

**APPLICATION FOR PROBIOTIC CULTURES IN FOODS
(REGULATION 26A)**

GUIDE FOR APPLICATION:

- i. All section in this form must be completed.
- ii. Where relevant, provide summary of information.
- iii. Submit copies of all references cited in the text as appendices.
- iv. All information must be submitted in Bahasa Malaysia or English.
- v. Twenty copies of this format must be submitted together with the necessary supporting document.
- vi. Applicants must submit studies carried out on the specific strain of the proposed culture and the studies should be published in current referred journals (less than ten years).
- vii. Application should be addressed to:

Pengarah/Director
Bahagian Keselamatan dan Kualiti Makanan/*Food Safety and Quality Division*
Kementerian Kesihatan Malaysia/*Ministry of Health*
Aras 4, Menara Prisma/*Level 4, Menara Prisma*
No. 26, Jalan Persiaran Perdana, Presint 3
62675 PUTRAJAYA
(Attn: Mrs. Sakhiah Binti Md Yusof)
(Tel: +603 – 8885 0797 ext 4095, Fax: +603 – 8885 0790)
Website: <http://fsq.moh.gov.my/>

PARTICULARS OF APPLICANT

1. Name of applicant :

(in full and in block letters)

2. Business address:

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3. Mailing address:

(if differ)

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4. E-mail address:

5. Telephone number: (O) Fax Number:

(M)

6. Type of business*:

* State:

a. Whether applicant is a 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, state names and addresses.

7. Name the probiotic culture to be added to the food (genus, species and strain).

8. Name the food(s) to which this probiotic culture is to be added (please specify the form of the culture to be added e.g. powder/ liquid/ suspension).

9. Provide the information of the source of the probiotic culture.

10. The probiotic should meet the criteria below (please provide scientific evidence):

i. Evaluated for its safety to human and beneficial to health as demonstrated in human studies

ii. Resistant to gastric acidity

iii. Resistant to bile acid

iv. Adhered to mucus and/or human epithelial cells and cell line

v. Able to hydrolyse bile salts

vi. Clear strain identification which conformation of the methodology

vii. Has long history of consumption

viii. Provide the information of the safety evaluation of probiotic culture in human as described below:

a. Transmissible antibiotic resistance gene

b. Assessment of metabolic activity, such as D-lactate production or bile salt reduction

c. Side effects found in clinical studies conducted in human subjects

d. Submit all data on safety evaluation derived from both chronic and acute studies conducted on the probiotic culture.

e. Epidemiological surveillance for undesired incidents among consumers after the product has been launched to market.

11. Name the media used for the culture and maintenance of the probiotic culture.

12. Provide detailed information on the functional role(s) of this probiotic culture.

13. State the minimum viable number of the probiotic culture at the end of the shelf life.

14. Show information regarding the stability and bioavailability of the probiotic culture in the food(s) in which it is to be added.

15. State the analytical method (validated method) to identify the purity of the probiotic culture in the processed and/or finished food.

16. Provide information on regulation / approval by other countries or recognized international agencies of this application.

17. Intention to combine with other strain to be added in food

Yes (If Yes, please proceed to question 18 to 21)

No (If No, Please proceed to question 21)

18. Name the culture to be combined (genus, species, strain)

19. Is the strain in Question 18 above listed under the Twelfth A Schedule, Food Regulations 1985?

20. Provide the safety evidence of the strains combination

21. Provide other relevant information (if any)

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 :