

APPLICATION FOR NUTRITION CLAIMS

Guide for application:

- i. All sections in this form must be completed.
- ii. Where relevant, provide summaries of information required so as to assist the Committee members in understanding the application.
- iii. Submit copies of all references cited in the text as appendices.
- iv. If the nutrient concerned is already in the NRV list, information for item numbers 9, 10, 11, 15, 16 and 17 need not be provided.
- v. All information requested in this format must be submitted in Bahasa Malaysia or English.
- vi. Twenty copies of this format must be submitted together with the necessary supporting document.

Application should be addressed to:

Director
Food Quality Control Division
Department of Public Health
Ministry of Health Malaysia
3rd. Floor, Block B
Health Offices Complex
Jalan Cenderasari
50590 Kuala Lumpur

1. Name of applicant (in full and in block letters) *:
2. Business address:
3. Mailing address:
4. E-mail address:
5. Telephone number: Fax Number:
6. Type of business:

* State:

- a. Whether applicant is manufacturer or its agent.
 - b. Whether this application is on behalf of a single firm or organization.
 - c. Whether this application is on behalf of a food processing industry or other firms or organizations.
 - d. If on behalf of the food processing or other industries or organizations, names and addresses of these.
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7. State the nutrient concerned and the proposed nutrition claim (nutrient content claim, comparative claim or nutrient function claim). If the said nutrient is to be added to food and it is not listed in Table (I) of Twelfth Schedule as a permitted nutrient supplement, a submission for its inclusion to the list has to be made to Ministry of Health Malaysia using the format entitled *Application for Addition to Nutrient Supplement List [Table (I) of Twelfth Schedule]*.
 8. Name the food(s) to which this nutrient is to be added.

9. State the limits of the probable daily intake of the nutrient in the diet.
10. State the chemical structure and formula of the nutrient(s) and describe it in precise chemical terms and state all physical properties.
11. Provide detailed information on the physiological role(s) of this nutrient.
12. If proposing a “nutrient content claim” or “comparative claim”, state the proposed criteria for making these claims and provide scientific justification.
13. If proposing a new “nutrient function claim” and the level of that nutrient to be considered as a “source” of that nutrient per 100 g or per 100 ml of the food, if it is not already in Table (II) in the Fifth A Schedule. Provide scientific justification for the proposed level.
14. If proposing a new “nutrient function claim”, provide sound scientific evidences for the claim. Clear benefits or supportive evidence for the claims must be derived from at least 5 clinical trials. Epidemiological and experimental studies and reviewed papers may be included as supportive evidences. Studies should include those conducted by other organizations or institutions. Result of all these studies should be published in refereed journals.
15. Show information regarding the stability and bioavailability of the nutrient(s) in the food(s) in which it is to be added.
16. State the analytical method to determine the amount of the nutrient(s) in the raw, processed and/or finished food
17. Submit all data on safety evaluation derived from both chronic and acute studies conducted on the nutrient(s).
18. Give examples of approval by other countries or recognized international agencies of this application.
19. Provide other relevant information.

Declaration:

I _____ (full name),
identity card / passport number _____,
hereby declare:

- a. that this application is made by myself / on behalf of

- b. that all particulars given in this form including all appendices attached are true and correct.

Signature:

Name (capital letter):

Designation:

Official stamp:

Date: