Chapter 7

Food Additives and Packaging in Thailand

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Thailand's food additives and food packaging are governed by the Food Act of B.E. 2522 (1979). The Act gives the Ministry of Public Health the authority to implement the Act through the Food and Drug Administration (FDA), which is a department within the Ministry. In general, imports of food for sale in the Kingdom require an import license and standard labeling according to domestic regulations. According to the Ministry of Public Health Announcement, there are four notifications under the Food Act to regulate use of food additives which are Notification No. 281, B.E. 2547 (2004), Notification No. 359, B.E. 2556 (2013), Notification No. 360, B.E. 2556 (2013), and Notification No. 363, B.E. 2556 (2013) and three notifications under this Act to control all food containers and packaging materials which are the Ministerial Notification No. 92, B.E. 2528 (1985), No. 117 B.E. 2532 (1989), No. 295, BE. 2548 (2005). Aside from the Thai FDA where is responsible for legislating the Food Act of food additives and packaging, there are two organizations, namely, the Thai Industrial Standards Institute (TISI) and the Office of the Consumer Protection Board (OCPB) also responsible for setting up regulations. TISI develops both mandatory and voluntary standards for food packaging for consumer protection and for the need of industry and trade while OCPB regulates the label of plastic packaging for consumer protection mainly. In addition, the Department of Science Service (DSS), which was appointed to be ASEAN Food Reference Laboratory (AFRL) in the area of food contact

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materials by the ASEAN Consultative Committee on Standard and Quality - Prepared Foodstuff Product Working Group (ACCSQ-PFPWG), is actively working on standard of food contact material for ASEAN.

Regulation of Food Additives in Thailand

Thailand has employed the principles of risk assessment to issue safety protection for consumers and to facilitate international trade. For regulations on food additives, the General Standard for Food Additives (GSFA) and Codex Advisory Specification for the Identity and Purity of Food Additives have been applied as the reference standards to issue Thailand regulations on food additives because of their international recognition, conscientious preparation and reliable scientific information. Codex member countries are involved in establishing and adopting them as international reference standards. The Thai regulations provide the list of authorized food additives approved for use in foods as well as use condition according to GSFA. The labeling of food additives also complies with the Codex General Standard for the Labeling of Food Additives when sold as such. This information helps food manufacturers to select the food additives that are allowed to be used according to the regulations. If they would like to use the food additives that are not included in such regulations, they need to submit the safety information and additional evidence documents for application to the Thai FDA in order to approve the use of those additives.

Regulatory Enforcement

According to the Ministry of Public Health Announcement, there are four notifications under the Food Act related to food additives.

1. **Notification of Food and Drug Administration (No.281) B.E. 2547 (2004)** in which it contains provisions in relation to the restriction on the usage of food additives i.e. the list of authorized substances and their quality/ standard and use condition that are prescribed in Codex standards. Nevertheless, the Thai FDA also issues additional authorized food additives beyond those listed in the Codex standards. Currently, there are 317 food additives authorized for use and passed the safety assessment (*1*).

Clause 2 of Notification defines that "Food additives mean substances that are not usually used as foods or as essential ingredients of foods whether the substances will or will not provide food value, but are added to foods for the benefits of processing technology, food coloring, food enhancing, packaging, storage or transportation that will affect the qualities or standards or characteristics of foods. Food additives shall also include substances not added to foods but are in the packaging containers together with the foods for the mentioned purposes such as moisture absorbers, oxygen absorbers, etc.

The statement in the first phrase shall not include nutrients added to supplement or adjust the nutritive values of foods such as protein, fat, carbohydrate, vitamins and minerals."

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Therefore, the food additives that are covered by these announcements include food additives used for production technology, processing aid and substances for quality maintenance or standard, e.g. moisture absorbers, oxygen absorbers etc., except for nutrients and flavoring materials that are regulated by other announcements.

Table 1. Cases of Authorized Food Additives and Information for Consideration to Permit the Use of Food Additives

Authorized food additives	*Information for consideration*
(1) New food additive	Submit information in accordance with the Environmental Health Criteria 70: Principle for the Safety Assessment of Food Additives and Contaminant in Food (Being revised to conform with the new criteria of Environmental Health Criteria 240: Principles and Methods for the Risk Assessment of Chemicals in Food) as follows: (1) Requirements of quality and standards (Specifications) consist of components, production methods, raw materials, impurities in the manufacturing process and stability.
	(2) Toxicity and studies in humans, e.g. absorption, distribution, metabolism, and excretion including residues of toxicological concern, general systemic toxicity, acute toxicity, genotoxicity, carcinogenicity, chronic toxicity, reproductive and developmental toxicity, neurotoxicity, immunotoxicity, food allergy and other food hypersensitivities, general principles of studies in humans and gut flora. These data are utilized to determine the safety for human exposure from an acceptable daily intake (ADI) and dietary exposure assessment of chemicals in food.
(2) New conditional use	Submit information as follows: 1. Information on substances, e.g. safety, quality or standards, components, etc. 2. Conditional use in food required. 3. Legal permission of use in other countries. 4. Research results representing the requirement for a reliable technology.

Clause 4 of Notification informs that the use of food additives must pass safety evaluation and their quality or standard of food additives must meet the requirement of the Codex Advisory Specification for the Identity and Purity of Food Additives or requirement of Food and Drug Administration for food additives

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additional permitted beyond the listed in the Codex standards. Moreover, clause 6 of Notification provides information about the conditions for the use of food additives which may be defined differently from the Codex standard depending on types of food additives, the actual technological requirement and necessity, and the exposure assessments based on the GSFA and the Thai national food consumption data, B.E. 2549 and current scientific evidence, for example, the use of colors, preservatives, and sweeteners.

However, the use of food additives according to the categories defined by Codex does not cover all kinds of foods in Thailand. In certain cases, the specific conditions of use of food additives are defined in the commodity standard such as that of cow's milk, margarine, blends, fat spreads and fat spread blends similar to the Codex standard for specific food products.

The use of food additives that are not included in these notifications must be approved based on their safety evaluation and technological justification prior to issuance of the Notification of the Food and Drug Administration to assign their quality or standard and condition of use. According to the procedure of law issuing, the information is required for consideration (under Clause 4(3) of this Notification) as described in Table 1.

2. **Notification of Food and Drug Administration No. 359 B.E. 2556 (2013)** in which it contains provisions in relation to the use of cyclamate and reissues the requirement of non-permitted use of cyclamates corresponding to Codex standards referred to Codex Advisory Specification for Identity and Purity of Food additives as well as specifies the conditional use according to the requirement of GSFA. However, the non-permitted use of cyclamates or sweeteners is restricted to some food products such as milk, flavored milk, jam, jelly, marmalade in a sealed container, chocolate and electrolyte drink. The qualities or standards and the maximum use of cyclamate and sodium salts or calcium salts of acid- are prescribed (*2*).

3. Notification of Food and Drug Administration No. 360 B.E. 2556 (2013) in which it contains provisions in relation to the use of steviol glycosides and reissues the requirement of non-permitted use of star gooseberry corresponding to Codex standards referred to Codex Advisory Specification for Identity and Purity of Food additives as well as specifies the conditional use according to the requirement of General Standard for GSFA. There are requirements for some foods which are different from GSFA such as drink containing milk as main ingredient in both liquid and powder milk (Food category code: 06.8.1), flavored beverage (Food category code: 14.1.4), and gum (Food category code: 05.3). However, all food products which are not permitted to use a sweetener such as milk, flavored milk, jam, jelly, marmalade in a sealed containers, chocolate and electrolyte drink are still banned (*3*).

4. **Notification of Food and Drug Administration No. 363 B.E. 2556 (2013)** in which it contains provisions in relation to food additives (issue 2): Labeling of food additives referred to Codex General Standard for the Labeling of Food Additives when sold as such in order to more effectively protect the consumers and provide information for food manufacturers to use food additives required by regulation.

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Summary

Thailand has permitted the use of food additives in accordance with the Codex standards which relate to food additives in order to protect the safety of consumers and enhance the international trade. However, the Codex standards are continuously being updated; therefore the Thai FDA Notifications have to be updated accordingly to comply with the Codex standards including oversight of the use of food additives in accordance with the laws and regulations.

Regulation and Standard of Food Contact Materials in Thailand

Food packaging in Thailand is regulated under the Food Act of B.E. 2522 (1979). Primarily, the food packaging needs to be clean and must not be contaminated of any hazardous substances to human health, pathogenic microorganisms, and artificial food colorings. This Food Act also specifies that the used containers are not permitted to be reused, unless it is glass, ceramic, or plastic. In addition, containers must not be previously used with fertilizer, poisonous substance, or substance likely to be harmful to human health. Moreover, there are specifications of packaging depending on the type of materials used.

According to the Ministry of Public Health Announcement, there are three notifications under the Food Act related to food packaging.

1. **Notification No. 92 B.E. 2528 (1985)** is for food containers, use of food containers, and prohibition of food containers material. This notification specifies the migration limits of lead and cadmium that leach from ceramic and enameled metal containers. The limits are specific to container/vessel shapes, for example, small deep vessels, large deep vessels, and so on (*4*).

2. **Notification No. 295 B.E. 2548 (2005)**. This notification regulates 12 types of plastic food packaging which are polyvinylchloride, polyethylene, polypropylene, polystyrene, polyvinylidene chloride, polyethylene terephthalate, polycarbonate, nylon, polyvinyl alcohol, polymethyl methacrylate, polymethyl pentene, and melamine.

Specifications under Notification No. 295 are divided into two categories. The first part sets limits for heavy metals such as lead, cadmium arsenic and barium in the plastic itself and other toxic substances which can migrate into food depending on the type of plastic used such as vinyl chloride monomer from polyvinylchloride, bisphenol A from polycarbonate and so on.

The second part sets limits for substances migration into four food simulants. The limits are specific to particular types of plastic, for example, polyvinylchloride, polyethylene, polypropylene, and polystyrene. Clause 5 of this Notification states that "the analysis of qualities or standards of dispersion of plastic containers shall be carried out by the methods prescribed by the Food and Drug Administration." Based on the present best knowledge, the migration tests are done using four food simulants: water for food with pH > 5, 4% acetic acid for food with pH < 5, n-heptane for fatty food, and 20% ethanol for alcoholic food.

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Clause 6 of Notification No. 295 specifies that plastic containers for milk or milk products and other products shall be made of polyethylene, ethylene, 1-alkene copolymerized resin, polypropylene, polystyrene, or polyethylene terephthalate. Two additional limits which are extracted substance by *n*-hexane and substance dissolved in xylene are also listed.

Clause 7 of Notification No. 295 prohibits the use of colored plastic containers to pack food, except in the following cases:

(a) Laminate plastics specifically the layer that does not directly contact with food;
(b) Plastics used to pack fruits with peel;
(c) Other cases which approval has been obtained from the Food and Drug Administration.

Clause 8 of Notification No. 295 prohibits the use of recycled plastic except using for packing food with peel.

Clauses 9 and 10 of Notification No. 295 prohibit using plastic containers that have previously been used for fertilizer, toxic substances or other hazardous substances to health. They also prohibit using plastic containers that have been used to pack other products which are not food and that bear a design of statement that may mislead the consumer (*5*).

3. **Notification No 117 B.E. 2532 (1989)** is for feeding bottles to be used by infants and children, which consist of bottle, lid, rubber teat, and rubber teat cover. The bottle, rubber teat, rubber teat cover shall be clean and shall have no color that can contaminate the food. In case the bottle is made of plastic, the plastic shall be of polycarbonate. The specifications of the container are divided into two parts. The first part sets the migration limits of lead and cadmium of the plastic material. The second part sets the migration limits of other heavy metals, potassium permanganate, and evaporation residues.

Although polycarbonate has been used safely as a baby milk bottle for over 40 years, recent research studies have implicated that bisphenol A (BPA), which is a raw material used for the production of polycarbonate, is a toxic substance.

The toxicology of BPA has been extensively studied by industry, government, and academic research groups using short and long term animal tests, including several reproduction studies. Therefore, the Thai FDA is highly concerned about the potential effect of BPA on infants and children. The Notification No. 117 is revised to use polypropylene, polyethersulfone and borosilicate glass instead of polycarbonate. In addition, the specifications for substances that migrate into food simulants are also revised.

The rubber teat can be made of natural rubber or synthetic rubber. They must not contain nitrosamine at a level greater than 0.01 mg/kg. This Notification regulates the migration limits of formaldehyde, zinc, volatile compound content,2-mercaptobenzothiazole (MBT), 2,6-bis(1,1-dimethylethyl) -4-methyl-phenol (BHT) and 2,2´-methylenebis(6-(1,1-dimethylethyl)-4-methyl-phenol) (*6*).

The Notification also requires that milk container must be clean, and must not be contaminated with any hazardous substances to human health, pathogenic microorganisms, and artificial food colorings.

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The second organization is the Thai Industrial Standards Institute (TISI) which is responsible for developing a set of industrial product standards in the food contact materials industry. TISI standards provide guidelines on quality and other properties of product and related processes. TISI develops both mandatory and voluntary Thai Industrial Standards (TIS) to suit the need and the growth of industry and trade, consumer protection, industrial promotion to be competitive in world market, environmental protection, and natural resources preservation.

At present, TISI has already developed 37 packaging standards. Among them are two mandatory standards for food packaging. These two standards are TIS 1136-2536 (Cling film) and TIS 2440-2552 (Stainless steel: seamed stockpots) (*7*).

The third organization is the Office of the Consumer Protection Board (OCPB) that is responsible for developing the mechanism for consumer protection as there are increasing numbers of products and services offered to the people. While the business operators have applied the advertising and marketing for sales promotion, this might be disadvantage to the consumers since they do not know the market situation, the fact about the product quality, and the reasonable price. Therefore, OCPB regulates the label of plastic packaging through the Notification No.9 B.E. 2544 (2001) and the label of melamine food packaging through the Notification No.18 B.E. 2547 (2004) to control the safety of melamine packaging (*8*).

It is worth noting that the Department of Science Service (DSS) is the governmental organization which is responsible for providing testing services of food additives and food packaging products and is involved in every committee concerning the regulation and standard of food packaging in Thailand.

Since 2012, the DSS has issued the Certificate of Analysis of food contact materials for Thai exporters. Importantly, DSS was appointed to be ASEAN Food Reference Laboratory (AFRL) in the area of food contact materials by the ASEAN Consultative Committee on Standard and Quality- Prepared Foodstuff Product Working Group (ACCSQ-PFPWG) in the 11th Meeting of PFPWG in 2010. The meeting requested that the DSS survey standards and regulations of food contact materials among ASEAN member countries. Then the DSS conducted such survey in 2011-2012. It was found that Brunei Darussalam, Cambodia, Myanmar and The Lao People's Democratic Republic (Lao PDR) have not developed the regulations for food contact material for prepared food products. Singapore has developed its own regulation while Indonesia, Malaysia, Philippines, Thailand and Vietnam developed their regulations based on Japanese Standard, European Commission, and the U.S. Code of Federal Regulations. The information obtained will be beneficial for the DSS to harmonize the standard of food contact material for ASEAN which will be implemented in 2015 when ASEAN community becomes a single market.

Summary

Although it seems that several notifications and mandatory standard of food packaging in Thailand have not been updated for a long time, the revising process will be initiated whenever there is scientific information concerning a new positive

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list. Developing the ASEAN standard of food contact materials, which will be accepted among ASEAN member countries, will be a key factor leading to a revising process for notifications and standards of Thailand.

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