Form for Checking Application and Recording defect for Category of Food Additives prolonging food qualities or standards

☐ **Form of Food Recipes Registration (Orr. 17)**

☐ **Form of Food Label Permission (Sor Bor. 3)**

Name–Last name of applicant/authorized person.....	*****Please bring this document and application form enclosed with corrective action at the next time (if any)*
Tel. .....E-mail.....	
Name of production premise/import.....	
No. of Registration of production/import/production premise.....	
Name of food (Thai).....	
Name of food (English)	

An applicant shall arrange all documents in the following sequence as below and own checking by marking with **✓** if documents are completed as specified, or with **x** if documents are incorrect or incomplete, or with **–** if not necessary

Details of documents checking	By applicant	By officer	Defect records
1. Application Form ☐ 1 copy of Orr. 17 ☐ 2 copies of Sor Bor. 3 (type only).			
*** In Orr. 17 Form, please write neatly or type details 1 copy and sign actual name***			
*** In Sor Bor. 3 Form, please type details only, correcting by hand writing is prohibited, 1 copy and sign actual name ***			
Fill in to complete details (*See guidance for filling in documents*).			
- Notification type (specify number and year of publishing such notification).			
- Name of food in Thai			
- Name of food in English (meaning of its name shall be consistent with its Thai name).			
- Food category (notify to be consistent with a particular controlled food category).			
- **Food description** (notify as fact which shall be conformed to test report of food analysis).			
- Type of packaging (specify details of both container and cover) *e.g. metal bucket and metal cover.*			
In case of plastic, type and color of plastic shall be indicated*., e.g. paper box (inside contains PE plastic bag colorless) or plastic bucket and cover PP white color*.			
- **Packing size** (can be specified in 2 types, in all sizes or in ranges) *e.g. net weight 50, 100 and 150 kg or net weight 50-150 kg.*			
*** shall specify in metric system; if food is solid, dried or powder, specify as net weight (unit as kg); if food is liquid, specify as net volume (unit as liter); if food is semi-solid, specify either net weight or net volume.			
- **Composition formula** (comply with product description, safe to consume).			
- (Food additives shall indicate common name of the food additives with INS number or other international codes of such chemicals and contents of raw material or ingredient as factual in percentage in ascending order for 100 %.			
*** If having mixed food additives as ingredients, detailed formula of such food additives shall be indicated.			
- Food or other objects other than food additives, common name or general name of such ingredients and percentage of contents shall be indicated.			
*** If details in an application form are not able to be filled, evidences of composition formula from the producer shall be attached and specified as "attached documents"			
- **Processing methods** (raw materials and processing aids including technological function agents for processing shall be complied with quality requirements or reference standards).			
*** If details in an application form are not able to be filled, evidences of processing methods from the producer shall be attached and specified as			

Unofficial

"attached documents"			
- Shelf life (specify to be complied with quality document of the products).			
- Production licensee.			
- Name of licensee..... (fill only case of production).			
In case of natural person, indicate name and last name correspond to the name of the food production licensee as in food production license (Orr. 2) *e.g. Mr. Sanun Siritarn*.			
In case of legal entity, indicate name and last name of authorized person of such legal entity *e.g. Samliam Co., ltd. by Mr.Gla Genggaj as administrator.*			
-Name of production premises.			
In case of production, fill name and location correspond to food production license (Orr.2).			
In case of import, fill in English name and location of production premise as fact appeared on certificate of production premise for food importation.			
- Import licensee.			
Fill name and location of import premise as fact appeared on import license Orr. 7.			
- License No. of production/import..... (indicate the number and date of the license in Form Orr. 2 and Orr.7)			
- Food analysis result from ..... (indicate an agency recognized by the Committee) *e.g. Department of Medical Sciences*.			
- Signing person (signed by a business operator or authorized managing director of a company).			
-The person who has his/her name corresponded to the name on the license of Orr. 2 or Orr. 7 shall sign and type or write his/her name and last name in Thai under the signature.			
- If he/she is a Board of Directors of the legal entity, shall sign the name and/or seal as specified in the certificate of legal entity registration (also enclose a copy of the certificate).			
*** his/her name and last name shall be typed or written under the signature in Thai ***			
- Warranty (indicate as presented fact).			
e.g. "To certify that details of food to be registered are in accordance with the Notification of the Ministry of Public Health regarding Food Additives."			
"To certify that labels of all containers and all size of containers are all the same.			
"To certify that food to be analyzed is the same as to be registered.			
2. Copy of licenses (all pages, all sheets) ☐Orr. 2 ☐ Sor Bor. 1 ☐ Orr. 7			
- License still valid.			
- Food category (back of the license) – correspond to products to be submitted.			
One set of original complemented documents for application from an applicant or certified copy by a business operator.			
*** Original evidence document from a producer shall be signed or sealed of production agency. If it is electronic document or its copy, (signature or sealed of production agency shall be made on it) import licensee shall certify that "it is document from a genuine producer" and also put down the signature***			
3. Document of 100% composition formula from a producer.			
-Food additives shall indicate common name of the food additives with INS number or other international codes of such chemicals and contents of raw material or ingredient as factual in percentage in ascending order for 100 %.			
- Indicate food serial number (if produce or repack).			
-Indicate functional group or purpose of use of the food additive e.g. Process Aid.			
*** If having mixed food additives as ingredients, detailed formula of such food additives shall be indicated.			
- Food or other objects other than food additives, common name or general			

Unofficial

name of such ingredients and percentage of contents shall be indicated.			
4. Document indicated processing methods			
-Indicate processing method, raw material used, processing aids including technological function agents			
-Indicate common name (full name) of raw materials or substances			
-If it is drying, drying process shall be indicated (if any)			
-Indicate processing methods of food additives in fact and correspond to the products.			
*** If use of food additives other than specified in the Notifications of the Ministry of Public Health, they shall be approved by the Food and Drug Administration***			
5. Documents indicated finished product specification.			
- Attach finished product specifications			
- Indicate details, packaging, shelf-life, and recommendation of food storage			
- Attach JECFA* specification of each food additive.			
A single food additive.			
- Attach all items of specification as specified in JECFA* Specification			
- Having complete specification as specified in the Notification for Single FA			
- Attach a document from the producer presented warranty clause of quality or standards of food additive as "the product meets standard quality as Codex Advisory Specification (from FAO/WHO) for the Identity and purity of food additive (or Announcement of the Ministry of Public Health, Re: Quality specification or standards of relevant single food additives, as the case maybe)" together with referenced specification.			
e.g. "We hereby certify that our product meet the standard requirement of Codex Advisory Specification for the Identity and Purity of Food Additive."			
Mixed food additives			
- Attach raw material specification of food additive (for mixed food additive).			
By attaching the following documents:			
- A copy of Orr. 18/Sor Bor. 3 or Notify food serial number			
- Attach specification from producers			
- Attach a document from producer presented warranty clause of quality or standards of food additive as "the product has standard quality as Codex Advisory Specification (from FAO/WHO) for the Identity and purity of food additive (or Announcement of the Food and Drug Administration regarding single food additives, or standards referred in relevant Notification of the Ministry of Public Health as the case maybe)", also attached together with referenced specification and warranty clause as "The product meets quality or standards as specified in Announcement of the Ministry of Public Health; Re: Quality specification or standards of mixed food additives."			
e.g." We hereby certify that raw materials (all food additives) used in the product meet the standard requirement of Codex Advisory Specification (from FAO/WHO) for the Identity and Purity of Food Additive and the finished product complied with the Announcement of the Food and Drug Administration regarding mixed food additives."			
6. One copy of Report of analysis result of qualities or standards.			
- Original copy (if use of common analysis result, submit a copy of the analysis result and notify food serial number or number a receipt of the application).			
- Validity of Analysis result not more than one year.			
- Name/address of producer/importer as indicated in a certificate of a food production premise.			
- Indicate completed detail as request to analyze			
- Analysis laboratory shall be an official or official certified laboratory, if			

Unofficial

laboratory is private laboratory, it shall be certified with ISO 17025 and also present complimented evidence.			
*** If repeated or additional analysis is undertaken, it shall be done by the same lab only, except when the same lab cannot analyze, a person who deliver a sample for analysis shall deliver an explanation by a letter.			
*** If indication of name of food and/or name of production/import premise is not consistent as notified in Form Orr. 17, a person who deliver a sample for analysis shall make a letter for reason of inconsistency.			
*** If use of common analysis result, such food shall be the same recipe, production method, and production premise as food that already permitted.			
7. One original copy of analysis result report of container.			
- If container is colored plastic (except white color) contacting with food in liquid form, it shall also be analyzed plastic properties as in Notification of Ministry of Public Health No.295 B.E. 2548.			
8. One original copy and one copy of certificate of production premise (in case of import).			
(shall follow Announcement of FDA regarding Certificate of production premise for food import)			
- The certificate shall be original copy or if it is a copy, certifying shall be made to the copy or the statement by an agency issued the certificate or official certified person such as Notary Public/government agency in a manufacturing country/ its embassy in Thailand, etc.			
- To have certification body (CB) accredited by accredited body (AB) under International Accredited Forum (IAF).			
- Name and address of a production premise.			
- Food Quality Assurance System (e.g. ISO 9001, 99002, GMP, HACCP or equivalent).			
- Scope of certified food (consistent with imported food category).			
- Day/month/year of certificate issuance (still valid, if expiry date is not indicated, validity is 1 year from the date of issuance).			
- If certificate is in other languages, translated copy in Thai or English which certified by Royal Thai Embassy in the manufacturing country or government or private agency that operate business of translation with the international standard with also warranty, shall be attached.			
9. Food label and complemented manual for sale.			
(shall follow Notification of Ministry of Public Health No.281 (B.E.2547) and No.363 (B.E.2556). (provide 4 sets of each kind of label, and 4 sets of sale complemented manual).			
- Thai language label.			
- Foreign language label (in case of import, if any).			
- Particular details on the label as follows:			
(1) Name of food (as indicated in Form Orr.17)			
(2) Food Serial Number.			
Label indicates only FDA mark but not the FDA number in the mark.			
Manual indicates only words "see on the label".			
(3) Name and address of producer or repacker or importer.			
Label indicates name and country of producer.			
Manual indicates production country and name and address of import premise.			
(4) Production lot (indicates as "Production Lot" or other statements that have the same meaning, e.g. LOT (NO. NUMBER) or BATCH (NO. NUMBER).			
Label indicates only associated statement "Production lot" or other statements that have the same meaning.			
Manual indicates only words "see on the label".			
(5) Net content (indicates words "net weight" or "net volume" as in Form Orr.17).			
Label indicates only one amount of sample as consistent with in Form Orr.17.			
Manual indicates only words "see on the label".			

Unofficial

(6) Day/Month and year of production/repacking and expiry			
(If shelf life of food is not more than 18 months shall also indicate month/year of expiry).			
Label indicates only associated statement.			
Manual indicates only words "see on the label".			
(7) Recipe shall be declared as follow:			
- Common name of food additives, INS number, percentages of content in descending order			
- Other ingredients declared in descending order.			
(if ingredients contain allergen shall also declare information for allergic person e.g. Allergenic information : contain lecithin from soy bean)			
(8) Direction of use, at least shall declare purpose, food category, recommended amount by percentages of food or percents.			
Having statement of "Use of...(indicate name of food).."other than above direction shall follow criteria prescribed in Notification of Ministry of Public Health regarding "Food additives".			
(9) Recommendation for storage (as indicated in document of specification.			
(10) Warning statement (if any) (as indicated in document of specification.			
In case sale to food producers that are not food additive repackers and does not declare details in (7) – (10) on the label, a statement "food additives used as raw material for food producing factory" shall be declared and manual or leaflet for sale in Thai language shall be attached.			
10. Document of checking used content of single or mixed food additives.			
- Completely fill all data in Calculating form for checking content of food additives under application.			
-Recommended use amount (see calculating method in annex of table).			
11. One copy of supporting document or evidence for declaration of statement or symbol on label (if any).			
12. One copy of other relevant documents or evidences (if any).			
13. One sample of food (if any).			
14. If produce for export when products are not complied with regulations, following evidence shall be submitted.			
- One copy of letter from purchaser with details of product that contain ingredients with qualities or standards complied with regulation of purchasing country or one copy of regulations of purchasing country.			
15. One copy of Power of Attorney.			

For applicant only	For officer only
1st time I knew ☐ Document completed and accurate. ☐ There are defectives and will be completely corrected within 10 working days from the day of application received. Sign.....(applicant/authorized person) (.....) Date.....	☐ Documents are completed and accurate. Issue receiving application form No..... ☐ Find defective as indicated above, request to correct within 10 working days from the day accept the application form if exceed the due date, application will be cancelled and further returned. Sign .....preliminary checking personnel Sign.....authorized officer Date.....
2nd time	☐ Completely defective correction.

Official

I ☐ Completely correct defectives. ☐ Not able to completely correct and agree in rejection of the application. Sign.....(person submit correction documents/authorized person) (.....) Date.....	☐ Return the application and all documents due to..... ☐ Not present to correct defectives within due date. ☐ Defective corrections are not complete. You have right to submit new application by preparing complete and accurate documents or can appeal for returning this application by making an appeal letter to Secretary General of Food and Drug Administration within 15 working days since the date of notifying received. Sign.....authorized officer Date.....

Unofficial