Public manual: Application for Permission of a product and correction of permitted items: for food other than specific controlled food, food supplements, royal jelly and its products, cow's milk, flavored milk, fermented milk, dairy products, ice-cream, beverages in sealed containers, food in sealed containers and food for special purpose.

Service agency: Food and Drug Administration, Ministry of Public Health.

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Criteria, Procedure, Conditions (if any) for application and consideration of permission

Criteria

1. Products shall be the following food categories:

1.1 Food prescribed qualities and standards and required food registration include 100% coffee (Coffee that not mixed with other ingredients)*, edible salt, vitamin fortified rice, alkalized egg, cream, chocolate, tea, herbal tea, some kinds of sauces, ice, soya milk in sealed containers**, drinking water in sealed containers, fish sauce, honey**, peanut oil, butter oil, palm oil, coconut oil, fat and oil, mineral water, vinegar, butter, cheese, ghee, food seasoning derived from hydrolysis or fermentation of soybean protein, jam, jelly and marmalade, semi- processed food, brine for cooking, margarine, blends, fat spread and blended fat spreads.

1.2 Food required label includes bread, sauces in sealed containers, husked rice flour, meat products, flavoring agents, premixed gelatin and jelly dessert, chewing gum and candy, ready to cook food and ready to eat food.

1.3 General food ***includes meat and meat products, plant and products, flour and its products, seasonings, sugar, spices, not ready to eat products for cooking. Note:

* exclude mixed coffee, instant mixed coffee, ready-to-drink coffee

** In case not recognized as a factory, application for a number of food production premise (SorBor.1 Form) and food registration (SorBor.5 Form) are not required, but the premise shall be followed Notification of Ministry of Public Health (No.342) B.E.2555 (2012) Re: Production Processes, Production Equipment, and Storage of processed food contained in ready-to-sell containers. If producer not recognized as a factory intends to receive a food serial number, the application forms for receiving a number of production premise (SorBor.1 Form) and Food Registration (SorBor.7 Form) may also be submitted.

*** General food which production premise has passed inspection according to Notification of Ministry of Public Health regarding Production Processes, Production Equipment, and Storage of a particular food and intend to present a food serial number.

2. Applying product

2.1 Shall previously have permission for production or import premise of the applying product and its license still valid. The food production premise shall also be complied with Good Manufacturing Practice according to the relevant Notifications of Ministry of Public Health.

2.2 Shall not be recognized as a food for special purpose according to Notification of Ministry of Public Health regarding food for special purpose (see additional details in Public Manual regarding

application for permission of a product and correction of permitted items: for food for special purpose).

2.3 Shall not be in a scope of novel food and food contained novel ingredients (see details in Public Manual regarding Application for safety assessment).

2.4 Shall have quality or standards according to a particular Notification of Ministry of Public Health and other relevant Notifications of Ministry of Public Health. The product shall have details of 100% ingredients of its recipe and its production process shall be complied with the recipe and a particular Notification of Ministry of Public Health together with qualities or standards of raw materials (if any) as data kept at a premise.

2.5 Qualities and standards prescribed Food as in (1) shall have data of analysis result of quality or standards which complied with a particular Notifications of Ministry of Public Health performed by internationally recognized official or private testing laboratory at least equal to ISO 17025 to be kept at the premise.

2.6 In case use of food additives shall be as follows:

2.6.1 Notification of Ministry of Public Health regarding a particular food such as use of food additive in jam jelly and marmalade in sealed containers, criteria of food additive prescribed in an annex of the Notification regarding jam jelly and marmalade in sealed containers shall be implemented.

2.6.2 Notification of Ministry of Public Health regarding food additives for products which their annexes of Notification relevant to use of food additives are not listed, such as use of food additives in cheese, semi-processed food, etc.

2.7 No use of prohibited substances to use in food and/or food prohibited to produce, import or sell according to relevant Notifications of Ministry of Public Health.

3. A product with health claim shall be assessed according to Public Manual regarding Application for Health claim assessment.

4. Food products contained other things or other objects that are not food in the packaging or container shall be followed the Notification of Ministry of Public Health regarding prescribed prohibited food packed with other things or objects which are in the food packages to be produced, imported or sold.

5. Use of food containers shall be complied with Notification of Ministry of Public Health regarding prescription of quality or standard for food containers, use of food containers and prohibition of use of things as food containers and use of plastic containers/colored plastic covers contacted with liquid or semi-solid food (excluding use of colored plastic for water contained in sealed containers) shall also have data of analysis report of colored plastic kept at the premise according to Notification of Ministry of Public Health regarding qualities or standard for container made from plastic.

6. Entitling of food name or brand or trademark or registered trademark shall be followed Notification of Ministry of Public Health regarding Labeling of prepackaged food and other specific relevant Notifications of Ministry of Public Health. See details at Bureau of Food web site http://food.fda.moph.go.th/data/news/255/590621 auto e/3 TheNaming.pdf

7. Food labeling shall be complied with Notification of Ministry of Public Health regarding labeling of prepackaged food and other specific relevant Notifications of Ministry of Public Health.

8. Nutrition labeling shall be complied with Notification of Ministry of Public Health regarding nutrition labeling and shall have data of analysis report kept at the premise.

9. Displaying of nutrition symbol on label shall be complied with Notification of Ministry of Public Health regarding the display of nutrition symbol on food label.

Conditions

(If applying at the Provincial Health Office, its Public Manual shall be applied.)

An applicant shall be a business operator or an authorized director of a legal entity or an authorized person (in case of applying via internet (E-Submission), he or she shall apply for Open ID from the Digital Government Development Agency (Public organization) (DGA), study procedure in Manual of User account at Open ID website and having permission to access a food system from the Food and Drug Administration or Provincial Public Health Office. See these details in Manual for E- submission) http://food.fda.moph.go.th/59004_AutoE-Sub.php

An applicant shall evaluate his/her product for compliance with law by own self and be able to give details relevant to applying products by answering screening questions related to the product via E-submission system

In case of applying for a new food serial number, data shall be filled in Form for Registration/Notification of food (SorBor.7 Form) via E-submission system at http://food.fda.moph.go.th/esubmission/

In case of applying for correction of details of food already received a food serial number by Form for Registration/Notification of food (SorBor.5 Form), an applicant shall arrange a Correction Form of details of registered/notified food (SorBor.6 Form) and supplementary documents, check details as in checklist, type accurate and complete data including other supplementary documents and sign by a licensee of permitted premise as indicated in a license or authorized director of a legal entity or an authorized person as in the Commercial Registration.

In case of applying for correction of details of food already received a food serial number by Form for Registration/Notification of food (SorBor.7 Form), an applicant shall submit document via internet system by filling in the correction form of details of registered food/notified food (SorBor.8 Form) at http://food.fda.moph.go.th/data/news/2559/590621_auto_e/7_ManualAutoE-Sub_N.pdf

In case of product details are not clear or not consistent with data specified in an application form, product samples or evidenced document relevant to the product such as food recipe, production method, purpose of use, method of consumption or use, dose for consumption or limit of use, container, storage, food label, etc. shall be provided for additional explanation when considering the application.

In case of complicated product or overlapping with relevant regulations, it shall be considered by working group/committee/or experts; therefore, its duration will be increased from the specified duration in this manual about 15 - 45 working days as the case maybe. In case of the application form or documents are not complete and/or having noncompliance leading to unable to consider, an officer will notify the applicant about noncompliance of documents or additional evidences to be submitted. The applicant shall correct or submit the additional documents within a specified duration, otherwise it will be deemed as the applicant discard the application.

the submitted application form order from 1 to 200 will be considered by the Bureau of Food for duration of 1 working day. Other orders will be proceeded on the next working day.

Channel for service

Venue for service	Working hour 24 hrs.
(Note: <u>http://food.fda.moph.go.th/esubmission/</u> for submission	
of SorBor.7 Form and correction of SorBor.8 Form)	
At website of Bureau of Food /website and online channel) 🥒	
Venue for service	Working hour open on
(Note: in case of submission for correction of SorBor.6 Form)	Monday through Friday
At One Stop Service Center (OSSC) on the 5 th floor of the	(except for official holiday)
Building 6	from 8.30 am to 4.30 pm
88/24 Ministry of Public Health, Tiwanon road, Nonthaburi	(break at lunch time)
11000	
or at a Provincial Health Office/ Contact by yourself at the	
agency	

Step, Duration and Responsible section

Total duration of proceeding: 1 to 2 working days

No.	Step	Duration	Responsible section
1)	-	0 min	-
	1. An applicant shall prepare documents and		
	information.		
	(Note: -)		
2)	-	0 min	-
	2. An applicant pay for application fee.		
	(note: a receipt is issued via internet or at the		
	counter of an agency)		
3)	-	0 min	
	3. Submit an application		
	(note: -)		
4)	Checking of documents	1 min	Bureau of Food
	Preliminary check documents and information		
	via E-submission (Note: (in case of submission of		
	SorBor.6 Form, an applicant shall contact at		
	responsible agency as an indicated channel of		
	submission (take 5 mins.)))		
5)	Checking of documents	15 mins	Bureau of Food
	Verification of accuracy and completeness of the		
	application and evidenced documents via E-		
	submission (Note: (in case of submission of		
	SorBor.6 Form, an applicant shall contact at		
	responsible agency as an indicated channel of		
	s <mark>ub</mark> mission (take 5 mins.)))		
6)	Signature/Having solution from a committee	7 mins	Food and Drug
	Consider to sign via E-submission		Administration
	(Note: (result of consideration is informed and		
	the applicant immediately receive evidence via		
	the system))		
7)	Checking of documents	5 mins	Bureau of Food
	Consider to sign (Note: (in case of submission for		
	correction SorBor.6 Form and supplementary		
	document by yourself (contact an agency as a		
	channel submitted)))		
8.	-	5 mins	Bureau of Food
	Record data		

No.	Step	Duration	Responsible section
	(Note: (in case of submission for correction		
	SorBor.6 Form and supplementary document by		
	yourself (contact an agency as a channel		
	submitted)))		

Items of documents and supplementary evidences

No.	Name and a number of documents and additional details	Government agency
	(if any)	issued the documents
1)	In case of applying for new Food Serial Number by SorBor.	
	7 Form, the following documents are required	
	Original document 0	
	Copy of document 0	
	Note (in case of submission at a province, the Public Manual	
	of a Provincial Health Office shall be applied)	
	1. Certificate of Organic from government agency or	
	agencies certified by government agency or international	
	certification bodies such as IFOAM (The International	
	Federation of Organic Agriculture Movements) National	
	Bureau of Agricultural Commodity and Food Standards	
	Original document 0	
	Copy of document 1	
	Note (if use word of "Organic" "Organic farming" "Natural	
	agriculture" or other words with similar meanings with name	
	of food is associated, and the copy of the document shall be	
	"truly certified by signing")	
	2. Documents or evidence in accordance with the	
	Notification of Ministry of Public Health (No.365) B.E. 2556	
	Re: Premium Labeling	
	Original document 0	
	Copy of document 1	
	Note (if use word of "Premium" with name of food is	
	associated and the copy of the document shall be "truly	
	certified by signing")	
2)	In case of Correction details of food which has been	
	registered/notified as in SorBor.5 Form, the following	
	documents are required	
	Original document 0	
	Copy of document 0	
	Note (in case of submission at a province, Public Manual of	

No.	Name and a number of documents and additional details	Government agency
	(if any)	issued the documents
	the Provincial Health Office shall be applied)	
	1. Form for correction details of food which has been	Bureau of Food
	registered/notified (SorBor. 6 Form)	
	Original document 2	
	Copy of documents 0	
	Note (shall be typed only and signed by the operator as in	
	the license or authorized director of a legal entity)	
	2. Checklist of SorBor.6 Form	Bureau of Food
	Original document 1	
	Copy of document 0	
	Note -	
	3. Evidence presenting current permission of a premise	Bureau of Food
	from the Food and Drug Administration or a Provincial	
	Health Office as the case maybe;	
	Original document 0	
	Copy of document 1	
	Note (make a copy of both front and back side and shall be	
	"truly certified by signing")	
	-In case of production food premise not recognized as a	
	factory (SorBor. 1 Form) and if having correction food	
	production premise (SorBor. 2 Form).	
	- In case of recognized as factory, food production license	
	(Orr.2 Form).	
	-In case of import, License for import or bringing into the	
	Kingdom (Orr.7 Form))	
	4. Copy of SorBor.5 Form and SorBor.6 Form has been	Food and Drug
	permitted to correct (if any) submitted to correct	Administration
	Original document 0	
	Copy of document 1	
	Note (The copy shall be "truly certified by signing" from the	
	operator as in the license or authorized director of a legal	
	entity or authorized person)	
	5. Original document indicated reason of correction of	
	name/ location of food production premise, in case of	
	correction of name/location of food production premise.	
	Original document 1	
	Copy of document 0	
	Note (In case of import, if it is a copy of document, it shall	
	I note the case of import, if it is a copy of document, it shall	

No.	Name and a number of documents and additional details (if any)	Government agency issued the documents
	be "truly certified by signing" from the operator as in a	
	license or authorized director of a legal entity or authorized	
	person)	
	6. Power of Attorney	Bureau of Food
	Original document 0	
	Copy of document 1	
	Note (If an applicant submit application at the Food and Drug	
	Administration and he/she is not a business operator as in a	
	license or authorized director of a legal entity, the copy has	
	been checked and verified by an officer of Bureau of Food	
	and shall be "truly certified by signing" from the officer).	
	7. Identification card	Department of
	Original document 0	Provincial
	Copy of document 1	Administration
	Note (shall be "truly certified by signing")	
	8. Document relevant to applying product	Bureau of Food
	Original document 1	
	Copy of document 0	
	Note (In case of product details are not clear or not consistent	
	with information indicated in an application form, product	
	sample or evid <mark>ence</mark> documents relevant to the product shall be	
	provided such as food recipe, production method, purpose of	
	use, method of consumption or use, dose for consumption or	
	limit of use, container, storage, food label, etc.)	
3)	In case of applying for correction of product with SorBor. 8	Bureau of Food
	Form by E-submission	
	Original document 0	
	Copy of document 0	
	Note (In case of applying for correction of a product in regional	
	area, an applicant can contact Provincial Health Office)	
	1. Attach file of document described reason of correction	
	food name or brand or location of food production	
	premise, if correction of name or location shall be an	
	original document from a producer	
	Original document 1	
	Copy of document 0	
	Note (supplement to applying SorBor. 8 Form as the case of a	
	particular correction maybe.)	

FEE		
No.	Details of Fee	Fee (Bath/percentage)
1)	Fee for consideration of application for food registration /notification (SorBor.7) (Note: (Order of Head of NCPO No.77/2559, Re: Increasing the Efficiency of Health Products Approval Process (by the virtue of Article 44 under the constitution of the Kingdom of Thailand) effects to application fee for food approval shall be paid by food business operators and the Notification of Ministry of Public Health, Re: Official fees in food approval process to be paid by applicants (B.E. 2560) dated 26 th July B.E.2560))	200 Bath
2)	Fee for consideration of application for correction details of registered/notified food (SorBor.6)(SorBor.8) (Note: (Order of Head of NCPO No.77/2559, Re: Increasing the Efficiency of Health Products Approval Process (by the virtue of Article 44 under the constitution of the Kingdom of Thailand) effects to application fee for food approval shall be paid by food business operators and the Notification of Ministry of Public Health, Re: Official fees in food approval process to be paid by applicants (B.E. 2560) dated 26 th July B.E.2560))	200 Baht
3)	Fee for consideration of application for registration/notification of food details referred to former approved recipes and production methods (condition under Notification of Ministry of Public Health, Re: Official fees in food approval process to be paid by applicants (B.E. 2560) dated 26 th July B.E.2560) (Note: (Order of Head of NCPO No.77/2559, Re: Increasing the Efficiency of Health Products Approval Process (by the virtue of Article 44 under the constitution of the Kingdom of Thailand) effects to application fee for food approval shall be paid by food business operators and the Notification of Ministry of Public Health, Re: Official fees in food approval process to be paid by applicants (B.E. 2560) dated 26 th July B.E.2560))	60 Baht

Channel for complaint and service suggestion

No.	Channel for complaint/ service suggestion
1)	Complaint and Enforcement Management Center

No.	Channel for complaint/ service suggestion		
	(Note: (Food and Drug Administration, 1^{st} floor Building 1 Tiwanon Road, Talardkwan		
	Subdistrict, Muang District, Nonthaburi Province, 11000 Tel. 025907354-55))		
2)	Bureau of Food		
	(Note: (Bureau of Food, Food and Drug Administration		
	88/24 Tiwanon Road, Muang District Nonthaburi Province 11000		
	E-mail: food@fda.moph.go.th/Tel. 02590 7195))		
3)	Provincial Health Office where food premise located		
	(Note: (if the food premise is located in a province, see details in Public Manual of the		
	particular Provincial Health Office))		
4)	Hot line 1556		
	(Note: (E-mail: 1556@fda.moph.go.th))		
5)	Public Service Center, The Office of the Permanent Secretary, the Prime Minister Office		
	(Note: (No.1 Pitsanuloke Road, Dusit District, Bangkok 10300/hotline 1111/www.1111.go.th/		
	P.O.box 1111 No.1 Pitsanuloke Road, Dusit District, Bangkok 10300))		
6)	PACC Call Center		
	(Note: (Office of Public Sector Anti-Corruption Commission (PACC office)		
	- 99 Moo 4 Software Park Building 2 nd floor Changwattana Road, Klongkluer Subdistrict,		
	Pakkred District, Nonthaburi Province 11120		
	- Hotline 1206/Tel. 0 2502 6670-80 ext 1900, 1904-7/Fax 0 2502 6132		
	- www.pacc.go.th/www. <mark>facebook.com/PACC</mark> .GO.TH		
	For foreign investor at The Anti-Corruption Operation Center		
	Tel: +66 92 668 0777/ Line: Fad.pacc /Facebook: The Anti-Corruption Operation Center/		
	E-mail :Fad.pacc@gmail.com))		

Form, example and manual of filling in

No.	Name of Form
1)	Example 1 Filling in SorBor. 6 Form
	(Note:-)
2)	Example 2 Filling in SorBor. 6 Form
	(Note:-)
3)	Example 3 Filling in SorBor. 6 Form
	(Note:-)
4)	Criteria of food naming
	(Note:-)
5)	Criteria for consideration of certification of production premise (import)
	(Note:-)
6)	Checklist of application and record of noncompliance for collection of registration and
	notification of food

No.	Name of Form	
	(Note:-)	
7)	Manual for permission via E-submission (SorBor.7)	
	(Note: (should verify updated information in the manual at website of Bureau of Food))	
8)	Manual for permission via E-submission (SorBor.8)	
	(Note: (should verify updated information in the manual at website of Bureau of Food))	

Note

In case of applying for correction of details of food already received a food serial number by Form for Registration/Notification of food (SorBor.5 Form), an applicant shall arrange a Correction Form of details of registered/notified food (SorBor.6 Form) which is being constructed for E-submission system.

Supporting documents for consideration: Application for Permission of a product and correction of permitted items: for food other than specific controlled food, food supplements, royal jelly and its products, cow's milk, flavored milk, fermented milk, dairy products, ice-cream, beverages in sealed containers, food in sealed containers and food for special purpose.

Service agency: Food and Drug Administration, Ministry of Public Health.

	List of documents	Original	Сору	Condition	
1	In case of applying for new food serial number by	0	0	(in case of submission at a province,	
	SorBor. 7 Form, the following documents are			the Public Manual of a Provincial	
	required			Health Office shall be applied)	
	1. Certificate of Organic from government agency	0	1	(if use word of "Organic" "Organic	
	or agencies certified by government agency or			farming" "Natural agriculture" or other	
	international certification bodies such as IFOAM			words with similar meanings associated	
	(The International Federation of Organic Agriculture			with name of food is associated, and	
	Movements) National Bureau of Agricultural			"the copy of the document shall be	
	Commodity and Food Standards			"truly certified by signing")	
	2. Documents or evidence in accordance with the	0	1	(if use word of "Premium" with	
	Notification of Ministry of Public Health (No.365)			name of food is associated and the	
	B.E. 2556 Re: Premium Labeling			copy of the document shall be	
				"truly certified by signing")	
2.	In case of Correction details of food which has	0	0	(in case of submission at a province,	
	been registered/notified as in SorBor.5 Form, the			Public Manual of the Provincial	
	following documents are required			Health Office shall be applied)	
	1. Form for correction details of food which has	2	0	(shall be typed only and signed by	
	been registered/notified (SorBor. 6 Form)			the operator as in the license or	
				authorized director of a legal entity)	
	2. Checklist of SorBor.6 Form	1	0	-	
	3. Evidence presenting current permission of a	0	1	(make a copy of both front and	
	premise from the Food and Drug Administration or			back side and shall be "truly	
	a Provincial Health Office as the case maybe;			certified by signing")	
				-In case of production food premise	
				not recognized as a factory (SorBor.	
				1 Form) and if having correction	
				food production premise (SorBor. 2	
				Form).	
				- In case of recognized as factory,	
				food production license (Orr 7.	
				Form))	
	4. Copy of SorBor.5 Form and SorBor.6 Form has	0	1	(The copy shall be "truly certified	
	been permitted to correct (if any) submitted to			by signing" from the operator as in	
	correct			the license or authorized director of	
				a legal entity or authorized person)	

	List of documents	Original	Сору	Condition	
	5. Original document indicated reason of correction of name/ location of food production premise, in case of correction of name/location of food production premise.	1	0	(In case of import, if it is a copy of document, it shall be "truly certified by signing" from the operator as in a license or authorized director of a legal entity or authorized person)	
	6. Power of Attorney	0	1	(If an applicant submit application at the Food and Drug Administration and he/she is not a business operator as in a license or authorized director of a legal entity, the copy has been checked and verified by an officer of Bureau of Food and shall be "truly certified by signing" from the officer).	
	7. Identification card	0	1	(shall be "truly certified by signing")	
	8. Document relevant to applying product	1	0	(In case of product details are not clear or not consistent with information indicated in an application form, product sample or evidence documents relevant to the product shall be provided such as food recipe, production method, purpose of use, method of consumption or use, dose for consumption or limit of use, container, storage, food label, etc.)	
3.	In case of applying for correction of product with SorBor. 8 Form by E-submission	0	0	(In case of applying for correction of a product in regional area, an applicant can contact Provincial Health Office)	
	1. Attach file of document described reason of correction food name or brand or location of food production premise, if correction of name or location shall be an original document from a producer	1	0	(supplement to applying SorBor. 8 Form as the case of a particular correction maybe.)	

Application form for permission

	List of documents	Condition	
1.	Example 1 Filling SorBor.6 Form	-	
2.	Example 2 Filling SorBor. 6 Form	-	
3.	Example 3 Filling SorBor. 6 Form	-	
4.	Criteria for food naming	-	

5.	Criteria for consideration of certificate of production	
	premise (in case of import)	
6.	Checklist of Application form for correction of -	
	Registered food/Notified food	
7.	Manual for application for permission by E- (should verify updated information in	
	submission (SorBor.7) the manual at website of Bureau of	
	Food)	
8.	Manual for application for permission by E- (should verify updated information in	
	submission (SorBor.8) the manual at website of Bureau of	
	Food)	