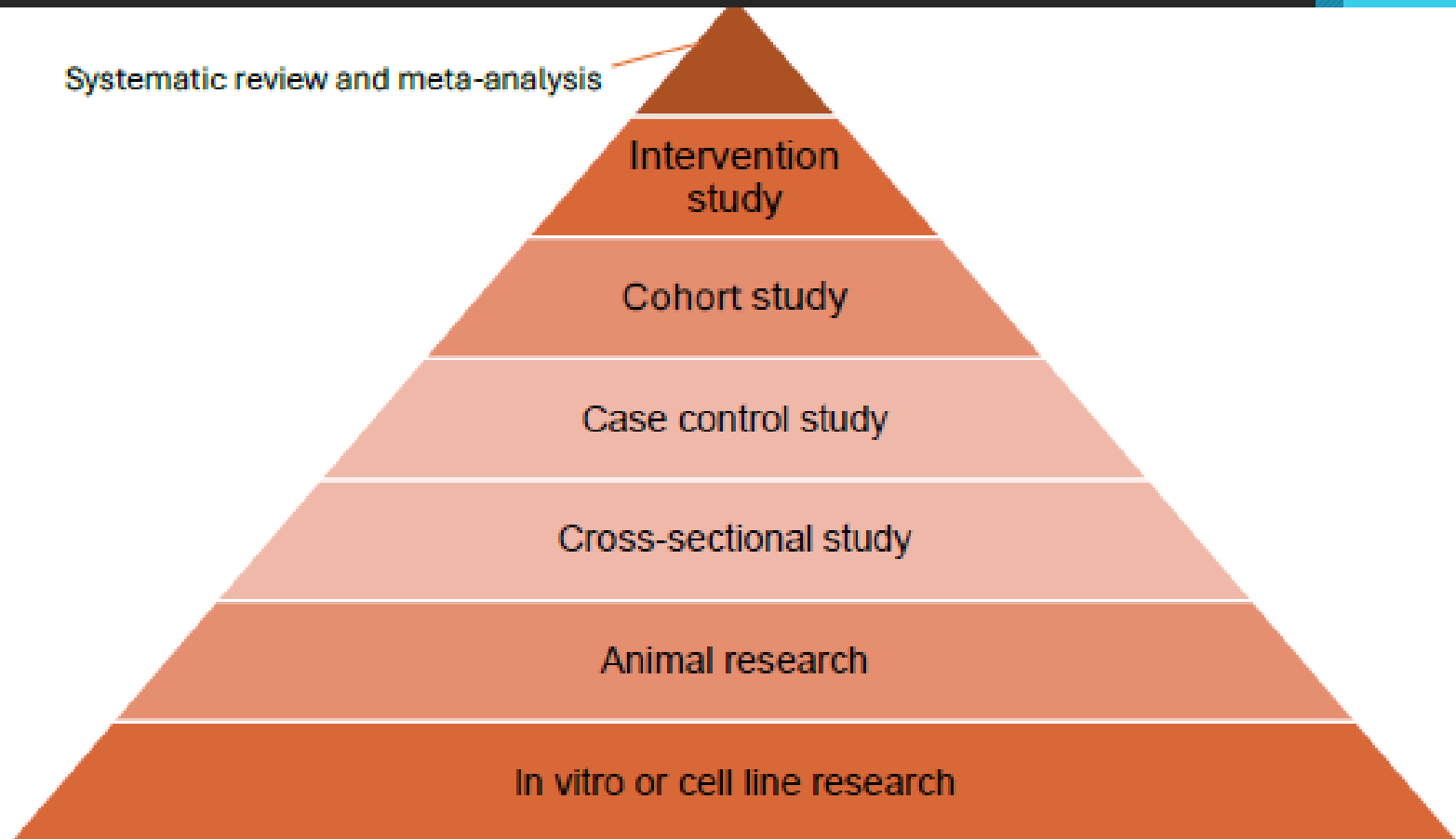
- **Step 2: Check for a cause-and-effect relationship**
 - Is there a clear and consistent link towards the claimed health effect?

- **Step 3: Rate the overall strength of evidence**
 - Based on steps 1 and 2, determine if the strength of evidence meets the required level to support the claim

Evidence Requirements

- Prioritize human intervention studies.
- Include systematic reviews/meta-analyses.
- Ensure consistency, biological plausibility, and relevance.
- Avoid outdated or low-quality studies.

Evidence Hierarchy Pyramid



Common Pitfalls

- Relying on animal or in vitro studies.
- Using informal or outdated sources.
- Exaggerating claims beyond evidence.
- Omitting study limitations.

Safety & Hazard Assessment

- Report adverse events, allergenicity, toxicology.
- State safe intake levels.
- Highlight any known interactions or risks.

National & International Regulatory Status

- Declare if claim is approved, rejected, or under review by other authorities.
- Attach evidence of approvals.
- Include effective dates.

Thank you

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