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Food and Agricultural Import Regulations and Standards

Food Product Registration in Thailand

2008

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Report Highlights:

Registering your product with the Thai Food and Drug Administration is a critical step in accessing the market. This report identifies the critical steps and the normal time frames within the approval process. It is intended as a guideline and a tool for working with your importer in support of your product's timely approval.

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Food Product Registration with the Thai Food and Drug Administration

Registering your product with the Thai Food and Drug Administration is a critical step in accessing the market. This report identifies the critical steps and the normal time frames within the approval process. It is intended as a guideline and a tool for working with your importer in support of your product's timely approval.

The Thai Food Act B.E.2522 (1979) divides food into four categories:

- I. Specific Controlled Food
- II. Standardized Food
- III. Food Required to Bear Label
- IV. General Food.

Each different food category has different documentation requirements. We would be pleased to work with you to help clarify the appropriate category of your item. Please email us at agbangkok@fas.usda.gov

I. Specific Controlled Food

- 1.1. Modified milk for infant and follow-up formula modified milk for infant and young children
- 1.2. Infant food and follow-up formula food for infant and young children
- 1.3. Supplementary foods for infant and young children
- 1.4. Sodium Cyclamate and food containing Sodium Cyclate
- 1.5. Food additives
- 1.6. Weight-control foods
- 1.7. Stevioside and food containing Stevioside
- 1.8. Beverages in sealed containers
- 1.9. Foods in sealed containers
- 1.10. Flavored milk
- 1.11. Yogurt milk
- 1.12. Cow's milk
- 1.13. Other milk products
- 1.14. Ice cream

II. Standardized Food

2.1 Electrolyte drinks	2.2 Tea
2.3 Herbal tea	2.4 Coffee
2.5 Soybean milk in sealed container	2.6 Ice
2.7 Drinking water in sealed container	2.8 Natural mineral water
2.9 Peanut oil	2.10 Coconut oil
2.11 Palm oil	2.12 Fat and oil
2.13 Butter oil	2.14 Butter
2.15 Cheese	2.16 Margarine
2.17 Ghee	2.18 Iodized table salt
2.19 Vitamin fortified rice	2.20 Alkaline-preserved eggs
2.21 Cream	2.22 Chocolate

2.23 Some types of sauces	2.24 Vinegar
2.25 Fish sauce	2.26 Honey
2.27 Food seasonings derived from the hydrolysis or fermentation of soybean protein	2.28 Jam, jelly, and marmalade in sealed containers
2.29 Food supplement	2.30 Royal jelly and royal jelly products
2.31 Semi-processed food	

III. Food Required to Bear Label

- 3.1 Special purpose foods
- 3.2 Irradiated foods
- 3.3 General food obtained through certain techniques of genetic modification/genetic engineering
- 3.4 Processed gelatin and jelly
- 3.5 Chewing gum and candy
- 3.6 Bread
- 3.7 Sauces in sealed containers
- 3.8 Brine for cooking
- 3.9 Brown rice flour
- 3.10 Meat products
- 3.11 Flavoring agent
- 3.12 Ready-to-cook and ready-to-eat foods

IV. General Food

- 4.1 Animals and their products such as fresh meat, fresh seafood, eggs, etc.
- 4.2 Plants and their products such as fresh vegetables, fresh fruits, nuts, etc.
- 4.3 Extracts/ synthetic substances such as herbal extract used as raw materials, etc.
- 4.4 Nutrients such as Amino acid used as raw materials, etc.
- 4.5 Flour and products such as cassava flour, mung bean noodle, noodle, etc.
- 4.6 Other not-ready-to-eat products for cooking
- 4.7 Seasonings such as seasoning pack in instant noodle, etc.
- 4.8 Sugar
- 4.9 Spices such as mustard, pepper, red pepper, etc.

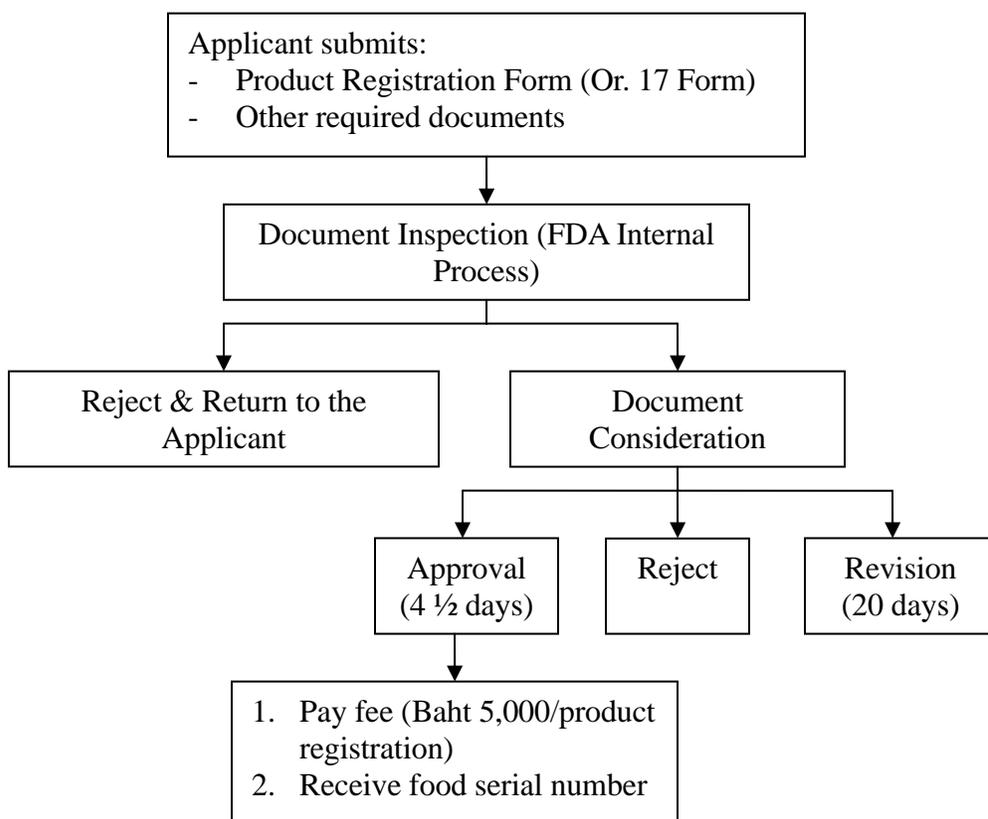
Import of Food Products under Food Category I

Importers of specific controlled food are required to register the products before importation for sale. Products that are registered must abide by what is specified in the registration form such as labeling, manufacturing process, product appearance, specifications and standards. Applications for product registration should be submitted to the Food Control Division, Food and Drug Administration. For those residing outside the Bangkok Metropolitan area, applications can be submitted to the appropriate Provincial Office of Public Health.

The approximate amount of time required for product registration, starting from submitting the application, is about one month and registering a product costs Baht 5,000 (\$150) per application. Delays are usually caused by inaccurate or vague details in the documents.

Products Categorized Under Category I - Specific Controlled Food and Related Ministry of Public Health Notifications

Product Group	The Ministry of Public Health Notification
1. Beverages in sealed containers	No. 214 B.E. 2543 (2000) No. 230 B.E. 2544 (2001)
2. Sodium Cyclamate and food containing Sodium Cyclamate	No. 113 B.E. 2531 (1988)
3. Modified milk for infant and follow-up formula modified milk for infant and young children	No. 156 B.E. 2537 (1994) No. 286 B.E. 2547 (2004) No. 307 B.E. 2550 (2007)
4. Flavored milk	No. 266 B.E. 2545 (2002)
5. Cultured milk	No. 289 B.E. 2548 (2005)
6. Cow's milk	No. 265 B.E.2545 (2002) No. 282 B.E.2547 (2004)
7. Other milk products	No. 267 B.E. 2545 (2002)
8. Food additives	No. 281 B.E. 2547 (2004)
9. Infant foods and follow-up formula food for infant and young children	No. 157 B.E. 2537 (1994) No. 171 B.E. 2539 (1996) No. 287 B.E. 2547 (2004)
10. Weight-control foods	No. 121 B.E. 2532 (1989)
11. Supplementary foods for infant and young children	No. 158 B.E. 2537 (1994)
12. Foods in sealed containers	No. 144 B.E. 2535 (1992) No. 179 B.E. 2540 (1997) No. 253 B.E. 2545 (2002) No. 301 B.E. 2549 (2006)
13. Ice cream	No. 222 B.E. 2544 (2001) No. 257 B.E. 2545 (2002)
14. Stevioside and food containing Stevioside	No. 262 B.E. 2545 (2002)

Product Registration, Labeling Approval and Notifying for Food Serial Number**Documents Required for Product Registration – Food Category I**

1. Product Registration Application Form (Or. 17 Form- Appendix 1) for each food product registration¹
2. Food Import License
3. An Original Copy of Lab Analysis Report
 - a. A Lab Analysis Report for required food product issued by government laboratory from the country of origin, government laboratory in Thailand or the private laboratory accredited by Thai government. The submitted lab analysis report should have been issued not more than one year. The analysis results must comply with the quality or standard specified in the Ministerial notification.
 - b. The analysis of quality or standard of dispersion of plastic containers shall be carried out by the methods prescribed by Food and Drug Administration only for colored plastic containers and food directly in contact with the container. There is a possibility that colored plastic container can give out color to contaminate with food. (As per MOPH no. 295 B.E. 2548 (2005): Quality or standard for container made from plastic)
 - c. Additional lab analysis reports are required for following products:

¹ For some products with different types and sizes of packaging, the importer will receive only one serial number. However, if the same products are from different manufacturer, the Thai importer has to submit 2 set of the application and will receive two different serial numbers.

- i. Food contains Aloe Vera. Analysis report on Anthraquinone Derivatives has to be submitted.
 - ii. Food contains peanut as ingredients. Analysis report on Aflatoxin has to be submitted.
 - iii. Food contains spirulina or chlorella pyrenoidosa. Analysis report on lead and arsenic has to be submitted. However, if food has spirulina or chlorella pyrenoidosa as major ingredients, analysis report on protein volume, type and volume of amino acid, lead and arsenic has to be submitted.
 - iv. Beverage contains caffeine. Analysis report on caffeine volume and volume of other nutrient ingredients as shown in label.
 - v. Infant food, follow-up formula food for infant and young children, Modified milk for infant and follow-up formula modified milk for infant and young children. Analysis report on type and volume of ingredients displayed in label.
 - vi. Food contains Wintergreen Oil or Methyl Salicylate. Analysis report on Methyl Salicylate and Free Salicylic acid has to be submitted.
 - vii. Food contains bird's nest. Analysis report on protein volume; type and volume of amino acid; and the analysis indicates that the product contains bird's nest as ingredients has to be submitted.
 - viii. Meat extracted soup. Analysis report on protein volume, type and volume of amino acid has to be submitted.
 - ix. Food contains ginseng and have the wording "Ginseng" as a part of product name. Analysis report indicates that the product contains ginsenoside has to be submitted.
 - x. Food contains any sweetener other than sugar. Analysis report on type and volume of that certain sweetener has to be submitted.
4. An Original Copy of Lab Analysis Report on Type and Volume of Nutrition (If necessary)
A Lab Analysis Report on type and volume of nutrition has to be issued by government laboratory from the country of origin, government laboratory in Thailand or a private laboratory accredited by Thai government. The submitted lab analysis report should have been issued not more than one year. However, if there is no change in product formula, the nutrition lab analysis issued over one year is acceptable. The Thai FDA requires food importers to submit lab analysis report on type and volume of nutrition under following conditions:
 - a. Nutrition Labeling required as per the Ministry of Public Health Notification no. 182 B.E. 2541 (1998) for the following food categories:
 - Foods which have nutrition claim.
 - Foods which utilizing food value in sale promotion.
 - Foods which define consumer groups in sale promotion.
 - Foods which add nutrition or have nutrition claim on labeling
 - b. Other foods required to have nutrition labeling as per the Ministry of Public Health Notification.
 - c. Food importer desires to have nutrition labeling
5. Four copies each of labels in Thai and in foreign language (if any). A translation of text in label or documents attached if the language used is not English.

6. Original copy from food manufacturer of product formulation (ingredient list²) and manufacturing flowchart³ (needed for filling the application form to declare the ingredients used). The information provided has to be clear enough for identifying the characteristic and physical properties of product.
7. Original copy of certificate of manufacturing premise with accurate details follow to the notification of the Ministry of Public Health (No. 193) B.E. 2543 (2000) or equivalent details to the mentioned notification of the Ministry of Public Health, or one of the following food qualities assurance system: General Principles of Food Hygiene as prescribed by International Food Standard FAO/WHO; Codex., HACCP, ISO, or other equivalent principles or systems. The certificate should have been issued not more than one year.
8. Other documents such as
 - a. Certificate of Free Sale in case there is any flavor ingredient used but cannot specify details
 - b. A certificate from the exporter’s home country government authority may be needed for food supplements in the form of mixture and novelty food in order to certify that such food is being sold as food in the manufacturer’s country.
 - c. Product sample 1 unit (in case more investigation needed from the Thai FDA)
9. A unit of product sample (in case of requesting the lab test from Thai government laboratory).

Historically products listed below are required special attention in preparing documents submitted to the Thai FDA:

a) Food in Sealed Containers

Product Type	Additional Documents/Actions Required	Reason
Canned Meat and Poultry	<p>FSIS Export certificate (FSIS Meat and Poultry Export Certificate of Wholesomeness) containing the following statement:</p> <p>“The canned or preserved meat and poultry products are heat treated and achieve commercial sterility (shelf stability) in accordance with FSIS canning regulations cited in 9 CFR 318.300 and 381.300”</p>	The document is used as process filing equivalent to ensure no Clostridium botulinum contamination in canned food.

² A) The sum of percentage of all ingredient used under ingredient list has to be equal to 100 percent

B) Any artificial or natural flavoring used has to be specified in the ingredient list.

C) Any oil or fat used has to clarify type of oil and fat i.e. coconut oil, palm oil.

³ A) Manufacturing flowchart has to explain how food ingredient listed used in manufacturing process.

B) If there is any heat treatment, time and temperature used has to be specified also

b) Beverages in Sealed Containers

Product Type	Items Required Special Attention
Fruit Juice	a) Maximum Preservative Level <ul style="list-style-type: none"> - Sulfur dioxide shall be not more than 70 mg. per 1 kg. of beverage. - Benzoic acid or sorbic acid or salts of both acids, to be calculated as acid, shall be not more than 200 mg. per 1 kg. of beverage. b) Food Labeling conditions according to MOPH notification no. 194, 214 and 252 such as <ul style="list-style-type: none"> - Declaration of “Utilizing preservatives” for any usage - Declaration of “Natural color” or “Artificial color” for any usage, etc. c) Food additives (i.e. coloring) shall comply with MOPH notification no. 281 and CODEX

c) Others

Product Type	Items Required Special Attention
Cultured Milk	Lab Analysis to comply with MOPH notification no. 289
Modified Milk for Infant	Lab Analysis to comply with MOPH notification no. 156
Cow’s Milk	<ul style="list-style-type: none"> - Lab Analysis to comply with MOPH notification no. 265 - Food additives usage has to be complied with the attachment of MOPH notification no. 265
Other Milk Products	- Lab Analysis to comply with MOPH notification no. 267

Import of Food Products Under Food Category II

The importer of food products under Food Category II has to submit the application for product record filing in order to receive the serial number from the Thai FDA. The importer has to submit product record filing application and must adhere to standard requirements for domestic sales in accordance with related notifications. The product record filing application process will take approximately 2 days.

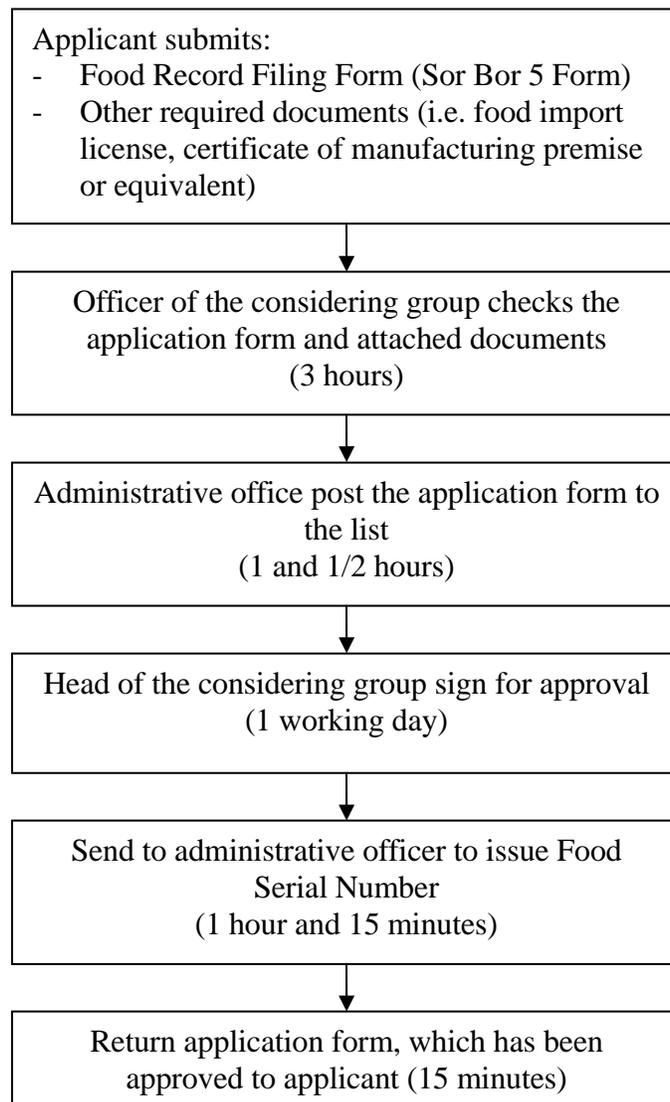
Products Categorized Under Category II – Standardized Food and Related Ministry of Public Health Notifications

Product Group	The Ministry of Public Health Notification
1. Coffee	No. 197 B.E. 2543 (2000) No. 276 B.E. 2546 (2003)
2. Iodized Table Salt ⁴	No. 153 B.E. 2537 (1994)
3. Vitamin Fortified Rice	No. 150 B.E. 2536 (1993)

⁴ Do not require to file application form for Food Record (Sor Bor 5 Form)

4. Alkaline-Preserved Eggs	No. 236 B.E. 2544 (2001)
5. Cream	No. 208 B.E. 2543 (2000)
6. Electrolyte Drinks	No. 195 B.E. 2543 (2000)
7. Chocolate	No. 83 B.E. 2527 (1984)
8. Tea	No. 196 B.E. 2543 (2000) No. 277 B.E. 2546 (2003)
9. Some Types of Sauces	No. 201 B.E. 2543 (2000)
10. Soybean Milk in Seal Containers	No. 198 B.E. 2543 (2000)
11. Vinegar	No. 204 B.E. 2543 (2000)
12. Peanut Oil	No. 23 B.E. 2522 (1979) No. 233 B.E. 2544 (2001)
13. Coconut Oil	No. 57 B.E. 2524 (1981) No. 235 B.E. 2544 (2001)
14. Palm Oil	No. 56 B.E. 2524 (1981) No. 234 B.E. 2544 (2001)
15. Butter Oil	No. 206 B.E. 2543 (2000)
16. Fat and Oil	No. 205 B.E. 2543 (2000)
17. Fish Sauce	No. 203 B.E. 2543 (2000)
18. Natural Mineral Water	No. 199 B.E. 2543 (2000)
19. Butter	No. 277 B.E. 2544 (2001)
20. Honey	No. 211 B.E. 2543 (2000)
21. Cheese	No. 209 B.E. 2543 (2000)
22. Margarine	No. 207 B.E. 2543 (2000)
23. Ghee	No. 226 B.E. 2544 (2001)
24. Food Seasonings Derived from the Hydrolysis or Fermentation of Soybean Protein	No. 202 B.E. 2543 (2000) No. 248 B.E. 2544 (2001)
25. Jam, Jelly and Marmalade in Sealed Containers	No. 213 B.E. 2543 (2000)
26. Royal Jelly and Royal Jelly Products ⁵	No. 212 B.E. 2543 (2000) No. 241 B.E. 2544 (2001)
27. Semi-Processed Food	No. 210 B.E. 2543 (2000)
28. Drinking Water in Sealed Containers	No. 61 B.E. 2524 (1981) No. 135 B.E. 2534 (1991) No. 220 B.E. 2544 (2001) No. 256 B.E. 2545 (2002)
29. Ice	No. 78 B.E. 2527 (1984) No. 137 B.E. 2534 (1991) No. 254 B.E. 2545 (2002)
30. Herbal Tea	No. 280 B.E. 2547 (2004)
31. Food supplement	No. 293 B.E. 2548 (2005) No. 309 B.E. 2550 (2007)

⁵ Prescribed food by the minister to have label submitted and require to file application form of Food Labeling (Sor Bor 3 Form)

Food Record Filing and Notifying for Food Serial Number**Documents Required for Food Record Filing – Food Category II**

1. Product Record Filing Application Form (Sor Bor. 5 Form) for each food product record filing
2. Food Import License
3. Original copy of certificate of manufacturing premise with accurate details follow to the notification of the Ministry of Public Health (No. 193) B.E. 2543 (2000) or equivalent details to the mentioned notification of the Ministry of Public Health, or one of the following food qualities assurance system: General Principles of Food Hygiene as prescribed by International Food Standard FAO/WHO; Codex., HACCP, ISO, or other equivalent principles or systems. The certificate should have been issued not more than one year.

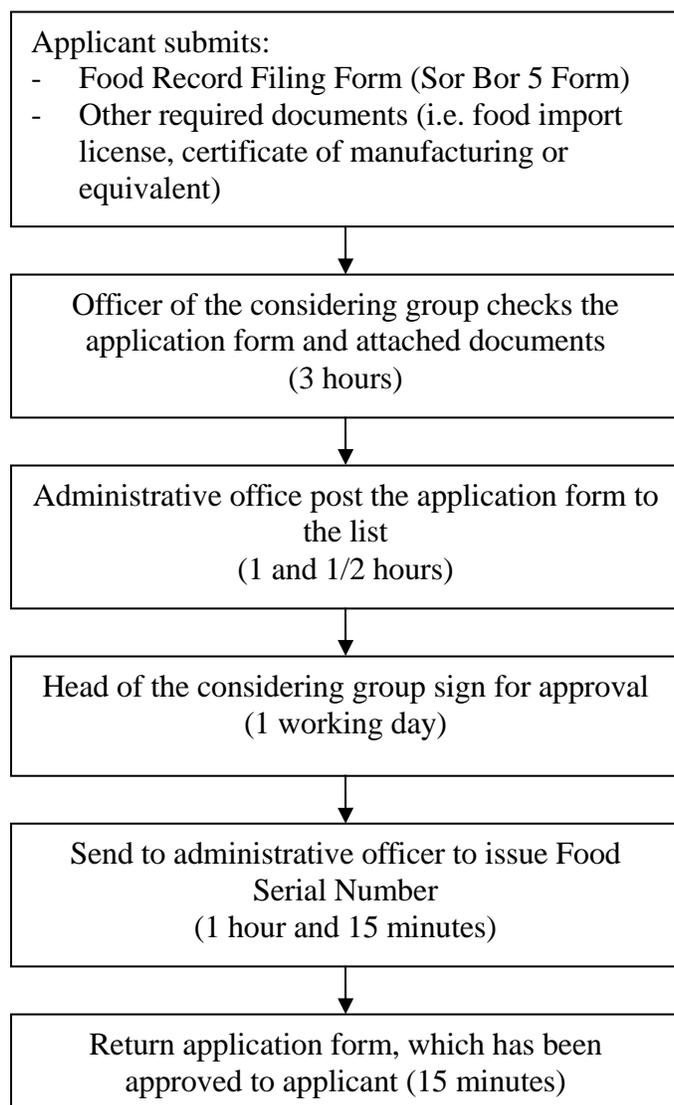
Import of Food Products under Food Category III

The importer of food products under Food Category III has to submit the application for product record filing in order to receive the serial number from the Thai FDA. The importer has to submit the application for product record filing in order to receive the serial number from the Thai FDA and must adhere to standard labeling requirements for domestic sales in accordance with related notifications. The product record filing application process will take approximately 2 days.

Products Categorized Under Category III – Food Required to Bear Label and Related Ministry of Public Health Notifications

Product Group	The Ministry of Public Health Notification
1. Bread	No. 224 B.E. 2544 (2001)
2. Sauces in sealed containers	No. 200 B.E. 2543 (2000)
3. Brine for cooking	No. 225 B.E. 2544 (2001)
4. Brown rice flour	No. 44 B.E. 2523 (1980)
5. Meat products	No. 243 B.E. 2544 (2001)
6. Flavoring agent	No. 223 B.E. 2544 (2001)
7. Processed gelatin and jelly	No. 100 B.E. 2529 (1986) No. 263 B.E. 2545 (2002)
8. Chewing gum and candy	No. 228 B.E. 2544 (2001)
9. Ready-to-cook and ready-to-eat foods ⁶	No. 237 B.E. 2544 (2001)
10. Special purpose foods	No. 238 B.E. 2544 (2001)
11. Irradiated foods	No. 103 B.E. 2529 (1986)
12. General food obtained through certain techniques of genetic modification/genetic engineering	No. 251 B.E. 2545 (2002)

⁶ Not required to submit GMP equivalent certificate

Food Record Filing and Notifying for Food Serial Number**Documents Required for Food Record Filing – Food Category III**

1. Product Record Filing Application Form (Sor Bor. 5 Form) for each food product record filing
2. Food Import License
3. Original copy of certificate of manufacturing premise with accurate details follow to the notification of the Ministry of Public Health (No. 193) B.E. 2543 (2000) or equivalent details to the mentioned notification of the Ministry of Public Health, or one of the following food qualities assurance system: General Principles of Food Hygiene as prescribed by International Food Standard FAO/WHO; Codex., HACCP, ISO, or other equivalent principles or systems. The certificate should have been issued not more than one year.

Import of Food Products under Food Category IV

Food products under this category require no serial number. However, the importer has to make sure that the product they are importing has been listed in their food import license. If not, the application of new food import license is required.

Documents Required for General Food Import to Thailand

1. Food Import License
2. Only for frozen food, original copy of certificate of manufacturing premise with accurate details follow to the notification of the Ministry of Public Health (No. 193) B.E. 2543 (2000) or equivalent details to the mentioned notification of the Ministry of Public Health, or one of the following food qualities assurance system: General Principles of Food Hygiene as prescribed by International Food Standard FAO/WHO; Codex., HACCP, ISO, or other equivalent principles or systems. The certificate should have been issued not more than one year.

Appendix 1: Food Registration Form (Orr 17 Form)

Form Orr.17

File No.

Date

(Only for government officer)

Application form of Food Registration

Specific Controlled Food by Ministry of Public Health in Notification No

Name of food in Thai.....

Name of food in other language.....

Type of food.....

Variety of food.....

Appearance.....

Kind of package	Size of package
--	--

List of ingredient (%)

Name	Quantity	Name	Quantity
.....
.....
.....

Production process

.....

.....

.....

.....

.....

Licensed manufacturer's name

Production premise's nameAddress

Trok/SoiRoadCommune No.

Sub-District/TambonDistrict/Amphur

ProvinceCountryTel.No

Licensed importer's name
Importation premise's name.....
Address.....Trok/Soi.....
RoadCommune No.
Sub-district/TambonDistrict/Amphur.....
Province.....Tel. No.
Manufacturing License or Import Food into Kingdom License No.
Issued dateMonthYear
Analysis report from

Together with the application, I am submitting

- 1) Sample of Label, 4 copies
- 2) Sample of Product, 1 Unit
- 3) Complete Application Form, 4 Copies
- 4) Analysis report, 4 copies
- 5) Other relevant information for food registration, 4 copies.

(Signature)The Applicant

Appendix 2 Product Record Filing Application Form (Sor Bor 5 Form)

Form Sor Bor. 5

File No.....

Date

Food Record/ Food Declaration Form.

Food Record

Manufacture

Food Declaration

Importation

Food Names	Type of Food/ Notificatio No.....	Food Serial Number

Signature.....Issuer

(.....)

Position

Date

Appendix 3 Sample of Ingredient List

Manufacturer Letter Head
[Address]

Date: _____

Product Name: _____

Name of Ingredients	Percentage
Ingredient A	50%
Ingredient B	10%
Ingredient C	10%
Ingredient D	10%
Ingredient E	7%
Ingredient F	5.5%
Ingredient G	4.5%
Ingredient H	1.8%
Ingredient I	0.8%
Ingredient J	0.4%

Company Stamp
Authorized Signature

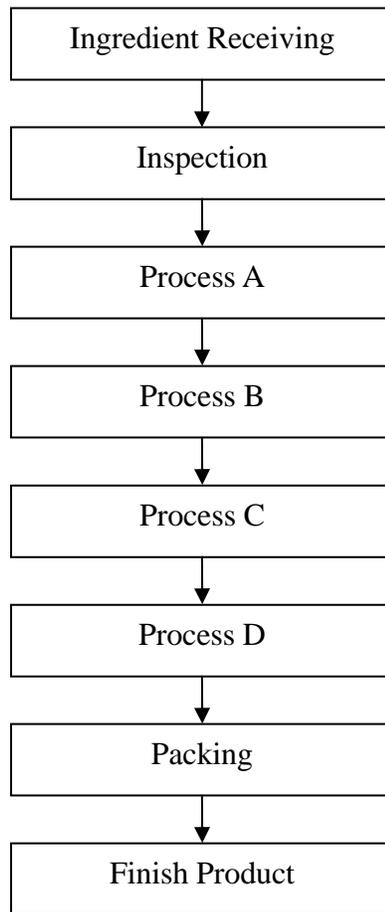
Appendix 4 Manufacturing Flow Chart

Manufacturer Letter Head
[Address]

Date: _____

Product Name: _____

Manufacturing Flow Chart



Company Stamp
Authorized Signature