

**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: 1. Three copies of food safety assessment report with supporting evidenced documents

2. One set of CD-ROM contained data supporting evidenced documents as specified in the annex of the Notification in attachment 1

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

.....

2. Name of safety assessment unit that safety assessment report has been prepared

.....

3. Summary of safety assessment result undertaken by the safety assessment unit as in item 4 as follows

.....

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>Please bring this document together with an application accepting form attached with correction of</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>incompleteness for the next time (if any)</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/ number (issue)	none	Yes/ number (issue)	none	
1.	Food safety assessment report with supporting evidenced documents as shown below					
	1.1 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.					
	1.2 Testing results of properties as probiotics as follows:					
	1) Resistance to gastric acidity					
	2) Bile salt resistance					
	3) Adherence to mucus and/or human epithelial cells and cell line					
	4) Bile salt hydrolase activity					
	5) Other properties (if any) as the case maybe					
	1.3 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:					
	1) Antimicrobial resistances					
	2) Assessment of metabolic activities such as D-lactate producing or bile salt deconjugation					
	3) Assessment of side-effects during human studies					
	4) Epidemiological surveillance of adverse incidents in consumers for post-marketing					
	5) Toxin production, if the strain being evaluation belongs to a species that is a toxin producer					
	6) Determination of hemolytic activity, if the strain being evaluation belongs to a species with known hemolytic potential.					
	1.4 Result of safety assessment of the probiotics from international risk assessment agency or other recognized countries (if any)					
2.	One set of CD-ROM contained data supporting evidenced documents					