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 **Note: HPB should be informed if there are any changes in the contact person's details*	
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):

☐	Nutrient function claim[1]
☐	Other function claim[2]
☐	Disease risk reduction claim[3]

Proposed wording of the claim:

[1] **Nutrient function claims** describe the health effect of a nutrient in growth, development and normal functions of the body, e.g. “Calcium helps to build strong bones and teeth”.
[2] **Other function claims** describe the health effects of other food constituents, e.g. “Probiotics help in digestion”.
[3] **Reduction of disease risk claims** describe the reduced risk of developing a disease or health-related condition when consuming a particular food as part of an overall healthy diet, e.g. “A healthy diet rich in fibre-containing foods such as wholegrains, fruits and vegetables may reduce the risk of some types of cancers”.

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Assessment Area(s)	Details required	Applicant's response
Name of ingredient, nutrient, or food constituent	State the type of nutrient, other substances, or a combination of nutrients/other substances for which the claim is being made.	*(e.g. Calcium)*
Characteristics of ingredient, nutrient or food constituent	Describe the: - chemical form - functional role - bioavailability (e.g. absorption rate, form used).	*(e.g. Calcium carbonate; Supports bone mineralisation; Absorbed at ~25–35% depending on vitamin D status.)*
Targeted consumer group	Describe age, gender, if recommended for specific medical condition(s)[4], etc.	*(e.g. General population and/or elderly at risk of osteoporosis.)*

[4] If the proposed food-health relationship covers a wider target population group than the groups studied (for example, a wider age range than covered by the included studies), the application must include justification of the validity of the extrapolation.

Health-benefit relationship	Explain how the active component(s) support the claimed benefit.	*(e.g. Calcium helps build strong bones and teeth)*
Usage conditions	Indicate the: - Amount of food/food constituent and how it should be consumed to obtain the claimed benefit (e.g. recommended serving and frequency of intake) - State whether this amount could be reasonably consumed as part of a balanced diet	*(e.g. 800–1000 mg/day; To be obtained from 2 servings of fortified beverage providing 400-500mg calcium per serve; Reasonable as part of a balanced diet.)*
Summary of scientific evidence	Provide an overall summary of the scientific evidence in this section. Detailed descriptions of individual studies should be included in Section C. Includes but not limited to: - Number of studies - Type of trial - Target population - Quality of evidence - Consistency and strength of effect	*(e.g. 6 human intervention and observational studies were identified, including 4 randomised controlled trials and 2 cross-sectional studies; Studies included healthy adults and postmenopausal women aged 18–75 years; The quality of evidence is high, studies consistently demonstrate a positive association between adequate calcium intake and improved bone mineral density.)*

Safety and hazard assessment	Note any adverse events, medication interactions, allergenicity, and toxicology findings. If none known, state so.	*(e.g. Generally safe within recommended levels. Excessive intake (>2500 mg/day above the tolerable upper intake level for adults) may cause kidney stones. No allergenicity found.)*
Overall conclusion	Substantiate the validity and robustness of the health claim application	*(e.g. Scientific evidence consistently supports calcium's role in maintaining bone health; It is safe and effective at recommended intake levels.)*

National and International Regulatory Status

State whether this claim has been assessed and approved for food use by any national regulatory body, and provide evidence of approval by attaching it to this application. Fill out relevant boxes under “Effective Date” to reflect the dates when the processes took place.

Regulatory Body	Effective Date				Evidence appended?
	Accepted	Rejected	Under consideration	Withdrawn	
					☐
					☐

Declaration of proprietary data

	Yes	No
The application contains proprietary data.	☐	☐
If yes, has the verifiable justification/declaration been provided?	☐	☐

DECLARATION AND SIGNATURE

I hereby confirm that, to the best of my knowledge, all relevant data to support the use of the proposed health claim have been submitted in the application.

I will also keep HPB informed if there are changes to the point-of-contact for this application.

Signature:
Name:
Designation:
Date:

Annex: Summary of Supporting Studies

Applicants should submit evidence from a minimum of two independent human intervention studies, demonstrating a consistent, statistically significant, and biologically plausible effect supporting the claimed relationship. Where available, we encourage the inclusion of systematic reviews and/or meta-analyses to support the totality of evidence. Applicants should fill in one table for each study and duplicate the table for each additional study.

No.	Factor	Justification
1	**Study identification** • Title and authors • Declaration of interest *Please include the full citation and attach the original research article*	
2	**Study type** • Systematic reviews and meta-analyses • Interventional human studies • Observational human studies (e.g. cohort, case-control studies) • Non-human studies (e.g. in vitro or animal studies) • Other studies (e.g. case report/series)	
3	**Study objective(s)**	
4	**Study population** • Health status • Age range • Gender • Ethnicity • Country	
5	**Study design** • Design information • Sample size (no. recruited, randomised, and included in final analysis) • Confounders measured and the method used to control confounding • Method used to measure health effect	
6	**Exposure and duration**	

	• Food matrix • Method and frequency of consumption • Amount consumed per day • Duration of intervention or study • Follow-up period • Background diet & assessment tools to measure food consumed	
7	**Study results & key findings** • Comparison of pre- and post-test values with statistical significance • Levels of intake to deliver function claimed • Adverse effects	
8	**Study quality** • Study limitations *E.g. method of randomisation, use of blinding, sample size, presence of control group, length of follow-up period, confounding factors* • Risk of bias *E.g. presence of selective outcome reporting (reporting only positive results), conflicts of interest* • Consistency of results *E.g. reproducibility of results across studies, presence of a dose-response relationship* • Directness of evidence *E.g. relevance of study population to target group, if intervention and outcomes measured are directly related to health claims being assessed, relevance of study setting (country, cultural context)*	
9	**Summary of study** • Consider findings that are both (i) in favour of and (ii) do not support the substantiation of the proposed claim[5]	

[5] This may include, but is not limited to, study limitations, inconsistency in data, or any adverse findings from the study that do not substantiate the proposed claim.

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