

**2. Application form for food safety assessment which not fall in scope of novel food under the Notification of the Ministry of Public Health (No.376) B.E.2559, Re: Novel Food**

2.2 Application form for use of probiotics in food other than prescribed in the Annex of the Notification of the Ministry of Public Health B.E.2554, Re: Use of Probiotics in food and the Notification of the Ministry of Public Health (No.346) B.E.2555, Re: Use of Probiotics in food (No.2) including checklist supporting for safety assessment and properties of probiotics as specified in Guidelines for the Evaluation of Probiotics in Food, Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food, 2002

Company/Partnership/Shop.....

Address.....

.....

Tel.....Fax.....

E-mail.....

Date.....Month.....B.E.....

Re: Request to assess use of probiotics in food other than prescribed in the Annex of the Notification of the Ministry of Public Health B.E.2554, Re: Use of Probiotics in food and the Notification of the Ministry of Public Health (No.346) B.E.2555, Re: Use of Probiotics in food (No.2)

To: Secretary General of Food and Drug Administration

Attachments: List of supporting evidenced documents in a number of.....items together with 1 set of CD containing such data

Since I am..... on behalf of (.Company/Partnership/Shop)..... intend to request for safety assessment and properties of probiotics for supporting of consideration of permission as follows:

1. genus, species, strain of microorganisms requesting for safety assessment and properties as probiotics

.....

In this regard, I have provided evidence supporting for safety assessment and properties as probiotics that have the details as attachments

Sign ..... applicant

(.....)

Preliminary Checklist supplementing for consideration of assessment of probiotics in food other than prescribed in the Annex of the Notification of the Ministry of Public Health B.E.2554, Re: Use of Probiotics in food and the Notification of the Ministry of Public Health (No.346) B.E.2555, Re: Use of Probiotics in food (No.2)

**Part 1** General information

|  |  |
|--|--|
| <p><b>Details of an applicant</b></p> <p>Name –last name of the applicant/authorized person.....tel.....</p> <p>E-mail .....name of producing/import premise.....</p> <p>Address..... Building .....</p> <p>Moo..... Trok/soi.....Street.....</p> <p>Tambol/subdistrict..... Ampoe/district.....</p> <p>Province..... Tel.....Fax.....</p> | <p><u>Please bring this document together with an application accepting form attached with correction of incompleteness for the next time (if any)</u></p> |
| <p><b>Details of prebiotics</b></p> <p>1. genus, species, strain of microorganisms requesting for safety assessment and properties as probiotics</p> <p>.....</p>  |  |

Part 2 Preliminary Checklist supplementing for consideration of assessment of probiotics in food other than prescribed in the Annex of the Notification of the Ministry of Public Health B.E.2554, Re: Use of Probiotics in food and the Notification of the Ministry of Public Health (No.346) B.E.2555, Re: Use of Probiotics in food (No.2)

| No. | Item of documents   | Applicant check           |      | Official check            |      | Record of checking |
|-----|---|---------------------------|------|---------------------------|------|--------------------|
|     |   | Yes/<br>number<br>(issue) | none | Yes/<br>number<br>(issue) | none |                    |
| 1.  | Results of identity of genus/species/strain are tested with valid appropriate and updated methodology for both phenotype and genotype, and nomenclature of such microorganism must be conformed to the current and scientifically recognized names. |                           |      |                           |      |                    |
| 2.  | Testing results of properties as probiotics as follows:   |                           |      |                           |      |                    |
| 2.1 | Resistance to gastric acidity   |                           |      |                           |      |                    |
| 2.2 | Bile salt resistance  |                           |      |                           |      |                    |
| 2.3 | Adherence to mucus and/or human epithelial cells and cell line  |                           |      |                           |      |                    |
| 2.4 | Bile salt hydrolase activity  |                           |      |                           |      |                    |
| 2.5 | Other properties (if any) as the case maybe   |                           |      |                           |      |                    |
| 3.  | Result of safety assessment of probiotic for human by test in vitro and in vivo and human studies for safety assessments and body's reaction to probiotics as follows:  |                           |      |                           |      |                    |
| 3.1 | Antimicrobial resistances   |                           |      |                           |      |                    |
| 3.2 | Assessment of metabolic activities such as D-lactate producing or bile salt deconjugation   |                           |      |                           |      |                    |
| 3.3 | Assessment of side-effects during human studies   |                           |      |                           |      |                    |
| 3.4 | Epidemiological surveillance of adverse incidents in consumers for post-marketing   |                           |      |                           |      |                    |
| 3.5 | Toxin production, if the strain being evaluation belongs to a species that is a toxin producer  |                           |      |                           |      |                    |
| 3.6 | Determination of hemolytic activity, if the strain being evaluation belongs to a species with known hemolytic potential.  |                           |      |                           |      |                    |
| 4.  | Result of safety assessment of the probiotics from international risk assessment agency or other recognized countries (if any)  |                           |      |                           |      |                    |

**Note:** If Health claims is made, Public manual item 9.2, Re: Application for health claim assessment shall be followed.

**Part 3 Checking result of completeness of supporting documents**

| For applicant of safety assessment only   | For official only  |
|---|--|
| <p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u><br/> <u>Part 1 Submission the application and evidenced documents</u></p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of supporting documents.</p> <p><input type="checkbox"/> Request to return supporting documents for assessment of specification and safety in case of incomplete documents</p> <p><input type="checkbox"/> Agree with defects and will further finish for correction within 15 working days from the day after the date of receiving the application (from date.....to date.....)</p> <p><u>If it is overdue, cancellation and return of the application and evidenced documents can be undertaken.</u></p> <p>Sign .....an applicant/authorized person<br/>           (.....)</p> <p>Date.....time.....</p> | <p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u><br/> <u>Part 1 Checking for the completeness of evidenced documents</u></p> <p><input type="checkbox"/> Complete documents to issue a receipt of payment for technical evaluation as in List 2 item 2.2(1) / List 2 item 2.2(5) of the Notification of the Ministry of Public Health, Re: Expenditure to be collected from an applicant of Process for consideration of food product permission B.E.2560</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the documents.</p> <p><input type="checkbox"/> Incomplete documents and consider to accept the application with a condition due to incomplete or incorrect documents as specify in checklist (defects found as above specified). The applicant shall correct or submit additional documents for the first round within 15 working days from the day after the date of receiving the application (from date.....to date .....) if it is overdue, the application will be terminated and further returned (the applicant shall be informed by signing and receive a copy)</p> <p>notify to proceed.....<br/>           .....<br/>           .....<br/>           Sign by an official.....<br/>           (.....)</p> <p>Date.....Time.....</p> |
| <p><u>Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents)</u></p> <p><input type="checkbox"/> I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation</p> <p>Sign .....applicant/authorized person<br/>           (.....)</p> <p>Date .....time.....</p>   | <p><u>Part 2 Acceptance of the application for technical document evaluation</u></p> <p><input type="checkbox"/> Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered.</p> <p>Sign by checking officer.....<br/>           (.....)</p> <p>Date .....time.....</p>   |

**Part 3 Checking result of completeness of supporting documents (continued)**

| For applicant of safety assessment only   | For official only   |
|---|---|
| <p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u><br/> <u>Part 1 Submission the application and evidenced documents</u></p> <p><input type="checkbox"/> I have submitted correcting or additional documents in the number of.....items as specified in the incompleteness recorded form.</p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of evidenced documents</p> <p><input type="checkbox"/> Request to return supporting documents for assessment of specification and safety in case of incomplete documents</p> <p><input type="checkbox"/> Agree with incompleteness and will further finish for correction within 15 working days from the day after the date of checking the completeness of evidenced documents of the application. (from date.....to date.....)</p> <p><u>If it is overdue, agree for cancellation and return of the application and evidenced documents.</u></p> <p>Sign ..... applicant/authorized person<br/>           (.....)</p> <p>Date .....time.....</p> | <p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u><br/> <u>Part 1 Submission the application and evidenced documents</u></p> <p><input type="checkbox"/> Correct or submit complete documents to issue a receipt of payment for technical evaluation as in List 2 item 2.2(1) / List 2 item 2.2(5) of the Notification of the Ministry of Public Health, Re: Expenditure to be collected from an applicant of Process for consideration of food product permission B.E.2560</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the documents.</p> <p><input type="checkbox"/> Incomplete documents and consider to accept the application with a condition due to incomplete or incorrect documents as specify in checklist (defects found as above specified). The applicant shall correct or submit additional documents for the second round within 15 working days from the day after the date of receiving the application (from date.....to date .....) if it is overdue, the application will be terminated and further returned (the applicant shall be informed by signing and receive a copy)</p> <p><input type="checkbox"/> Return the application together with supporting documents for assessment of safety since the correction is not undertaken or additional documents are not submitted on due date.</p> <p>You have right to renew the submission by providing with accurate and complete documents or may appeal for document return at this time by submit a letter of appeal to the Secretary General of the Food and Drug Administration within 15 working days from the day of receiving the returned application.</p> <p align="right">Signed by checking official.....<br/>           (.....)</p> <p>Date .....time.....</p> |
| <p><u>Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents)</u></p> <p><input type="checkbox"/> I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation</p> <p>Sign .....applicant/authorized person<br/>           (.....)</p> <p>Date .....time.....</p>   | <p><u>Part 2 Acceptance of the application for technical document evaluation</u></p> <p><input type="checkbox"/> Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered.</p> <p align="right">Sign by checking officer.....<br/>           (.....)</p> <p>Date .....time.....</p>  |

**Part 3 Checking result of completeness of supporting documents (Continued)**

| For applicant of safety assessment only   | For official only  |
|---|--|
| <p><u>3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)</u><br/> <b><u>Part 1 Submission the application and evidenced documents</u></b></p> <p><input type="checkbox"/> I have submitted corrective or additional documents in the number of.....items as specified in the incompleteness recorded form.</p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of evidenced documents.</p> <p><input type="checkbox"/> Request to return supporting documents for assessment of specification and safety.</p> <p>Sign ..... applicant/authorized person<br/>           (.....)</p> <p>Date .....time.....</p> | <p><u>3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)</u><br/> <b><u>Part 1 Checking for the completeness of evidenced documents</u></b></p> <p><input type="checkbox"/> Correct or submit complete documents to issue a receipt of payment for technical evaluation as in List 2 item 2.2(1) / List 2 item 2.2(5) of the Notification of the Ministry of Public Health, Re: Expenditure to be collected from an applicant of Process for consideration of food product permission B.E.2560</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the documents.</p> <p><input type="checkbox"/> Return the application together with supporting documents for assessment of safety since the correction is not undertaken or additional documents are not submitted on due date.</p> <p>You have right to renew the submission by providing with accurate and complete documents or may appeal for document return at this time by submit a letter of appeal to the Secretary General of the Food and Drug Administration within 15 working days from the day of receiving the returned application.</p> <p>Signed by checking official.....<br/>           (.....)</p> <p>Date .....time.....</p> |
| <p><b><u>Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of complete documents)</u></b></p> <p><input type="checkbox"/> I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation</p> <p>Sign .....applicant/authorized person<br/>           (.....)</p> <p>Date .....time.....</p>   | <p><b><u>Part 2 Acceptance of the application for technical document evaluation</u></b></p> <p><input type="checkbox"/> Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered.</p> <p>Sign by checking officer.....<br/>           (.....)</p> <p>Date .....time.....</p>  |