Taiwan

Import food regulations and control in Thailand

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Bureau of Food
Thai FDA

TAIPEI_2014 International Symposium on Safety Management of Imported Foods



Scope of presentation

- Update on overview Thai Food Act
- Procedures and Requirements for Importing Food Products
- Additional concern for food product
- Conclusion

Food Legislation in Thailand

Food Act 1979

Objective:

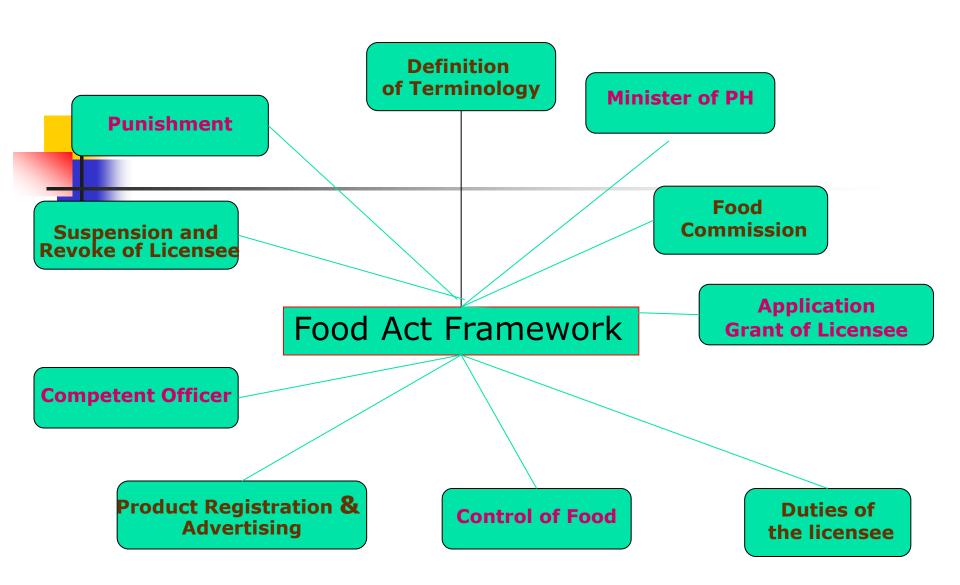
To protect consumers against unsafe, substandard and deceptive food.

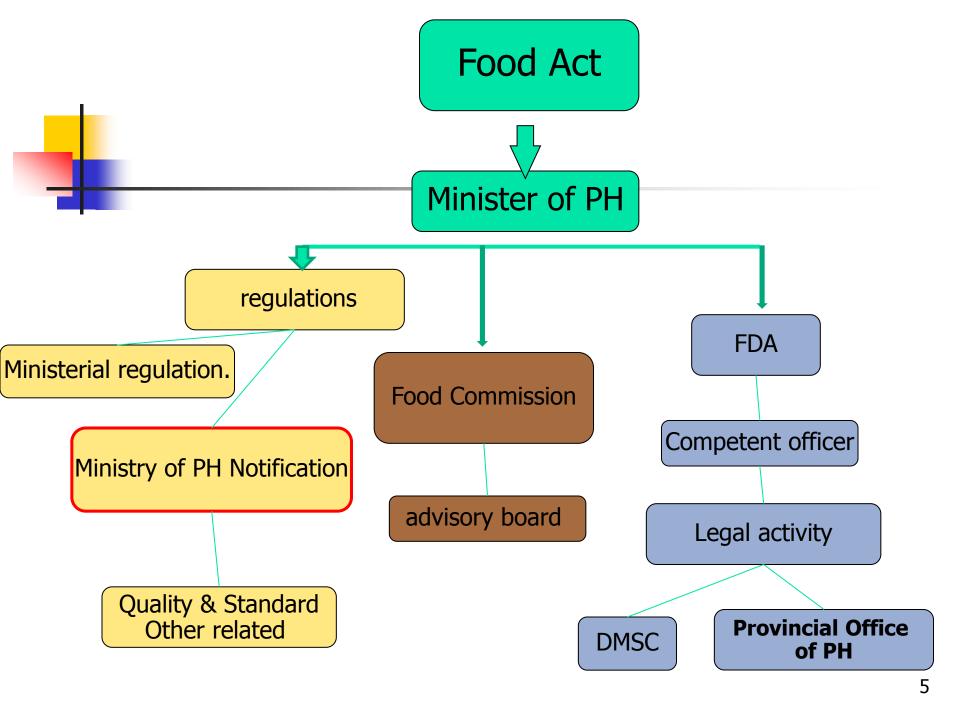
Management system:

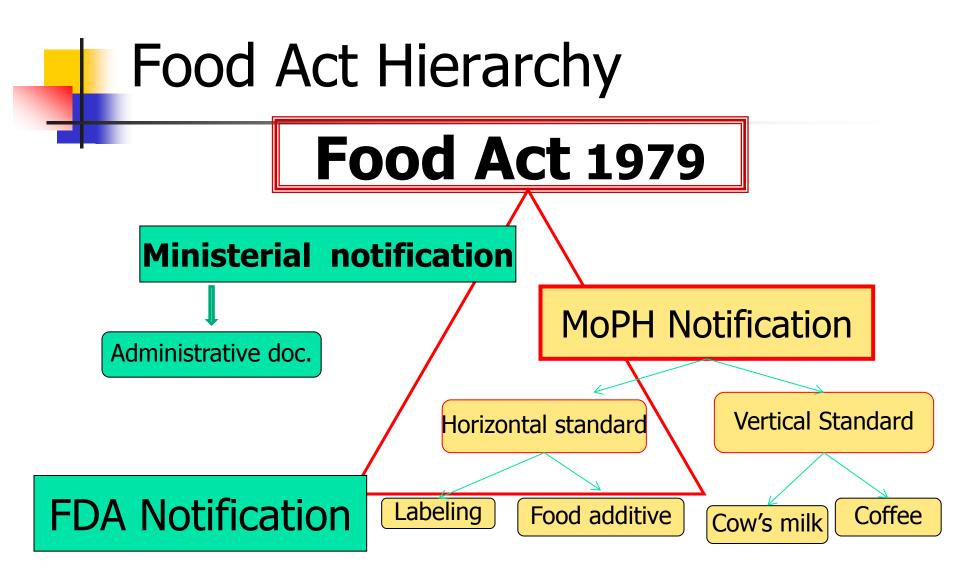
Approval prior to sale for both local and imported products including advertising

Authorized agency:

Food and Drug Administration (FDA)







MoPH: Ministry of Public Health

"Food"



means edible items and those which sustain life

- (1) Substance can be eat, drunk, sucked or gotten in to the body either by mouth or by other means, no matter in what form, but not including medicine, psychotropic substances, narcotic under the law as the case may be.
- (2) Substance intended for use or to be used as ingredients in the production of food including food additive, coloring matter and flavoring

According to the article 4 under Food Act 1979





The Food Act classify food into 3 categories as follows:

- 1. Specific Controlled Food, e.g.: Infant Food, Milk, Food for weight control, <u>Food additive</u>, etc.
- 2. Standardized Food, e.g.: Fat & oil, Drinking water, Coffee, Tea, Fish sauce, Soy sauce, Dietary supplement, etc.
 - 3. Labeled Food, e.g.: Bakery product, Snack, etc.

according to article 6 under the Food Act 1979

List of Specific controlled Food



- Modified Milk for Infant and Modified Milk of follow up Formula for Infant and young children
- 2. Food for Infant and Food of follow up Formula for Infant and young children
- 3. Supplementary Food for Infant and Young Children

- 4. Food for Weight Control
- 5. Food Additives
- 6. Stevioside and FoodContaining Stevioside

7. Sodium Cyclamate and Foods Containing Sodium Cyclamate

List of Standardized Food

- Cow's Milk
- Flavoured Milk
- Other Milk Products
- Drinking Yoghurt
- Ice Cream
- Cream
- Beverage in Sealed Containers
- Honey
- Chocolate

- Coffee
- Tea
- Herb Tea
- Electrolyte Drink
- Drinking Water in Sealed Containers
- Ice
- Soybean Milk in Sealed Containers
- Mineral Water

List of Standardized Food

- Food in Sealed Containers
- Semi-processed Food
- Butter
- Cheese
- Margarine
- Ghee
- Coconut Oil
- Peanut Oil
- Butter Oil
- Palm Oil
- Vitamin fortified Rice
- Alkaline-preserved Egg

- Fat and oil
- Edible salt
- Fish Sauce
- Some Particular Kinds of Sauces
- Seasonings derived from the Hydrolysis or Fermentation of Soybean
- Jam, Jelly and Marmalade in Sealed Containers
- vinegar
- Dietary Supplement
- Royal Jelly and Royal Jelly Product
- Garlic product

List of Standard Labeled Food



- 1. Bread
- 2. Sauce in Sealed Containers
- 3. Mimic fish sauce
- 4. Flour of Hushed Rice
- 5. Meat Product
- 6. Flavoring Agents
- 7. Gelatin and jelly dessert
- 8. Chewing Gum and Candy
- 9. Ready to Eat and Ready to Cook Food
- 10. Food for Special Dietary Use
- 11. Irradiated Food
- 12. Food obtained through certain techniques of genetic modification / genetic engineering

Management system

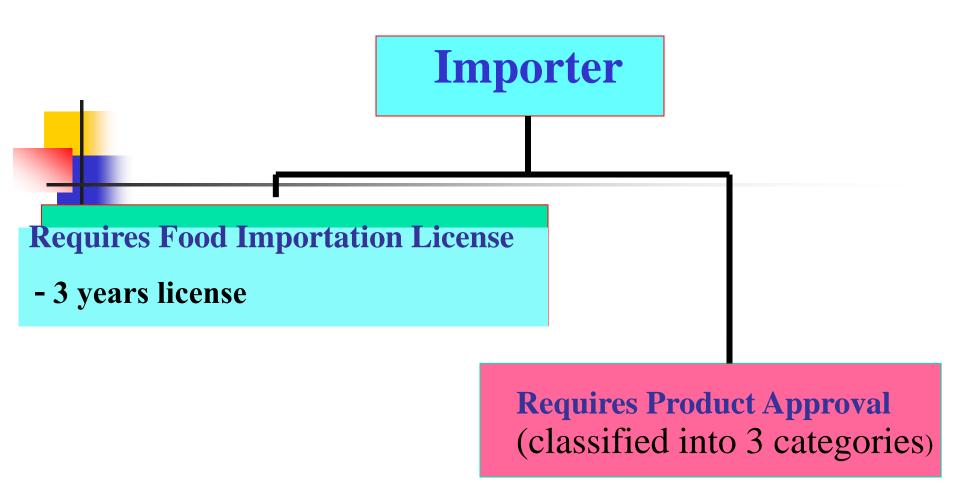
- - Food Standard section (article 6)
 - Pre-market control section
 - manufacturing/ importer
 - products
 - labeling (if any) (article 6)
 - advertising (article 6,40-41)
 - Post- market monitoring section (article 6)



(article14 -15,31)



 Procedures and Requirements for Importing Food Products



- Temporary Import Food license*

* Trade Exhibition /academic research

FOOD IMPORTER



Requires Food Importation License.

- 1. Submit application form with supporting documents such as company registration, type of food, list of ingredients in the product, warehouse lay out, etc.
- 2. FDA verifies the application and advises on corrections (if necessary)
- 3..FDA issues the license

FEE: 15,000 Baht per 3 calendar years
Time for issue: 7 working days

Detail of required document for Food Importation License

- 1. An application form of Import Food into the Kingdom Licence.
- 2. A copy of domestic registration.
- If an applicant is alien; a work permit in Thailand which issued by the Labour Department shall be attached.
- 3. A copy of Trade or Commercial Registration.
- 4. A copy of company registration which declared objectives and authorised person of the company.
- 5. A copy of certifying nationality of company (List of share holders) from the Ministry of Commerce.
- 6. Certificate of proxy to act on behave of applicant entity (for juristic person) with excise tax of 30 Baht.

The company stamp is also required if it specified in the company registration.

- 7. 2 Sets of the following scaled plans and photo
- 7.1 Location map of the importation premise, storage area and nearly buildings.
- 7.2 Storage area plan



Storage area plan

- its surroundings
- adequate area for each food item
- adequate ventilation and lighting system
- equipments of methods for keeping quality of food which shall be installed (if necessary)

Document required for application of Temporary Import Food License (for Trade Exhibition of Person, Juristic Person, and Organizations).

- Application form Orr. 12
- Copy of domestic registration.
- Copy of company registration. (If any)
- Letter of intent to import and manage such products after trade exhibition that shall be not for sale, distribution, given and shall be responsible for its standard quality and safety which may occur.
- Certificate of exhibition place as evidence.
- Letter of confirmation from exhibition organizer denote that the company participates in the trade exhibition.
- Food importation documents such as: Invoice, Bill of Lading, or Air Way Bill.
- Health certificate or Certificate of Free Sale which is issued by government authorities or parties which is certified by the government.

Documents required for application of Temporary Import Food License (for Academic Research).

- Application form Orr. 12
 - Copy of domestic registration.
 - Copy of company registration. (If any)
- Copy of approved research project from human research project committee of the Ministry of Public Health which indicate the target group for research and qualification, experience of research group as evidence.
- Certificate of confirmation that products in this research will be utilised within the approved boundary of the project only, no commercial sale or distribution and agree to be inspected and followed to the result of the research.
 - *Should the imported product is unsafe, FDA has the right to retain or revoke the product.
- Report of research result shall be gradually submit to the FDA
- Food importation documents such as: Invoice, Bill of Lading, or Air Way Bill.
 - Health certificate or Certificate of Free Sale which is issued by government authorities or parties which is certified by the government

Food Products



[14 items such as Food additives, Cow's milk, Modified food for infant, etc.]

3.Labeled Foods

[a] Standard labeled Foods

[12 items such as Bread, Jelly dessert, etc]

[b] Non-notified labeled Foods

2.Standardized

Foods

[31 items such as Tea, Coffee, Fat and oil, Instant food, etc.]

1.Specific Controlled Foods

Required registration for Certificate of Food Recipe

Application form with supporting documents:

- -- Name of food;
- -- Name and quantity of ingredients in the food
- -- Manufacturing process
- -- Type of packaging material / size of packing
- -- Analysis report issued by government lab.or accreditation lab.
- -- Labeling
- -- Certificate of Free Sale (if any)
- -- Manufacturing certificate

-FEE: 5,000 baht / recipe, Time: 35 working days

Manufacturing Certificate

Mandatory requirement for certain food manufacturing;

- Imported product : Certificate should be issued by recognized regulatory agency or manufacturing license/food license by recognized/relevant authority.
- The Certificate should be valid and define the expiration date of use of such certificate within **ONE** year as from the issuing date of such certification except the evidence from such certificate are still valid.
- Other equivalent system such as quality management system (ISO 9001,9002)





Original copy of manufacturing certificate

- certified copy of certificates to be certified or recommendations from the issuing offices or
- certified by embassy of manufacturer's country in Thailand or
- certified by governmental office or
- certifying body such as notary public, etc.,



State of Utah

ON M. HUNTSMAN, JR.

GOMETHOF

GARY R. HERBERT

Department of Agriculture and Food LEONARD M. BLACKHAM Commissioner

KYLE R. STEPHENS Deputy Commissioner CHRIS S. CRNICH, DYM Director, Regulatory Services

Issued by Government

GOOD MANUFACTURING PRACTICE CERTIFICATE

We hereby certify that

Name & Address of Manufacturer

Manufacturing Plant

Is currently under inspection as a manufacturer of health food or dietary supplements.

has all the facilities to comply with the GOOD MANUFACTURING

PRACTICE (Code of Good Manufacturing Practice).

We also certify that is an inspected facility and the manufacturing plant in which the product is produced is subject to inspections at suitable intervals.

Inspection evaluates and assures compliance with the Utah Wholesome Food Act and the Utah Food Protection Rule (FPR), which identifies the standard for proper facility construction, good manufacturing practices (GMP), and fulfills requirements of those applicable laws and rules in the State of Utah

Don Mc Cellen

Don McClellan Division of Regulatory Services

State of Utah, County of Salt Lake Subscribed and sworn to before me this 19th day of January 2006.

Notary Public

Notary Public

Residing in Salt Lake County



NOTARY PUBLIC ANN MICHELLE JACK 350 N. Redwood Road Salt Lake City, UT 84116 COMMISSION EXPIRES February 28, 2007 STATE OF UTAH

350 North Redwood Road, PO Box 146500, Salt Lake City, UT 84114-6500 telephone 801-538-7100 • facsimile 801-538-7126 • http://ag.utah.gov

Scope

GMP

Valid Certificate

GMP Certificate



Certificate

Certificate of Registration

TTF99145

Far East Bio-Tec Co., Ltd. Far East Microalgae Ind. Co., Ltd.

Scope: The Related Activities of Production of: Microalgae

13F, No.3, Yuancyu St., Nangang District., Taipei city, Taiwan, No.15, Da Ho Rd., Hsin Nan Village Kao Shu Hsiang Ping Dung Hsien Taiwan

AFNOR ASIA certifies that all the arrangements covering the above mentioned activities and locations are established to meet the requirements of the international standard.

ISO 22000 : 2005

ORIGINAL DATE OF CERTIFICATION

11-MAY-2009

DATE OF ISSUE

18-JUL-2012

DATE OF EXPIRY

APPROVED BY

- Just

Trevor Wilmer
Director for Certification
ON BEHALF OF
AFNOR ASIA

1 Name and address of

② company

3 Scope

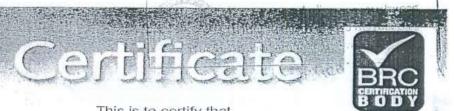
System

(5) Expiry date

© Credit Body (CB)
Accredit Body
(AB)







This is to certify that

Incopack N.V. BRC site code: 1721122 Siemenslaan 21 3650 DILSEN-STOKKEM BELGIUM

has been evaluated by ISACert B.V., a n RvA accredited Certification Body, No. C241 and found to meet the requirements of

Global Standard for Food Safety

Issue 6: July 2011

Mixing of cream or cream analogue; UHT-treatment and aseptic filling into spray cans

Exclusions from Scope:

Product Categories:

07 - Dairy, liquid egg

Achieved Grade:

Certificate No.

BRC-IS 135050

Refers to the report No.

BRC-IS 135050

Audit programme:

Repeat Announced

Date of audit:

2013/07/237 (73550110312041)

Certificate issue date:

นัลอิรละtos2ลารและอาจำนาญการพิเศษ

Re-audit due date:

2014-08-19

Certificate expiry date

Authorised by

chin gange ? 2 0 711.8, 2556

Angelle Jansen Certification Manager

This certificate remains the property of ISACert B.V., P.O. Box 6006, NL-6710 AA Ede, The Netherlands For verification of validity: +31 (0)318 658 750 or info@isecert.com

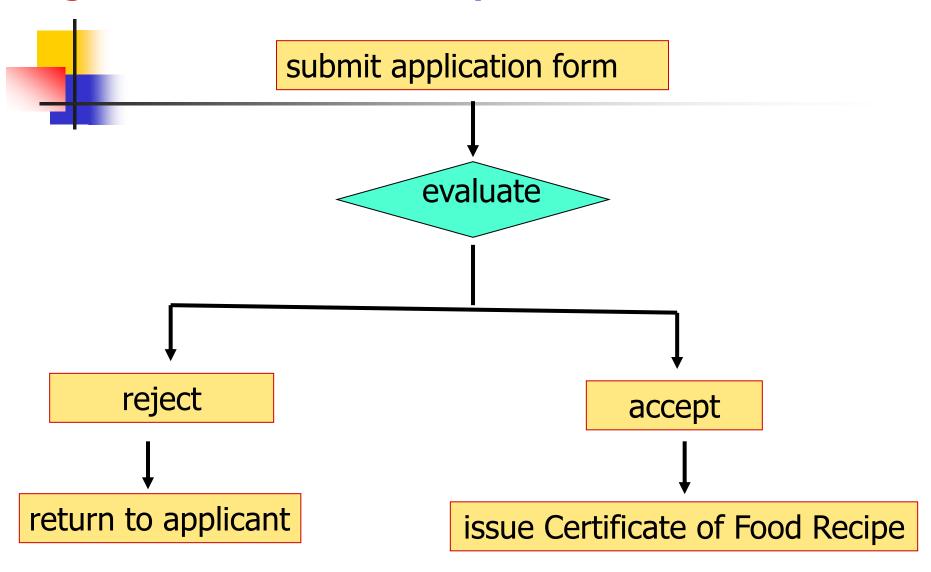






- 1 Name and address of
- ② company
- ③ System
- § Scope
- ⑤ Expiry date
- **6** Credit Body (CB) Accredit Body (AB)

Registration Procedure of Specific Controlled Food





2.Standardized Foods

Divide into 2 class:

- Required registration
 similar procedure specific controlled food , but
 different in application form.
 - 2. Required notification

-FEE: No charge

Standardized Foods

Required notification

Notification form with supporting documents:

- A photocopy of food importation license
- Manufacturing Certificate issued by authorized agency

-FEE: No charge

-Time: 3 working days

Exemption from Dietary Supplement comply with its regulation.



3. Other Food

(a) Standard labeled Foods

- Requires notification

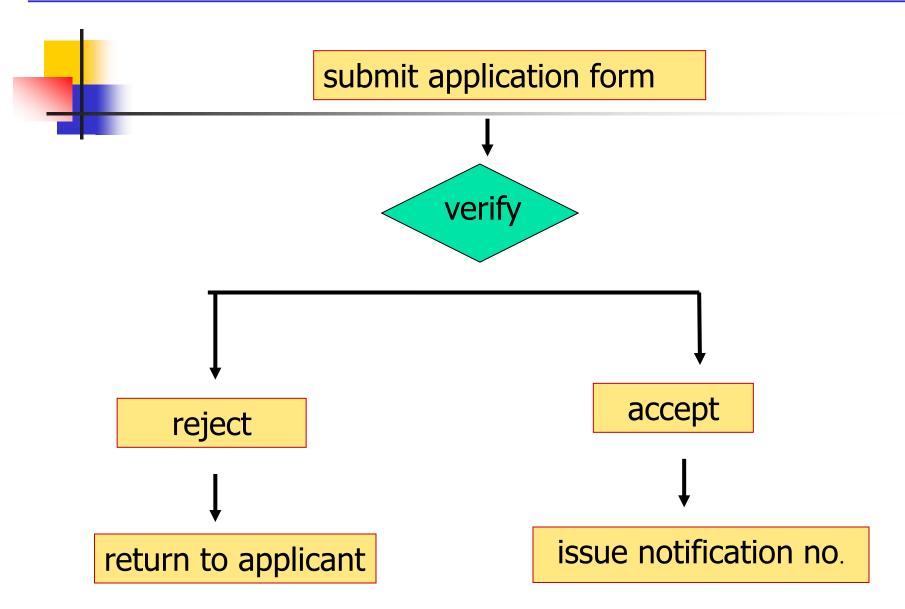
- FEE: No charge

- Time :3 days

(b) Labeled Foods

- Registration or notification is not required, but the product must be produced up to the prescribed quality or standard and labeling comply with labeling regulation.

Notification for Standardized Food and Standard Labeled Food



Application can be submitted at

- For facility located in Bangkok:
 - One Stop Service Center Food and Drug Administration Ministry of Public Health Nonthaburi
 - Tel. 02-590-7175
- For facility located in other provinces,
- more information visit website
 - WWW: fda.moph.go.th
 - e-mail address: food@fda.moph.go.th



ADDITIONAL CONCERN FOR FOOD PRODUCT

- Product classification
- Product formulation
- Analytical report of product
- The use of food additive
- Guideline for vitamins & mineral fortification (if any)
- Packing material



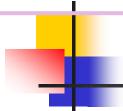
ADDITIONAL CONCERN FOR FOOD PRODUCT (cont.)

- Labeling requirement
- Specific statement for some type of products
- Claims requirement (if any)
 - e.g. halal logo
- Banned and restricted products

Product classification

- 1. Identify the product to be imported for which category it falls into.
- 2. Verify against your importation license to see if the product falls within the categories indicated in the license prior to filing the application. Otherwise, importer must apply for an additional food category intended to import.

Product classification(cont)/Product formulation



- 3. Quality and standard of the product must comply with the quality and standard set forth by regulation.
- 4. Provide Product formulation percentage weight by weight including food additive information by providing name of food additive, quantity and its functional use.



Analytical report

- Analytical report issued by government laboratory or accreditation lab.
- The standard of these food products have to meet the standards specified in the MoPH Notifications.



The use of food additives

- The use of food additives in the product shall comply with the MoPH Notification no.281 B.E.2547(2003): Food Additive or
- Codex standard : General Standard for Food Additive

www.codexalimentarius.net

Other than above, seek for FDA approval

Guideline for vitamins & minerals fortification

- 10-200 % of Thai RDI for W/S vitamins
- 10-150 % of Thai RDI for F/S vitamins
- 10-150 % of Thai RDI for minerals
- 10-120 % of Thai RDI for Fe, Zn
- F and I required FDA Approval case by case

(MoPH notification 182 entitled : Nutrition Labeling)

 exemption DS. allowed 15-100 % of Thai RDI. (MoPH notification 293 entitled : Dietary Supplement)

Note: w/s: water soluble, F/S: fat soluble

Thai Recommended Daily Intake (Thai RDI)

65 g.	Thiamin	1.5 mg.	Iron
20 g.	Riboflavin	1.7 mg.	lodine
300 mg.	Niacin	20 mg.NE	Magnesium
50 g.	Vitamin B6	2 mg.	Zinc
300 g.	Folate	200 mcg.	Copper
25 g.	Biotin	150 mcg	Potassium
800 mcg.RE	Pantothenic Acid	6 mg.	Sodium
2 mcg.	Iron	15 mg.	
60 mg.	lodine	150 mcg.	
5 mcg.	Magnesium	350 mg.	
10 mg.	Zinc	15 mg.	
80 mcg.	Copper	2 mg.	
800 mg.	Potassium	3,500 mg.	
800 mg.	Sodium	2,400 mg.	
	20 g. 300 mg. 50 g. 300 g. 25 g. 800 mcg.RE 2 mcg. 60 mg. 5 mcg. 10 mg. 80 mcg. 800 mg.	20 g. Riboflavin 300 mg. Niacin 50 g. Vitamin B6 300 g. Folate 25 g. Biotin 800 mcg.RE Pantothenic Acid 2 mcg. Iron 60 mg. Iodine 5 mcg. Magnesium 10 mg. Zinc 80 mcg. Copper 800 mg. Potassium	20 g. Riboflavin 1.7 mg. 300 mg. Niacin 20 mg.NE 50 g. Vitamin B6 2 mg. 300 g. Folate 200 mcg. 25 g. Biotin 150 mcg 800 mcg.RE Pantothenic Acid 6 mg. 2 mcg. Iron 15 mg. 60 mg. lodine 150 mcg. 5 mcg. Magnesium 350 mg. 10 mg. Zinc 15 mg. 80 mcg. Copper 2 mg. 80 mcg. Potassium 3,500 mg.

15 mg.

150 mcg.

350 mg.

15 mg.

2 mg.

3,500 mg.

2,400 mg.



Food Packaging

 Standard of plastic ceramic container and coated metal container

Notification of MoPH No.92 B.E. 2548 (1985)

Standard of plastic container

Notification of MoPH No. 295 B.E. 2548(2003)



Standard of baby feeding bottle

Notification of MoPH No. 117 B.E. 2532 (1989)

Labeling: General Requirement

Required Thai text on the label for prepackaged food

- Name of food
- Name and quantity of the ingredients in the food
- 2 Net content
 - Food registration no. /Food notification no.

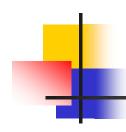


- Name and address of manufacturer, in case of imported product must be shown name and address of importer
- Manufacturing date/expiration date/best before
- Suggestion/ warning statement [if any]
- Specific requirement [if any]
 MoPH notification no. 194 B.E. 2543 (2000) entitled: Labeling

The forth coming is MoPH. Notification 367 (2014) entitled :: Food Labelling for $Pre_{\bar{4}3}$ Packed Foods

e.g.: specific statement requirement

- for caffeine drink (energy drink)
- suggested consumption maximum of 2 servings/day may cause palpitation otherwise.
 - not recommended for children and pregnant



Labeling for GM. food

Statement "Genetic Modification" must be shown on the label for Genetic Modified Foods such as

"soy bean from genetic modification"



Claims regulation

- Nutrition claims
- Health claims (on process)
 - Other claims



- 1. Notification of Ministry of Public Health No.182 B.E. 2541 (1998) entitled: Nutrition labeling
 - Nutrient content
 - Nutrient comparative
 - Nutrient function Claim

2. Notification of Ministry of Public Health No.305 B.E. 2550 (2007) entitled: Labeling Requirement of Snack Foods

Notification of MoPH (No.305) B.E.2550 (2007) Re: Labelling Requirement of Snack Foods



- Potato Chips
- Corn Chips
- Rice Crisps (extrude)
- Biscuits
- Stuffed wafers











Compulsory nutritional labelling



Nutrition Information

 Contain Cholesterol more than 2 mg/serving size

Amount Per Serving

Total energy kcal

Total Fat g.

Cholesterot mg (in case of significant content)

Protein g.

Total Carbohydrate g.

Sugar g.

Sodium mg.

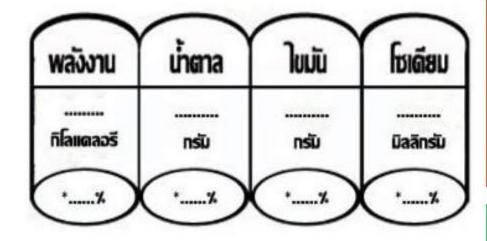
* Thai recommend daily intakes for ages of 6 years and up (Thai RDI) with percent diary values are based on a 2,000 calorie diet



สัญลักษณ์ทางโภชนาการแบบ GDA



ดุณดาทางโภชนาการต่อ ดวรแบ่งกิน ดรั้ง



* ดิดเป็นร้อยล:ของปริมาณสูงสุดที่บริโภดใดต่อวัน

พลังงานทั้งหมด ไม่ควรเกิน 2,000 กิโลแคลอรี/วัน

น้ำตาล(Total Sugar)
ไม่ควรเกิน 65 กรัม/วัน
-40 กรัม จาก ผัก(2 g) ผลไม้(30g)
และนม (8g)
-25 กรัม จาก Added Sugar

ไขมันทั้งหมด ไม่ควรเกิน 65 กรัม/วัน

โซเดียม ไม่ควรเกิน 2,400 มก./วัน

ข้อมูลโภชนาการ

นนึ่งหน่วยบริโภค: 1 960 (25 ครัม)

จำนวนหน่วยบริโภสต่อสอง: 1

คุณค่าทางโภชนาการต่อหนึ่งหน่วยบริโภค

พลังงานทั้งหมด 130 กิโลแคลอรี

	ร้อยละของปริมาณที่แนะนำต่อวัน *
ใขมันทั้งหมด 7 n.	11 %
โปรตีน 2 n.	
คาร์โบไฮเตรดทั้งหมด 16 ก. น้ำตาล 11 ก.	5 %
โซเดียม 25 มก.	1 %

ร้อยละของปริมาณสารอาหารที่แนะนำให้บริโภคต่อรันสำหรับคนไทยอายุตั้งแต่ 6 ปีขึ้นไป
 (Thai RDI) โดยคิดจากความต้องการพลังงานรับละ 2,000 กิโลแคลอรี





คุณค่ำทางโภชนาการต่อ 1 ชอง

น้ำตาล	ใขมัน	โซเคียม
11	7	25
กรัม	กรัม	มิลลิกรับ
	11	11 7

* กิดเป็นร้อยละของปริมาณสูงสุคที่บริโภคได้ต่อวัน



Other claims

Halal logo certificate





Halal logo certificate

Halal logo certificate is defined as food permitted under the Islamic Law.

Halal certificate issued by the Office of Central Islamic Affairs committee of Thailand.

More information visit: www.halal.or.th



Banned & Restricted products



Restricted products

- Food Additive
- Caffeine drink

Foods prohibited to manufactured, imported or sold

Notification of MoPH (No.292) B.E. 2548

- Dulcin or chemical name is "para-phentolcarbaminde" which used as sweetener
- Clycamic acid and its salt excluded salt of Cyclamic acid which is Sodiumcyclamate (allow to manufacture for export)
- AF-2 Furylfamide which used as food additive
- Food containing AF-2 or cyclamic acid or salt of cyclamic acid except sodium clycamate

Foods prohibited to manufactured, imported or sold

Notification of MoPH (No.292) B.E. 2548

Potassium bromate as food additive

 Food containing Daminozide or Succinic acid 2,2-dimetlhydrazide

Food prohibited to manufactured, imported or sold

- Small size package of processed jelly dessert containing
 Glucomanan which has a diameter not more than 4.5
 centimeters.
 Notification of MoPH (No.263) B.E. 2545
- Puffer fish and Food containing Puffer fish meat as ingredient
 Notification of MoPH (No.264) B.E. 2545
- Genetically modified food containing Cry9C DNA Sequence and food containing such genetically modified food

Notification of MoPH (345) A.D. 2012



Food prohibited to manufactured, imported or sold

Notification of MoPH (No.344) B.E. 2555 (2012)

Food contained melamine and its analogues (Cyanuric acid) is the prohibited food to be produced, imported or sold at the following limits

- (1)Exceeding 1 mg/kg for modified milk for infant, modified milk of follow up formula for infant and young children, infant food, food of follow up formula for infant and young children food and supplementary food for infants and young children
- (2) Exceeding 2.5 mg/kg for other kinds of food.

Food prohibited to be import or sold

Following foods whose declared "expiration date" or "best before date" has been passed;

Notification of MoPH (No.174) B.E. 2539

- (1) Modified Food (other than milk) for Infant and Young Children
- (2) Supplementary Food for Infant and Young Children
- (3) Modified Milk for Infant and Young Children
- (4) Drinking Yoghurt
- (5) Pasteurized Milk
- (6) Food for Special Purpose

Food prohibited to be import or sold (cont.)



Notification of MoPH (No.296) B.E. 2549

reconsideration

 Foods produced from cows and cow products from the origin countries with risk from Bovine Spongiform Encephalopathy (BSE)

Great Britain, Portugal, France, Ireland, Switzerland, Belgium, Germany, The Netherlands, Denmark, Italy, Liechtenstein, Luxembourg, Spain, Czech Republic, Greece, Japan, Slovakia, Slovenia, Austria, Finland, Israel, Poland, Canada and USA (24 countries)

Food prohibited to be import or sold (cont.)

- Except milk and milk product, gelatin and collagen required to have a Safety Certificate stating the country of origin and free from Bovine Spongiform Encephalopathy (BSE).
- Gelatin made from bone. Except gelatin made from bone that have a Certificate stating the country of origin and free from BSE.

Substances prohibited to be used as ingredients in food

Notification of MoPH (No.151) B.E. 2536, (No.247) B.E. 2544

- Brominated vegetable oil
- Salicylic acid
- Boric acid
- Borax
- Calcium iodate or Potassium iodate
- Nitrofurazone
- Beta-agonist
- Potassium chlorate

Substances prohibited to be used as ingredients in food (cont.)

- 4
 - Formaldehyde, Formaldehyde solution, para-Formaldehyde
 - Coumarin
 - Dihydro-coumarin or Benzodihydropyrone or 3,4-Dihydrocoumarin or Hydrocoumarin
 - Diethylene Glycol or Dihydroxydiethyl ether or Diglycol or 2,2'-oxybis-ethanol or 2,2'-oxydiethanol
 - Methyl alcohol or Methanol (except for food processing aid for export)



conclusion

Food legislation in Thailand is Food Act B.E. 2522 (1979)

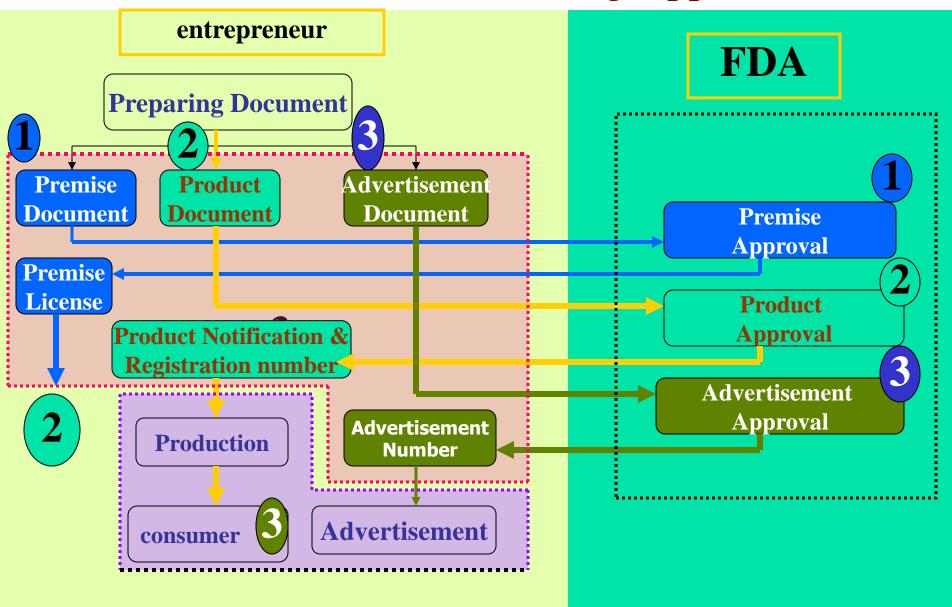
For imported food into Thailand

- 1. Approval of the Importation license.
- 2. Approval of the Product.

Food Categories and How to Apply

Categories	Imported Food
A. Specific Controlled Food	 Apply for Importation License Register for Approval Number
B. Standardized Food	 Apply for Importation License Notify for Approval Number*
C. Labeled Food 1. Notify standard labeled food	1.1. Apply for Importation License 1.2. Notify for Approval Number*
2. Non-notify standard labeled food	2.1 Apply for Importation License 2.2

Procedure for Pre-marketing Approval



Required document for importing products

document	Cat.1	Cat.2	Cat.3
1. Manufacturing certification	$\overline{\checkmark}$	$\overline{\checkmark}$	√?
2. Certificate of free sale	$\overline{\mathbf{V}}$	√?	√?
3. Product formulation	$\overline{\mathbf{V}}$	✓	√
4. Manufacturing process	$\overline{\mathbf{V}}$	✓	√
5. The use of food additive	$\overline{\mathbf{V}}$	√	√
6. Analytical report	V	√	√

Note : ☑ required document for product submission

[✓] for applicant self-verification and keep for post market monitoring check

Required document for importing products

document		Cat.2	Cat.3
7. Instruction of use (if any)	$\overline{\checkmark}$	$\overline{\checkmark}$	√?
8. Shelf-life	$\overline{\mathbf{V}}$	√?	√?
9. Labeling	$\overline{\mathbf{V}}$	✓	√
10. Nutrition Labeling (if any)	V	✓	√
11. Other claims	V	√	√
12. Packaging material information	V	√	√

Note : ☑ required document for product submission

[✓] for applicant self-verification and keep for post monitoring programme

Application can be submitted at

- For facility located in Bangkok:
 - One Stop Service Center
 Food and Drug Administration
 Ministry of Public Health
 Nonthaburi
- For facility located in other provinces,
- more information visit website

WWW: fda.moph.go.th

e-mail:food@fda.moph.go.th



THAI FOOD AND DRUG ADMINISTRATION For more information please visit: www.fda.moph.go.th



Answers