Application form for food safety assessment <u>which not fall in scope of novel food</u> under the Notification of the Ministry of Public Health (No.376) B.E.2559, Re: Novel Food including checklist supporting for safety assessment

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

Re: Request to assess safety of food which not fall in a scope of novel food under the Notification of the Ministry of Public Health (No.376) B.E.2559, Re: Novel Food

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 assess safety of food or its compositions which not fall in scope of novel food for consideration of permission as follows:

1. Name of a requested food product or raw material to be assessed for safety
   - in Thai.....
   - in English.....
   - Scientific name.....
   - Chemical name and molecular formula.....

2. Purpose for consumption / Expectation from consumption e.g. to be antioxidants
.....
.....

3. Preparation method before consumption and daily recommended dose
.....
.....

4. Production process (if it is extract, kinds and concentration of solvent, extract ratio shall be specified) / Name of innovation or technology of production.
.....

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

Sign ..... applicant

(.....)

Preliminary Checklist supplementing for consideration of 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

Part 1 General information

Details of an applicant Name –last name of the applicant/authorized person.....tel..... E-mail .....name of producing/import premise..... Address..... Building ..... Moo..... Trok/soi.....Street..... Tambol/subdistrict..... Ampoe/district..... Province..... Tel.....Fax.....	Please bring this document together with an application accepting form attached with correction of incompleteness for the next time (if any)
Details of Novel food 1. Name of a requested food product or raw material to be assessed for safety - in Thai..... - in English..... - Scientific name..... - Chemical name and molecular formula..... 2. Purpose for consumption / Expectation from consumption e.g. to be antioxidants .... 3. Preparation method before consumption and daily recommended dose .... 4. Production process (if it is extract, kinds and concentration of solvent, extract ratio shall be specified) / Name of innovation or technology of production. .... 5. Evidences of receiving permission from the Food and Drug Administration such as Food Serial Number, Food Recipe license, Food Registration/Food Notification documents of such particular food (if any).	

<u>Part 2</u> Preliminary Checklist supplementing for safety assessment of food which not fall in scope of novel food

No.	Item of documents	applicant		Official check		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue)	none	
1 1.1	**General information of ingredient** Scientific, Chemical name, or common name					
1.2	Part of use					
1.3	Geographical origin/source of origin of composition					
2. 2.1	**General information of product** Recipe formula of product					
2.2	Purpose of use of such product					
2.3	Action/Health effect and expectation from consumption					
2.4	Country of producer (in case of import)					
2.5	Evidences presenting permission from the Food and Drug Administration					
3. 3.1	**Information on history of consumption as food** Duration of use for consumption as food (if it is used for another purpose, please indicate) and specify country where such food is generally consumed.					
3.2	Description of use includes purpose, form of use, duration of use in such form, targeted consumer group					
3.3	consumption data					
4. 4.1	**Specification of compositions** Characteristic					
4.2	Physical or chemical property					
4.3	Information on identity of ingredient					
4.4	Quantity of active ingredient/active substance/ marker					
4.5	Quantity of processing aid residues					
4.6	Requirement of impurities					
4.7	Microbiological criteria					
4.8	Specific requirements (i.e. relevant toxins)					
4.9	Stability (if any)					
4.10	Other information (i.e. sensitivity to light, heath stability) (in any)					
5. 5.1	**Specification of product** Characteristic					
5.2	Physical or chemical property					

No.	Item of documents	applicant		Official check		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue)	none	
5.3	Quantity of active ingredient/active substance/ marker					
5.4	Quantity of processing aid residues					
5.5	Requirement of impurities					
5.6	Microbiological criteria					
5.7	Specific requirements (i.e. relevant toxins)					
5.8	Stability (if any)					
5.9	Other information (i.e. sensitivity to light, heat stability) (if any)					
6 6.1	**Certificate of analysis** Certificate of analysis for ingredient					
6.2	Certificate of analysis for product					
7. 7.1	**Storage** Storage condition					
7.2	Shelf life					
8. 8.1	**Production process/Synthesis/ Extraction method** Preparation procedure / production method					
8.2	Type and concentration of solvent (in case of extract substance)					
8.3	Type of active substance or category of substance from extraction (in case of extract)					
8.4	Extraction ratio between ingredient and 1 gram of active ingredient (in case of extract)					
9. 9.1	**Basic information on chemical substances used in production**(*) Chemical name, i.e. CAS No., INS No.					
9.2	Specification of chemical substances and functional use of such substances					
10 10.1	**Characteristic/ Recommendation for consumption** 1 Serving size (metric system)					
10.2	Frequency (times/day)					
10.3	Preparation method before consumption /Cooking method					
10.4	Targeted consumer					
10.5	Warning statement/ Recommendation for consumption (if any)					
11 11.1 11.1.1	**Information on safety** Biochemical Characteristics (if any) Absorption, distribution, and excretion					
11.1.2	Biotransformation					

No.	Item of documents	applicant		Official check		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue)	none	
11.1.3	Effect on enzyme and other parameters					
11.1.4	Reaction and fate of the food					
11.2 11.2.1	Toxicological study in animal(Full paper) Acute toxicity					
11.2.2	Sub-chronic toxicity					
11.2.3	Chronic study (in case no chronic study, at least clinical research study in healthy people shall be submitted)					
11.3 11.3.1	Study for use of pure culture (in case use of pure culture in production process) Specific properties of microorganism					
11.3.2	Testing of reception and distribution of antimicrobial resistance and form of the resistance					
11.3.3	Evaluation of metabolic action					
11.3.4	Information on pathogenic trend					
11.4	Toxicity studies in specific area (in case of manifestation)					
11.5	Clinical research study or Epidemiological report (**)					
11.6	Other studies (if any)					
12	**Nutritional data**(***)					
13	**Result of safety assessment from international risk assessment agency or other recognized countries (if any)**					

Note:

1. (*) In case chemical substance is made by microorganism, Identity and safety data of such microorganism used in production of the chemical substance shall be submitted.
2. (**) Only in case of novel food notifying expectation to health, clinical research study shall be submitted. If No expectation to health, Clinical research study may be submitted (if any).
3. (***) Only in case such novel food shall be complied with relevant Notifications of Ministry of Public Health.

I do hereby certify that supporting evidence documents for consideration of food safety assessment attached herewith are true and trustworthy and if an official have any query in these documents, I agree to give more additional data for official when requesting.

Sign ..... an applicant/authorised person

(.....)

Part 3 Checking result of completeness of supporting documents

For applicant of safety assessment only	For official only
1st time (1st submission) ***Part 1 Submission the application and evidenced documents*** ☐ Sign to accept checking result of the completeness of supporting documents. ☐ Request to return supporting documents for consideration of food safety assessment in case of incomplete documents ☐ 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.....) If it is overdue, cancellation and return of the application and evidenced documents can be undertaken. Sign .....an applicant/authorized person (.....) Date.....time.....	1st time (1st submission) ***Part 1 Checking for the completeness of evidenced documents*** ☐ 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 ☐ Incomplete documents and the applicant request to return the documents. ☐ 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) notify to proceed..... .... Sign by an official..... (.....) Date.....Time.....
Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed 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.....	***Part 2 Acceptance of the application for technical document evaluation*** ☐ Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered. Sign by checking officer..... (.....) Date .....time.....

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

For applicant of safety assessment only	For official only
2nd time (1st 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 to accept checking result of the completeness of evidenced documents ☐ Request to return supporting documents for assessment of specification and safety in case of incomplete documents ☐ 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.....) If it is overdue, agree for cancellation and return of the application and evidenced documents. Sign ..... applicant/authorized person (.....) Date .....time.....	2nd time (1st round of submission to correct the defects) ***Part 1 Submission the application and evidenced documents*** ☐ 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 ☐ Incomplete documents and the applicant request to return the documents. ☐ 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) ☐ 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 Submission the application and evidenced documents for evaluation of technical documents (case of completed 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.....	***Part 2 Acceptance of the application for technical document evaluation*** ☐ Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered. Sign by checking officer..... (.....) Date .....time.....

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

For applicant of safety assessment only	For official only
3rd time (2nd round of submission to correct the defects) ***Part 1 Submission the application and evidenced documents*** ☐ I have submitted corrective or additional documents in the number of.....items as specified in the incompleteness recorded form. ☐ Sign to accept checking result of the completeness of evidenced documents. ☐ Request to return supporting documents for assessment of specification and safety. Sign ..... applicant/authorized person (.....) Date .....time.....	3rd time (2nd round of submission to correct the defects) ***Part 1 Checking for the completeness of evidenced documents*** ☐ Correct or submit complete documents to issue a 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 ☐ 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 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.....	***Part 2 Acceptance of the application for technical document evaluation*** ☐ Document is complete, receipt of payment for technical document evaluation is presented and to accept the application is considered. Sign by checking officer..... (.....) Date .....time.....