

Application form for safety assessment of Food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food Additives (the 2<sup>nd</sup> case)

Company/Partnership/Shop.....  
Address.....  
.....  
Tel.....Fax.....  
E-mail.....  
Date.....Month.....B.E.....

Re: Request to evaluate food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food additives

To: Secretary General of Food and Drug Administration

Attachment: Numbers of evidenced documents for consideration .....items

Since I am..... on behalf of (Company/Partnership/Shop)..... intend to..... (produce/import) a product of food additives name ..... which such product contain food additive ..... (common name and INS number of the food additive (if any) that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re : Food additives.

So that evidenced documents and all data required according to a safety assessment application form of food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food Additives have been enclosed for further consideration of its condition of use.

Sign..... Business operator  
(.....)

Name-last name (an applicant).....tel.....

**Preliminary Checklist supplementing for consideration for assessment of Food that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food Additives**

<b>Details of an applicant</b> Name –last name of the applicant/authorized person.....tel..... E-mail .....name of producing/import premise..... License No.of production/import/producing premise..... <b>address for document delivery (if any)</b> No..... Trok/soi.....street.....Moo..... tambol/subdistrict..... ampoe/district.....Province..... Tel.....	<p align="center"><u>Please bring this document together with an application form attached with correction of incompleteness for the next time (if any).</u></p>
<b>Details of applied food additive</b> Name of the food additive:..... (in Thai) Name of the food additive:..... (in English) Technological function:..... To be used in food:.....	

Explanation : Request an applicant to arrange documents in sequence as indicated in the following list and also check with mark ✓ by your ownself

Details of document checking part 1 : required documents or evidences				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
1.	Two copies of application forms for food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food additives	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
2.	One copy of identification card or passport of the applicant	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
3.	One copy of Commercial Registration Certificate or Objective of Legal Entity Registration document and Authorized officer on behalf of legal entity( in case of assigning authority)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
4.	One copy of power of attorney from a business operator (in case of assigning authority)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
5.	Two copies of Checklist with signature to confirm completeness of documents	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
6.	One set of assessment forms of food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of Ministry of Public Health Re: Food additives as specified in the checklist together with supporting data for consideration of safety assessment	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	I have intention for confidential keeping of data/evidence number of pages ..... (if any)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

Details of document checking part 1 : required documents or evidences				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
7.	One set of CD-ROM contained with evidence and document data.	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

**Note** If an applicant has intention for confidential keeping of data/evidences in some parts or whole of the application, the applicant shall arrange a list of the confidential data of safety assessment that intend to be kept secret together with reason to request for such confidential.

Details of Checklist Part 2: Safety assessment data					
No.	Item of document	Additional explanation	Checked by the applicant	Verified by an official	Incompleteness recorded
1.	<b>Data on safety of food additive (Specification)</b> **latest version**	<u>Source of reference</u> (1) Codex Advisory Specification for the Identity and Purity of Food Additives (2) Announcement of the Food and Drugs Administration Re: Prescription of Quality and standards of single food additives (there are 4 issues)			
1.1	Chemical name		<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
1.2	Coding Number as International Numbering System: INS		<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
1.3	Safety limit value (as the case maybe)	(1) Acceptable daily intake; ADI, or (2) Provisional Tolerable Weekly Intake; PTWI, or (3) Provisional Maximum Tolerable Daily Intake; PMTDI, or (4) Maximum Tolerable Daily Intake; MTDI	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
2.	<b>Data of necessity on production technology of each food proposed to use the particular food additive</b>	<u>Source of reference</u> (1) Codex General Standard for Food Additives; GSFA) latest version (2) Codex Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989)			
	Table presented details of - Food category number - Food category name	The most detailed sub category of food shall be indicated that able to cover proposed food product by refer to the Notification of the Ministry of Public Health Re: Food additives	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	- the amount of food additive requested to use	the figure in unit of milligram per 1 kilogram of food shall be specified”	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	- Purpose of use or Functional use	Refer to Codex Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989) latest version,	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

Details of Checklist Part 2: Safety assessment data					
No.	Item of document	Additional explanation	Checked by the applicant	Verified by an official	Incompleteness recorded
		so that the purpose of use or functional use informed shall conform to specified functional use in the specification.			
	- at least 3 issues of Academic or research document/summary content <i>[Summary of content together with full version of Academic or research document shall be provided]</i>	Reliable academic document or research study that present efficiency and necessity of functional use of the food additives in the amount and purpose of use or fuctional use in proposed food products.	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
3.	<b>Law and Regualtion Data</b> <i>[Please attach law and regulations of each referred country]</i> <input type="checkbox"/> EU <input type="checkbox"/> Australia-NewZealand <input type="checkbox"/> USA <input type="checkbox"/> Japan <input type="checkbox"/> Codex Standard	*Latest version* of Law or regulations presenting of at least 2 countries on acceptance of use the particular food additives in the proposed food in the countries having reliable system of safety assessment such as EU, Australia- New Zealand, USA and Japan.	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

**Note:** 1. Codex Advisory Specification for the Identity and Purity of Food Additives available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>

2. Announcement of the Food and Drugs Administration Re: Quality and Standards of Single Food additives (there are 4 Issues) available at: <http://food.fda.moph.go.th/FoodAdditives.php>

3. Codex Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989) available at: <http://www.codexalimentarius.org/standards/list-of-standards/>

**Checking result of completeness of supporting documents**

For an applicant only	For official only
<p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u></p> <p><b><u>Part 1 Submission for checking an application and evidenced documents</u></b></p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of evidenced documents</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for assessment of specification and safety in case of incomplete documents</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</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 checking the completeness of evidenced documents of 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 (.....)</p> <p>Date.....time.....</p>	<p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u></p> <p><b><u>Part 1 Checking for the completeness of evidenced documents</u></b></p> <p><input type="checkbox"/> Complete documents to issue a receipt of payment for technical evaluation as in List No.2 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 as the case maybe as follows:</p> <p><input type="checkbox"/> List 2 item 2.2(2) rate of expenditure 69,000 Bath;</p> <p><input type="checkbox"/> List 2 item 2.2(5) rate of expenditure 45,000 Bath</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 <u>terminated and further returned</u> (the applicant shall be informed by signing and receive a copy)</p> <p>notify to proceed.....</p> <p>.....</p> <p>.....</p> <p>Sign by an official..... (.....)</p> <p>Date.....Time.....</p>
<p><b><u>Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed 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 (.....)</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>Signed by checking officer..... (.....)</p> <p>Date .....time.....</p>

Checking results of completeness of supporting evidenced documents (continue)

For an applicant only	For official only
<p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u></p> <p><b><u>Part 1 Submission the application and evidenced documents</u></b></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>Sign ..... applicant/authorized person (.....)</p> <p>Date .....time.....</p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of evidenced documents</p> <p>Sign ..... applicant/authorized person (.....)</p> <p>Date .....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for assessment of specification and safety in case of incomplete documents</p> <p>Sign ..... applicant/authorized person (.....)</p> <p>Date .....time.....</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 (.....)</p> <p>Date .....time.....</p>	<p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u></p> <p><b><u>Part 1 Checking for the completeness of evidenced documents</u></b></p> <p><input type="checkbox"/> Complete documents to issue a receipt of payment for technical document evaluation as in List No.2 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 as the case maybe as follows:</p> <p><input type="checkbox"/> List 2 item 2.2(2) rate of expenditure 69,000 Bath;</p> <p><input type="checkbox"/> List 2 item 2.2(5) rate of expenditure 45,000 Bath</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 <u>terminated and further returned</u> (the applicant shall be informed by signing and receive a copy) notify to proceed.....</p> <p>.....</p> <p>.....</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..... (.....)</p> <p>Date .....time.....</p>
<p><b><u>Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed 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 (.....)</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>Signed by checking official..... (.....)</p> <p>Date .....time.....</p>

3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)

**Part 1 Submission the application and evidenced documents**

I have submitted correcting or additional documents in the number of.....items as specified in the incompleteness recorded form.

Sign ..... applicant/authorized person  
(.....)

Date .....time.....

Sign to accept checking result of the completeness of evidenced documents.

Sign ..... applicant/authorized person  
(.....)

Date .....time.....

Request to return supporting documents for assessment of specification and safety.

Sign ..... applicant/authorized person  
(.....)

Date .....time.....

**Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of complete documents)**

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.

Sign ..... applicant/authorized person  
(.....)

Date .....time.....

3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)

**Part 1 Checking for the completeness of evidenced documents**

Complete documents issue a receipt of payment for technical evaluation as in List No.2 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 as the case maybe as follows:

List 2 item 2.2(2) rate of expenditure 69,000 Bath;

List 2 item 2.2(5) rate of expenditure 45,000 Bath

Incomplete documents and the applicant request to return the documents.

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.

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.

Signed by checking official.....

(.....)

Date .....time.....

**Part 2 Acceptance of the application for technical document evaluation**

Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.

Signed by checking official.....

(.....)

Date .....time.....

Form for Assessment of food additives that its conditions of use or additional conditions of use have not been prescribed under the Notification of the Ministry of Public Health Re: Food additives

1. Safety data of the food additive

- (1) Chemical name.....
- (2) Code number as in International Numbering System: INS .....
- (3) Safety limit (as the case maybe)
  - (3.1) Acceptable daily intake; ADI ..... milligram/ Kilogram bodyweight/day
  - (3.2) Provisional Tolerable Weekly Intake; PTWI ..... milligram/ Kilogram bodyweight/week
  - (3.3) Provisional Maximum Tolerable Daily Intake; PMTDI ....milligram/Kilogram bodyweight/day
  - (3.4) Maximum Tolerable Daily Intake; MTDI ..... milligram/Kilogram bodyweight/day
- (4) Quality or Standard requirements (Specification) **\*\*latest version\*\*** [please attach the full issue]
  - Codex Advisory Specification for the Identity and Purity of Food Additives details as in document No. ....
  - Announcement of the Food and Drugs Administration, Re: Quality or standard Requirements of Single food additive Specification (Issue No....) details as in document No. ....



2. Data of necessity on production technology of each food proposed to use the particular food additive

Food category number	Food category name	Limit of the food additive proposed to use milligram per 1 kilogram of food)	Propose of use or Functional use	Name of academic documents or research study /summary of content (please attach full version) (inThai only)
(1)				1. Name of academic documents or research study ..... summary of content ..... <i>details are in document no. ....</i>
				2. Name of academic documents or research study ..... summary of content ..... <i>details are in document no. ....</i>
				<i>... the number of documents are not limited...</i>
(2)				1. Name of academic documents or research study ..... summary of content ..... <i>details are in document no. ....</i>
				2. Name of academic documents or research study ..... summary of content ..... <i>details are in document no. ....</i>
				<i>... the number of documents are not limited...</i>
(3), (4), (5) Category of food proposed to use the particular food additive				

### 3. Law or regulations of countries having reliable system of safety assessment

\*Latest version\* of Law or regulations presenting of at least 2 countries on acceptance of use the particular food additives in the proposed food in the countries having reliable system of safety assessment such as EU, Australia- New Zealand, USA and Japan (please attach full version of the referred law and regulation of each country).

Food category number	Food category name	Maximum permitted limit (milligram per 1 kilogram of food)			
		EU <sup>1</sup>	Australia- NewZeland <sup>2</sup>	Japan <sup>3</sup>	USA <sup>4</sup>
(1)					
(2)					
<i>..... the number of documents are not limited....</i>					

1 Specify name of referred EU standard. *Details as in document No. ....*

2 Specify name of referred Australia-NewZealand standards. *Details as in document No. ....*

3 Specify name of referred Japan standard. *Details as in document No. ....*

4 Specify name of referred USA standard. *Details as in document No. ....*