Application form for safety assessment of food additives that qualities or standards have not been prescribed under the Notification of Ministry of Public Health Re: Food Additives (the 1st case)

Company/Partnership/Shop.....

Address.....

.....

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

E-mail.....

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

Re: Request to evaluate food additives that qualities or standards 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 contains food additive ..... (common name and INS number of the food additive (if any)) that not yet been prescribed qualities or standards 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 addittives that qualities or standards have not been prescribed under Notification of Ministry of Public Health Re: Food Additives are enclosed for further consideration of its specification.

Sign..... Business operator

(.....)

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

Case 1-1 Food additive

Preliminary Checklist supplementing for consideration for assessment of Food additives that qualities or standards have not been prescribed under the Notification of Ministry of Public Health Re: Food Additives

Details of an applicant Name –last name of the applicant/authorized person.....tel..... E-mail .....name of producing/import premise..... License No.of production/import/producing premise..... **address for document delivery (if any)** No..... Trok/soi.....street.....Moo..... tambol/subdistrict..... ampoe/district.....Province..... Tel.....	Please bring this document together with an application form attached with correction of incompleteness for the next time (if any).
Details of applied food additive **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 safety assessment of food additives that qualities or standards (Specification) have not been prescribed under the Notification of Ministry of Public Health Re: Food additives	☐ yes ☐ none	☐ complete ☐ incomplete	
2.	One copy of identification card or passport of the applicant	☐ yes ☐ none	☐ complete ☐ 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)	☐ yes ☐ none	☐ complete ☐ incomplete	
4.	One copy of power of attorney from a business operator (in case of assigning authority)	☐ yes ☐ none	☐ complete ☐ incomplete	
5.	Two copies of Checklist with signature to confirm completeness of documents	☐ yes ☐ none	☐ complete ☐ incomplete	
6.	One set of documents for considering food additive assessment as specified in the checklist together with the following details:	☐ yes ☐ none	☐ complete ☐ incomplete	
	Summary of overall data of food additive being assessed for safety (in Thai) that cover items as follows: ● Specification data (from part 2 of document item 1.1 – 1.5) ● Safety assessment data (from part 2 of document item 2.1-2.5)	☐ yes ☐ none	☐ complete ☐ incomplete	
	I have intention for confidential keeping of data/evidence number of pages ..... (if any)	☐ yes ☐ none	☐ complete ☐ incomplete	
7.	One set of CD-ROM contained with evidence and document data.	☐ yes ☐ none	☐ complete ☐ 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	Specifications of food additive				
1.1	Product composition formula	-express as 100% of composition formula of the produst - Ingredients other than the food additive to be assessed for safety, their specification shall also be attached	☐ yes ☐ none	☐ complete ☐ incomplete	
1.2	Chemical characteristics of the food additive to be assessed for safety	May specify as technological function	☐ yes ☐ none	☐ complete ☐ incomplete	
1.3	Reactions and Fate of Food Additives in Food	Such as reaction between the food additive and chemical in the food or in case the food additive is destroyed or degraded due to process of cooking or preparing food which leads to efficiency reduction	☐ yes ☐ none	☐ complete ☐ incomplete	
1.4	Identity and Purity to be assessed for safety consist of		☐ yes ☐ none	☐ complete ☐ incomplete	
	1.4.1 Chemical name				
	1.4.2 International numbering system of the food additive (if any)	such as CAS number, EC Number			
	1.4.2 Method of production				
	1.4.3 Incoming raw materials used				
	1.4.4 Impurities occurred in production				
	1.4.5 Stability	May specify stability of the food additive during storage and reactions in test system			
	1.4.6 Residue of processing aids				
	1.4.7 Methods of analysis	Standardised Test method and internationally recognized shall be contained with (1) specificity (2) limit of detection,(LOD) (3) limit of quantification, (LOQ) (4) accuracy (5) precision			
1.5	Safety limit (as the case maybe)(if any)	Acceptable daily intake; ADI or Provisional Tolerable Weekly Intake; PTWI or Provisional Maximum Tolerable Daily Intake; PMTDI or Maximum Tolerable Daily Intake; MTDI	☐ yes ☐ none	☐ complete ☐ incomplete	
2	Safety study data of food additive being assessed for safety				
2.1	Toxicological study that specify the following indicators	Experimental design as specified by Organization for Economic Co-operation and Development (OECD) as the following case:			

Details of Checklist Part 2: Safety assessment data					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
		- Repeated Dose 28-Day Oral Toxicity Study in Rodents - Repeated Dose 90-Day Oral Toxicity Study in Rodents - Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents - Chronic Toxicity Studies - Combined Chronic Toxicity/Carcinogenicity Studies			
	(a) Functional Manifestations	Specify reaction of the food additive in metabolism including biochemical reaction of the food additive in living organisms	☐ yes ☐ none	☐ complete ☐ incomplete	
	(b) Morphological Manifestations		☐ yes ☐ none	☐ complete ☐ incomplete	
	(c) Neoplasms	Specify mechanism of carcinogen effect to genetic or DNA binding and mechanism of such carcinogen does not have directly toxic effect to DNA	☐ yes ☐ none	☐ complete ☐ incomplete	
	(d) Reproduction and Developmental Toxicity	1.Toxicity study of reproduction system based on OECD Test Guideline NO. 415: One-Generation Reproduction Toxicity Study (OECD, 1983), OECD Test Guideline NO. 415: Reproduction/ Developmental Toxicity Screening Test (OECD, 1995d), OECD Test Guideline NO. 422: Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test (OECD, 1996) or the NTP 35-day screening protocol (Harris et al., 1992) both single generation and multigeneration 2. Developmental Toxicity study based on OECD Test Guideline NO. 414: Prenatal Developmental Toxicity Study (OECD, 2001a) and USEPA's Prenatal Toxicity Study (USEPA, 1998c)	☐ yes ☐ none	☐ complete ☐ incomplete	
	(e) In Vitro Studies	in vitro experiment use of human cell or membrane or prepared mixture of human enzyme (receptors) and subcellular factors such as - gene mutation in bacteria - gene mutation in mammalian cell lines - chromosomal aberrations include micronuclei and aneuploidy in cultured mammalian cells - Test on DNA destruction in primary cultures of mammalian cells normally use of rat hepatocytes etc.	☐ yes ☐ none	☐ complete ☐ 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
	Other toxicity studies (if any) such as Neurotoxicity, Immunotoxicity		☐ yes ☐ none	☐ complete ☐ incomplete	
2.2	The Use of Metabolic and Pharmacokinetic Studies in Safety Assessment as follows:	Biochemical, physiological studies and mathematics that are fundamental reaction of chemical in bodies, there are 2 characters (1)toxicokinetics are relations of chemical transfer and migration from active site of parent substance and/or active metabolites (2) toxicodynamics are relations of reaction between chemicals and/or active metabolites at active site and final result or toxicological response			
	(a) Identifying Relevant Animal Species	Experimental design in suitable animal study to identify and describe hazard characteristic as the effect of chemical exposure including consideration of different species of laboratory animals and possibility of variation in human.	☐ yes ☐ none	☐ complete ☐ incomplete	
	(b) Determining the Mechanisms of Toxicity		☐ yes ☐ none	☐ complete ☐ incomplete	
	(c) Metabolism into Normal Body Constituents	Absorption, distribution, metabolism and excretion including residues of toxicological concern	☐ yes ☐ none	☐ complete ☐ incomplete	
	(d) Effects of the Gut Microflora on the Chemical and Effects of the Chemical on the Gut Microflora	Specify possibility of the chemical in food that may effect to host microflora in gut microflora and give an effect on changing of such chemical response by consideration on Antibacterial activity and increased substrate for gut microflora gut microflora	☐ yes ☐ none	☐ complete ☐ incomplete	
2.3	Influence of Age, Nutritional Status, and Health Status in the Design and Interpretation of Studies		☐ yes ☐ none	☐ complete ☐ incomplete	
2.4	Human studies used for safety assessment as follows:	Data of accidental exposure from occupation and basic exposure for toxicological study of residuals in food. It may be Clinical Trial/Study or Epidemiological Studies, etc.			
	(a) Epidemiological Studies		☐ yes ☐ none	☐ complete ☐ incomplete	
	(b) Food Intolerance	Food allergy and other food hypersensitivities are reactions that have specificity to food or ingredients of the food occurred in hypersensitive person	☐ yes ☐ none	☐ complete ☐ 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
2.5	Acceptable Daily Intake: ADI	Express data used to specify the following limit (a) No-observed-effect level: NOEL (b) Safety factor for calculation (c) Toxicological versus physiological responses (d) Comparison between ADI and probability of actual human exposure to such food additive.	☐ yes ☐ none	☐ complete ☐ incomplete	

Note :

1. If the food additive is produced from microorganisms, data of identity and safety of the microorganism used to produce the food additive shall also be submitted.
2. Additional study of the details as in document of Criteria and guidance for safety assessment of food additives or conditions of use other than described under the Notification of the Ministry of PublicHealth (No.281) B.E. 2547 (2004) Re: Food additives.

I do hereby certify that supporting evidence documents for consideration of 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/authorized person

(.....)

Checking result of completeness of supporting documents

For an applicant only	For official only
1st time (1st submission) ***Part 1 Submission for checking an application and evidenced documents*** ☐ Sign to accept checking result of the completeness of evidenced documents Sign .....an applicant/authorized person (.....) Date.....time..... ☐ Request to return supporting documents for assessmentof specification in case of incomplete documents Sign .....an applicant/authorized person (.....) Date.....time..... ☐ 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.....) 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 proceed to contact safety assessment unit as prescribed by the Food and Drug Administration ☐ 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 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/authorizedperson (.....) 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. Signed by checking officer..... (.....) Date .....time.....

Checking results of completeness of supporting evidenced documents (continued)

The applicant only	Officer 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 incomppleteness 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 in case of incomplete documents Sign ..... applicant/authorized person (.....) Date .....time..... ☐ 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 Checking for the completeness of evidenced documents*** ☐ Complete documents, proceed to contact safety assessment unit as prescribed by the Food and Drug Administration ☐ Incorrect or incomplete documents and the applicant request to return the documents of safety assessment. ☐ 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) notify to proceed..... .... ☐ Return the application together with supporting documents for assessment of specification 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 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 evaluation is presented and to accept the application is considered. Signed by checking official..... (.....) Date .....time.....

3rd time (2nd 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. Sign ..... applicant/authorized person (.....) Date .....time.....	3rd time (2nd of submission to correct the defects) ***Part 1 Checking for the completeness of evidenced documents*** ☐ Complete documents, proceed to contact safety assessment unit as prescribed by the Food and Drug Administration. ☐ Incorrect or incomplete documents and the applicant request to return the documents of safety assessment. ☐ Return the application together with supporting documents for assessment of specification 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. Signed by checking official..... (.....) Date .....time.....