Application form: the 2nd Case

Application form for quality or standard and safety assessment of container that use of substance or chemical that affect nature of food contained in such the container

Company/Partnership/ Shop.....

Address.....

.....

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

E-mail.....

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

Re: Request to assess quality or standard and safety of container that use of substance or chemical that affect nature of food contained in such container

To: Secretary General of Food and Drug Administration

Since I am.....on behalf of Company/Partnership/shop)..... operate business to ☐ produce food ☐ import food with premise license of production /import No.....

☐ manufacture food container ☐ import food container

☐ other please specify.....

intend to.....(manufacture/import/use)... of container that use of substance or chemical that affect nature of food contained in such the container by use of substance.....

to have property of the container.....

by having information as follows:

Name and address of manufacturer of material used for manufacturing container and substance used in the container that affect nature of food contained in such the container .....

Name and address of container molding manufacturer.....

.....

So evidence documents and information are submitted in accordance with form of quality or standard and safety of container that use of substance or chemical that affect nature of food contained in such the container are enclosed with all details for supporting to request for the approval from the Food and Drug Administration for further consideration of its quality or standard.

Regards,

(sign)..... Applicant

(.....)

Preliminary Checklist: the 2nd case

Preliminary Checklist supplementing for consideration of quality or standard and safety assessment of container that use of substance or chemical that affect nature of food contained in such the container

Part 1 General information

Details of an applicant Name –last name of the applicant/authorized person.....tel..... E-mail .....name of premise..... **Address for document delivery (if any)** No..... Building..... Moo..... Trok/soi ..... street..... 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 submitted container that use of substance or chemical that affect nature of food contained in such the container by use of substance..... to have property of the container.....	

Part 2 Preliminary Checklist

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 or evidence checking (part 1)				
No.	**Item of document**	**Checked by the applicant**	**Verified by an official**	**Incompleteness record**
1.	Two copies of application forms of quality or standard and safety assessment of container that use of substance or chemical that affect nature of food contained in such the container	☐ yes ☐ none	☐ complete ☐ incomplete	
2.	One copy of identification card or passport of the applicant with signature of certifying	☐ 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 legal entity) and with signature of certifying	☐ yes ☐ none	☐ complete ☐ incomplete	
4.	One copy of license of conducting factory business (in case of container manufacturer) with signature	☐ yes ☐ none	☐ complete ☐ incomplete	
5.	One copy of certifying letter of power of attorney from a business operator that indicate power to submit and receive to correct, accept and follow the consideration (in case of assigning authority) together with one certifying true copy of identification card of grantor and proxy	☐ yes ☐ none	☐ complete ☐ incomplete	
6.	Two copies of Checklist with signature to confirm completeness of documents	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (part 1)				
No.	**Item of document**	**Checked by the applicant**	**Verified by an official**	**Incompleteness record**
7. Information of the container and information of specific characteristics of substance in the container that affect nature of food contained in such container				
7.1.	Information of container composition may be presented as structure or composition formula	☐ yes ☐ none	☐ complete ☐ incomplete	
7.2	Sample of the container	☐ yes ☐ none	☐ complete ☐ incomplete	
7.3	Document presenting list of substance used for material preparation in container manufacturing	☐ yes ☐ none	☐ complete ☐ incomplete	
7.4	Document presenting list and information of substance used in mixing or composing of material layer /texture in container manufacturing, the substance affect nature of food contained in such container together with safety information of such substance that may include	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.1 Common chemical name	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.2 Chemical name (IUPAC system)	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.3 Synonyms	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.4 CAS Registry Number	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.5 Trade Name	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.6 Chemical formula	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.4.7 Technological function to container or contained food	☐ yes ☐ none	☐ complete ☐ incomplete	
7.5	Document presenting production process of food container including quantity of substance used in the process	☐ yes ☐ none	☐ complete ☐ incomplete	
7.6	Information presenting mechanism of reaction between substance and material used in container manufacturingtogether with supporting technical documents	☐ yes ☐ none	☐ complete ☐ incomplete	
7.7	Mechanism of occurring reaction between substance in the container (which affect nature of food) and food including its performance and effect to food contained in such	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (part 1)				
No.	**Item of document**	**Checked by the applicant**	**Verified by an official**	**Incompleteness record**
	container together with supporting technical documents			
7.8	Document presenting specification or properties of the container	☐ yes ☐ none	☐ complete ☐ incomplete	
7.9	Document presenting specification or properties of the substance used in the container which affect nature of food contained in such container	☐ yes ☐ none	☐ complete ☐ incomplete	
7.10	Document presenting summary of properties of the container or special characteristics or effect to food in such container or information relevant to feature or condition in container usage together with supporting technical documents such as	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.10.1 Feature or procedure of usage	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.10.2 Type of food to be contained	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.10.3 Usage condition	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.10.4 Special feature or effect to food contained in such container	☐ yes ☐ none	☐ complete ☐ incomplete	
	7.10.5 Recommendation of usage (if any)	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
8. **Safety assessment data**					
8.1	Safety limit of substances in the container (which affect nature of food)	Safety limit of the substances such as: Acceptable daily intake; ADI ,or Provisional Tolerable Weekly Intake; PTWI, or Provisional Maximum Tolerable Daily Intake; PMTDI, or Maximum Tolerable Daily Intake; MTDI or Cumulative Estimated Daily Intake(CEDI)	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
8.2	Information of permission to use the substance in container or in food contact materials or in food from reliable sources	Example • If the substance is food additive which its safety assessed by The Joint FAO/WHO Expert Committee on Food Additives (JECFA) or having Specification as prescribed under Codex Advisory Specification for the Identity and Purity of Food Additives and conditions prescribed for use in food • If the substance is permitted to use in food contact materials such as - as in community list or register of substance in EC 450/2009 on active and intelligent materials and articles intended to come into contact with food or from the Union list EU 10/2011 on plastic materials and articles intended to come into contact with food by EU - as US legislation of food contact materials • approval substance under the criteria of ENVIRONMENTAL HEALTH CRITERIA 240 : Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009)	☐ yes ☐ none	☐ complete ☐ incomplete	
8.3	Report of analysis of the used substance that may migrate into food together with the method of analysis	Standardized 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	☐ yes ☐ none	☐ complete ☐ incomplete	
8.4	Summary of safety study of the substance having details as in No.				

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
	8.1 as follows:				
	8.4.1 Toxicological study that specify the following indicators:	Experimental design as specified by Organization for Economic Co-operation and Development (OECD) as a case may be as follows: - 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	☐ yes ☐ none	☐ complete ☐ incomplete	
	(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	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
		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)			
	(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	
	(f) Other toxicity studies (if any) such as Neurotoxicity, Immunotoxicity		☐ yes ☐ none	☐ complete ☐ incomplete	
	8.4.2 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	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
		the effect of chemical exposure including consideration of different species of laboratory animals and possibility of variation in human.			
	(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	☐ yes ☐ none	☐ complete ☐ incomplete	
	(e) Influence of Age, Nutritional Status, and Health Status in the Design and Interpretation of Studies		☐ yes ☐ none	☐ complete ☐ incomplete	
	8.4.3 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	
	8.4.4 Determination of safety limit for human exposure by Acceptable daily intake; ADI, or Provisional Tolerable	Express data used to specify the following limit: (a) No-observed-effect level: NOEL (b) Safety factor for calculation (c) Toxicological versus	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
	Weekly Intake; PTWI, or Provisional Maximum Tolerable Daily Intake; PMTDI, or Maximum Tolerable Daily Intake; MTDI, or Cumulative Estimated Daily Intake(CEDI)	physiological responses (d) Comparison between ADI and probability of actual human exposure to such food additive.			
8.5	Information of legislation, regulations, or quality or standard requirements relevant to applying container of manufacturing country or the country to be referred		☐ yes ☐ none	☐ complete ☐ incomplete	
	8.5.1 summary document of official control system, legislation, regulation or quality and standard requirements as in 8.5		☐ yes ☐ none	☐ complete ☐ incomplete	
	8.5.2 documents/ information of approval (if any)		☐ yes ☐ none	☐ complete ☐ incomplete	
	8.5.3 Information of legislation, regulations, or quality or standard requirements relevant to applying material of manufacturing country or the country to be referred(if any)		☐ yes ☐ none	☐ complete ☐ incomplete	
8.6	Test report of quality and standard analysis in accordance with legislation, regulation or quality and standard requirements of the	Report of safety assessment or recommendation from safety assessment agency in countries such as ☐ South Korea ☐ Canada ☐ EU or (specified country).....	☐ yes ☐ none	☐ complete ☐ incomplete	

Details of document or evidence checking (Part 2)					
No.	**Item of document**	**Additional explanation**	Checked by the applicant	Verified by an official	Incompleteness recorded
	manufacturing or aforementioned reference country	☐ USA ☐ Japan ☐ Australia-New Zealand ☐ Others (specify)			
8.7	One set CD-ROM contained supporting documents and evidences for consideration		☐ yes ☐ none	☐ complete ☐ incomplete	
8.8	I have intention for confidential keeping of data/evidence in a number of .....pages (if any)		☐ 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.

I do hereby certify that supporting evidence documents for consideration of quality or standard and 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 ..... Applicant/authorized person

(.....)

Part 3 Checking result of completeness of supporting documents

For applicant 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. Sign .....an applicant/authorized person (.....) Date.....time..... ☐ Request to return supporting documents for consideration of quality or standard and safety assessment 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 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(3) ☐ Incomplete documents and the applicant request to return the supporting documents for consideration 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 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 a checking officer..... (.....) 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 a checking officer..... (.....) Date .....time.....

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

For applicant 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 .....an applicant/authorized person (.....) Date.....time..... ☐ Sign to accept checking result of the completeness of supporting documents. Sign .....an applicant/authorized person (.....) Date.....time..... ☐ Request to return supporting documents for consideration of quality or standard and safety assessment 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 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.....	2nd time (1st round of submission to correct the defects) ***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(3) ☐ Incomplete documents and the applicant request to return the supporting documents for consideration 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 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. Sign by a checking officer..... (.....) 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 a checking officer..... (.....) Date .....time.....

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

For applicant 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 correcting or additional documents in the number of.....items as specified in the incompleteness recorded form. Sign .....an applicant/authorized person (.....) Date.....time..... ☐ Sign to accept checking result of the completeness of supporting documents. Sign .....an applicant/authorized person (.....) Date.....time..... ☐ Request to return supporting documents for consideration of quality or standard and safety assessment Sign .....an applicant/authorized person (.....) Date.....time.....	3rd time (2nd round of submission to correct the defects) ***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(3) ☐ Incomplete documents and the applicant request to return the supporting documents for consideration of safety assessment. ☐ 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. Sign by a checking officer..... (.....) 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 a checking officer..... (.....) Date .....time.....

Part 4 Additional explanation relevant to supplementing information for consideration of quality or standard and safety assessment of container that use of substance or chemical that affect nature of food contained in such the container

1. Information of legislation, regulation to be referred: updated versions of legislation, regulation or quality or standard requirements, which relevant to materials used to manufacture or food containers/food contact materials of a manufacturing country or of a country having reliable system of safety assessment presenting permission or approval for use of applying plastic to manufacture food packaging or food contact materials such as EU or USA.

2. Test report of quality or standard in accordance with legislation, regulation or quality or standard requirements of a manufacturing country or referred country shall be original, validity not exceed 1 year from the reporting date which tested by agency or organization prescribed in the Announcement of the Food and Drug Administration regarding Prescribed government agency or institute for testing of food packaging, feeding bottles and milk containers for infants and young children, dated 26th October B.E 2558.

3. Information about toxicity studies for safety assessment of substance supplementing for application may refer to guidelines for ENVIRONMENTAL HEALTH CRITERIA 240 : Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009), or Guidance for Industry and Other Stakeholders Toxicological Principles for the Safety Assessment of Food Ingredients (Redbook 2000), or Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations (September 1999; April 2002), or Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food (June 2006), etc.

4. Other documents as necessary such as

4.1 Recognized and reliable technical recommendations from internationally recognized agency, organization or scientific body such as Codex Scientific committee, European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN), or Food Standard Australia New Zealand (FSANZ), etc.

4.2 Peer-reviewed published articles that can be searched via reliable data base such as Elsevier (Science direct, Embase, Scopus), The Cochrane Library, Pubmed, BIOSIS, TOXNET, NAPRALERT, Thai-journal citation index centre or Food Safety Authority of foreign countries, etc.