SULIT / CONFIDENTIAL BKKM/SFG/03/2018

## **APPLICATION FOR NUTRITION CLAIMS**

## **Guide for application:**

- i. All sections in this form must be completed.
- ii. Executive summaries of the application should be provided to assist the Committee members in understanding the application.
- iii. Where relevant, provide summaries of information required that related to the application.
- iv. Submit copies of all references cited in the text as appendices.
- v. 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.
- vi. All information requested in this format must be submitted in Bahasa Malaysia or English.
- vii. Twenty copies of this format must be submitted together with the necessary supporting document.

## Application should be addressed to:

Senior Director for Food Safety and Quality Ministry of Health Malaysia

Level 4, Menara Prisma

No 26 Jalan Persiaran Perdana, Presint 3

62675 PUTRAJAYA

(u.p : Special Purpose Food Section, Standard and Codex Branch)

- 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.
- 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 added nutrient, 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 Permitted Added Nutrient 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. In addition, details summaries of the related studies are required in table form.
- 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. All available literature including both positive and negative findings on the proposed claim must be provided. If the list is too extensive, provide hard copies only for more recent studies. Other studies can be provided in a bibliographic listing. Data from human intervention trials are preferred. 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. In addition, details summaries of the related studies are required in table form.
- 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). In addition, details summaries of the related studies are required in table form.
- 18. Give examples of approval by other countries or recognized international agencies of this application.
- 19. Provide other relevant information.

Declaration:	
I	pálodponamennbiedentingerelayddeclare:
a. that this application is made by myself / on behalf of	
b. that all particulars given in this form including all appendices	s attached are true and correct.
Signature:	
Name (capital letter):	
Designation:	
Official stamp:	
Date:	