

Application form for quality or standard and safety assessment of material used for feeding bottle and milk containers for infant and young children which its materials have not been prescribed under Notification of Ministry of Public Health (No.369) B.E. 2558

Re: Feeding bottle and milk containers for infant and young children

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

Re: Request to assess quality or standard and safety of other materials used for feeding bottles and milk containers for infant and young children

To: Secretary General of Food and Drug Administration

Since I am.....on behalf of (Company/Partnership/Shop)..... operate business to  produce  import feeding bottles and milk containers for infant and young children in accordance with Notification of Ministry of Public Health (No.369) B.E. 2558, Re: Feeding bottles and milk containers for infant and young children with license No..... to operate the business relate to feeding bottles and milk containers for infant and young children.

others, please specify.....

intend to assess specification and safety of other materials used for feeding bottles and milk containers for infant and young children which have not been prescribed in the aforesaid Notification as follows:

1. Feeding bottles

Item	Trade mark/Brand (if any)	type of materials(specify)
<input type="checkbox"/> feeding bottles Containing size.....	.....	..... .....
<input type="checkbox"/> protective cover	.....	..... .....
<input type="checkbox"/> locking ring	.....	..... .....

Item	Trade mark/Brand (if any)	type of materials(specify)
<input type="checkbox"/> feeding teat	.....	..... .....
<input type="checkbox"/> sealing disc	.....	..... .....
<input type="checkbox"/> .....	.....	..... .....

2. Reused milk containers for infants and young children

Item	Trade mark/Brand (if any)	Type of materials(specify)
<input type="checkbox"/> sippy cup Composed of .....	.....	..... ..... ..... .....
<input type="checkbox"/> ..... Composed of	.....	..... ..... ..... .....

Note: If a container composesof many parts, each part shall be specified such as a sippy cup composed of cup, lid and straw as well as materials of each component shall also be specified.

3. Disposable milk container for infants and young children

Item	Trade mark/Brand (if any)	Type of materials(specify)
<input type="checkbox"/> plastic bag for breast milk storing	.....	..... .....
<input type="checkbox"/> .....	.....	..... .....

By having information of manufacturers of material or plastic and of feeding bottles molding and milk containers for infants and young children as follows:

Name and address of manufacturers of material or plastic.....

.....  
.....

Name and address of manufacturers of feeding bottles molding and milk containers for infants and young .....  
.....

So evidence documents and information are submitted in accordance with form of quality or standard and safety assessment for other materials used for feeding bottles and milk containers for infant and young children are enclosed with all details for supporting to request for the approval from the Food and Drug Administration for further consideration of its qualities or standards that having the following details as attachments.

Picture of colors of feeding bottles or milk containers for infant and young children (1 picture)

Sample of feeding bottles or milk containers for infant and young children

Documents/evidences relevant to materials used in manufacturing as follows (*data shall be filled in the Form or relevant documents shall be attached*)

Document presenting name and information of materials or plastic used for manufacturing of feeding bottles and milk containers for infant and young children (*1<sup>st</sup> order document*)

Document presenting name list and information of chemical used for preparation of materials or plastics (*2<sup>nd</sup> order document*)

Document presenting specification or properties of the chemicals used for preparation of materials or polymers (*3<sup>rd</sup> order document*)

Document presenting process flow diagram: material or plastic preparation (*4<sup>th</sup> order document*)

Document presenting information of specification or properties of material or plastics (*5<sup>th</sup> order document*)

Document presenting process flow diagram: molding process of the feeding bottles or milk containers for infants and young children (*6<sup>th</sup> order document*)

Document presenting name list and information of chemicals used in molding of the feeding bottles or milk containers for infants and young children (*7<sup>th</sup> order document*)

Document presenting summary of information of property or information relevant to characteristic or condition of usage the feeding bottles or milk containers for infants and young children (*8<sup>th</sup> order document*)

Evidenced document relevant to information of approval, legislation, regulation or quality and standard requirements relevant to material used/ the feeding

bottles or milk containers for infants and young children of manufacturing country or of country to be referred together with summary of official control legislation, regulation or quality and standard requirements aforementioned. (9<sup>th</sup> and 10<sup>th</sup> order document)

Test report of quality or standard analysis in accordance with legislation, regulation or quality and standard requirements of the manufacturing or aforementioned reference country.

Other documents as necessary (if any).

.....

One copy of a license for conducting factory business or

One copy of a company limited registration certificate

Letter of power of attorney (if any)

Regards,

(sign)..... Applicant  
(.....)

Form No. 1 name and information of materials or plastics used for feeding bottles  
and milk containers for infants and young children

name and information of materials or plastics used for feeding bottles and milk containers for infants and young children	
item	Details
Common Name	
Chemical name (IUPAC system)	
Synonyms	
CAS Registry Number	
Trade Name	
Chemical formula	
Chemical structure	
<p><i>Note</i></p> <p>1. If it is copolymer, type and ratio of monomer used in reaction shall be specified.</p> <p>2. If it is polymer blends, types and ratio of the blends shall be specified.</p> <p>3. If it is novel materials or plastics which chemical structure not be able to present, representative chemical structure can be presented instead; and number average molecular weight (<math>M_n</math>) and weight average molecular weight (<math>M_w</math>) shall be specified.</p>	
Molecular weight	

Name and address of material manufacturer

.....  
 .....

Note: if use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows: .....

.....  
 .....

(sign).....Applicant

(.....)

## Form No. 2 Name list and information of chemical used for preparation of materials or plastics

**Name list and information of chemical used for preparation of materials or plastics**

Specify list of all chemicals used for preparation of materials or plastics such as monomers, additives, polymer production aids, solvents, catalyst.

*Note* If it is polymer blends, list of all chemicals used shall be specified in accordance with each type of polymer blend

Name of chemical (IUPAC system)	CAS Registry Number	function	Usage content (%)

(sign).....Applicant

(.....)

Form No. 3 Information of specification or properties of chemicals used for preparation of materials or polymers

Submitted materials or polymers to be assessed having list of all chemicals used for preparation of materials or polymers in a number of varieties.....include		
Name of the chemicals	Specification/property (physical/chemical)	value

Note - Specification/Properties such as density, viscosity, melting point, maximum impurity level, solubility in food simulants, glass transition point, Melt Flow Index, etc.

- If use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows: .....

.....

(sign).....Applicant

(.....)

Form No.4 Production process : Preparation process of materials or plastics

**Preparation process of materials or plastics**

(presenting preparation process including chemical reaction or equation; condition of chemical reaction in each step)

*Note*

1. If it is copolymer, monomer and its ratio used in reaction shall be specified.
2. If it is polymer blends, types and ratio of polymer blended shall be specified.

Note If use of attachments instead of filling details in a Form, please mark ✓ in  together with documents specified

Documents attached as follows: .....

(sign).....Applicant

(.....)



Form No.5 Information of specification or properties of materials or plastics

Name of materials or plastics.....

Specification/properties (Physical/Chemical )	value

Note - Specification/Properties such as density, viscosity, melting point, maximum impurity level, solubility in food simulants, glass transition point, Melt Flow Index, etc.

- If use of attachments instead of filling details in a Form, please mark ✓ in  together with documents specified

Documents attached as follows: .....

.....

(sign).....Applicant

(.....)

Form No. 6 process flow diagram: molding process of the feeding bottles or milk containers for infants and young children

Molding process of feeding bottles or milk containers for infants and young children

*Note: If use of colors, additives, polymer production aids, step of their use shall also be specified.*

Name and address of material manufacturers.....  
.....

Note If use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows:.....  
.....

(sign).....Applicant

(.....)

Form No. 7 Name list and information of chemicals used in molding of feeding bottles or milk containers for infants and young children

Name list and information of chemicals used in molding process of feeding bottles or milk containers for infants and young children

Specify list of chemical name used in molding process of feeding bottles or milk container for infants and young children such as materials or plastics including additives, polymer production aids, solvents, catalyst and color. (if any)

Table with 4 columns: Chemical name (IUPAC system), CAS Registry Number, Function, Usage content (%). The table contains 12 empty rows for data entry.

Note: - If use of attachments instead of filling details in a Form, please mark ✓ in ☐ together with documents specified

☐ Documents attached as follows:

.....

(sign).....Applicant

(.....)

Form No. 8 Summary of information of property or information relevant to characteristic or condition of usage  
the feeding bottles or milk containers for infants and young children

Usage characteristics (reusable/disposable)	Food varieties to be contained	Usage condition (Specify maximum-minimum temperature and in use maximum duration)
Recommendation for usage (if any)		

Note: - If use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows: .....

.....

(sign).....Applicant

(.....)

Form No. 9 Summary of official control, legislation, regulation, or quality and standard requirements relevant to material used to manufacture the feeding bottles or milk containers for infants and young children of manufacturing country or of country to be referred

Materials used in manufacturing	
Competent agency in charge of official control or authorization for legislation, regulation or quality and standard requirements relevant to material used to manufacture of manufacturing country or of country to be referred	Name of legislation, regulation or quality and standard requirements*
Document/information of approval (if any)	
Document/information submitted for safety assessment of materials for approval by manufacturing country or country to be referred. (if any)	

**Note - \*Please attach information of approval, legislation, regulations, or quality and standard requirements. Requirements relevant to materials submitted as specified in attached legislation, regulations shall also be summarized, specified or indicated.**

- If use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows:.....  
 .....

(sign).....Applicant

(.....)

Form No. 10 Summary of official control system, legislation, regulation or quality and standard requirements relevant to material used to manufacture the feeding bottles or milk containers for infants and young children of manufacturing country or of country to be referred

Feeding bottles or milk containers for infants and young children	
Competent agency in charge of official control or authorization for legislation, regulation or quality and standard requirements relevant to the feeding bottles or milk containers for infants and young children of manufacturing country or of country to be referred	Name of legislation, regulation or quality and standard requirements*
Document/information of approval (if any)	
Document/information submitted for safety assessment of materials for approval by manufacturing country or country to be referred. (if any)	

**Note - \* Please attach information of approval, legislation, regulations, or quality or standard requirements. Requirements relevant to materials submitted as specified in attached legislation, regulations shall also be summarized, specified or indicated.**

- If use of attachments instead of filling details in a Form, please mark  in  together with documents specified

Documents attached as follows: .....

(sign).....Applicant

(.....)

Preliminary Checklist supplementing for consideration of quality or standard and safety assessment of material used for feeding bottle and milk containers for infant and young children which its materials have not been prescribed under the Notification of Ministry of Public Health (No.369) B.E. 2558, Re: Feeding bottle and milk containers for infant and young children supporting for consideration of approval by the Food and Drug Administration

**Part 1 General information**

<p><b>Details of an applicant</b>                  Name –last name of the applicant/authorized person.....tel.....                  E-mail .....name of premise .....                  Operate business of <input type="checkbox"/> producing <input type="checkbox"/> import feeding bottle and milk containers                  License No. of business relevant to feeding bottle and milk containers for infant and young children.....                  .....  <input type="checkbox"/> Other, please specify.....  <b>address for document delivery (if any)</b>                  No..... Building ..... Moo..... Trok/soi.....                  street..... tambol/subdistrict..... ampoe/district.....                  Province..... Tel.....</p>	<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>
<p><b>Details of submitted materials</b>  <b>Variety No.1</b>                  Name of material.....(Thai)                  Name of material.....(English )                  Used for : <input type="checkbox"/> Feeding bottle (please specify <input type="checkbox"/> protective cover <input type="checkbox"/> locking ring <input type="checkbox"/> feeding teat <input type="checkbox"/> sealing disc)  <input type="checkbox"/> Milk containers for infant and young children reused type, please specify.....  <input type="checkbox"/> Milk containers for infant and young children disposable type, please specify.....</p>	
<p><b>Variety No.2 (if any)</b>                  Name of material.....(Thai)                  Name of material.....(English )                  Used for : <input type="checkbox"/> Feeding bottle (please specify <input type="checkbox"/> protective cover <input type="checkbox"/> locking ring <input type="checkbox"/> feeding teat <input type="checkbox"/> sealing disc)  <input type="checkbox"/> Milk containers for infant and young children reused type, please specify.....  <input type="checkbox"/> Milk containers for infant and young children disposable type, please specify.....</p>	

**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				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
1.	Two copies of application forms for safety assessment of quality or standard and safety assessment of material used for feeding bottle and milk containers for infant and young children which its materials have not been prescribed under the Notification of Ministry of Public Health (No.369) B.E. 2558, Re: Feeding bottle and milk containers for infant and young children supporting for consideration of approval by the Food and Drug Administration	<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 with signature of certifying	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
3.	One copy of Commercial Registration or of Certificate of Objective of Legal Entity Registration and Authorized officer on behalf of legal entity ( in case of legal entity) and with signature of certifying	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
4.	One copy of license of conducting factory business (in case of manufacturer) with signature of certifying	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
5.	One certifying copy of 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 copy of identification card of grantor and proxy with signature of certifying	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
6.	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	
7.	One set of supporting documents for considering quality or standard and safety assessment with the following details:	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.1 Name and address of material or plastic producer	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.2 Name and address of molding manufacturer of feeding bottle or milk container for infant and young children	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.3 One Picture of colors of feeding bottles or and milk containers for infant and young children	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.4 Sample of feeding bottles and milk containers for infant and young children	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	



Details of document or evidence checking				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
	7.5 Documents/evidences relevant to materials used in manufacturing of feeding bottles and milk containers for infant and young children (1 <sup>st</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.1 Common chemical name	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.2 Chemical name (IUPAC system)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.3 Other Synonyms	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.4 CAS Registry Number	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.5 Trade Name	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.6 Chemical formula	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.7 Chemical structure	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.5.8 Molecular weight	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.6 Document presenting name list and information of all chemicals used for preparation of materials or plastics (2 <sup>nd</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.7 Document presenting specification or properties of chemicals used for preparation of materials or polymers (3 <sup>rd</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.8 Document presenting production process : Preparation process of material or plastic preparation (4 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.9 Document presenting information of specification or properties of materials or plastics (5 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.10 Document presenting production process : Molding process of feeding bottles or milk containers for infants and young children (6 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.11 Document presenting name list and information of chemicals used in molding of feeding bottles or milk containers for infants and young children (7 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.12 Document presenting summary of information of property or information relevant to characteristic or condition of usage the	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

Details of document or evidence checking				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
	feeding bottles or milk containers for infants and young children (8 <sup>th</sup> order document)			
	7.12.1 usage characteristic	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.12.2 food type to be contained	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.12.3 usage condition	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.12.4 Recommendation for usage (if any)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.13 Information of approval, legislation, regulation or quality and standard requirements relevant to material used of manufacturing country or of country to be referred (9 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.13.1 summary document of official control system, legislation, regulation or quality and standard requirements as in 7.13	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.13.2 Documents/information of approval (if any)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.13.3 Document/information of submission for safety assessment of materials for approval from manufacturing country or the country to be referred (if any) such as <input type="checkbox"/> South Korea <input type="checkbox"/> Canada <input type="checkbox"/> EU or (specified country))..... <input type="checkbox"/> USA <input type="checkbox"/> Japan <input type="checkbox"/> Australia-New Zealand <input type="checkbox"/> Others (specify) .....	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.14 Information of legislation, regulations, or quality or standard requirements relevant to feeding bottles or milk containers for infants and young children of manufacturing country or the country to be referred (10 <sup>th</sup> order document)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.14.1 summary document of official control system, legislation, regulation or quality and standard requirements as in 7.14	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.14.2 Documents/information of approval (if any)	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
	7.14.3 Document/information of submission for safety assessment of materials for approval from manufacturing country or the country to be referred (if any) such as	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	

Details of document or evidence checking				
No.	Item of document	Checked by the applicant	Verified by an official	Incompleteness record
	<input type="checkbox"/> South Korea <input type="checkbox"/> Canada <input type="checkbox"/> EU or (specified country))..... <input type="checkbox"/> USA <input type="checkbox"/> Japan <input type="checkbox"/> Australia-New Zealand <input type="checkbox"/> Others (specify) .....			
	7.15 Test report of quality and standard analysis in accordance with legislation, regulation or quality and standard requirements of the manufacturing or aforementioned reference country	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
8.	One set CD-ROM contained supporting documents and evidences for consideration	<input type="checkbox"/> yes <input type="checkbox"/> none	<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
9.	I have intention for confidential keeping of data/evidence in a number of .....pages (if any)	<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.

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
<p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u></p> <p><b><u>Part 1 Submission the application and evidenced documents</u></b></p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of supporting documents.</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for consideration of quality or standard and safety assessment 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 <b><u>within 15 working days</u></b> from the day after the date of receiving the application (from date.....to date.....)</p> <p><b><u>If it is overdue, cancellation and return of the application and evidenced documents can be undertaken.</u></b></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 2 item 2.2(3)</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the supporting documents for consideration of safety assessment.</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 <b><u>within 15 working days</u></b> from the day after the date of receiving the application (from date.....to date.....) if it is overdue, the application will <b><u>be terminated and further returned</u></b> (the applicant shall be informed by signing and receive a copy)</p> <p>notify to proceed. ....</p> <p>.....</p> <p>.....</p> <p>Sign by a checking officer..... (.....)</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>Sign by a checking officer..... (.....)</p> <p>Date .....time.....</p>

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

For 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 .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of supporting documents.</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for consideration of quality or standard and safety assessment 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 <b>15 working days</b> from the day after the date of receiving 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>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 evaluation as in List 2 item 2.2(3)</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the supporting documents for consideration of safety assessment.</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 <b>within 15 working days</b> from the day after the date of receiving the application (from date.....to date .....) if it is overdue, the application will <u>be terminated and further returned</u> (the applicant shall be informed by signing and receive a copy) notify to proceed. ....</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. 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>Sign by a checking officer..... (.....)</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>Sign by a checking officer..... (.....)</p> <p>Date .....time.....</p>

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

For applicant only	For official only
<p><u>3<sup>rd</sup> time (2<sup>nd</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 .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of supporting documents.</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for consideration of quality or standard and safety assessment</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p>	<p><u>3<sup>rd</sup> time (2<sup>nd</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 evaluation as in List 2 item 2.2(3)</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the supporting documents for consideration of safety assessment.</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>Sign by a checking officer..... (.....)</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>Sign by a checking officer..... (.....)</p> <p>Date .....time.....</p>

Part 4 Additional explanation relevant to supplementing information for consideration of quality or standard and safety assessment of material used for feeding bottle and milk containers for infant and young children which its materials have not been prescribed under the Notification of Ministry of Public Health (No.369) B.E. 2558, Re: Feeding bottle and milk containers for infant and young children supporting for consideration of approval by the Food and Drug Administration

1. Information of legislation, regulation to be referred : updated versions of legislation, regulation or quality or standard requirements, which relevant to feeding bottles or milk containers for infants and young children of a manufacturing country or of a country having reliable system of safety assessment presenting permission or approval for use of a particular material to manufacture feeding bottles or milk containers for infants and young children or 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 26<sup>th</sup> October B.E 2558.

3. Other documents as necessary such as

3.1 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.

3.2 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.