

FY2011 Financial Supports for Promoting the “Sixth Industry” in Agriculture,
Forestry and Fisheries and Rural Areas
Creation and Promotion of the “Sixth Industry” for Pioneering the Future
Overseas Business Support Project for Japanese Food Industry in East Asia

**“Investigation of Commodity Food Standards
and Food Additives in Asia” (III)**

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1. Purpose of the Investigation

In order to strengthen management practices and international competitiveness of Japanese food industry that is facing quantitative saturation and maturity in domestic market, it is necessary to address developing business in East Asian

regions where attractive market is forming due to increasing population and dynamically growing economy.

In the past, Japanese food industry has been reluctant to develop new business in East Asia due to lack of information and understanding on food standards, methods of analysis, and conditions for use of food additives in the countries. The information including consistency with international standards such as Codex Standards should be compiled on database. Providing these information enable Japanese food industry to start and promote new business or facilitate smooth business in East Asian regions.

This investigation aimed to encourage Japanese food industry to enter into the East Asian market and to enable to start new business there, by using results of the investigation discussed at a workshop, training courses and/or individual consulting sessions held in Japan or in such East Asian countries, and by disseminating those results on the ILSI Japan website.

2. Outline of the Investigation

In order to expand distribution of foods and food materials in East Asian region according to MAFF (Ministry of Agriculture, Forestry and Fisheries)'s "East Asian Food Industry Revitalization Strategy", product standards, methods of analysis, and conditions for use of food additives for foods and food materials are required to be standardized or harmonized in the Region. This project intends to investigate the product standards, methods of analysis, and conditions for use of food additives on main foods and food materials in major countries in the Region and to contribute to the promotion and easier business developments of Japanese food industries and those in East Asian countries by means of exchanging and sharing information and dialogues on procedures for quality control and measures for resources and environments in the Region. This investigation was conducted with the help of specialists in the countries surveyed.

The results of the investigation were discussed at the "International Conference for Sharing Information on Food Standards in Asia" held at Hotel Mulia Senayan in Jakarta in Indonesia on February 21, Tuesday, 2012. The Conference was attended by total 127 participants from 9 ASEAN countries (Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam), plus Australia, China, Korea, Japan, UK, and USA, from those Governments as well as food industries. The interests of the administrators and food industries in harmonization of the standards for foods and agricultural products in the ASEAN countries were very high and the topics were actively discussed.

Further, the investigation included in this year general information on “Halal”, and preliminary survey on the Indian market in addition to the previous investigation on Codex, Korea, China and ASEAN countries, such as Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam, and preliminary study for preparation for the Database of the information collected.

2.1 Countries covered by the Investigation :

In the light of marketability (including population), business activities of Japanese companies possessing overseas subsidiaries and market potential in East Asian countries, we selected 5 countries in the FY2009 project; the Republic of Korea, the People's Republic of China, Malaysia, Singapore, and the Philippines. In FY2010, we added 3 countries; Indonesia, Thailand, and Vietnam, and in the FY2011 project, we examined the possibility to further expanded to India market.

2.2 Food(s) covered by the Investigation :

When designing the investigation program, the first pilot study covered instant noodles, carbonated drinks and prepared frozen foods which were considered to be relatively common in the region for the FY2009 project. Further, the information of milk was also collected for reference in FY2010. In the FY2011 project, related regulatory framework and conditions for use of food additives in target countries, and general information on “Halal” were added and investigated.

2.3 Methods of the Investigation :

This project was conducted by International Life Sciences Institute (ILSI Japan) with cooperation of ILSI's international network, namely ILSI Korea, ILSI Focal Point in China and ILSI Southeast Asia Region (ASEAN countries). Practically, the Investigation was conducted under the following procedures:

- (1) ILSI Japan determined survey items and target countries, and designed and prepared investigation forms.
- (2) ILSI Japan sent the investigation program and forms to ILSI branch offices concerned in the target countries. Local meetings were held as required and the investigation forms were modified according to conditions in the target countries.
- (3) ILSI branch offices in the target countries filled the investigation results into the forms in English and prepared the investigation report in each target country.
- (4) ILSI Japan compiled and analyzed the data filled, and translated into Japanese if needed.

- (5) Investigators in this project extracted the issues for standardization and harmonization of commodity food standards and conditions for use of food additives.
- (6) ILSI Japan convened an International Conference together with the persons from relevant Government Agencies, Experts in the Region, participants from Japanese companies to share and exchange the results.
- (7) ILSI Japan published the reports and disseminated those on the ILSI Japan website.

2.4 Project Team :

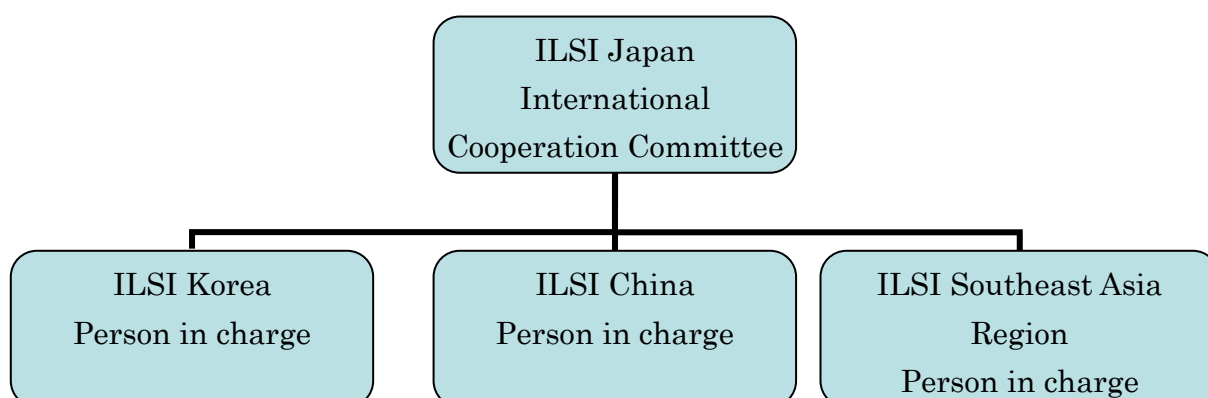
ILSI Japan set up the project team within its “International Cooperation Committee”, an organization of ILSI Japan. The team consisted of members representing each fields including food standards, methods of analysis, food additives, “Halal” and market of India. The team designed the program and proposed items to be investigated. These items were determined based on the discussions within ILSI branch offices (Korea, China and Southeast Asia Region). The project team conducted the investigation with the help of ILSI international network, especially with the following ILSI branch offices.

ILSI Japan branch: Japan

ILSI Korea branch: Korea

ILSI China branch: China (not including Hong Kong and Taiwan)

ILSI Southeast Asia Region branches: Malaysia, Singapore, Philippines,
Indonesia, Thailand, and Vietnam



2.5 Schedule of the Investigation :

This proposed project was conducted according to the following schedule.

Preliminary investigation and program design: July – September, 2011

Filling in the investigation forms: October – December, 2011

Collection and analyzing the data and extraction of future tasks: January, 2012

International conference: February 21, 2012 (Jakarta, Indonesia)

Preparation of the report: February – March 31, 2012

Duration of the survey program: 9 months

3. The Investigation Results for Each Country

3.1 Commodity Standards developed by Codex Alimentarius Commission

For defining the contents of "Food Standards", Commodity Standards developed by Codex Alimentarius Commission¹, which could be commonly accepted by member countries, were used in this investigation as a standard.

3.1.1 Elaboration of Codex Commodity Standards

Figure 3.1-1 shows relationship between Commodity Standards and General Standards in Codex.

Codex Alimentarius Commission has two types of functionally classified committees; Commodity Committees which deal with Commodity Standards, and General Subject Committees which deal with general subjects horizontally applied to overall foods. Standards developed by the Commodity Committee should be reviewed for overall foods and be approved by General Subject Committees.

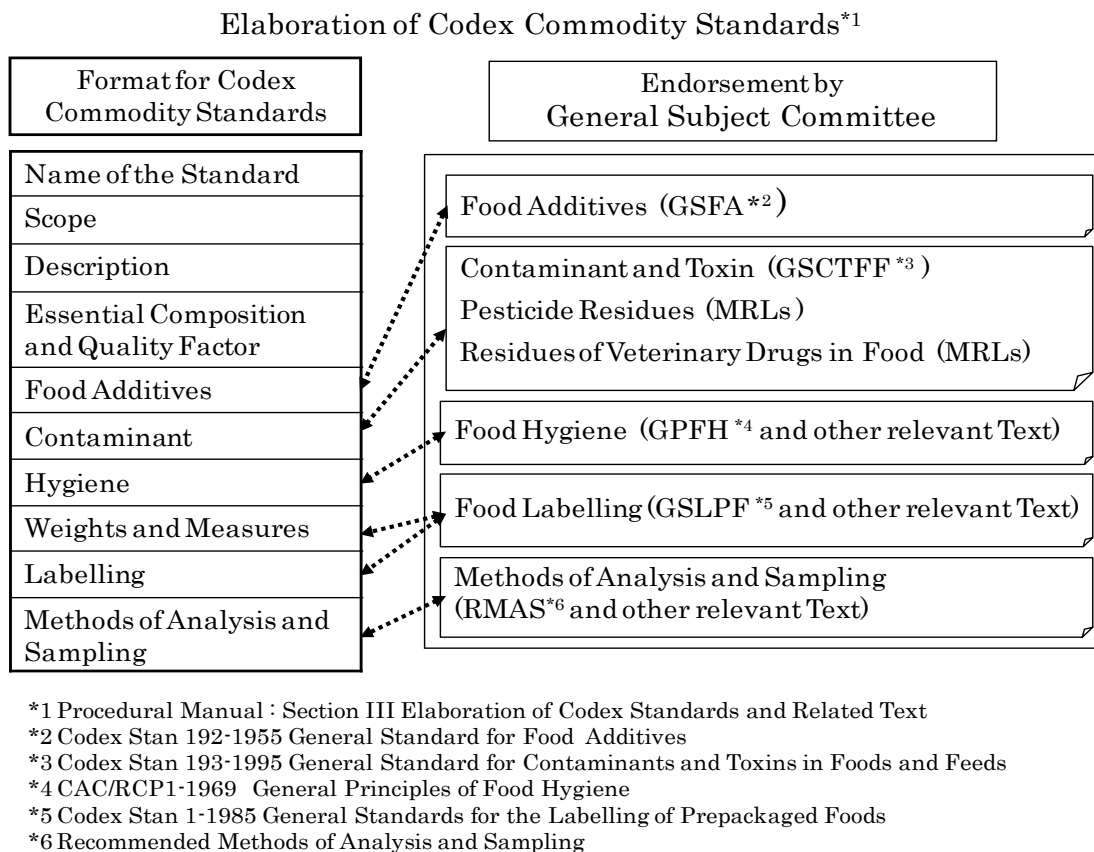


Figure 3.1-1 Commodity Standards developed by Codex Alimentarius Commission

¹ Codex Alimentarius Commission is an intergovernmental body established in 1962 by FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization) to implement the joint FAO/WHO Food Standards Programme. Its purpose is protecting the health of consumers and ensuring fair practices in the food trade through development of international food standards. Food standards developed by Codex Alimentarius Commission are intended to harmonize food standards worldwide under the multilateral trade agreement. http://www.codexalimentarius.net/web/index_en.jsp

For the format for commodity standards, requirements for description of items consisting standards, relations to General Subject Committees, method of elaboration of Commodity Standards is defined in detail in Codex Procedural Manual, 20th Edition².

As of July 2011, Codex Alimentarius Commission has defined commodity standards for 300 food items and local standards for 13 food items³.

This standard is relatively inconvenient to overview the status of each standard against overall standards since standard numbers in the table were assigned generally according to the year of issued in the original version. On the other hand, ANNEX B in General Standards for Food Additives⁴ (GSFA) presents Food Category System (FCS) which is used to develop standards for use of food additives and describes individual category items. ANNEX C provides cross-reference list between the FCS and developed commodity food standards. These are more useful to overview the overall standards.

3.1.2 Codex General Standard for Food Additives

General Standard for Food Additives (GSFA) has been considered since early 1990's at the Codex Committee on Food Additives (CCFA) and the work for establishing conditions for use of food additives has been being undertaken.

Basic framework of the GSFA, such as definitions and general principles for the use of food additives are defined in Preamble.

With regard to the conditions for use of individual food additives, those that have been determined to be safe and assigned an Acceptable Daily Intake (ADI) as "Not Specified (NS)" based on the safety evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) can be used for all foods with their minimum requirement level under Good Manufacturing Practice (GMP). On the other hand, for those that their ADI were assigned, the conditions for use are considered individually based on their functionality and purpose of use, and established in accordance with their food categories under the International Numbering System (INS) defined in Preamble.

The Preamble of the GSFA (CODEX STAN 192-1995) is copied in the following pages.

² ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_20e.pdf

³ http://www.codexalimentarius.net/web/standard_list.do?lang=en

⁴ http://www.codexalimentarius.net/gsfonline/docs/CXS_192e.pdf

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CODEX GENERAL STANDARD FOR FOOD ADDITIVES
CODEX STAN 192-1995
PREAMBLE

1. SCOPE

1.1 FOOD ADDITIVES INCLUDED IN THIS STANDARD

Only the food additives listed herein are recognized as suitable for use in foods in conformance with the provisions of this Standard.⁵ Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe⁶ by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)⁷ and an International Numbering System (INS) designation by Codex will be considered for inclusion in this Standard. The use of additives in conformance with this standard is considered to be technologically justified.

1.2 FOODS IN WHICH ADDITIVES MAY BE USED

This Standard sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex. The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and this standard. The General Standard for Food Additives (GSFA) should be the single authoritative reference point for food additives. Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives (CCFA) when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, CCFA will appraise the technological need.

⁵ Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.

⁶ For the purpose of this standard “determined, on the basis of other criteria, to be safe” means that the use of a food additive does not pose a safety concern under conditions of use described by JECFA as being of no toxicological concern (e.g. use levels defined circumstances).

⁷ A data base of food additive specifications with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc., are available in English at the JECFA website at FAO. <http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en> The database has a query page and background information in English, French, Spanish, Arabic and Chinese. The reports of JECFA are available at the JECFA website at WHO. <http://www.who.int/ipcs/food/jecfa/en/>

1.3 FOODS IN WHICH ADDITIVES MAY NOT BE USED

Food categories or individual food items in which the use of food additives is not acceptable, or where use should be restricted, are defined by this Standard.

1.4 MAXIMUM USE LEVELS FOR FOOD ADDITIVES

The primary objective of establishing maximum use levels for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed its ADI.

The food additives covered by this Standard and their maximum use levels are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum use levels to an appropriate method for verifying the compatibility of a proposed maximum level with the ADI.

Annex A of this Standard may be used as a first step in this regard. The evaluation of actual food consumption data is also encouraged.

2. DEFINITIONS

- a) ***Food additive*** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities⁸.
- b) ***Acceptable Daily Intake (ADI)*** is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk⁹.
- c) ***Acceptable Daily Intake "Not Specified" (NS)*** ¹⁰ is a term applicable to a food

⁸ Codex Alimentarius Procedural Manual.

⁹ Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), p. 111 (1987). For the purposes of this Standard, the phrase "without appreciable health risk" means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health.

¹⁰ For purposes of this Standard, the phrase acceptable daily intake (ADI) "not limited" (NL) has the same meaning as ADI "not specified". The phrase "acceptable ADI" refers to an evaluation by JECFA, which established safety on the basis of an acceptable level of treatment of food, limited numerically or by GMP,

substance of very low toxicity for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.

For the above reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice as defined in section 3.3 below.

- d) ***Maximum Use Level*** of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.

The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

The use of food additives in conformance with this Standard requires adherence to all the principles set forth in Sections 3.1 – 3.4.

3.1 FOOD ADDITIVE SAFETY

- a) Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the use levels proposed.
- b) The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake¹¹ from all food sources. Where the

rather than on a toxicologically established ADI.

¹¹ Codex members may provide the CCFA with intake information that may be used by the Committee in establishing maximum use levels. Additionally, the JECFA, at the request of the CCFA, will evaluate intakes of additives based on intake assessments submitted by Codex members responding to a call for data. The CCFA will consider the JECFA evaluations when establishing the maximum use levels for additives.

food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers.

- c) The quantity of an additive added to food is at or below the maximum use level and is the lowest level necessary to achieve the intended technical effect. The maximum use level may be based on the application of the procedures of Annex A, the intake assessment of Codex members or upon a request by the CCFA to JECFA for an independent evaluation of national intake assessments.

3.2 JUSTIFICATION FOR THE USE OF ADDITIVES

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

- a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
- b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
- c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
- d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3.3 GOOD MANUFACTURING PRACTICE (GMP)¹²

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:

- a) The quantity of the additive added to food shall be limited to the lowest

¹² For additional information, see the Codex Alimentarius Commission Procedural Manual. Relations Between Commodity Committees and General Committees- Food Additives and Contaminants.

- possible level necessary to accomplish its desired effect;
- b) The quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,
 - c) The additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

3.4 SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES

Food additives used in accordance with this Standard should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission¹³ or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by conformance of additives to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMP.

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS

4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES FROM INGREDIENTS AND RAW MATERIALS INTO FOODS

Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:

- a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard;
- b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard;
- c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or

¹³ An index (CAC/MISC 6) of all specifications adopted by the Codex Alimentarius Commission, as well as the year of adoption, is available at the Codex website (<http://www.codexalimentarius.net>). These specifications, prepared by the JECFA, are also being published in 2006 in the “Combined Compendium of Food Additive Specifications,” FAO JECFA Monographs No. 1, which consists of four volumes and in subsequent JECFA Monographs. The specifications are also available at the JECFA website (<http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en>). Although specifications for flavouring agents are not included in the printed compendium, with the exception of those few which have an additional non-flavour technological function, they are included in an online searchable database at the JECFA website at FAO. <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>

ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.

4.2 SPECIAL CONDITIONS APPLYING TO THE USE OF FOOD ADDITIVES NOT DIRECTLY AUTHORISED IN FOOD INGREDIENTS AND RAW MATERIALS

An additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard, including that any maximum level applying to the food is not exceeded.

4.3 FOODS FOR WHICH THE CARRY-OVER OF FOOD ADDITIVES IS UNACCEPTABLE

Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.

- a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.
- b) 13.2 - Complementary foods for infants and young children.

5. FOOD CATEGORY SYSTEM¹⁴

The food category system is a tool for assigning food additive uses in this Standard. The food category system applies to all foodstuffs.

The food category descriptors are not to be legal product designations nor are they intended for labelling purposes.

The food category system is based on the following principles:

- a) The food category system is hierarchical, meaning that when an additive is recognized for use in a general category, it is recognized for use in all its sub-categories, unless otherwise stated. Similarly, when an additive is recognized for use in a sub-category, its use is recognized in any further sub-categories or individual foodstuffs mentioned in a sub-category.
- b) The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated.
- c) The food category system takes into consideration the carry-over principle. By doing so, the food category system does not need to specifically mention

¹⁴ Annex B to this Standard.

compound foodstuffs (e.g., prepared meals, such as pizza, because they may contain, pro rata, all the additives endorsed for use in their components), unless the compound foodstuff needs an additive that is not endorsed for use in any of its components.

- d) The food category system is used to simplify the reporting of food additive uses for assembling and constructing this Standard.

6. DESCRIPTION OF THE STANDARD

This Standard consists of three main components:

- a) Preamble

- b) Annexes

- i. Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.
- ii. Annex B is a listing of the food category system used to develop and organize Tables 1, 2, and 3 of the standard. Descriptors for each food category and sub-category are also provided.
- iii. Annex C is a cross-reference of the food category system and Codex commodity standards.

- c) Food Additive Provisions

- i. Table 1 specifies, for each food additive or food additive group (in alphabetical order) with a numerical JECFA ADI, the food categories (or foods) in which the additive is recognized for use, the maximum use levels for each food or food category, and its technological function. Table 1 also includes the uses of those additives with nonnumerical ADIs for which a maximum use level is specified.
- ii. Table 2 contains the same information as Table 1, but the information is arranged by food category number.
- iii. Table 3 lists additives with Not Specified or Not Limited JECFA ADIs that are acceptable for use in foods in general when used at quantum satis levels and in accordance with the principles of good manufacturing practice described in Section 3.3 of this preamble. The Annex to Table 3 lists food categories and individual food items excluded from the general conditions of Table 3. The provisions in Tables 1 and 2 govern the use of additives in the food categories listed in the Annex to Table 3.

Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed.

Tables 1, 2, and 3 do not include references to the use of substances as processing aids¹⁵.

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¹⁵ Processing Aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product: Codex Alimentarius Commission Procedural Manual.

Table 3.1-A Description/Definition (General)

	Description / Definition
Related Legislation	CODEX STAN 192-1995 CAC/GL 66-2008 CODEX STAN 107-1981
General Description/Definitions	
Definition of food additives	CODEX STAN 192-1995 Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.
Flavour	GUIDELINES FOR THE USE OF FLAVOURINGS CAC/GL 66-2008 (ア) Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings. (イ) Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients (Section 2.3) within the conditions as referred to in 3.5. They are not intended to be consumed as such.
Processing aids	CODEX STAN 107-1981 Processing aid means a substance or material not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.
Carry-over	4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:

		<ul style="list-style-type: none">a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard;b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard;c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.
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3.2 Japan

3.2.1 Summary Chart of Relationship between Food Regulatory System and Commodity Food Standards

Summary chart of relationship between food regulation system and commodity food standards in Japan is shown in **Figure 3.2-1** in a way that Codex Alimentarius Commission presented in **Figure 3.1-1**. This section was prepared because it is important to introduce regulatory framework on foods in Japan for mutual understanding among member countries.

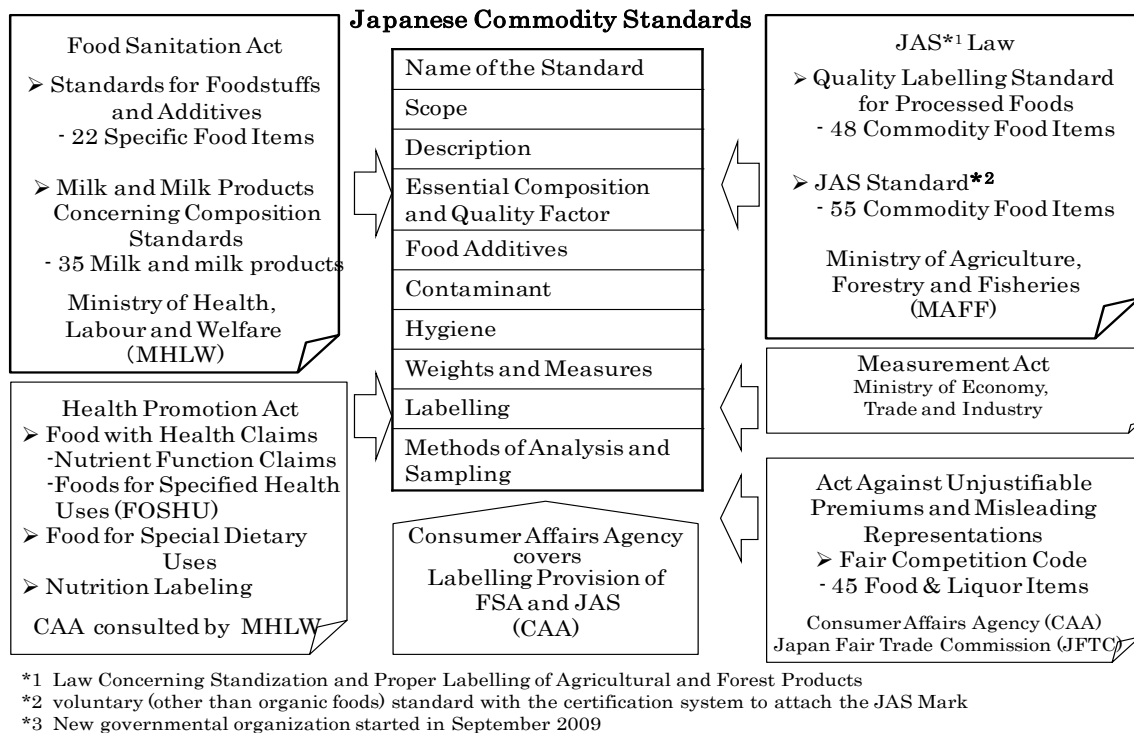


Figure 3.2-1 Japanese Food Regulatory System

3.2.2 Commodity Food Standards

3.2.2.1 The Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products

The law consists of combination of “JAS Standards System” which is voluntary except for the JAS Standards for Organic Foods, and "the Quality Labelling Standards System" which mandate for quality labelling purposes including name of food, raw materials and place/country of origin.

(1) The Quality Labelling Standards System

The Quality Labelling Standards System provides cross-category standards for fresh foods, processed foods and genetically modified foods, and individual standards for 3 fresh foods and 48 processed foods (see **FY2009 Report Table 3.2-1**).

(2) JAS Standards System

JAS Standards mainly stipulate quality, composition, grade and usefulness for food, forest and agricultural products including silk and rush tatami facing. JAS Standards System is a certification system to bear JAS marks on the label through certification by Registered Certifying Bodies. Products should meet to JAS standards, standards for maintenance and quality control in manufacturing facility, performance of production process control etc. As of March 2010, JAS Standards for food define 55 items in five areas (see **FY2009 Report Table 3.2-2**).

3.2.2.2 Food Sanitation Act and related regulations

Food Sanitation Act stipulates matters related food safety including food additives, pesticide residues, contaminants and hygiene.

(1) Standards for Foodstuffs and Additives (Notification of Ministry of Health and Welfare No. 370)

Standards for Foodstuffs and Additives define standards for component, production and storage for 22 specific food items, in addition to general standards for component, production, processing and preparation, and storage for food (see **FY2009 Report Table 3.2-3**).

(2) Ministerial Ordinance on Compositional Standards for Milk and Milk Products (Ordinance of Ministry of Health and Welfare No. 52)

For milk and milk products, the ordinance specifically stipulates standards for component, production, storage and hygiene (see **FY2009 Report Table 3.2-4**).

3.2.2.3 Fair Competition Code for Labelling of Food Items

Fair Competition Code based on Act against Unjustifiable Premiums and Misleading Representations stipulates voluntary standards for labelling of food items for individual firms and industry associations (see **FY2009 Report Table 3.2-5**), and is governed by Consumers Affairs Agency and the Fair Trade Commission. When their activities violate the code, penalty shall be imposed to their business activity. The Fair Trade Commission could take an action against even an outsider in accordance with social recognition of the code.

3.2.3 Acts and Regulations related to Food Additives

3.2.3.1 Overview

In Japan, food additives are regulated by the Ministry of Health, Labour and Welfare (MHLW). The main legal basis for regulation of food additives is found in the Food Sanitation Act (Act No. 233 of December 24, 1947) and its subsidiary

legislations including;

- The Food Sanitation Act Enforcement Regulations, July 13, 1948
- MHLW Notification No.370, December 28, 1959 “Specifications and Standards for Foods, Food Additives, etc.”
- Cabinet Office Ordinance No.45, August 31, 2011 on the criteria of labelling pursuant to item (1) of Article 19 of Food Sanitation Act

The Act provides that:

- 1) Substances that are not permitted as food additives are not allowed to be used as food additives;
- 2) Permitted food additives that do not comply with specifications prescribed under the Food Sanitation Act, where such specifications are so described, are also not allowed to be used as food additives.
- 3) Manufacturing and/or use of permitted food additives should comply with standards of manufacture/use, including maximum level of use, prescribed under the Food Sanitation Act, where such standards are so described.
- 4) The government is responsible to compile “The Japanese Standards for Food Additives” to contain the standards and specifications.

Additionally, among some of 55 JAS Mark standards under the Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products (JAS Law), use of some food additives are restricted in the food so described. JAS Mark is voluntary certification system.

JAS Law also has the “Quality Labelling Standard” system. Among several standards of the system, all processed foods except for alcohol beverage are regulated by the “Quality Labelling Standard for Processed Foods” (Notification No.513 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000). Food additives used in processed foods should be labeled in accordance with the standard (see 3.2.3.7).

3.2.3.2 Food Additive Definition & Functional Classes

Food additive in Japan is defined in Article 4-2 of the Food Sanitation Act as follows.

“Food additives” means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.

Consequently, “food additive” includes both substances remaining in the finished food products, such as food colours and preservatives, and substances not remaining in the finished products, such as infiltration-supporting agents. Any substances

added to food in order to maintain or increase the nutritional value of food is also included in “food additive”.

Article 4 of the Act also defines the term “natural flavouring agent” as follows.

“Natural flavouring agent” means food additives, intended for use for flavouring food, which are substances obtained from animals or plants, or mixtures thereof.

Neither “processing aid” nor “carry over” is defined in Article 4 (definition), but these are defined in one of the regulations for food labelling, i.e., the provisions of article 19, paragraph 1, item 1-e of the Cabinet Office Ordinance No.45, 2011, on the criteria of labelling pursuant to item 1 of Article 19 of Food Sanitation Act. The provision defines that;

“Processing aids” means substances added to a food in processing the food, which are: 1) removed from the food before the completion of the food, 2) derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or 3) present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food.

“Carry-over” means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished food at levels less than those normally required to achieve any technical or functional effect in the food.

The provisions of item 2 of article 1 of the Cabinet Office Ordinance No.45, 2011, on the criteria of labelling pursuant to item 1 of Article 19 of Food Sanitation Act, defines 8 functional classes of food additive. In case such food additive is used in food, not only the name of food additive but also the functional class of such food additive is requested to be labeled on the food. These 8 functional classes are 1) sweeteners, 2) colours, 3) preservatives, 4) thickeners/stabilizers/gelling agents, 5) antioxidants, 6) colour enhancers, 7) bleaching agents, and 8) antimold agents.

3.2.3.3 Permitted Food Additives and Maximum Limits

Several lists of permitted food additives are described below. Newly designated food additive is listed as “Designated food additives” on the Attached Table 1 of the Food Sanitation Act Enforcement Regulations, July 13, 1948. There is no classification of function in these lists. Functional class of food additive is an important matter in labelling regulation.

1) Designated food additives

As of March 2012, 423 additives are designated as approved by the Minister of Health, Labour, and Welfare under Attached Table 1 of the Food Sanitation Act Enforcement Regulations, July 13, 1948.

Separately from the designation process described below (**3.2.3.6 Assessment of Food Additives**), the MHLW has started a project to designate certain food additives which are not permitted their use in Japan but seemed to be important in international harmonization. The MHLW itself even carries out additional safety test when necessary. This action underlies such background that there is a growing possibility that imported foods may contain food additives that are authorized in other countries but unauthorized in Japan.

The numbers and examples of food additives which are newly designated to the list by this process in last 6 years are;

2006	8	propanol, isopropanol, amyl alcohol, hydroxypropyl cellulose, natamycin, etc.
2007	6	acetaldehyde, 2-ethyl-3-methylpyridine, butanol, potassium alginate, etc.
2008	18	calcium L-ascorbate, polysorbate 20, magnesium hydroxide, etc.
2009	6	nisin, isovaleraldehyde, 2,3-dimethylpyrazine, valeraldehyde, etc.
2010	18	2-ethylpyrazine, sodium stearoyl lactylate, calcium sorbate, propionaldehyde, etc.
2011	12	5-ethyl-2-methylpyridine, pyrazine, 1-penten-3-ol, 3-methyl-2-butenal, isoquinoline, etc.

2) Existing food additives

Until 1995, the designation system had been applied only to chemically synthesized food additives. In 1995, Food Sanitation Act was amended and all types of additives are equally subject to the designation system, ignoring they are synthetic or non-synthetic, with minor exceptions, that is;

Substances that were already marketed or used on the date of the amendment of the Food Sanitation Act in 1995 were listed on the Existing Food Additives. The list was noticed in 1996 for the first time. The MHLW is conducting continuous survey of marketing and use of Existing Food Additives, and such additives that are no more marketed nor used are delisted from the list. The last delisting was in May, 2011, 53 food additives are delisted from the list.

Beside the marketing and use survey, akane-shikiso or Madder colour, colour from root of *Rubia tinctorum*, had been delisted from the list of Existing Food Additives

based of the report from Food Safety Council in 2004.

As of March 2012, there are 365 Existing Food Additives in the list.

3) Natural flavouring agents

“Natural flavouring agent” is a food additive which is exempted from the designation system of food additives. Chemicals which can be used for extraction of natural flavouring agents and maximum residual level of such chemicals are regulated by the manufacturing standards for several natural flavouring agents.

“List of plant or animal sources of natural flavourings” is given in Appendix 2, the CAA Notice, No. 377, October 20, 2010. This list is for labelling of “Natural flavouring agents” and is NOT a positive list of source of flavouring agents. If someone manufacture natural flavouring agent from a source which is not listed on the list, some scientifically proper name which can specify the source should be labeled on the flavour agents.

4) Substances that are both generally provided for eating or drinking as foods and used as food additives

Substances that are both generally provided for eating or drinking as foods and used as food additives have been excluded from the designation system.

“List of substances which are generally provided for eating or drinking as foods and which are used as food additives” is given in Appendix 3, the CAA Notice, No. 377, October 20, 2010. This list is also NOT a positive list of food additives that are both generally provided for eating or drinking as foods and used as food additives. If someone manufactures a food additive from a source which is not listed on the list, some scientifically proper name which can specify the source should be labeled on the flavour agents.

Standard of Use for food additives, including the maximum level of use, are described in the MHLW Notification No.370, 1959 “Specifications and Standards for Foods, Food Additives, etc.”. Generally, if a food additive preparation contains food additives for which standards for use have been established, the established standards are regarded as standards for use for the preparation, but some exemption are specified.

3.2.3.4 Prohibited Substances as Food Additives

The food additive is controlled by the designation system (positive list) and there is no list of prohibited substances as food additives (negative list). However, among some of 55 JAS Mark standards under the Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products (JAS Law), use of some food

additives are restricted in the food so described. JAS Mark is voluntary certification system.

3.2.3.5 Specifications for Food Additives

Food additives that are produced, imported and distributed must follow the specifications laid out in the MHLW Notification No.370, 1959 “Specifications and Standards for Foods, Food Additives, etc.”.

3.2.3.6 Assessment of Food Additives

Designation of a food additive is normally based on application from a person who wishes to use it. The MHLW will ask the Food Safety Commission for opinions concerning health effects of the food additive and the Pharmaceutical Affairs and Food Sanitation Council to discuss the adequacy of draft standards. If the discussion of the Pharmaceutical Affairs and Food Sanitation Council proves that the additive is safe and effective, it will be designated as an additive approved for use.

Documents accompanying an application should contain;

- 1) Summary of documentation
- 2) Documentation on origin or details of development and overseas conditions on use
- 3) Documentation on physicochemical characteristics and specifications
- 4) Documentation on effectiveness
- 5) Documentation on safety
- 6) Documentation on draft standard of use

3.2.3.7 Labelling of Food Additives

Labelling of food additives in foods is regulated by both Food Sanitation Act and JAS law. The “Quality Labelling Standard for Processed Foods” (Notification No.513 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000) requests food manufacturers that “Names of food additives shall be labeled in the descending order by weight in the total ingredients, pursuant to the provisions of article 1, item 2-e, item 4, article 11 and article 12 of the Cabinet Office Ordinance No.45, 2011, on the criteria of labelling pursuant to item 1 of Article 19 of Food Sanitation Act.

3.2.3.8 “Japanese Standards of Food Additives”

According to the article 21 of Food Sanitation Act, regarding additives for which the specifications and standards have been established pursuant to the provisions of Article 11, paragraph 1 and additives for which the labelling standards have been established pursuant to the provisions of Article 19, paragraph 1, the Minister of

Health, Labour and Welfare shall compile the Japanese Standards of Food Additives to contain such specifications and standards.

The 1st edition of Japanese Standards of Food Additives were issued in 1960, the latest one is the 8th edition issued in 2007. English translation of the 7th edition, issued in 1999, is available on website¹⁶.

3.2.4 Case Study

Regulations on the use of food additives in specific food categories are studied for “Instant Noodles”, “Carbonated Soft Drinks”, “Prepared Frozen Foods” and “Cow’s Milk”. The most approximate Codex Commodity Standards or GSFA Food Categories are also described in Table 3-2. Generally under the FSA, the standards of use of food additives in specific food categories are defined at “**Japanese Standards of Food Additives**” (JSFA), and not defined at each commodity standards, which more focus on hygienic standards of each food categories.

(1) Instant Noodles (**Table 3.2-1**)

Standards for “Instant Noodles” is defined by Food Sanitation Act, but it only includes specification and standards of storage for oil-processed type Noodles. Limitation of use of some food additives to Instant Noodles (including their attached soups) are defined at JSFA. Standards including maximum limits for use of food additives are also defined by JAS Law.

(2) Carbonated Soft Drinks (**Table 3.2-2**)

In Food Sanitation Act, there is a standard of use for food additives in “non-alcoholic beverage”. Carbonated Soft Drinks is a subcategory of non-alcoholic beverage in FSA and there is no independent standard for Carbonated Soft Drinks in FSA.

“Carbonated Soft Drinks” is one of 55 JAS Mark standards under JAS Law. Limitation in use of some food additives to non-alcoholic beverage are defined at JSFA. Food additives which can be used in JAS Mark Carbonated Soft Drinks are restricted.

(3) Prepared Frozen Foods (**Table 3.2-3**)

“Frozen Foods” is defined and standard for use of food additive in “Frozen Foods” is set in Food Sanitation Act. Under the Food Sanitation Act, the limitations in use of food additives are applied to the foods to be frozen, not to the frozen foods themselves. “Prepared Frozen Foods” is one of JAS Mark standards under JAS Law. There is a

¹⁶ <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa>

food category similar to “Frozen Foods” in Japan only in Korea, “Frozen Foods” nor “Prepared Frozen Foods” is not defined in the other East Asian countries .

(4) Cow’s Milk (**Table 3.2-4**)

Use of food additives in Cow’s Milk is prohibited by Food Sanitation Act. There is no JAS Mark standards for Cow’s Milk.

Table 3.2-A Description/Definition (General)

	Description / Definition	Reference
Related Legislation	Food Sanitation Act, 1947	http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=02
General Description/Definitions		
Definition of food additives	“Food additives” means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.	FSA Article 4, 2 http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html
Flavour	Flavour is classified in the food additive category. “Natural flavouring agent” means food additives, intended for use for flavouring food, which are substances obtained from animals or plants, or mixtures thereof.	FSA Article 4, 3
Processing aids	Processing aid is classified in the food additive category. “Processing aids” means substances added to a food in processing the food, which are: 1) removed from the food before the completion of the food, 2) derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or 3) present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food.	Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948
Carry-over	“Carry-over” is defined, but only for labelling purposes. “Carry-over” means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished product at levels less than those normally required to achieve any technical or functional effect in the food.	Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948

Table 3.2-B Description/Definition (Specific)

		Description / Definition	Reference
Related legislation		Food Sanitation Act, 1947	http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=02
Specific descriptions / Additional explanations			
1	List of Designated Food Additives	Food additive is listed as “Designated food additives” on the attached table 1 of the Food Sanitation Act Enforcement Regulations, 1948. There is no classification of function in these lists. As of March 2012, 423 additives are designated as approved by the MHLW.	http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x
2	List of Existing Food Additives	Substances that were already marketed or used on the date of the amendment of the FSA in 1995 were listed on the Existing Food Additives. The MHLW is conducting continuous survey of marketing and use of food additives on the list. As of March 2012, there are 365 Existing Food Additives in the list.	http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add
3	List of Plant or Animal sources for Flavouring agents	“List of plant or animal sources of natural flavourings” is given in Appendix 2, the CAA Notice, No. 377, 2010. This list is for labelling of “Natural flavouring agents” and is NOT a positive list of source of flavouring agents.	http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-nat.flavors
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	Substances that are both generally provided for eating or drinking as foods and used as food additives have been excluded from the designation system. “List of substances which are generally provided for eating or drinking as foods and which are used as food additives” is given in Appendix 3, the CAA Notice, No. 377, 2010.	http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-general.provd.add
Negative list (if any)		There is no negative list of food additives under FSA.	

<p>Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives</p>	<p>The last 8th edition is issued in 2007. English translation of 7th edition, issued in 1999, is available on website.</p>	<p>http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa</p>
<p>Official publication and/or gazette for food additives</p>	<p>Regarding additives for which the specifications and standards have been established pursuant to the provisions of Article 11, paragraph 1 and additives for which the labelling standards have been established pursuant to the provisions of Article 19, paragraph 1, the MHLW shall compile the Japanese Standards of Food Additives to contain such specifications and standards.</p>	<p>http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa</p>

Table 3.2-1 Case Study 1 Instant Noodles

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act	JAS Law (voluntary standards)
Scope and/or Description	Codex stan 249-2006 (Standard for Instant Noodles), (06.4.3) Pre-cooked pastas and noodles and like products	Standards for “Instant Noodles” is defined in Food Sanitation Act, but it only includes specification and standards of storage for oil-processed type Noodles. Limitation of use of some food additives to Instant Noodles (including their attached soup powder) are defined at JSFA.	Positive List (limitation in use)
Positive and/or Negative List			
Use Limitation and/or Maximum Level, if any			

“JAS” Law : The Law Concerning Standardization and Proper Labelling of Agriculture and Forestry Products.

Table 3.2-2 Case Study 2 Carbonated Soft Drinks

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act	JAS Law (voluntary standards)
Scope and/or Description	(14.1.2.1) Fruit juice	Maximum level of several food additives in “non-alcoholic beverage” is set in “the Standards for use of Food Additives ” Standards of soft drinks are described in FSA. But no positive/negative list on food additives in it.	http://www.ffcr.or.jp/zaidan/FFC_RHOME.nsf/pages/spec.stand.fa -Preservatives: only sodium benzoate and p-hydroxybenzoic acid allowed -Antioxidants: only L-ascorbic acid and sodium L-ascorbate allowed -Emulsifiers: only sucrose fatty acid esters and glycerin fatty acid esters allowed
Positive and/or Negative List	(14.1.3.1) Fruit nector		
	(14.1.4.1) Carbonated water-based flavoured drinks		
	(14.2.2)		

Use Limitation and/or Maximum Level, if any	Cider and Perry	In “the Standards for use of Food Additives”, maximum level of several food additives in “non-alcoholic beverage” is set and some food additives are prohibited to be used in “non-alcoholic beverages”.		
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Table 3.2-3 Case Study 3 Prepared Frozen Foods

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act		JAS Law (voluntary standard)
Scope and/or Description	Not applicable	Specifications of prepared frozen foods are described in FSA.		Positive List (limitation in use)
Positive and/or Negative List		No positive/negative list on food additives in it.		
Use Limitation and/or Maximum Level, if any		The restrictions in use of food additives are applied to the foods to be frozen, not to the frozen foods.		

Table 3.2-4 Case Study 4 Cow’s Milk

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act		JAS Law (voluntary standard)
Scope and/or Description	01.1.1.1 Milk (plain)	Use of food additives in milk is prohibited or restricted by FSA	http://www.mhlw.go.jp/english/topics/foodsafety/dl/t-1.pdf	No JAS Mark standard for Cow’s Milk
Positive and/or Negative List				
Use Limitation and/or Maximum Level, if any				

3.3 Korea

3.3.1 Laws and Regulations Related to Food Standards

3.3.1.1 Administrative Authorities

Administrative authorities in Korea shown in **Table 3.3-1** are responsible for food administration in accordance with food categories and control items.

Table 3.3-1 Food Safety Control System in Korea¹⁷

Section	Production (Agriculture, Farming, Aquafarming)	Imported	Domestic
Agricultural Products	MIFAFF	KFDA	
Marine Products	MIFAFF	KFDA	
Livestock Products	MIFAFF	MIFAFF KFDA (Standards for Residual Harmful Substances)	
Bottled Mineral Waters	Ministry of Environment		
Alcoholic Beverages	National Tax Service KFDA (Standards for Residual Harmful Substances)		
School Meals	MEST Education Bureau KFDA (Safety Management for Group Feeding Facilities except for School Feeding Facilities)		

MIFAFF : Ministry for Food, Agriculture, Forestry and Fisheries

KFDA : Korea Food & Drug Administration

MEST : Ministry of Education, Science and Technology

KFDA¹⁸ is a law-enforcement agency to promote the public health by ensuring the safety and efficacy of foods and pharmaceuticals, and to support the development of food and pharmaceutical industries. MIHWAF (Ministry of Health, Welfare and Family Affairs)¹⁹ is responsible for policymaking and legislation related to food safety. Korean Fair Trade Commission (KFTC) and Korea Consumer Agency (KCA) are responsible for proper labelling and protecting consumers.

Unlike in Japan, there is no independent body for risk assessment in Korea. As presented in **Table 3.3-1**, KFDA and MIFAFF have both functions of risk management and risk assessment as two separate groups in the organizations intending to help consistent management and communication based on scientific assessment.

¹⁷ Cherl-Ho Lee; 2009 ILSI BeSeTo Meeting on Food Safety: Report of the First Meeting in Seoul, Korea, 16p, 2009.

¹⁸ KFDA; Vision <http://www.kfda.go.kr/eng/index.do>

¹⁹ MIHWAF; Food Safety Management http://english.mw.go.kr/front_eng/jc/sjc0101mn.jsp?PAR_MENU_ID=1003&MENU_ID=10030101
(Accessed: 2010/03/16)

3.3.1.2 Related Laws and Regulations

Laws and regulations related to food include as follows; Food Sanitation Act, Health Functional Food Act, and Health Promotion Act set by MIHWAF; Monopoly Regulation, Fair Trade Act, and Fair Labelling and Advertizing Act set by Korea Fair Trade Commission; Consumer Protection Act covered by Korea Consumer Agency. Among these acts and regulations, Food Sanitation Act is mainly related to food standards. The Act and related rules in English version can be seen on the Web site of KFDA²⁰.

MIFAFF provides quality labelling standards for proper labelling of agricultural products, fisheries products and livestock products. Scopes for these products are as follows;

- Agricultural Quality Standards: All agricultural products other than processed products (to which Food Sanitation Act is applied)
- Marine Quality Standards: All marine products including processed products (Disease Control Law of Marine Animals is applied to live marine animals and plants imported from third country)
- Livestock Quality Standards: Meat, milk, egg and their processed products

Moreover, MIFAFF operates various quality certification systems for labelling and food safety. The systems and their marks are shown as follows.

- Specific labelling certification system: Good Agricultural Practices (105 items), organic processed foods, genetically modified foods



- Safety Certification System: HACCP, Traceability (agricultural products, livestock products, marine products), Livestock Products Safety Management System, SafeQ



²⁰ KFDA ; Relevant Rule <http://eng.kfda.go.kr/index.php> (Accessed: 2010/03/19)

3.3.2 Summary of Food Standards in Korea

Figure 3.3-1 is shown to compare existing food standards in Korea to Codex Standards. Food Code defined by Food Sanitation Act is mandatory standards including 29 food items. While, Korean Industrial Standards (KS) developed by Ministry of Knowledge Economy, Agency for Technology and Standards (KATS) is a voluntary standard like JAS standard to obtain certification mark. There are also MIFAFF standards covering some processed food, however we focused on 29 food items in Food Code and KS standards for further investigation. Meanwhile, food Additive Code²¹ laying down specifications and their criteria for use (including analytical methods) is commonly applied to all food.

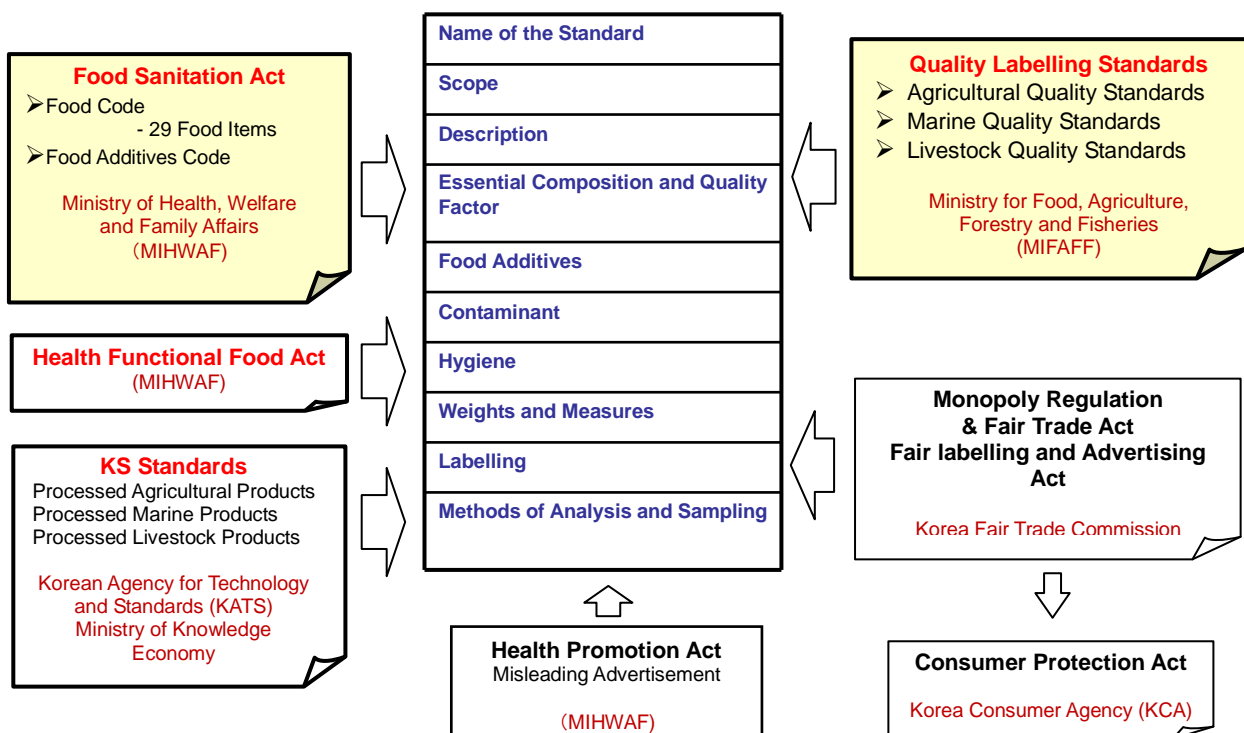


Figure 3.3-1 Summary Chart of Food Standards in Korea

3.3.2.1 Food Standards in Food Code

Food Code defines the followings: (1) Methods for food production, processing, preparation, usage, storage, as well as specifications of food composition, which are stipulated in Article 7-1 of Food Sanitation Act, (2) materials and production method for apparatus, container and packaging stipulated in Article 9-1, and (3) labelling standards for foods, food additives, apparatus, containers, packages and genetically modified foods stipulated in Article 10-1. Food Code provisions are shown below.

²¹ KFDA: Korea Food Additive Code (<http://fa.kfda.go.kr/foodadditivescode.html>) (Accessed: 2010/03/19)

- Article 1 General Provision
- Article 2 General Standard and criteria for common foods
- Article 3 Standards for long shelf life foods
- Article 4 Standards and criteria for common processed foods
- Article 5 Commodity standards and criteria

Tables of commodity standards defined in Food Code are presented in FY2009 Report Tables 3.3-2 and 3.3-3.

3.3.2.2 Korean Industrial Standards (KS standards) defined by KATS²²

KS standard is the set of national standards established under Industrial standardization Act. The use of KS mark (**Figure 3.3-2**) on the label is authorized to the products which meet KS standards through factory inspection and audit. KS standards provide three types of standards; "product standard" for product quality and measurement method, "procedure standard" for requirements for analysis, test, inspection, and standardization of measurement, and "horizontal standard" for specific technology and technology regime. These standards can be developed based on proposals from stakeholders, and be set through the investigation by Korean Industrial Standardization Committee. Total number of KS standards is over 22,000 and 513 standards of them are related to food including "product standard" and "procedure standard" such as analytical methods for nutrients²³. Lists of food "product standards" are presented in **FY2009 Report Tables 3.3-4 to 3.3-7**.



Figure 3.3-2 KS mark

3.3.3 Laws and Regulations related to Food Additives

3.3.3.1 Overview

In Korea, food additive management is controlled by Korean Food & Drug Administration (KFDA). The main legal basis is Korea Food Sanitation Act (KFSA), and its enforcement decree & regulations. And there are following Codes & Standards relating to food additives:

Korea Food Additive Code (KFAC), 2010, 2011,

²² KATS (<http://kats.go.kr/english/index.asp>) (Accessed: 2010/03/19)

²³ KATS: Search for Korean Industrial Standards
http://www.kats.go.kr/english/com/search_ks.asp?OlapCode=ATSU28Search (Accessed:2010/03/19)

Korea Food Code (KFC), 2010, and
Korea Food Labelling Standard (KFLS)

3.3.3.2 Food Additive Definition & Functional Classes

1) Food additive

Food additives is defined in Article 2.2 of KFSA as “materials added to or mixed with foods or materials used for wetting foods in the processes of manufacturing, processing, or preserving foods. In such cases, food additives shall include materials used in sterilizing or disinfecting apparatus, containers or packages, which may be transferred to foods in an indirect manner”.

This definition is similar to that in Japan, which includes substances that are used during manufacturing and do not remain in final foods or that are used for nutrition purpose.

2) Flavourings

Flavourings(“착향료” in Korean) is recognized as included in food additives. There is no clear definition of “Flavourings” in KFSA, but from its standard of use in KFAC, it is assumed to be defined as “additives used (only) for adding flavourings for foods”. There are two groups in food additives used for flavourings. One is ‘synthetic flavouring substances’ in synthetic additives. All of the permitted chemicals used for flavourings are classified in this group, but there are some substances that also appear in KFAC individually listed individually by their names and such substances have obligatory specifications. Another group is called ‘natural flavouring substances’ in natural additives. It is defined as follows and listed by the name of raw materials. There also be a special restriction in career, extraction solvents, etc.:

“These materials are obtained from the following origins listed in Table 1 by processes such as extraction and distillation. They are used to add or enhance aroma. There are refined oils, extracts, and Oleoresin (spice oleoresin, whose specification is separately set, is excluded) in this group. Ethanol, water, or vegetable oils can also be added for the purpose of keeping the quality of the products.”

3) Processing aids

There is no clear definition of ‘Processing aids’ in KFSA, but the glossary on KFDA WEB site (only in Korean)²⁴ defines it as follows:

“They are food additives that are not specified their function but are used in foods during manufacturing or processing, or used for other purposes. Representatively

²⁴ <http://www.kfda.go.kr/fa/index.do?nMenuCode=9&mode=view&boardSeq=8271> (Korean Only)

includes n-Hexane.”

The concept which is similar to its definition in Codex can be found in Article 1.A.7) c) (9) of “Detailed labelling Standard” (Attachment 1 to KFLS) as follows:

“When a food additive is added during manufacturing but removed from the final product, declaration of such additive can be exempted.”

4) Carry-over

It is not defined in KFAC, but its principle is partially appeared in Article 2. 5. 3) (2) of KFC as follows:

“Even the case that a food additive that cannot be used in a food exists in such food, if it is derived from a raw material for which the food additive can be used, the restriction on the use of food additives may not be applied as long as it exists within the level permitted in such raw material.”

Further, Article 1.A.7) c) (8) of Detailed labelling Standard (Attachment 1 to KFLS) explains such concept as exemption of declarations:

“If a food additive is contained in the final food as “carry-over” from its raw materials and the volume of such additive in the final food is lower than its effective volume, declaration of such additive can be exempted.”

Functional Classes

Food additives in KFAC are not classified with their functions, but KFDA consumer site²⁵ introduces food additives’ functions as follows:

- 1) to prevent foods from change of the quality or from rotting: preservatives and antioxidants
- 2) to keep or supplement the quality of foods: emulsifiers and nutrients
- 3) to manufacture foods: coagulants, leaving agents, thickeners /stabilizers
- 4) to improve palatability: colourants, flavourings, flavour enhancers, sweeteners.

In KFLS the classifications are also appeared at the declaration rule of food additives (see **3.3.3.7 Labelling of food additives**).

3.3.3.3 Permitted Food Additives and Maximum Limits

All of the permitted food additives are categorized into one of two types namely “synthetic additives” or “natural additives”. They are listed in KFAC with each

²⁵ <http://www.foodnara.go.kr>: Korean only

definitions, usages (limitations), and specifications if available. However, in case of natural additives and additives used for sterilizing or disinfecting apparatus, etc., there is another system called “temporal standard” that enables distribution of such substances without having official specifications/standards by required data submission from provider to KFDA in advance.

There is no classification system that is similar to Japan, like “existent additives” and “designated additives”. All of the permitted food additives are recognized as having the same meaning as “designated food additives” in Japan. Explanation of Natural flavourings is not mentioned here because it has already appeared at 3.3.3.2 2). When counting the number of items listed in KFAC, the number of additives are 602 total, as of Nov. 2011 (Note: Substances categorized under one group name like “synthetic flavourings” are counted as “one (group)”, and that additives distributed with temporal specifications (some natural additives and additives used for the purpose of sterilizing or disinfecting apparatus) are not included in this number).

Usage and limitation of food additives are listed in KFAC. For Additives which are distributed with temporal standard, usage and limitation are included in each temporal standard.

3.3.3.4 Prohibited Substances as Food Additives

In principle, the positive list of food additives are managed under the KFSA, however, for some individual food items negative list of food additives are described.

3.3.3.5 Specifications for Food Additives

They are listed on KFAC. For Additives which are distributed with temporal standard, specifications are included in each temporal standards.

3.3.3.6 Assessment of Food Additives

According to Article 6 of KFSA, synthetic chemicals require designation by KFDA as having no human health concern for use as a food additive. (1) of article 7 also regulates that the establishment and publication of 1. Standards for manufacturing, processing, using, cooking or storing foods or food additives, and 2. Specifications for the ingredients of foods or food additives. (Remark: there is a kind of exemption for additives not directly used in food.) There is a guideline on KFDA food additive WEB site²⁶ (only in Korean) explaining the basic principle, designation procedure, and the required data for designation of food additives and/or amendment of their established standards/specifications. In its basic principle it is mentioned that food

²⁶ <http://www.kfda.go.kr/fa/index.do?nMenuCode=7> (Korean only)

additives will undergo scientific evaluation regarding its safety, technical necessity and effectiveness of its use. In case of some natural additives or additives used for sanitation of apparatus, of which criteria and standards are not published under part 1 of Article 7, the provider may submit (or KFDA may ask the provider to submit) a dossier according to another notification to establish a (so-called) “temporal standards and specifications”.

3.3.3.7 Labelling of Food Additives

There are some rules in declaration of food additives as ingredients of foods. They are regulated in attachment 1 of KFLS. There are some categories including of which usage should be declared in addition to their names, of which names for declaration are limited, which should be declared with their main function names, or which can be declared as a group with the group name.

3.3.3.8 KFAC (Korean Food Additive Code)

As mentioned above, KFAC contains specifications and standards of each listed food additives. It also contains General Provisions; Manufacturing standards; General principle in use of food additives; General test methods; and Reagents & Standards used in Analysis. There also be specifications for some preparations of specific additives, and general standard for mixed preparations.

3.3.4 Case Study

In order to compare the contents of food standards set in Food Code and those in KS standard, Instant Noodles, Carbonated Soft Drinks, Prepared Frozen Foods, and Cow’s Milk were chosen as examples.

(1) Instant Noodles (Table 3.3-2)

Food Code regulates food additives that should not be detected in noodles. There are several detailed voluntary standards of fried noodles and dried noodles in KS standard, but those standards do not have restrictions of food additives beyond those in regulated in Food Code.

(2) Carbonated Soft Drinks (Table 3.3-3)

The same as the case in Noodles, the restriction in use of food additives for carbonated soft drinks are only described in Food Code, and KS standards has no optional restrictions beyond those in Food Code.

(3) Prepared Frozen Foods (Table 3.3-4)

Similar to the style in Japan, Food Code has the standard of Prepared Frozen Foods

and KS standard has more detailed individual standards such as for prepared frozen dumplings and frozen battered shrimps. But the restriction in use of food additives are only described in Food Code, and KS standards has no optional restrictions beyond those in Food Code.

(4) Cow's Milk (**Table 3.3-5**)

Prohibitions and/or restrictions in use of food additives for Cow's Milk are described in Food Code. Standards for, Milk and Milk products in KS standards has no optional restrictions beyond those in Food Code.

Table 3.3-A Description/Definition (General)

	Description/Definition	Reference
Related legislation	Korea Food Sanitation Act (KFSA), 2010 Korea Food Additive Code (KFAC), 2010, 2011 Korea Food Code (KFC), 2010	KFSA (refer to PDF file) KFAC (http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp ; English) Korea Food Code (http://www.kfda.go.kr/eng/eng/index.do?nMenuCode=43&searchKeyCode=122&page=1&mode=view&boardSeq=66020 ; English)
General Description/Definitions		
Definition of food additives	Food additives is defined in Article 2.2 of KFSA as “materials added to or mixed with foods or materials used for wetting foods in the processes of manufacturing, processing, or preserving foods. In such cases, food additives shall include materials used in sterilizing or disinfecting apparatus, containers or packages, which may be transferred to foods in an indirect manner”.	FSA Article 2. 2
Flavours	Flavourings is recognized as one category of food additives. There is no clear definition of “Flavourings” in KFSA, but from its standard of use in KFAC, it is assumed to be defined as “additives used (only) for adding flavourings for foods”. There are two groups in food additives used for flavourings. One is ‘synthetic flavouring substances’ in synthetic additives. All of the permitted chemicals used for flavourings are classified in this group, but there are some substances that also appear in KFAC individually with their names because they have obligatory specifications. Another group is ‘natural flavouring substances’ in natural additives. It is defined as follows and listed by the name of raw materials. There also be a special limitation in career, extraction solvents, etc.: “These materials are obtained from the following origins by processes such as extraction and distillation. They are used to add or enhance aroma. There are refined oils, extracts, and Oleoresin (spice oleoresin whose specification is separately set is excluded). Water, ethanol, vegetable oil can be added for preserving quality”.	KFAC http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English) http://www.kfda.go.kr/fa/index.do?nMenuCode=12&page_gubun=1&gongjeoncategory=4&key=&keyfield (Korean) Korea FoodNara Glossary Site (Korean) http://www.foodnara.go.kr/foodnara/dic-list.do?s_eq=6867&mid=S07&boardId=dictionary&searchKey=착향료&searchType=1&page=1 KFAC I. General Provisions (3) p.1. http://www.kfda.go.kr/fa/index.do?page_gubun=1&serialno=107&nMenuCode=12&page_gubun=1&gongjeoncategory=2&keyfield=foodadditivename&key=천연착향료&page=1 (Appendix 1)

Processing aids	<p>There is no clear definition of 'Processing aids' in KFSA, but the glossary on KFDA WEB site (only in Korean) defines it as follows: "They are food additives that are not specified their function but are used in foods during manufacturing or processing, or used for other purposes. Representatively includes n-Hexane."</p> <p>The concept which is similar to its definition in Codex can be found in Article 1.A.7 c) (9) of "Detailed labelling Standard"(Attachment 1 to KFLS) as follows: "When a food additive is added during manufacturing but removed from the final product, declaration of such additive can be exempted."</p>	<p>Glossary of Food Additives (Korean) http://www.kfda.go.kr/fa/index.do?nMenuCode=9&mode=view&boardSeq=8271</p>
Carry-over	<p>It is not defined in KFAC, but its principle is partially appeared in Article 2. 5. 3) (2) of KFC as follows: "If a food additive that cannot be used in a food is derived from a raw material for which the food additive can be used, the restriction on the use of food additives may not be applied within the range of such deriving the raw material."</p>	<p>Korea Food Code (2-1-8) Korea Food Code Article 2.5.3 http://www.kfda.go.kr/eng/eng/index.do?nMenuCode=43&searchKeyCode=122&page=1&mode=view&boardSeq=66020</p>

Table 3.3-B Description/Definition (Specific)

	Description/Definition		Reference
Related legislation	Korea Food Sanitation Act (KFSA), 2010 Korea Food Code (KFC), 2010 Korea Food Additives Code (KFAC), 2010, 2011		
Specific descriptions / Additional explanations			
1	List of Designated Food Additives	<p>As of November 2010 (Notification #2010-82), 602 food additives in total are approved with the permission to use in respectively designated food groups. Standard and specification of the synthetic additives (400 items), natural additives (195 items) and mixed additives (7 items) are listed in the current KFAC.</p> <p>The e-book of English version still contains those officially deleted which are summarized in the appendix 2 (33 synthetic additives and 12 natural additives deleted from KFAC).</p> <p>Flavouring agents of which synthetic ones are covered under the</p>	<p>Article 3_ A, 3_ B, 3_ C of Korea Food Additive Code</p> <p>Appendix 2 (Excel file)</p> <p>http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English e-book)</p> <p>http://www.kfda.go.kr/fa/index.do?nMenuCode=12&page_gubun=1&gongjeoncategory=1 (Korean)</p>

		item No 424 of synthetic food additives list can be accessed separately in the KFAC.	
2	List of Existing Food Additives	Not applicable in Korea.	
3	List of Plant or Animal sources for Flavouring agents	Natural Flavourings are categorized as one of Natural additives, and raw materials of Natural flavourings are listed in a table of this item in KFAC. The list consists of 272 of each substances and general description “raw materials that are appropriate for 2. Requirements for Raw Materials. Common in Food Codes”.	http://www.kfda.go.kr/fa/index.do?page_gubun=1&serialno=107&nMenuCode=12&page_gubun=1&gongjeoncategory=2&keyfield=foodadditive&key=천연착향료&page=1 (Korean)
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	Not applicable in Korea.	
Negative list (if any)		In principle, the positive list of food additives are managed under the Korea Food Sanitation Act. However, for some individual food items (e.g. Instant noodles, carbonated beverages, etc.), negative list of food additives are described.	
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives		General provisions of KFAC provides the information of [weight, volume and temperature], [tests], [container], and [definition of terms]. KFAC main text provides standards for manufacturing and preparation, general standards for food additive used in foods, food contact surface sanitizing solutions and general test methods as well.	http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English)
Official publication and/or gazette for food additives		http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (KFAC)	

Table 3.3-2 Case Study 1 Instant Noodles

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	Specification of noodles are described in Korea Food Code.	http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=040&level=2&step_2=009 (English Definition)	Fried Noodles (KS H 2508), Dried Noodles (KS H 2505), Raw Noodles (KS H 2506), and Cooked Noodles (KS H 2507)	KS H 2505 KS H 2506 KS H 2507 KS H 2508
Positive and/or Negative List	Positive /negative list of food additives for noodles should be complied in Korea.		Noodles were specified as fried noodles and non-fried noodles.	Refer to the table 3.3-8 of the report (p 36, ILSI Japan 2010)
Use Limitation and/or Maximum Level, if any	Below food additives should not be detected in the products : - Prepared Tar Dyes (colour) - Preservatives - Titanium dioxide Sodium Stearoyl Lactylate is permitted for use in noodles.		Tar colour should not be detected.	

Table 3.3-3 Case Study 2 Carbonated Soft Drinks

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	Specification of carbonated beverages are described in Korea Food Code- Carbonated beverages, Carbonated water.	http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=040&level=2&step_2=011 (English) Korea Food Additives Code http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English)	Carbonated soft drinks	KS H 2016
Positive and/or Negative List	Positive/negative list on food additives (Korea Food Additives Code).		No positive/negative list included. It is recommended to follow the Korea Food Code.	
Use Limitation and/or Maximum Level, if any	Some food additives are allowed to use in carbonated beverages and maximum levels in soft drinks are set as below: - Preservatives: Benzoic acid, sodium benzoate, potassium benzoate, and calcium benzoate less than 0.6g/kg are permitted to only carbonated beverages (excluding carbonated water). - Ester Gum less than 0.1/kg			

	<p>- Manganese gluconate (no maximum level specified)</p> <p>Some food additives are not allowed to use in carbonated beverages:</p> <p>-Food Red No.2 -Food Red No. 2 Aluminum Lake.</p>			
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Table 3.3-4 Case Study 3 Prepared Frozen Foods

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	<p>Food additive standards for frozen food should comply to those for respective food item as designated in the Korea Food Code and/or Food Additive Code.</p> <p>“Frozen food” means a food made by filling the manufactured, processed, cooked food into container and packaging materials after freezing treatment for the purpose of long-term storage.</p> <p>(1) Frozen food not requiring heat process before consumption: Frozen food that can be consumed without a separate heating process.</p> <p>(2) Frozen food requiring heating process before consumption: Frozen food that can be consumed only after a separate heating process.</p>	<p>Korea Food Code 3-1-2 (English; http://www.kfda.go.kr/eng/eng/index.do?nMenuCode=43&searchKeyCode=122&page=1&mode=view&boardSeq=66020)</p>	<p>Frozen prepared dumplings (KS H 4001), Frozen prepared croquet (KS H 4002), Frozen battered Shrimps (KS H 4003), Frozen Fried Pork (KS H 4004), and Frozen Fried Fish (KS H 6032)</p>	<p>KS H 4001 KS H 4002 KS H 4003 KS H 4004 KS H 6032</p>
Positive and/or Negative List				
Use Limitation and/or Maximum Level, if any				

Table 3.3-5 Case Study 4 Cow's Milk

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	Milk is defined as the milk pasteurized or sterilized.	Processing of Livestock Products Act. Article 4.2. "SANITARY CONTROL FOR LIVESTOCK PRODUCTS" Notification on Standard and Specification of Livestock Products (No. 2010-2) http://www.qia.go.kr/view/webQiaCom.do?id=7660&type=1_41jgbz (Korean)	There is no positive/negative list in KS. Milk was included in the milks (KS H 2195) in KS.	KS H 2195
Positive and/or Negative List	Use of food additives in milk is prohibited or restricted under the Korea FSA.			
Use Limitation and/or Maximum Level, if any	(Sanitary control for livestock products has designated milks for milk, fortified milk, reconstituted milk, and lactic acid bacteria added milk.)			

3.4 China

3.4.1 Regulatory Framework on Foods

Framework of food administration in China is stipulated by “Food Safety Law of the People's Republic of China” which was promulgated in February 28, 2009 and went into effect in June 1, 2009.

As there have been various kinds of food standards in China, food companies confused which standard should be complied with. Since Food Safety Law went into effect, unification of standards to develop national standard produced drastic improvements. Food poisoning incidents caused by frozen dumplings in China, January, 2008 or Infants death incidents by melamine contaminated milk in China, September, 2008 were discussed as violation examples and then the law was enacted under these considerations. Accordingly, article 1 of 'Food Safety Law' reads this law is formulated to assure food safety and safeguard people's health and life.

The law comprehensively covers areas from food hygiene to food safety, and clearly stipulates clarification of responsibility of ministries in charge of food issues, newly setting of food recall system, sections responsible for monitoring, control and assessment of risk. State Council decided to set up “Food Safety Committee” according to the law to establish system shown below in **Figure 3.4-1** with the purpose of securing food safety and ensuring the public health and safety.

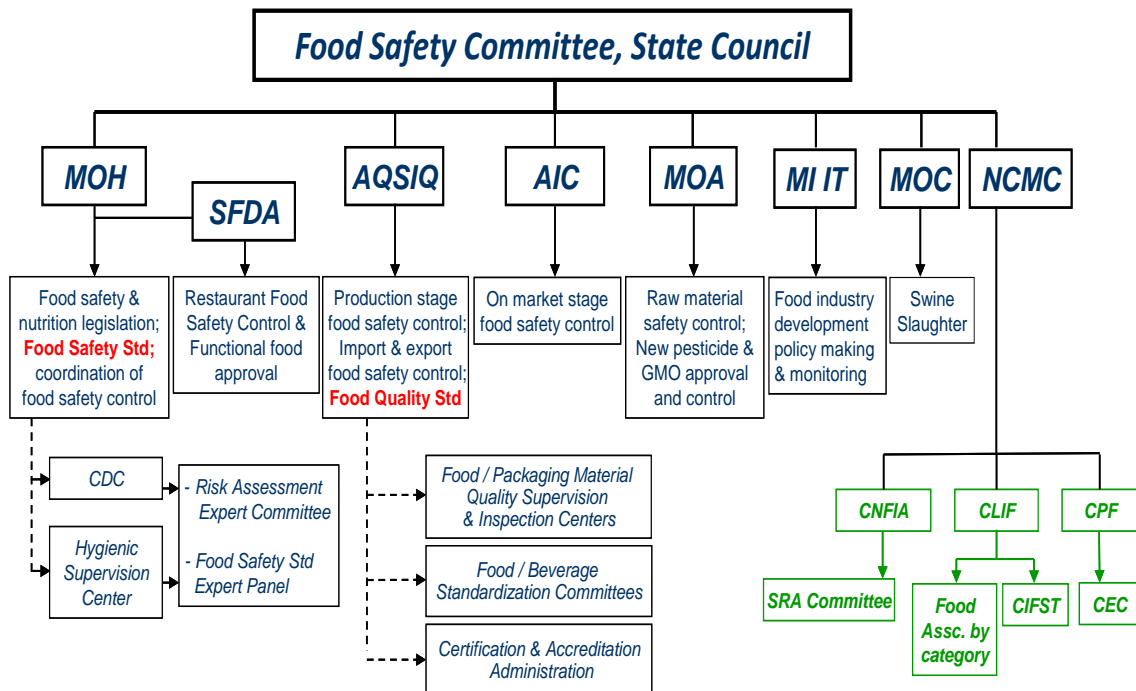


Figure 3.4-1 Food administration system established according to Food Safety Law

Food administration was so far conducted by plural governing systems where several concerned governments had been controlling many process of food manufacturing, distributions and sales and the system was blamed whenever food incidents happened because administration procedures were overlapped or responsibilities were ambiguous. So, in this Food Safety law, each concerned government is clearly defined and assigned to be responsible for any process or steps in food production. Especially, duties of relevant ministries responsible for food safety are stipulated by Food Safety Law as follows.

➤ Ministry of Health (MOH)

MOH is responsible for overall coordination among food related governments and as a director general on food safety. In addition, it determines standards and conditions for food manufacturing, food distribution process, and conditions for the permission of manufacturing and distributions, and conducts general administrations related to food safety. More specifically, 1st: Drafting of the laws and regulations related to food safety, 2nd: Establishment of standards and conditions related to food safety, 3rd: Establishment of standard guideline and technological guideline, 4th: General coordination of food safety assurance, 5th: Search and investigation of major food safety accidents, 6th: Establishment of food safety standards, 7th: Risk assessment of foods and related subjects and their prevention, 8th: Establishment of quality for food safety research institutes and of examination cords, 9th: Organized PR on major food safety information and etc.

The lower organizations include Administration of Quality supervision (to set food safety standards and inspection methods in food manufacture and their supervision), The State Administration for Industry and Commerce (to supervise food distribution), and State Food and Drug Administration (to supervise food service and to approve functional foods).

➤ Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

AQSIQ is responsible for food safety in its production, as a director general for the safety of exported and imported food and controls various permissions for food manufacturing process. More specifically, it is in charge of food safety management. 1st: supervise food production; according to the Product Quality Act and the Food Safety Act and their downstream regulations and orders, it conducts quality examinations in its production or under processing, hygiene assessments, permissions of domestic food productions, and enforcement of food safety and quality inspection, and research and investigation of major food safety

accidents, 2nd: supervise food importation and exportation; according to Food Safety Act and Imported and exported product Inspection Act and their downstream regulations and orders, it inspects and controls quality, hygiene and safety conditions, examines and controls imported foods including drinks, alcoholics and sugars, food additives, food containers, packing materials, utensils and equipment for food productions, and establishes risk alarming systems and quick dealing systems, and takes preparatory actions on possible imported and exported food risks, and 3rd: administer the national Standardization Management Committee; according to the Food Standardization Act and its downstream regulations and orders, prepares drafts on laws and regulations for food standardization, execute food standardization, and establish and revise the national food standards.

➤ State Food Drug Administration (SFDA)

SFDA is a national administration controlled by MOH, and responsible for supervision on food safety in food and drink industry and restaurants and the similar facilities in consumption process. Then, it supervises permissions on catering and restaurant business. More specifically, it is in charge of food safety affairs below. 1st: in the consumption process, determines plans and policies on food safety supervisions, conducts related safety actions and prepares drafts on laws and regulations related to food safety. 2nd: in the consumption process, determines permissions on food catering and restaurant services and supervises food safety. 3rd: in the consumption process, establishes food safety management standards and supervises them, conducts food safety inspections and audits and publishes food safety management information. 4th: supervise the local government in the food consumption process, and teaches first aid, inspections and information technology. 5th: develops international interactions, and cooperation activities.

➤ Food Safety Committee(FSC)

FSC, assumes the risk assessment of food safety, is responsible for establishment of food safety standards, investigates major food safety accidents. And it conducts risk assessment of food and food additives biological, chemical and physical harms. The Committee consists of experts from the field of medicine, agriculture, food, and nutrition. Safety evaluation of pesticides, fertilizers, growth regulators, veterinary medicines, feeds and feed additives is required to include experts in food safety risk assessment committee. Food safety risk assessment is required to use the scientific methodology, and to be based on the information of food safety risk monitoring, and scientific data and related

information. Furthermore, if a safety issue is once revealed by way of the food monitoring or incident report, it at once conducts the investigation and re-evaluation of the food concerned.

➤ **Ministry of Agriculture (MOA)**

MOA is one of organization in the State Council Department with jurisdiction over the development of agriculture and rural economy. And it is in charge of the inspection and its analysis of pesticide residues in food, of residual veterinary drugs. These tasks are collaborated by the Department Of Health. Its main responsibilities are, 1st: Establish agricultural and rural economic development strategy, the medium-and long-term plan, and run them. In addition, it examines agriculture developmental policy, prepares drafts on laws and regulations for agricultural developments, and proceed with the rural economic reform, 2nd: Investigates the fishing industry on behalf of the country, exercise the supervision and management over fishing ports and processing plants, 3rd: Prepares drafts on laws and regulations for quarantine of animals and plants, and organizes and supervises quarantine of domestic plants and animals, 4th: Handles international agricultural affairs, organizes and develops international economic and technological transactions and cooperations, and 5th: Involved in daily works on poverty alleviation and development of the State Council Department.

3.4.2 Summary of Food Standards in China

Chinese Food Safety National Standards are mandatory standards established and issued by Health Administration Department of the State Council. National standard code (Guo jia Biao zhun, GB) is provided by Standardization Administration Department of the State Council, and is published after reviewed by Food Safety National Standards Review Board.

National Codes applied to areas other than food are published through the same process by relevant agencies, then, are kept by Standardization Administration of China (SAC). First 2 or 3 alphabets of National Standard Code are common for all industrial areas.

GB	Mandatory standard
GB/T	Recommended standard

National codes are published as GB (Mandatory standard) or GB/T (Recommended standard). The following code numbers allow you to identify standard. SAC issues

list of all National Standards²⁷. Examples of GB standards for foods include GB 2760 “Hygiene standard for use of food additives” and GB 7718 “Labelling standard for packaging containers”.

The overall system structure for food standards in China characterizes three levels of standards shown in **Figure 3.4-2**; National standard, Industry & Local Standard defined as regional standard and industry associations’ voluntary standard, and Enterprise Standard. These all standards are expected to be unified as national standards, though, standardization requires more time.

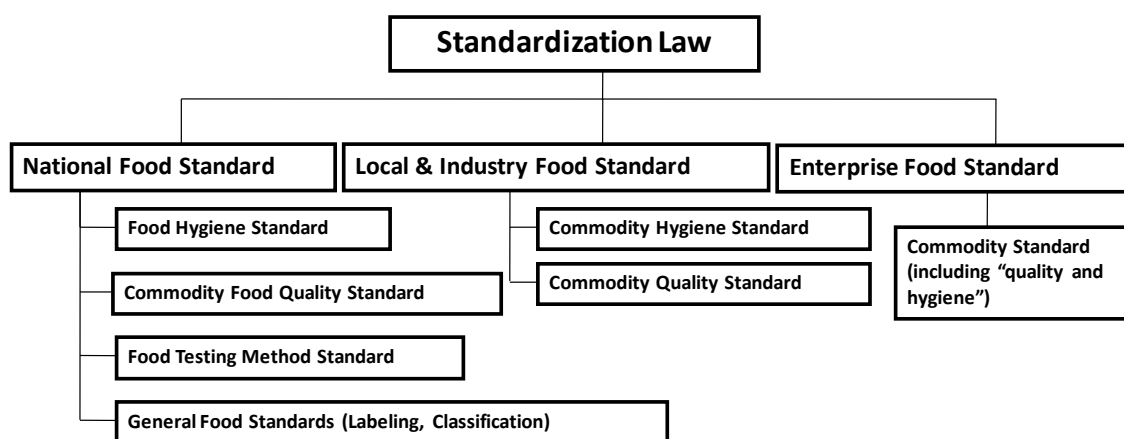


Figure 3.4-2 Three levels of standards in China

In case of a certain food category defined by National Standard, the Standard should be complied. Penalty provisions against violation are also stipulated clearly. For food without National Standard, Industry & Local Standard is applied. In this case, the health administrative department of each province, autonomous district, or municipalities directly under the Central Government reviews the food standard, confirms it pursuant to National Standard, and submits it to Health Administration of State Council. For food with only Enterprise Standard, each company shall submit the standard to the health administrative department of each province, autonomous region, municipalities directly under the Central Government and complies with it.

Summarizing the above, summary chart of food standards existing in China is presented in **Figure 3.4-3** to compare with Codex Standard. For items in Codex Standard, for example, “Scope”, “Description” and “Essential Composition and Quality Factor” are defined by corresponding GB standard. GB 2760 (Hygienic standards for uses of food additives) and GB 14880 (Hygienic standards for use of nutritional fortification substances in foods) correspond to “Food Additives”, GB 2762 (Max levels in foods of Contaminants) and GB 2763 (Maximum residues limits for pesticides in foods) correspond to “Contaminant”. Basically, GB standards almost

²⁷ <http://www.sac.gov.cn/>

completely correspond to Codex Standards. For “Weights and Measures”, JJF1070 pursuant to Measurement Act like in Japan, and standards set by AQSIQ shall be applied.

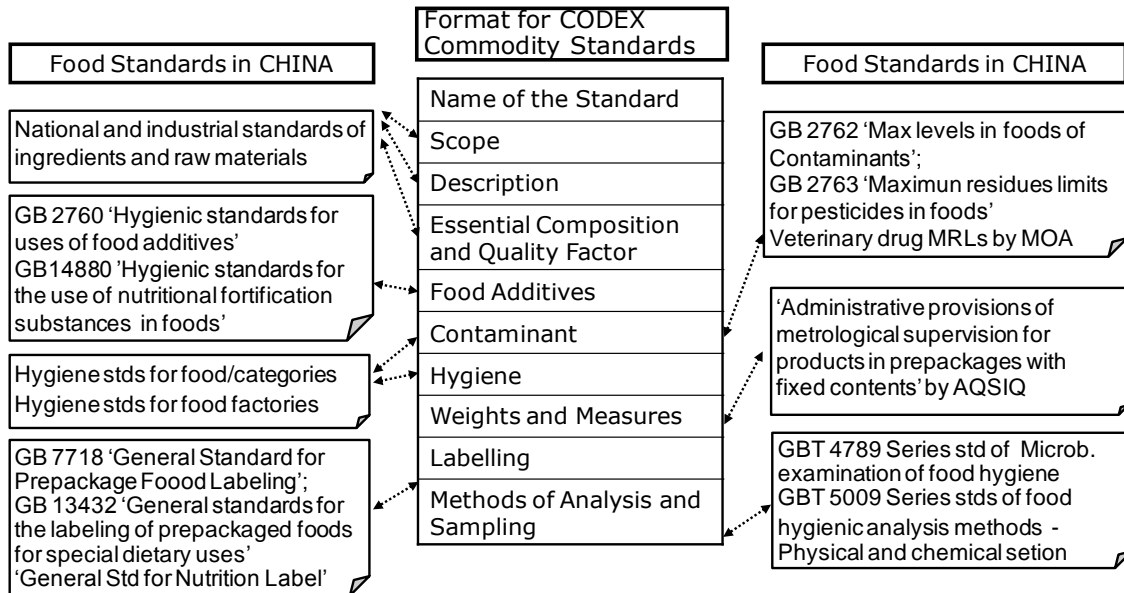


Figure 3.4-3 Summary of Food Standards in China

For specific examples, see summary of food standards (Figure 3.4-4~6) described in “3.4.4 Case Study” Commodity Standards below. Plotting the corresponding items of GB standards and other standards on the Codex Standards, it was found that the Chinese food standards relatively correspond to the Codex Standards. Though the same may not be said for all foods, the Chinese standards are well organized from the viewpoint of consistency with Codex Standards.

3.4.3 Acts and Regulations related to Food Additives

3.4.3.1 Overview

“Standard” of China is equivalent to the "Specifications" or "Standards" in Japan, according to the Standardization Act, and is controlled by National Standardization Management Committee. There are over 1,800 national food safety standards and over 7,000 local food safety standards, and over 70,000 company standards and so much overlapped. In this context, Food Safety Act is to arrange, integrate and unify the standards. The Act allows State Council Department only to be responsible for establishing and publishing the National Standards. Accordingly, where the National Standard is defined the national standard is the only one to follow.

China's food additive regulations are all basically listed in the “Standards on Use of Food Additives by GB2760 (from now on, unless otherwise specified, appendix or

table mean those referred to from GB2760)". This standard defines general principals for the use of food additives including flavours and processing aids, and imposes food producers on duties not to use other chemicals than food additives nor substances harmful to human bodies in the food production. Furthermore, there are limitations on a type of food additives used, a food category to be added, and a dose to add. Use of food additives is only approved when it is necessary of the technological merits in the food production and regarded as safe through a scientific evaluation. A food additive production needs its permission.

3.4.3.2 Food Additive Definition & Functional Classes

1) Food additives

Food additives generally refer to chemically synthesized or natural substances to be added to foods in order to improve food quality and colour, flavour and taste, and for the need of preservation and processing technical merits, including nutritional fortifying substances, flavouring agents and processing aids.

Food additives are required to comply with the below basic requirements.

- a) Not do a harm to human by all means.
- b) Not fake food decay or adulteration.
- c) Not use to fraud quality defects or poor quality.
- d) Not deteriorate food nutrition.
- e) Use at as a low dose as possible.
- f) Not remain in a food in case of a processing aid with its limit un-specified.

International Number System (INS) refers to the international numbering of food additives, which is used for being in lieu of the description of complicated chemical structure names. Chinese Number System (CNS) refers to the Chinese numbering of food additives (Normative Annex E of this standard).

2) Flavourings

Flavouring agents and flavouring essences are used in food in order to impart, modify or improve flavours in the food and may include non-flavouring food ingredients. But substances that have only salt, sweet, or sour taste and flavour enhancers are excluded from the definition. Flavourings are usually not intended to be consumed as such.

To apply the Application of flavouring agents shall be implemented according to the Normative Annex B.1 of this Standard.

3) Processing aids

Food processing aids refer to various kinds of substances to enable food processing to go with a swing smoothly, regardless of irrelative to food itself, for example, nutritional substances for filtration aids, clarification clarifiers, absorption absorbents, lubrication lubricants, decoating mold release agents, decolouring agents, peeling agents, solvents extraction solvents, and nutritional substances for fermentation, etc. Processing aids are not allowed to remain in the used food unless otherwise specified.

The application of food processing aids shall be based on Normative Annex C to the Standard.

4) Carry-over

Besides direct addition, the food additives can be brought introduced into the foods through the food ingredients in the following cases;

- a) The use of the food additive in the food ingredients can only be allowed according to this standard;
- b) The level of use of this additive in the food ingredients should not exceed the allowable maximum level;
- c) These ingredients shall be applied in the normal production process. And the content of this additive in the food should not exceed the level that is carried over by the ingredients;
- d) The content of this additive brought introduced into the food by the ingredients shall be obviously lower than the usually required level of it that which is directly added to this the food.

3.4.3.3 Permitted Food Additives and Maximum Limits

There is no one list showing all the approved food additives and it is published as a notice whenever approved. Except for nutrient supplements, approved substances are listed in the standard when "Standards on Use of Food Additives by GB2760" is revised. Now its latest version GB2760 (2760-2011) lists flavouring agents, food processing aids, and gum bases at Table B, Table C, and Table D, respectively. Food categories of the other food additives and maximum dosages are listed in Table A of GB 2760. In addition, Standards on use of nutrient supplements are listed in GB 14880.

3.4.3.4 Prohibited Substances as Food Additives

It is a positive list system and no lists to show food additives that you can't use.

3.4.3.5 Specifications for Food Additives

Specifications of approved food additives are published as an official standard to follow at the same time of their approval but their compendium is not published.

3.4.3.6 Assessment of Food Additives

For a production, sales, use and/or import of a new food additive, an organization or individual (hereinafter referred to as the applicant) shall submit a license application of the food additive and the following materials:

- a) Generic name of the additive, functional classification, doses of use and food categories to use.
- b) Technical information on its usefulness and reports and literature on the effectiveness.
- c) Specifications of food additive, process information and analysis methods on quality, detecting method from foods and related explanatory materials.
- d) Safety evaluation reports, materials and its origin information, chemical structure and physical properties, its production technique information, toxicological and safety information and quality examination reports.
- e) Labels, brochures, and product samples.
- f) Any information on other regional or country registration that helps make its production possible and evaluate its safety.

For the application to widen food uses or to enlarge doses, of the forth articles, submission of technical information can be excluded.

3.4.3.7 Labelling of Food Additives

Because there were cases that a name unfamiliar to consumers such as chemical name was used for food additive declaration on food labelling, it is defined in the law that the generic name defined in the national standard (GB2760) shall be used in the label on a prepackaged food product.

- a) All the food additives* are required to be declared** by
 1. its generic name,
 2. functional group and INS number, or
 3. functional group and its generic name.

*: flavourings and gum bases can be declared by each functional group name only.

** : all the food additives (other than flavourings/gum bases) in a food product should be declared in the same manner in its labelling.

- b) A prepackaged foods and a food additive shall be described of certain items defined in the law on label or in its instruction document.
- c) Its description should be clear and easily distinguishable and written in Chinese.

3.4.4 Case Study

General overviews on instant noodles, carbonated beverages, frozen cooked food, the milk of GB standards are shown in **Figure 3.4-4** to **3.4-6** and their detailed categories are shown in **Figure 3.4-1**. There are no food categories that fit instant noodles or frozen cooked food in China.

Table 3.4-A Description/Definition (General)

	Description/Definition	Reference
Related legislation	GB2760-2011 Standard for Use of Food Additives	http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodagxxw/cmsmedia/document/doc321.pdf
General Description/Definitions		
Definition of food additives	“Food additives” refer to the artificially or chemically synthetic or natural substances to be added to foods in order to improve food quality and colour, flavour and taste, and for the need of preservation and processing technology, including nutritional fortification substances, flavouring agents and processing aids.	GB2760-2011 Article 2. Terms and definitions: 2.1 Food additive
Flavours	The flavouring agents and flavouring essences are used in foods in order to create, change or improve the flavour of foods. The flavouring agents are usually made into flavouring essences for flavouring the food, but some of them may be directly added into the food. The flavouring agents and flavouring essences exclude the substances which only make the food sweet, sour or salty and the flavour enhancer. Flavours are not used as a directly consumed ingredient.	GB2760-2011 Annex B. Provision on Use of Flavouring Agents: B.1 Principles for application of flavouring agents and flavouring essences
Processing aids	Food processing aids refer to various kinds of substances to enable food processing to go with a swing smoothly, regardless of irrelative to food itself, for example, nutritional substances for filtration aids, clarification clarifiers, absorption absorbents, lubrication lubricants, decoating mold release agents, decolouring agents, peeling agents, solvents extraction solvents, and nutritional substances for fermentation, etc. Processing aids are not allowed to remain in the processed food (where they are used) unless otherwise specified.	GB2760-2011 Article 2. Terms and definitions: 2.4 Food processing aid; Annex C. Provisions on Use of Processing Aid for Food Industry (“processing aid”): C.1 Principles for use of processing aids
Carry-over	Besides direct addition, the food additives can be brought introduced into the foods through the food ingredients in the following cases; 1. The use of the food additive in the food ingredients can only be allowed according to this standard; 2. The level of use of this additive in the food ingredients should not exceed the allowable maximum level; 3. These ingredients shall be applied in the normal production	GB2760-2011 Article 3. Principles for use of food additives: 3.4 Carry-over principles

	<p>process. And the content of this additive in the food should not exceed the level that is carried over by the ingredients;</p> <p>4. The content of this additive brought introduced into the food by the ingredients shall be obviously lower than the usually required level of it that which is directly added to this the food.</p>	
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Table 3.4-B Description/Definition (Specific)

		Description/Definition	Reference
Related legislation		GB2760-2011 Standard for Use of Food Additives	http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxxw/cmsmedia/document/doc321.pdf
Specific Descriptions/Definitions			
1	List of Designated Food Additives	There is no one list showing all the approved food additives and it is published as a notice whenever approved and later they will be listed as new approved additives in total as GB3760 or GB14880 is revised.	
2	List of Existing Food Additives	Not applicable in China.	
3	List of Plant or Animal sources for Flavouring agents	A list of natural flavouring agents is shown in Appendix B.2 of GB2760.	
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	Not applicable in China.	
Negative list (if any)		There is no negative list of food additives under GB2760	

Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives	The specifications of food additive, including analytical method, are part of National Food Safety Standards, which should be issued by Ministry of Health. Nevertheless, there are still some food additives that lack of specification, and MOH is working on that to cover the gap as soon as possible.	http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodagxxw/s69/index.html
Official publication and/or gazette for food additives		

(1) Instant Noodles

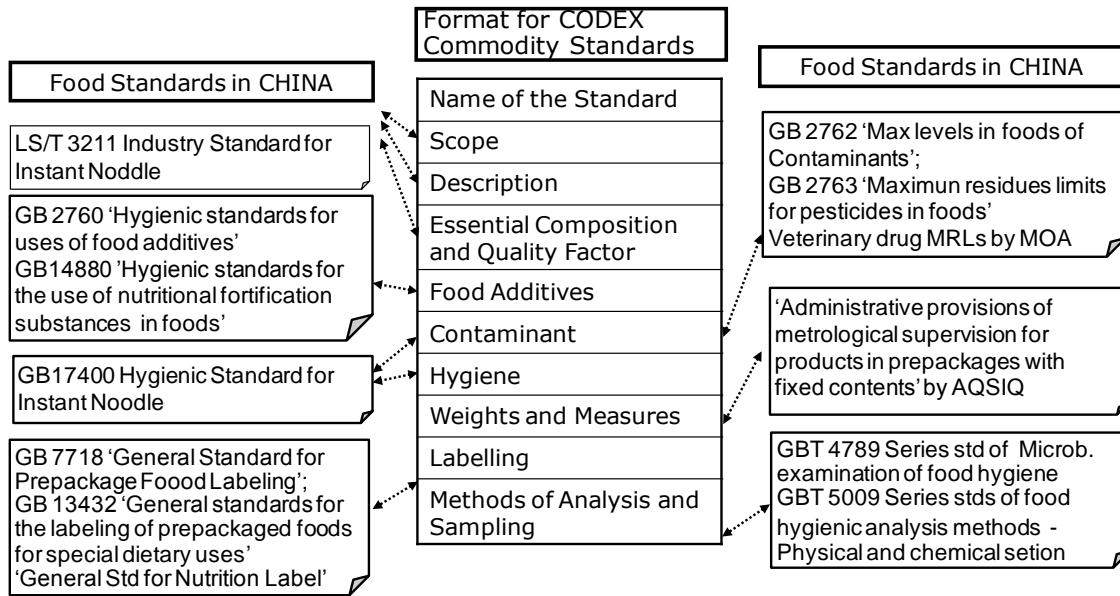


Figure 3.4-4 Summary of Food Standards in Instant Noodles

(2) Carbonated Soft Drinks

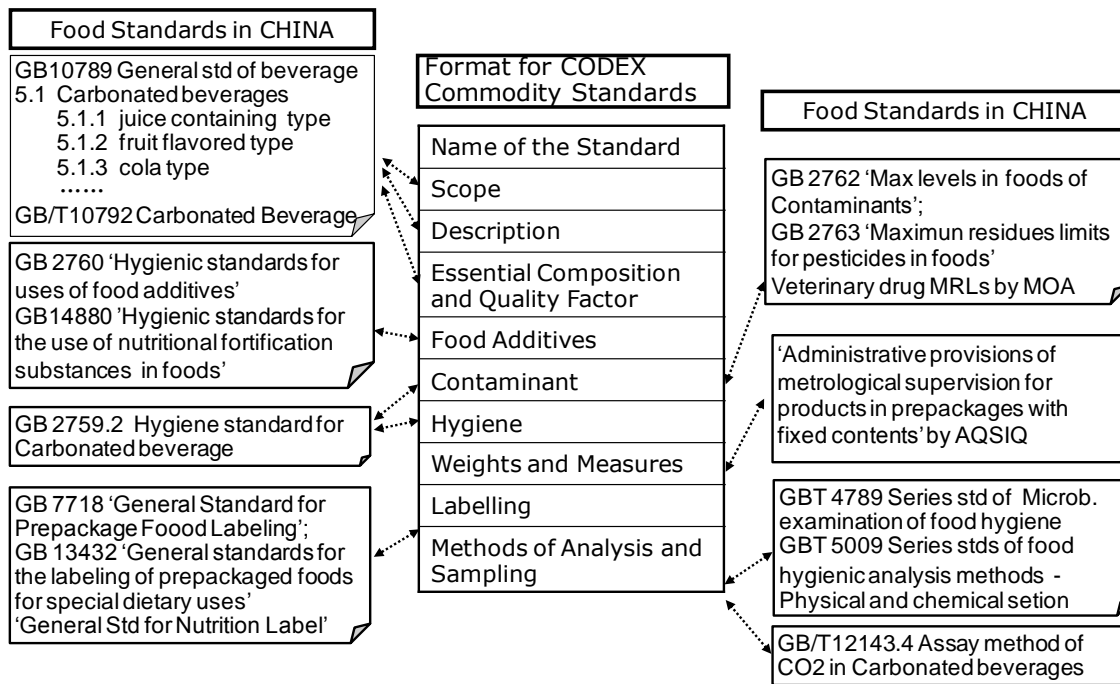


Figure 3.4-5 Summary of Food Standards in Carbonated Soft Drinks

(3) Prepared Frozen Foods

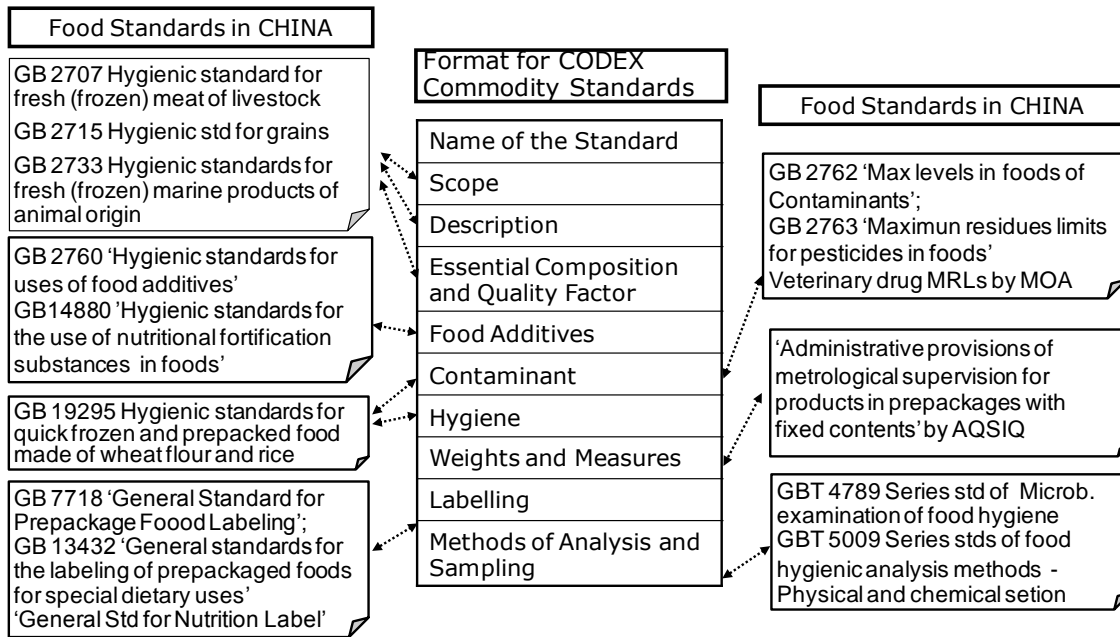


Figure 3.4-6 Summary of Food Standards in Prepared Frozen Foods

Table 3.4-1 Case Study Instant Noodles, Carbonated Soft Drinks, Prepared Frozen Foods, and Cow's Milk

Food Categories	Food Categories in GB2760	Reference
1. Instant Noodles	06.0 Cereals and cereal products 06.03 Wheat flour and its product 06.03.01 Wheat flour 06.03.01.01 All-purpose wheat flour 06.03.02 Wheat flour product 06.07 Pre-cooked (instant) noodles and rice	Accessories should be compliant with requirement of “12.0 Condiment” and/or “4.2.2.2 Dried Vegetable”, etc.
2. Carbonated Soft Drinks	14.0 Beverage 14.04 Water-based flavoured beverage 14.04.01 Carbonated drink 14.04.01.01 Cola type carbonated drink 14.04.01.02 Other carbonated drink	
3. Prepared Frozen Foods	06.0 Cereals and cereal products 06.03 Wheat flour and its product 06.03.01 Wheat flour 06.03.01.01 All-purpose wheat flour 06.03.01.02 Special wheat flour 06.03.02 Wheat flour product 06.03.02.01 Fresh pasta 06.08 Frozen rice and flour product 06.1 Filling for grain product	Product with filling, e.g., meat or veg, should meet corresponding requirement of Food Additives for meat or veg in GB2760.
4. Cow's Milk	01.0 Milk and dairy product 01.01 Pasteurized milk, sterilized milk and recombined milk 01.01.01 Pasteurized milk 01.01.02 Sterilized milk	Cow's Milk is not allowed to add flavouring agent and flavouring essence.
<input type="checkbox"/> In GB2760-2011, the Table of allowed Food Additives (A.1) is organized by the name of food additives instead of Food Categories. <input type="checkbox"/> There is not any “Voluntary Standard” for use of Food Additives in China.		

3.5 Southeast Asia (Malaysia, Singapore, Philippines, Indonesia, Thailand, Vietnam)

3.5.1 Malaysia

3.5.1.1 Food Administration

Main administrative bodies responsible for food safety and hygiene control in Malaysia are Ministry of Agriculture and Agro-Based Industry and Ministry of Health. Their main roles are shown in **Table 3.5-1**.

Table 3.5-1 Food Safety Control System in Malaysia

	Safety and hygiene control for production and primary processing	Safety and hygiene control for processed foods
	Ministry of Agriculture and Agro-Based Industry (MOA)	Ministry of Health (MOH)
Agricultural products	Department of Agriculture (DOA)	Food Safety and Quality Division (FSQD)
Marine Products	Fisheries Department (DOF)	
Livestock products	Department of Veterinary Services (DVS)	

3.5.1.2 Acts and Regulations related to Commodity Standards

Major acts and regulations related to Commodity Standards are presented in **Figure 3.5-1**.

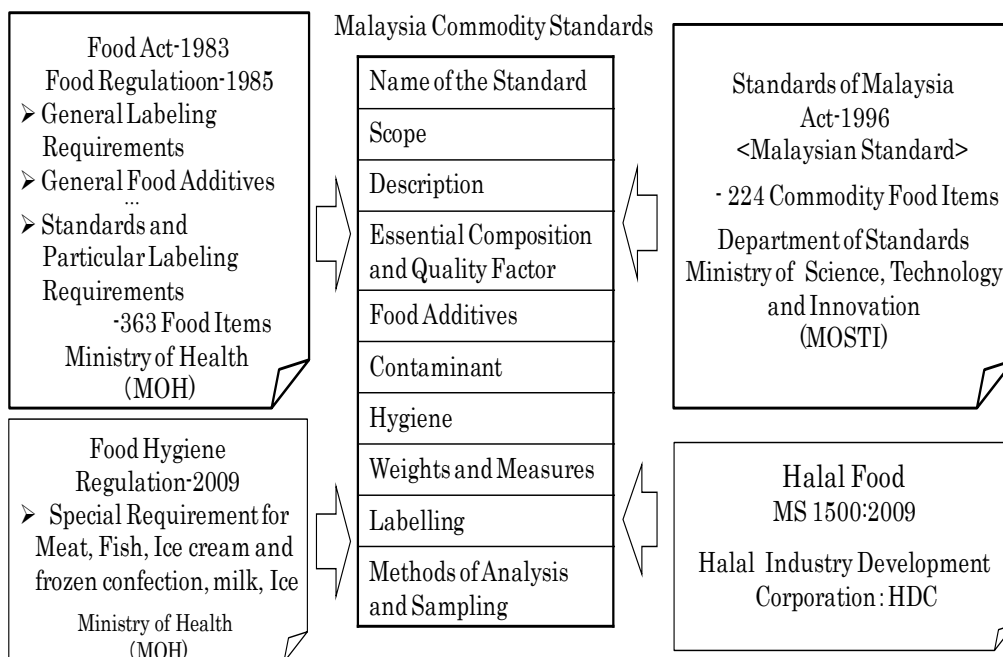


Figure 3.5-1 Malaysian Commodity Standards and Relevant Laws

3.5.1.3 Food Act (jurisdiction : MOH)

(1) Food Act- 1983²⁸

The Food Act is a key law in food administration. It was enforced to protect the public against health hazards and fraud in the preparation, sale and use of foods. The Act stipulates permissible range in the preparation, sale and use of foods. It gives legal authority to relevant agencies to carry out their duties in implementing the Act. Such legal authority includes the power of the Minister of Health to stipulate the supplementary provisions compiled as Food Regulations-1985.

(2) Food Regulations-1985²⁹

Supplementary provisions are compiled in Food Regulation-1985. Food Regulation-1985 is continuously updated on amendment and newly setting of regulations. Food Regulation-1985 provides requirements for labelling, food additives and supplement, packaging, contaminants, bacterial toxin etc., and Standards and Particular Labelling Requirements for 363 food items (**FY2009 Report Table 3.5-2**). It stipulated minimum definition, component standard and special labelling requirements.

(3) Food Hygiene Regulations-2009³⁰

Food Hygiene Regulation-2009 regulates hygienic requirements against those who handle foods, as well as the conduct and maintenance of food premises. A food premise is defined in the Regulation as a place "used for or in connection with the preparation, preservation, packaging, storage, conveyance, distribution or sale of any food, or the relabelling, reprocessing or reconditioning of any food". The Regulation sets Special Requirements for Meat, Fish, Ice cream, and Frozen confection, Milk, and Ice in handling, preparation, packaging, supply, storage and sale. For vending machine, same special regulation is stipulated.

3.5.1.4 Malaysian Standards

As commodity standards, Malaysian Standards (MS) stipulated by Ministry of Science, Technology and Innovation (MOSTI) occupies important place in food regulations. They are national standards for all industries pursuant to ISO, but are basically voluntary standards.

Malaysian Standards shown in **FY2009 Report Table 3.5-3** are in the same format for the Codex Commodity Standards.

²⁸ <http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=22>

²⁹ <http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21>

³⁰ http://fsq.moh.gov.my/uploads/Food_Hygiene_Regulations_2009.pdf

Approximately 6,000 Malaysian Standards are issued. As of March, 2010, there are 454 Malaysian Standards issued in International Classification of Standards (ICS) code 67 (Food technology). Of them, 224 Malaysian Standards are related to Specifications (**FY2009 Report Table 3.5-4**). These are basically voluntary standards and a certified mark can be labeled by obtaining official certification.

Recently, standardization of Malaysian Standards for agricultural products including fresh vegetables and fruits are proceeding as a national policy. As of end of February 2010, 30 items (**FY2009 Report Table 3.5-4**) are registered as mandatory standards referred by administrative authority.

3.5.1.5 Halal System

Halal System is a system to examine raw materials of food, production process, quality of products permissible under Islamic Law, and to certify and label halal-compliant products. Halal Development Company (HDC) is responsible for examination of standards and promotion of halal industry. As MS standards, MS 1500:2009 is established as main standards. It is said that any food without halal mark can not be distributed in Malaysian market. Therefore, we should give due consideration to Halal system.

The Malaysian government recently announced its intentions of enacting a Halal Act, and it will be positioned as the dominant conception of current Halal system. While it is still unclear as to what kind of provisions would be found within the Act, it should likely have a significant impact on the production, distribution, sales and so on.

Halal system in South East Asia is reviewed in **Chapter 5**.

3.5.1.6 Laws and Regulations related to Food Additives

3.5.1.6.1 Overview

In Malaysia, food additives are regulated by the Food Safety and Quality Division (FSQD) within the Ministry of Health. The main legal basis for regulation of food additives in Malaysia is found in Subregulation 19 of the Food Regulations 1985. The Subregulation provides that:

- 1) Substances that are not permitted as food additives are not allowed to be used as foods additives;
- 2) Permitted food additives that do not comply with standards prescribed under the Food Regulations, where such standard is so prescribed, are also not allowed in food;

- 3) Addition of food additives to foods is prohibited unless expressly allowed under the Food Regulations;
- 4) Food additives used in foods should not exceed the maximum permitted levels

3.5.1.6.2 Food Additive Definition & Functional Classes

Food additives are defined in the Food Regulations as follows:

“Food additive means any safe substance that is intentionally introduced into or on a food in small quantities in order to affect the food’s keeping quality, texture, consistency, appearance, odour, taste, alkalinity, or acidity, or to serve any other technological function in the manufacture, processing, preparation, treatment, packing, packaging, transport, or storage of the food, and that results or may be reasonably expected to result directly or indirectly in the substance or any of its by-products becoming a component of, or otherwise affecting the characteristics of, the food, and includes any preservative, colouring substance, flavouring substance, flavour enhancer, antioxidant and food conditioner, but shall not include added nutrient, incidental constituent or salt.”

As noted in the definition, food additives are divided into 7 functional classes in Malaysia, as follows:

- 1) Preservatives;
- 2) Antimicrobial agents;
- 3) Colouring substances;
- 4) Flavouring substances;
- 5) Flavour enhancers;
- 6) Antioxidants; and
- 7) Food conditioners;

Food conditioners are further divided into 11 subcategories, including

- i) Emulsifiers;
- ii) Antifoaming agents;
- iii) Stabilizers;
- iv) Thickeners;
- v) Modified starches;
- vi) Gelling agents;
- vii) Acidity regulators;
- viii) Enzymes;

- ix) Solvents;
- x) Glazing agents; and
- xi) Anticaking agents

Some of the substances listed within the functional class for food conditioner may also be used in certain instances as food processing aids.

3.5.1.6.3 Permitted Food Additives and Maximum Limits

Use of an additive in food is on the condition that:

- 1) The additive is permitted by the Regulations to be in any ingredient used in the manufacture of the food;
- 2) The proportion of the additive in the final product does not exceed the maximum proportion, if any, permitted by the Regulations for that ingredient;
- 3) The total proportion of the additive in the final product does not exceed the maximum proportion, if any, permitted by the Regulations for that product;
- 4) The food into which the additive is carried over does not contain the additive in greater quantity that would be the case if the food were made under proper technological conditions and in accordance with sound manufacturing practices; and
- 5) The additive carried over is present in the food at a level that is significantly less than that normally required for the additive to achieve an efficient technological function in its own right;

Permitted food additives and maximum limits are found in the Sixth, Sixth (A), Seventh, Eighth, Ninth, Tenth and Eleventh Schedules of the Food Regulations. Limitations on the use of permitted food additives are that they must not be used to conceal any damage to or any inferiority in the quality of foods.

3.5.1.6.4 Prohibited Substances as Food Additives

Prohibited flavouring substances are found in the Eight Schedule of the Food Regulations. There is no other negative list of prohibited food additives, since only permitted additives are allowed to be used in food.

3.5.1.6.5 Specifications for Food Additives

Specifications for food additives are found in Malaysian Standard (MS) 1281 Part 1 to Part 8 for acidity regulators, preservatives, antioxidants, flavour enhancers, stabilizers, thickeners and gelling agents, solvents, anticaking agents and colouring substances.

3.5.1.6.6 Assessment of Food Additives

New food additives must first be evaluated by the Expert Committee on Food Additives and Contaminants and approved by the FSQD. Information and data requirements for the assessment include:

- 1) Chemical and/or common name of proposed additive (Trade names are not acceptable);
- 2) Specific type of food for which requested and classification of product under the Food Regulations 1985 (to state proposed regulation number and reason);
- 3) Proposed minimum and maximum levels of use in each food item;
- 4) The purpose of the additive in each food item and evidence that the additive will have the intended physical or other technical results when added to the particular food item;
- 5) Evidence as to whether or not the same objectives can be obtained by good manufacturing practice or by additives currently approved in Malaysia;
- 6) The limits of the probably daily intake of the additive in the diet;
- 7) Evidence of approval and if approval has been rejected by any statutory body or authority;
- 8) Chemical structure and formula of the additive in precise chemical terms and all physical details;
- 9) Recognized standard of purity for the additive, e.g. Joint FAO/WHO Expert Committee on Food Additive (JECFA), Food Chemicals Code, British Standards Institute, etc.
- 10) Information regarding the stability and persistence of the additive in the food(s) in which it is to be used;
- 11) The advantages which will occur to the consumer from the use of this additive;
- 12) If intended use of the additive is in packaging materials, the maximum amount(s) (supported by evidence) that may be incidentally absorbed by the food(s) from the food packaging materials should be stated;
- 13) Evidence in the form of a request or requests from manufacturers of a specific type of food or food setting out the purpose to be served by the additive and establishing the need for it;
- 14) Analytical method to determine the amount of additive in the raw, processed and/or finished food;
- 15) Analytical method to determine any substance formed in or on such food because of the use of the food additive;
- 16) Outline of the method of manufacture of the additive;

- 17) Full details of the analytical controls used during the various stages of manufacturing, processing and packing;
- 18) Full details of pharmacological and toxicological investigations carried out according to the general terms of reference given in World Health Organization Technical Report, Series 144, "Procedures for the testing of intentional food additives to establish their safety for use", specifically:
 - (a) acute, short term and long term (chronic) toxicity studies. Chronic toxicity data should be given for at least two species, one of which should be the dog and carried out over the major portion of the life span of the experimental animal. Chronic toxicity experiments should aim to give the data needed to establish a 'no-effect' level;
 - (b) reporting of any physiological effects or any abnormal reactions, including carcinogenesis, teratogenesis in pregnant species, sensitivity, tolerance or idiosyncrasy in response to the additive;
 - (c) biochemical information on the possible mode of action if available; metabolic studies to show rate, extent and mode of elimination;
 - (d) evidence of non-interference with essential dietary constituents;
 - (e) summary and bibliography of pertinent literature.

Additionally, it is also possible for applications to be made for existing permitted additives to be added into other standardized food items within the Food Regulations. Information required for such applications include:

- 1) The technological function and proposed minimum and maximum levels;
- 2) Exposure assessment for additives which have an ADI

3.5.1.6.7 Labelling of Food Additives

The presence of additives in foods in general should be listed on the label in the form – "*contains permitted (state the type of the relevant food additive)*". Additional labelling requirements for specific additives used in food include:

- 1) For sulphite or sulphur dioxide, the words "*contains sulphur dioxide*";
- 2) For flavour enhancers, the words "*contain (state the chemical name of the flavour enhancer) as permitted flavour enhancer*";
- 3) For polydextrose added as a food conditioner, the words "*Sensitive individuals may experience a laxative effect from the excessive consumption of food containing polydextrose*";
- 4) For food conditioners, the words "*contains (state the class name of the food conditioner) as permitted food conditioner*".

3.5.1.7 Case Study

(1) Instant Noodles (Table 3.5-2)

Standards for use of food additives in “pasta”, “instant wheat noodle” and “instant rice noodle (beehoon)” are described. There are Malaysian Standard for instant wheat noodle (MS526:2009) and instant rice noodle (MS1112:1988).

In each case standard for use of food additives is regulated by the Food Regulations 1985.

(2) Carbonated Soft Drinks (Table 3.5-3)

Standards for use of food additives in “flavoured drink” and “ready-to-drink beverages” are described. There are Malaysian Standard for “ready-to-drink beverages (carbonated and non-carbonated)” (MS601:1994).

In each case standard for use of food additives is regulated by the Food Regulations 1985.

(3) Prepared Frozen Foods (Table 3.5-4)

There is no food category for “prepared frozen foods” in Malaysia. Standards for use of food additives in “meat frankfurters” and “meat burgers” are described. There are Malaysian Standard for “meat frankfurters” (MS1125:2003) and “meat burgers” (MS1126:2003).

In each case standard for use of food additives is regulated by the Food Regulations 1985.

(4) Cow’s Milk (Table 3.5-5)

Food additives are prohibited according to Food Regulations 1985.

Table 3.5-A1 Description/Definition (General)

	Description / Definition	Reference
Related legislation	Food Regulations 1985	http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21
General Description/Definitions		
Definition of food additives	Food additives are defined in the Food Regulations as follows: “Food additive means any safe substance that is intentionally introduced into or on a food in small quantities in order to affect the food’s keeping quality, texture, consistency, appearance, odour, taste, alkalinity, or acidity, or to serve any other technological function in the manufacture, processing, preparation, treatment, packing, packaging, transport, or storage of the food, and that results or may be reasonably expected to result directly or indirectly in the substance or any of its by-products becoming a component of, or otherwise affecting the characteristics of, the food, and includes any preservative, colouring substance, flavouring substance, flavour enhancer, antioxidant and food conditioner, but shall not include added nutrient, incidental constituent or salt.”	Food Regulations 1985, Part V Regulation No. 19 (1)
Flavours	“Flavouring substance” means any substance that, when added to food, is capable of imparting flavour to that food and includes spices specified in regulation 286 to 333. “Natural Flavouring Substance” means any flavouring substance obtained exclusively by physical processes from vegetable, fruit or animal, either in their natural state or processed, for human consumption. “Nature Identical Flavouring Substance” means any flavouring substance chemically isolated from aromatic raw materials or obtained synthetically, and are chemically identical to substances present in natural products intended for human consumption, either processed or not.	Food Regulations 1985, Part V Regulation No. 22 (1) Food Regulations 1985, Part V Regulation No. 22 (2) (a) Food Regulations 1985, Part V Regulation No. 22 (2) (b)
Processing aids	Processing aids are considered as food additives under the functional class of “food conditioner”.	Food Regulations 1985, Part V Regulation No. 25 (1)

Carry-over	“Carry-over” principle is described in general in the Food Regulations, with restricted list of additives allowed to be carried over for infant formula.	Food Regulations 1985, Part V Regulation No. 19 (5); Food Regulation No.389 (5) (for infant formula)
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Table 3.5-B1 Description/Definition (Specific)

		Description / Definition	Reference
Related legislation		Food Regulations 1985	http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21
Specific Descriptions/Definitions			
1	List of Designated Food Additives	Includes preservative, antimicrobial agent, colouring substance, flavouring substance, flavour enhancer, antioxidant, antioxidant and food conditioner.	Food Regulations 1985, 6 th , 6 th (A), 7 th , 9 th , 10 th & 11 th Schedules; 21 st Schedule, Table II (for infant formula)
2	List of Existing Food Additives	There is no such list in Malaysia.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Malaysia.	
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Malaysia.	
Negative list (if any)		There is a list of flavouring substances the use of which is prohibited or limited in Malaysia.	Food Regulations 1985, 8 th Schedule, Table I

<p>Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives</p>	<p>Found in Malaysian Standard 1282 Parts 1-8 for acidity regulator; preservative; antioxidant; flavour enhancer; stabilizer, thickener and gelling agent; solvent; anticaking agent; and colouring substance.</p>	<p>MS 1282: Part 1: 1992 MS 1282: Part 2: 1992 MS 1282: Part 3: 1992 MS 1282: Part 4: 1992 MS 1282: Part 5: 1992 MS 1282: Part 6: 1992 MS 1282: Part 7: 1992 MS 1282: Part 8: 1995</p>
<p>Official publication and/or gazette for food additives</p>	<p>No official publication and/or gazette for food additives. However, updates on food additives are announced on the FSQD, MOH, Malaysia website.</p>	<p>http://fsq.moh.gov.my/v3/index.php?option=com_k2&view=item&layout=item&id=224&Itemid=104</p>

Table 3.5-2 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Pasta	Food Regulations 1985
Positive and/or Negative List	Should not contain any prohibited flavouring substances under the Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any	May contain Transglutaminase and sulphur dioxide or sulphites, as permitted food conditioner at < 200mg/kg.	
Scope and/or Description	Instant wheat noodles	MS 526:2009 Instant wheat noodles
Positive and/or Negative List	Food additives are permitted in accordance with Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Instant rice noodles	MS 1112:1988 Instant rice noodles (beehoon)
Positive and/or Negative List	Preservatives are prohibited.	
Use Limitation and/or Maximum Level, if any	Other additives are permitted in accordance with Food Regulations 1985.	

Table 3.5-3 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Flavoured drink	Food Regulations 1985, 354 and PartV
Positive and/or Negative List	Should not contain any prohibited flavouring substances under the Food Regulations 1985. May contain permitted preservative, colouring substance and food conditioner in accordance with Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any	1. Ester gum: <150mg/l 2. β-cyclodextrin: <150mg/l 3. Caffeine-containing plant extract as flavouring substance:	

	<p><200mg/l</p> <ol style="list-style-type: none"> 4. Sulphur dioxide: <140mg/l 5. Benzoic acid: <350mg/kg 6. Agaric acid: <20mg/kg 7. Total hydrocyanic acid (free and combined): <1mg/kg 8. Pulegone: <100mg/kg (except peppermint or mint flavoured beverages) or 250mg/kg (for peppermint or mint flavoured beverages) 9. Quassin: <5mg/kg 10. Quinine: <85mg/kg 11. Thujones: <0.5mg/kg 	
Scope and/or Description	Ready-to-drink beverages	MS 601:1994 Ready-to-drink beverages (carbonated and non-carbonated)
Positive and/or Negative List	<p>Permitted acidity regulators: citric acid, phosphoric acid, lactic acid, malic acid, acetic acid, fumaric acid, tartaric acid (including the sodium, potassium and calcium salts)</p> <p>Permitted colours, nutritive and non-nutritive sweeteners in accordance with Food Regulations 1985.</p> <p>Permitted mineral salts: sodium carbonate and sodium bicarbonate</p> <p>Permitted preservatives and flavouring agents</p>	
Use Limitation and/or Maximum Level, if any	<ol style="list-style-type: none"> 1. Sulphuric acid: <140ppm 2. Benzoic acid: <350ppm 3. Sorbic acid: <350ppm 4. Caffeine: <150ppm 5. Quinine: 40-85ppm 6. Ascorbic acid: 10mg/100ml 	

Table 3.5-4 Case Study 3 Prepared Frozen Foods

	Description/Definition	Reference
Scope and/or Description	Meat frankfurters	MS 1125:2003
Positive and/or Negative List	Food additives are permitted in accordance with Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Meat burgers	MS 1126:2003
Positive and/or Negative List	Food additives are permitted in accordance with Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any		

Table 3.5-5 Case Study 4 Cow's Milk

	Description/Definition	Reference
Scope and/or Description	Milk, raw milk or fresh milk	Food Regulations 1985
Positive and/or Negative List	Food additives are prohibited according to Food Regulations 1985.	
Use Limitation and/or Maximum Level, if any		

3.5.2 Singapore

3.5.2.1 Food Administration

Administrative body responsible for food standards, safety and hygiene control is consolidated in Agri-Food and Veterinary Authority (AVA) of Ministry of National Development. AVA administers wide range of animals, pets, agriculture and fishery, as well as foods.

3.5.2.2 Summary Chart of relationship of Food Law System and Singapore Commodity Standards

The chart is presented in **Figure 3.5-2**.

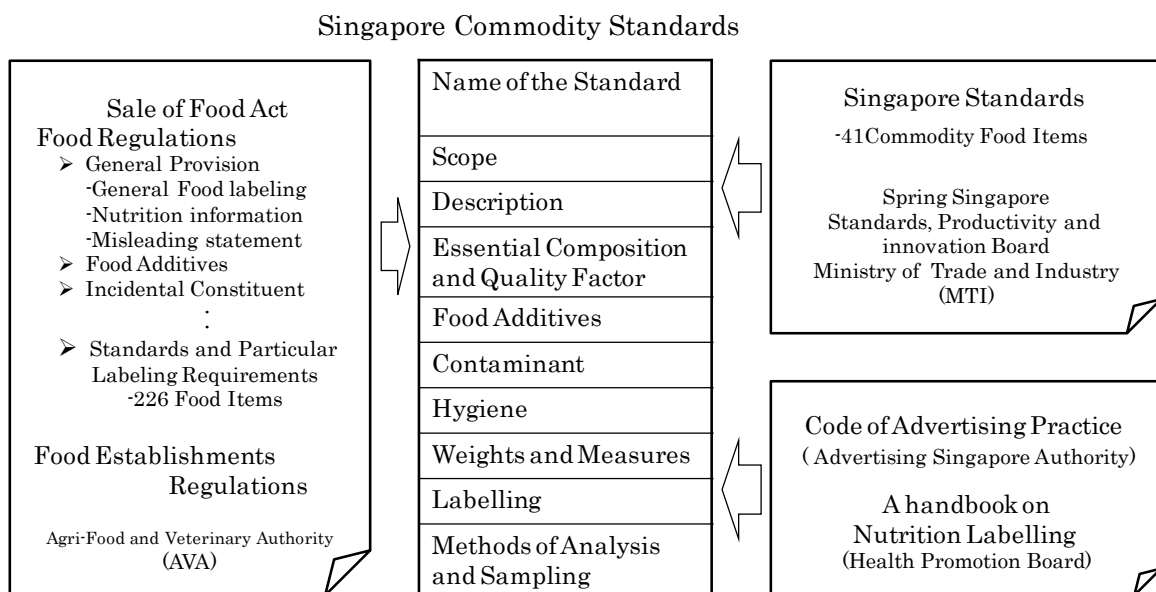


Figure 3.5-2 Singapore Commodity Standards and Relevant Laws

3.5.2.3 Sale of Food Act

AVA (Agri-Food and Veterinary Authority) collectively administers Sale of Food Act. AVA was a bureau which originally administered primary products. In 2000, AVA was reorganized to administer quality and safety of food related substances for securing food safety.

(1) Sale of Food Act-2002³¹

Sale of Food Act is established for securing wholesomeness and purity of food and fixing standards for preventing the sale or other disposition, or the use of articles dangerous or injurious to health, and for providing for the regulation of food establishments.

³¹[http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/8725/Attach59 legislati on_SaleofFoodAct.pdf](http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/8725/Attach59_legislati on_SaleofFoodAct.pdf)

(2) Food Regulation-2006³²

Supplementary provisions of Sale of Food Act are compiled in Food Regulation and is continuously updated on amendment and newly setting of regulations. Food Regulation provides detailed general requirements for labelling, food additives, contaminants, bacterial toxin, container packaging, irradiated food, and commodity standards. In the Chapter 4, commodity standards and the special labelling requirements for 226 food items (**FY 2009 Report Table 3.5-8**) are listed. It stipulated minimum definition, component standards and special labelling requirements.

(3) Food Establishments Regulations-2009³³

Food Establishments Regulation in Sale of Food Act regulates provides general food hygiene requirements against food handlers and food establishment.

3.5.2.4 Singapore Standards

Singapore Standard (SS) exists as commodity standard which are administered by Standards, Productivity and innovation Board (Spring Singapore) of Ministry of Trade and Industry (MTI). While, Singapore Standards is national standards for all industries pursuant to ISO, it is basically voluntary standards (it may become mandatory standards when issues related to safety, environment and health are referred by administrative authority).

Singapore Standards shown in **FY2009 Report Table 3.5-9** are in the same format as for Codex Commodity Standards.

The number of Singapore Standards set by Food Standard Committee is approximately 90. And commodity standards excluding for analytical methods and implementation are 41 standards (**FY 2009 Report Table 3.5-10**) out of them. These are basically voluntary standards, but, certified mark can be labeled by obtaining official certification.

3.5.2.5 Laws and Regulations related to Food Additives

3.5.2.5.1 Overview

In Singapore, food additives are regulated by the Agri-Food and Veterinary Authority of Singapore (AVA). The main legal basis for regulation of food additives in Singapore is found in the Food Regulations. The Regulations expressly prohibit

³² http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/11405/FoodRegulations_1.pdf

³³ http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/8729/Attach64_legislative_on_Sale_FdEstb_rules.pdf

the use of substances in food that are not permitted food additives according to the Regulations while expressly permits the use of food additives which are permitted and the proportion of use are specified in the Regulations.

3.5.2.5.2 Food Additive Definition & Functional Classes

Food additives are defined in the Food Regulations as follows:

“Food additive includes –

- i) all substances, which are components of food, the intended use of which results or may reasonably be expected to result, directly or indirectly, in their affecting the characteristics of food but does not include any foreign substance mixed with food as a result of contamination, or improper handling of the food during the preparation, processing, packing or storage of the food; and
- ii) anti-caking agents, anti-foaming agents, anti-oxidants, sweetening agents, chemical preservatives, colouring matters, emulsifiers or stabilizers, flavouring agents, flavour enhancers, humectants, nutrient supplements, sequestrants and other general purpose food additives.”

Food additives are divided into 14 functional classes in Singapore, as follows:

- 1) Anti-caking agents;
- 2) Anti-foaming agents;
- 3) Anti-oxidants;
- 4) Sweetening agents;
- 5) Chemical preservatives;
- 6) Colouring matter;
- 7) Emulsifiers and stabilizers;
- 8) Flavouring agents;
- 9) Flavour enhancers;
- 10) Humectants;
- 11) Nutrient supplements;
- 12) Sequestrants;
- 13) Gaseous packaging agents; and
- 14) General purpose food additives

In Singapore, food processing aids are included as general purpose food additives.

3.5.2.5.3 Permitted Food Additives and Maximum Limits

Food additives are allowed to be used in foods provided that they are permitted food

additives and are used in accordance with the levels specified in the Food Regulations. Food ingredients that are added to foods may also contain food additives for the types of additives permitted and in accordance with the levels specified for the food ingredients.

Permitted food additives and maximum limits are found in the Third, Fourth, Fifth, Sixth, Seventh, Eighth Schedules of the Food Regulations. Limitations on the use of permitted food additives are that they must not be used to conceal any damage to or any inferiority in the quality of foods.

3.5.2.5.4 Prohibited Substances as Food Additives

According to Regulation 22(7), prohibited flavouring agents include coumarin, tonka bean, safrole, sassafras oil, dihydrosafrole, isosafrole, agaric acid, nitrobenzene, dulcamara, pennyroyal oil, oil of tansy, rue oil, birch tar oil, cade oil, volatile bitter almond oil containing hydrocyanic acid and male fern. There is no other negative list of prohibited food additives, since only permitted additives are allowed to be used in food.

3.5.2.5.5 Specifications for Food Additives

According to Regulation 15(4), specifications for food additives and purity criteria for food additives used in food in Singapore must conform to the specifications as recommended by the Joint Expert Committee on Food Additives (JEFCA).

3.5.2.5.6 Assessment of Food Additives

There are no articulated procedures for the assessment and approval of new food additives found in the existing regulations.

3.5.2.5.7 Labelling of Food Additives

Food additives are required to be declared on the ingredients list of food labels using the “appropriate designation”³⁴. Regulation 5(4)(b)(i) defines this term as a description, being a specific and not a generic name or description, which shall indicate to a prospective purchaser the true nature of the ingredient, constituent or product to which it is applied except as provided in the “First Schedule”. Food additives that are allowed to use general terms include:

- 1) Colourings, when forming an ingredient of some other food as “colourings/colouring matter”;

³⁴<http://www.ava.gov.sg/NR/rdonlyres/B96B0EC2-1D1E-4448-9C25-ABD8470D2BF4/20119/AGuidetoFoodLabellingandAdvertisementsVersionOctob.pdf>

- 2) Flavourings, when forming an ingredient of some other food as “flavouring”;
and
- 3) Acacia, karaya, tragacanth, carob, gellan, ghatti, guar and xanthan gums as
“edible gum”

Additionally, there are certain requirements for the labelling of specific food additives, such as:

- 1) Foods containing tartrazine as a synthetic colouring must declare the presence of the colouring with the terms “tartrazine”, “colour (102)”, “colour (FD Yellow #5)” or other equivalent terms;
- 2) Presence of sulphites must be declared for food containing sulphites in concentration of 10 mg/kg or more as an ingredient that is known to cause hypersensitivity;
- 3) For foods containing aspartame as a sweetener, the words “*PHENYLKEONURICS: CONTAINS PHENYLALANINE*”
- 4) Foods that contain certain sweeteners, if added at the maximum permitted levels, require advisory statements on product labels as per the requirements highlighted in page 13 of “A Guide to Food Labelling and Advertisements” published by the AVA in October 2011:

3.5.2.6 Case Study

(1) Instant Noodles (Table 3.5-6)

There is a Singapore Standard for “Dried noodles and pasta products” (SS219:1979). Standard for use of food additive in pasta including “Dried noodles and pasta products” is regulated by the “Food Regulations”.

(2) Carbonated Soft Drinks (Table 3.5-7)

Standard for use of food additives in “Soft drinks” and “Carbonated and non-carbonated beverages” are set in the “Food Regulations” and the Singapore Standard for “Carbonated and non-carbonated beverages” (SS62:1997), respectively.

(3) Prepared Frozen Foods

There is no food category for “prepared frozen foods” in Singapore.

(4) Cow’s Milk (Table 3.5-8)

Food additives are prohibited according to Food Regulations.

Table 3.5-A2 Description/Definition (General)

	Description/Definition	Reference
Related legislation	Food Regulations	http://www.ava.gov.sg/NR/rdonlyres/OCA18578-7610-4917-BB67-C7DF4B96504B/19280/2web_SOF_FoodRegulations15April2011.pdf
General Description/Definitions		
Definition of food additives	<p>“Food additive includes –</p> <p>i) all substances, which are components of food, the intended use of which results or may reasonably be expected to result, directly or indirectly, in their affecting the characteristics of food but does not include any foreign substance mixed with food as a result of contamination, or improper handling of the food during the preparation, processing, packing or storage of the food; and</p> <p>ii) anti-caking agents, anti-foaming agents, anti-oxidants, sweetening agents, chemical preservatives, colouring matters, emulsifiers or stabilizers, flavouring agents, flavour enhancers, humectants, nutrient supplements, sequestrants and other general purpose food additives.”</p>	Food Regulations, Part I, Definitions
Flavours	<p>“Flavour Agent” means any wholesome substance that when added or applied to food is capable of imparting taste or odour, or both, to a food.</p> <p>“Natural Flavouring Agents” shall include natural flavouring essences, spices and condiments.</p> <p>“Synthetic Flavouring Essences or Extracts” shall include any artificial flavour or imitation flavour which may resemble the sapid or odoriferous principles of an aromatic plant, fruit or vegetable or any other food, except that the flavouring principle shall be derived in whole, or in part, from either chemical synthesis or any other sources that does not involve extraction or isolation therefrom of the sapid or odoriferous principles present in an aromatic plant, fruit or vegetable or any other food.</p>	<p>Food Regulations, Part III, Regulation No. 22 (1)</p> <p>Food Regulations, Part III, Regulation No. 22 (5)</p> <p>Food Regulations, Part III, Regulation No. 22 (9)</p>

Processing aids	“Processing Aids” are considered as “General Purpose Food Additives”, which means any substance which serves a useful and specific purpose during either the processing or packing of a food and shall include processing aid.	Food Regulations, Part III, Regulation No. 28 (1)
Carry-over	Food ingredients that are added to foods may also contain food additives for the types of additives permitted and in accordance with the levels specified for the food ingredients.	Food Regulations, Part III, Regulation No. 15 (4)

Table 3.5-B1 Description/Definition (Specific)

		Description/Definition	Reference
Related legislation		Food Regulations	http://www.ava.gov.sg/NR/rdonlyres/OCA18578-7610-4917-BB67-C7DF4B96504B/19280/2web_SOF_FoodRegulations15April2011.pdf
Specific Descriptions/Definitions			
1	List of Designated Food Additives	Anti-caking agents, anti-foaming agents, anti-oxidants, sweetening agents, chemical preservatives, colouring matter, emulsifiers and stabilizers, flavouring agents, flavour enhancers, humectants, nutrient supplements, sequestrants, gaseous packaging agent, general purpose food additives	Food Regulations, 3rd, 4th, 5th, 6th, 7th, 8th Schedules
2	List of Existing Food Additives	There is no such list in Singapore.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Singapore.	
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Singapore.	
Negative list (if any)		There is a list of prohibited substances for use as flavouring agents.	Food Regulations, Part III, Regulation No. 22 (7)

Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives	Follows JECFA specifications.	Food Regulations, Part III, Regulation No. 15 (4)
Official publication and/or gazette for food additives	There is no official publication and/or gazette for food additives. However, official circulars are issued when food regulations are amended.	http://www.ava.gov.sg/NR/rdonlyres/40210FDA-4EA7-4EAB-AD16-214FAC01036C/18743/circular_FoodAmendmentRegulations2011.pdf http://www.ava.gov.sg/NewsEvents/Circulars/

Table 3.5-6 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Pasta	Food Regulations
Positive and/or Negative List	Permitted flavouring agents and colouring matters according to Food Regulations.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Dried noodles and pasta products	SS 219:1979
Positive and/or Negative List	Not specified.	Dried noodles and pasta products
Use Limitation and/or Maximum Level, if any		

Table 3.5-7 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Soft drinks	Food Regulations
Positive and/or Negative List	Food additives are permitted in accordance with Food Regulations.	
Use Limitation and/or Maximum Level, if any	<ol style="list-style-type: none"> 1. Ester gum: < 100ppm 2. Sucrose acetate isobutrate: < 300ppm 3. Dimethyl polysiloxane: < 10ppm 4. Calcium disodium ethylenediaminetetraacetate: <33ppm 5. Sulphur dioxide: <60ppm 6. Benzoic acid: <160ppm 7. Methyl or propyl para-hydroxy benzoate: <160ppm 8. Sorbic acid: <300ppm 9. Dimethyl carbonate: <250ppm 10. Acesulfame-K: <350ppm 	

	11. Saccharin: <80ppm 12. Cyclamates (as cyclamic acid): <250ppm 13. Neotame: 20ppm 14. Steviol glycosides (as steviol): < 160ppm 15. Sucralose: <300ppm	
Scope and/or Description	Carbonated and non-carbonated beverages	SS 62:1997
Positive and/or Negative List	Permitted acidity regulators including citric acid, tartaric acid, malic acid, phosphoric acid, ascorbic acid, acetic acid, adipic acid, fumaric acid, hydrochloric acid, dl-lactic acid, dl-malic acid, ortho-phosphoric acid and L(+)-tartaric acid	Carbonated and non-carbonated beverages
Use Limitation and/or Maximum Level, if any	Permitted food colours, clouding agents, foaming agents, emulsifying and stabilizing agents, and preservatives	

Case Study 3 Prepared Frozen Foods

There is no food category for “prepared frozen foods” in Singapore.

Table 3.5-8 Case Study 4 Cow’s Milk

	Description/Definition	Reference
Scope and/or Description	Milk	Food Regulations
Positive and/or Negative List	Food additives are prohibited according to Food Regulations.	
Use Limitation and/or Maximum Level, if any		

3.5.3 Philippines

The 1987 Constitution of the Philippines³⁵ stipulates that “the State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems”. Based on the above, Consumer Act of the Philippines³⁶ requires “to develop and provide safety and quality standards for consumer products” and give the enforcement power Department of Health to respect with foods and pharmaceuticals.

3.5.3.1 Food Administration

Administrative bodies mainly responsible to food safety and hygienic control are Department of Health and Department of Agriculture. Major roles of these departments are shown in **Table 3.5-9**.

Table 3.5-9 Food Safety Control System in Philippines

	Safety and Hygiene of Agricultural Products and Primary Processed Foods Department of Agriculture (DA)	Safety and Hygiene of Processed Foods Department of Health (MOH)
Agricultural products	Bureau of Plant Industry (BPI)	Bureau of Food and Drugs (BFAD) The Law was amended in August 2009 to strengthen capability of BFAD and to augment human resources. Under new law, BFAD was renamed into Food and Drug Administration (FDA).
Marine Products	Bureau of Fisheries and Aquatic Resources (BFAR)	
Livestock products	Bureau of Animal Industry (BAI) National Meat Inspection Service (NMIS) Bureau of Agricultural and Fisheries Product Standard (BAFPS)	

3.5.3.2 Food Law System and Commodity Standards

Chart of the relationship is shown in **Figure 3.5-3**.

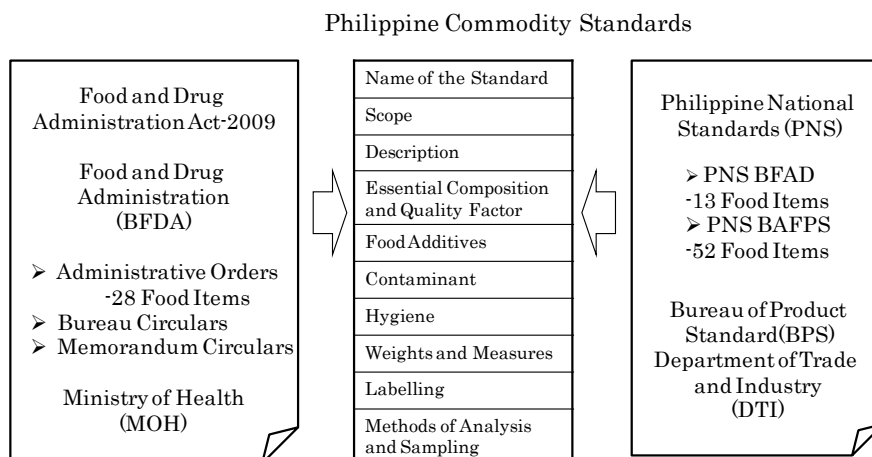


Figure 3.5-3 Philippine Commodity Standards and Relevant Laws

³⁵ http://www.gov.ph/index.php?option=com_content&task=view&id=200034&Itemid=26

³⁶ <http://www.gov.ph/?s=Consumer+Act+of+the+Philippines>

(1) Food and Drug Administration Law³⁷

It is a major food law of the Republic of the Philippines known as the Republic Act 9711 (2009 revised version of Republic Act 3720).

This Law was established with purpose of ensuring “safety and purity of food and cosmetics, and safety, efficacy and quality of drugs and medical devices intended for use of the public”, and authorizes Department of Health (MOH) to enforce regulatory policy including measures for setting of evaluation method for quality of food standards and providing safe and clean foods.

Moreover, the Law transfers responsibilities of implementing this Law to Bureau of Food and Drugs (BFDA) and delegates the developing rules and regulations for safety of foods and drugs, and common standards and guidelines in the use of nutrition and health claims in foods and drugs.

Specific rules and regulations are implemented by publication of Administrative Order (AO), Bureau circulars (BC) or Memorandum Circulars (MC).

(2) Administrative Order and Circulars³⁸

Administrative orders related to commodity standards are presented in **FY 2009 Report Table 3.5-14**. As they are relatively limited coverage, the Philippines is half way to standardization. When prompt action is needed, relevant administrative bodies coordinate to develop mandatory standards within the framework of Philippine national standards described below. Examples of composition of commodity standards set by AO and BC are shown in FY2009 Report (p.98 in the upper part).

(3) Philippine National Standards (PNS)

From the standpoint of commodity standards, Philippine National Standards (PNS) set by Department of Trade and Industry (DTI) and Department of Product Standard (DPS) occupies important place. It is within the framework of PNS for all industries pursuant to ISO. Philippine National Standards is basically voluntary standard, but, certification mark can be labeled by obtaining official certification. Format of the standard are same as that of Codex Standard. Comparison is shown in **FY2009 Report Table 3.5-15**.

Philippine National Standards in ICS code 67 (Food technology) related to food are totally 89 standards. Twenty one standards with PNS BFAD which is standard number set by DTI and DPS together with Bureau of Food and Drugs (BFAD)(past

³⁷ <http://www.fda.gov.ph/republic%20acts/RA%209711-BFAD%20Strengthening%20Law.pdf>

³⁸ http://www.fda.gov.ph/laws_medical%20deivce.html

name of FDA) are mandatory standards (**FY2009 Report Table 3.5-16**). There are 13 commodity standards excluding standards for processing.

Also, there are some standards for fresh foods attached PNS BAFPS standard number set with cooperation of Bureau of Agricultural and Fisheries Product Standard (BAFPS). **Table 3.5-17** shows standards for specifications, grade and classification of specific food, and these are mandatory standards as well.

3.5.3.3 Laws and Regulations related to Food Additives

3.5.3.3.1 Overview

In the Philippines, food additives contained in processed foods are regulated by the Food and Drug Administration (FDA) of the Philippines. Food additives are defined in the Food, Drug and Cosmetic Act (Republic Act No. 372), which forms the legal basis for regulation of food additives in the Philippines. Subsidiary regulations on food additives have been issued by the FDA, including the following:

- 1) Administration Order (AO) No. 88A s. 1984 on Regulatory Guidelines Concerning Food Additives
- 2) FDA Circular No. 2006-016 on Updated List of Food Additives

3.5.3.3.2 Food Additive Definition & Functional Classes

Food additives are defined in the Food, Drug and Cosmetic Act as follows:

“Food additive means any substance the intended use of which results or may reasonably be expected to result, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown thorough scientific procedures to be safe under the conditions of intended use.”

Processing aids and flavouring substances are also considered as food additives in the Philippines. Processing aids are defined in AO No. 88A s. 1984 as:

“Processing aids are additives that are used in the processing of food to achieve a specified technological purpose and which may or may not result in the presence of residues or derivatives in the final product.”

The Philippines has adopted the functional classes for food additive listed in the

Codex Alimentarius General Standard for Food Additives (GSFA), which include:

- 1) Acidity regulator;
- 2) Anticaking agent;
- 3) Antifoaming agent;
- 4) Antioxidant;
- 5) Bleaching agent;
- 6) Bulking agent;
- 7) Carbonating agent;
- 8) Carrier;
- 9) Colour;
- 10) Colour retention agent;
- 11) Emulsifier;
- 12) Emulsifying salt;
- 13) Firming agent;
- 14) Flavour enhancer;
- 15) Flour treatment agent;
- 16) Foaming agent;
- 17) Gelling agent;
- 18) Glazing agent;
- 19) Humectant;
- 20) Packaging gas;
- 21) Preservative;
- 22) Propellant;
- 23) Raising agent;
- 24) Sequestrant;
- 25) Stabilizer;
- 26) Sweetener;
- 27) Thickener

3.5.3.3.3 Permitted Food Additives and Maximum Limits

The Philippines has adopted the Codex Alimentarius GSFA with regard to the general principles for the use of additives in food as well as for the maximum permitted use levels. According to FDA Circular No. 2006-016, the Philippines shall automatically adopt any food additive and functional classes that have been accepted by the Codex Alimentarius Commission. The one exception however is for the use of cyclamates as sweeteners.

3.5.3.3.4 Prohibited Substances as Food Additives

Administrative Order No. 122 s. 1970 on General Regulation Governing the

Prohibition of the Use of Cyclamic Acid and its Salts (B-6.3 Food Additives and Preservatives) placed a ban on the use of cyclamates in foods; while Administrative Order No. 125 s. 1970 on General Regulation for Labelling Artificial Sweeteners in the Dietary Management of Disease in Man; Prohibited Artificial Sweeteners (B-6.2 Food Additives & Preservatives) placed a ban on use of dulcins and p-4000 (5-Nitro-2-propoxyaniline).

3.5.3.3.5 Specifications for Food Additives

Specifications for food additives are in accordance with the specifications of identity and purity recommended by the Codex Alimentarius Commission, JECFA or, in the absence of such specifications, by responsible international regulating bodies.

3.5.3.3.6 Assessment of Food Additives

Although the Philippines largely follows the Codex Alimentarius GSFA as the basis for its additive regulations, there is a process for seeking approval from the FDA for new food additives as outlined in AO No. 88-A s 1984. Information and data requirements for the approval of new approvals include:

- 1) The chemical identity and composition of the additive, its physical, chemical and biological properties, and specifications for its purity;
- 2) A description of the method of manufacture and a list of substances used in the synthesis, extraction or another method of preparation;
- 3) The amount of the food additive proposed for use and the purpose for which it is proposed, together with the directions and recommendations regarding the proposed use;
- 4) Data establishing that the food additive will have intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics directly or indirectly of food and the amount necessary to accomplish this;
- 5) Assay method(s) for determining the amount of the food additive in the raw, processed and/or finished food and of any substance formed in or on such food because of its use;
- 6) Proposed tolerance or maximum level of use, if required to ensure its safety;
- 7) Full reports or investigation made with respect to the safety of the additive, including information as to the methods and controls used in conducting such investigations;
- 8) Or in lieu of reports or investigations as stated in 7), official documents from the country of origin containing standard procedures adopted in evaluating the safety of food additives and a certification from the health authorities in

that country, indicating the present status of the additive. These documents shall be duly authenticated by the Philippines Consulate;

- 9) A sample of the food additive and a sample of food containing the additive

3.5.3.3.7 Labelling of Food Additives

The labelling requirements for additives used in food are included in Administrative Order No. 88-B s. 1984 on Rules and Regulations Governing the Labelling of Prepackaged Food Products Distributed in the Philippines. AO No. 88-B s. 1984 requires that food additives be declared in the ingredients list by their common name or their functional class name on the food label. Processing aids and food additives carried over into food (from another food that was used as an ingredient) at levels less than those required to achieve a technological function do not need to be declared in the list of ingredients.

3.5.3.4 Case Study

- (1) Instant Noodles (**Table 3.5-10**)

Standard for use of food additives in “Flour sticks (pancit canton)” is described.

There is a Philippines National Standard for “pancit canton” (PNS/BFAD 18:2008).

- (2) Carbonated Soft Drinks (**Table 3.5-11**)

Standard for use of food additives in “Citrus beverage products” is described. There

is a Philippines National Standard for “Citrus beverage products” (PNS/BFAD 11:2007).

- (3) Prepared Frozen Foods

There is no food category for “prepared frozen foods” in the Philippines.

- (4) Cow’s Milk (**Table 3.5-12**)

The use of food additives in “Fresh milk” (PNS BFAD 36: 2007) is prohibited.

Table 3.5-A3 Description/Definition (General)

	Description/Definition	Reference
Related legislation	Department of Health Administration Order No. 88-A s.1984 on Regulatory Guidelines Concern Food Additives Department of Health, Food and Drug Administration Circular No. 2006-016 on Updated List of Food Additives	http://www.fda.gov.ph/AO/ao%2088a%20s.%201984.pdf http://www.fda.gov.ph/BC%202006-016.pdf
General Description/Definitions		
Definition of food additives	Food additives are defined in the Food, Drug and Cosmetic Act as follows: “Food additive means any substance the intended use of which results or may reasonably be expected to result, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown thorough scientific procedures to be safe under the conditions of intended use.”	http://www.fda.gov.ph/BC%202006-016.pdf
Flavours	“Flavouring Substances” refer to flavour preparations composed of substances derived from plant/animal products and/or chemically synthesized substances whose significant function in food flavouring rather than nutritional.	AO No. 88-A s.1984, 1
Processing aids	“Processing Aids” are additives that are used in the processing of food to achieve a specified technological purpose and which may or may not result in the presence of residues or derivatives in the final product.	AO No. 88-A s.1984, 1
Carry-over	Defined in general according to BC 2006-16	FDA Circular No. 2006-016, Part III, C

Table 3.5-B3 Description/Definition (Specific)

		Description/Definition	Reference
Related legislation		Department of Health Administration Order No. 88-A s.1984 on Regulatory Guidelines Concern Food Additives Department of Health Food and Drug Administration Circular No. 2006-016 on Updated List of Food Additives	http://www.fda.gov.ph/AO/ao%2088a%20s.%201984.pdf http://www.fda.gov.ph/BC%202006-016.pdf
Specific Descriptions/Definitions			
1	List of Designated Food Additives	Follows Codex GSFA.	FDA Circular No. 2006-016, Table 2
2	List of Existing Food Additives	There is no such list in Philippines.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Philippines.	FDA Circular No. 2006-016, Part VI
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Philippines	
Negative list (if any)		Cyclamates, dulcins and p-4000 (5-nitro-2propoxyaniline) are prohibited from use in foods as sweeteners. Administrative Order No. 122 s.1970 on General Regulation Governing the Prohibition of the Use of Cyclamic Acid and its Salts Administrative Order No. 125 s. 1970 on General Regulation for Labelling Artificial Sweeteners in the Dietary Management of Disease in Man; Prohibited Artificial Sweeteners	http://www.fda.gov.ph/AO/ao%20122%20s%201970.pdf http://www.fda.gov.ph/AO/ao%20123%20s.%201970.pdf
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives		Follow JECFA specifications.	FDA Circular No. 2006-016, Part III, A (5)

Official publication and/or gazette for food additives	There is no official publication and/or gazette for food additives in the Philippines. However, additional food additive and functional classes by Codex are automatically added to the list of additives/functional classes.	FDA Circular No. 2006-016, Part VII
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Table 3.5-10 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Flour sticks (pancit canton)	PNS/BFAD 18:2008 Flour sticks (pancit canton)
Positive and/or Negative List	Usage of food additives in accordance with FDA Circular No. 2006-016 and Codex GSFA. Permitted additives include acidity regulators, antioxidants, colours, flour treatment agents, raising agents and stabilizers. Carry-over of other additives are allowed as approved by FDA and in accordance with Codex principles on carry-over of food additives.	
Use Limitation and/or Maximum Level, if any	1. Sodium hydroxide: GMP 2. Butylated hydroxyanisole (BHA): <100mg/kg 3. Butylated hydroxytoluene (BHT): <200mg/kg 4. Tocopherol: GMP 5. Tartrazine: <300mg/kg 6. Sunset Yellow: <300mg/kg 7. Phosphates (as sodium or potassium phosphates): <2,200mg/kg 8. Sodium carbonate: <2,600mg/kg 9. Potassium carbonate: <2,600mg/kg	

Table 3.5-11 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Citrus beverage products	PNS/BFAD 11:2007 Citrus beverage products
Positive and/or Negative List	Usage of food additives in accordance with FDA Circular No. 2006-016 and Codex GSFA.	

<p>Use Limitation and/or Maximum Level, if any</p>	<p>Permitted additives include:</p> <ol style="list-style-type: none"> 1. acidity regulator (citric acid, malic acid, calcium carbonate, adipates) 2. anticaking agent (calcium aluminum silicate – synthetic, microcrystalline cellulose; aluminum silicate, carnauba wax) 3. antioxidant (ascorbic acid, calcium ascorbate, erythorbic acid, potassium ascorbate, sodium ascorbate, sodium erythorbate) 4. colour (carotenoids, chlorophylls, chlorophyll copper complexes, sulphites, carbon dioxide, phosphates, ethylenediaminetetraacetic acid/EDTA) 5. stabilizer/thickener (calcium chloride, carob bean gum, carrageenan, gellan gum, guar gum, gum arabic, karaya gum, lactic and fatty acid esters of glycerol, pectins, potassium alginate, sodium alginate, tara gum, tragacanth gum, xanthan gum, agar, konjac flour, sodium carboxymethylcellulose) 6. sweetener (acesulfame potassium, aspartame, saccharin, sucralose) 7. Processing aids (antifoaming agents:- polydimethylsiloxane; clarifying agents/filtration aids/flocculating agents :- adsorbent clays, adsorbent resins, activated carbon – only from plants, bentonite, cellulose, chitosan, colloidal silica, diatomaceous earth, gelatin – from skin collagen, ion exchange resin – cation and anion, kaolin, perlite; enzyme preparations:- pectinases – for breakdown of pectin, proteinases – for breakdown of proteins, amylases – for breakdown of starch, cellulases – limited use to facilitate disruption of cell walls; packaging gas:- nitrogen, carbon dioxide) 	
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Case Study 3 Prepared Frozen Foods

There is no food category for “prepared frozen foods” in the Philippines.

Table 3.5-12 Case Study 4 Cow's Milk

	Description/Definition	Reference
Scope and/or Description	Fresh milk	PNS/BAFPS 36:2007
Positive and/or Negative List	Usage of food additives in accordance with FDA Circular No.2006-016 and Codex GSFA.	
Use Limitation and/or Maximum Level, if any		

3.5.4 Indonesia

3.5.4.1 Food Administration

In Indonesia, Ministry of Agriculture is responsible for agriculture, Ministry of Marine Affairs and Fishery for fishery, Ministry of Industry for industries, and Ministry of Health and National Agency for Drug and Food Control for health.

3.5.4.2 Acts and Regulations related to Commodity Standards

Major acts and regulations related to Commodity Standards are presented in Figure 3.5-4.

Indonesian Commodity Standards

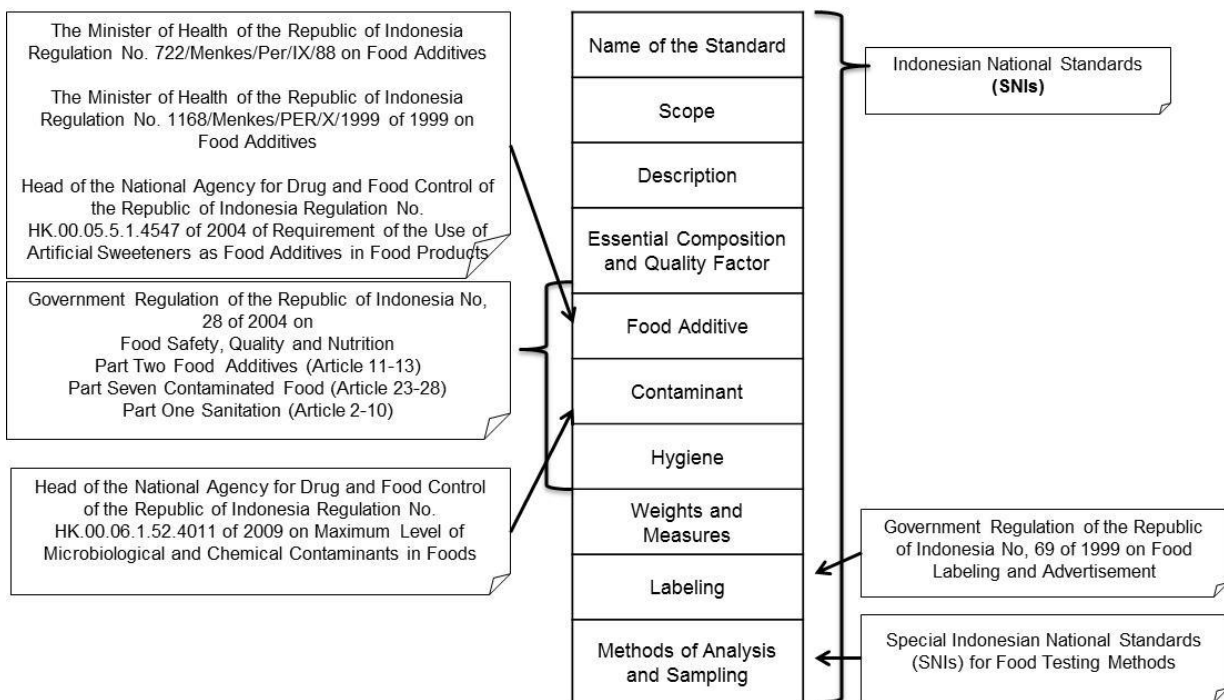


Figure 3.5-4 Indonesian Commodity Standards and Relevant Laws

3.5.4.3 Food Relevant Laws and Regulations

(1) Act of the Republic of Indonesia No. 7 of 1996 on Food

In the year of 1996, the Government of Indonesia issued the Act of the Republic of Indonesia No. 7 of 1996 on Food. The definition of food in the Food Act further indicates its comprehensive coverage:

“Food is everything that originates from biological sources and from water, either processed or unprocessed, that is intended to be eaten or drunk by humans, including food additives, basic food materials and other materials used in the preparation, processing and/or manufacture of food and drink.” The official amplification appended to the legislation states that the Food Act covers the following aspects:

- Technical criteria concerning food - covering safety, quality and nutrition as well as provisions for labelling and advertising foods.
- Responsibilities of those who produce, store, transport and/or distribute food, together with legal sanctions to enforce the determinations. (This aspect includes import and export of foods.)
- The role of government and society in achieving self-sufficiency in food and diversity in the foodstuffs consumed.
- The role of government in fostering a domestic food industry aiming to improve the characteristics of food for domestic consumption and for export.

(2) Government Regulation of the Republic Indonesia No. 69 of 1999 on Food Labelling and Advertisement

Based on the Food Act as the main foundation in the development food-related regulations, in the year of 1999 the Government of Indonesia issued the Government Regulation of the Republic Indonesia No. 69 of 1999 on Food Labelling and Advertisement. Important statements in several articles are:

- (1) any persons producing or importing any packaged food into Indonesian territory to be traded shall be obliged to stick up label on and or in the food packaging;
- (2) labelling as mentioned in paragraph (1) shall be done in such way that it is not easy to stick off, not easy to lose its colour or damaged, and shall lie on the part of the packaging which is easy to see and read;
- (3) any statements on the Label shall be written or printed by using Indonesian language, Arabic numbers and Latin letters; and
- (4) the label as set forth in mentioned statement (2) shall contain any information on the food, at least :
 - a. Name of product;
 - b. List of ingredients;
 - c. Net weight or net contents;
 - d. Name and address of any party who produces or imports the food into Indonesian territory;
 - e. Date, month, and year of minimum durability.

(3) Government Regulation of the Republic of Indonesia No. 28 of 2004 on Food Safety, Quality and Nutrition

Another government regulation that was developed under the umbrella of the Food Act is the Government Regulation of the Republic of Indonesia No. 28 of 2004 on Food Safety, Quality and Nutrition which was issued in 2004.

It is clearly stated in the Government Regulation No. 28/2004 on Food Safety, Quality and Nutrition, Article 2 that any person who is responsible for administering the activities on the food chain that includes food production, storage, transportation and distribution shall meet the sanitation requirements in compliance with the prevailing legislation. In Article 3 it is further stated that the sanitation requirements in all the food chain shall be met by applying good practices guidelines that include:

- (a) Good Agricultural Practices;
- (b) Good Fresh Food Production Practices;
- (c) Good Manufacturing Practices;
- (d) Good Food Distribution Practices;
- (e) Good Food Retail Practices; and
- (f) Good Ready-to-Serve Food Production Practices.

Sanitation requirements set in the regulation among others area:

- (a) Avoiding the use of land whose environment has the potential to threaten food safety;
- (b) Controlling the biological contamination, animal and plant diseases that threaten food safety;
- (c) Reducing to the minimum chemical residues in food as the consequence of using fertilizers, pest and disease control drugs, growth hormone and inappropriate animal drugs;
- (d) Killing or preventing the pathogenic microorganisms and reducing the number of other microorganisms in food; and
- (e) Controlling the process, among others by selecting the raw materials, using food additives, processing, packaging, storage and transportation.

3.5.4.4 Indonesian National Standards

In term of standards of food commodities, it is stated in Article 29 that the Head of the Agency who is responsible for the field of national standardization (National Standardization Agency of Indonesia) shall set forth the food quality standard, which is declared as the Indonesian National Standard (SNI), in accordance with the prevailing legislation

Furthermore, it is stated in Article 30, paragraph 1 that the Indonesian National Standard as contemplated in Article 29 may be imposed compulsorily, taking into account the people's security, safety and health or the environmental sustainability and/or that economic considerations shall meet certain quality standards. Paragraph 2 states the compulsory imposition of the Indonesian National Standard

as contemplated in paragraph 1 shall be carried out by the Minister who is responsible for industry (Ministry of Industry), agriculture (Ministry of Agriculture), fishery (Ministry of Marine Affairs and Fishery) or the Head of the Agency (National Agency for Drug and Food Control) in accordance with their respective duties and authority in coordination with the Head of the agency who is responsible for national standardization. Paragraph 3 states any matters in connection with application and evaluation of the appropriateness of the Indonesian National Standard that is imposed compulsorily shall, as contemplated in paragraph 2, be carried out in accordance with the prevailing legislation. Paragraph 4 states any person who produces or distributes the types of food as contemplated in paragraph 1 shall meet the Indonesian National Standard in accordance with the prevailing legislation.

3.5.4.5 Laws and Regulations related to Food Additives

3.5.4.5.1 Overview

In Indonesia, food additives are regulated by the National Agency for Drug and Food Control (NADFC or BPOM). The main legal basis for regulation of food additives in Indonesia is found in the Act of the Republic of Indonesia Number 7 of 1996 on Food, in Chapter 2 (on Food Safety), Part 2 (on Food Additives). The Act provides that:

- 1) Substances that have been declared as prohibited in food are not allowed to be used as food additives;
- 2) Substances permitted as food additives are not allowed in food if they are in excess of the maximum threshold limits;
- 3) The government is responsible for determining which materials are prohibited to be used as food additives and which are allowed to be used, including setting of maximum threshold limits; and
- 4) Food additives that are intended to be used in food, but of which the impact on human health is not yet known, must undergo an evaluation of its safety and intended use in food production and processing

Additionally, Government Regulation of the Republic of Indonesia Number 28/2004 on Food Safety, Quality and Nutrition also contains similar provisions that reinforce the Act, as well as additional provision such as:

- 1) Only expressly permitted food additives are allowed to be used in food; and
- 2) The Head of the National Agency for Drug and Food Control (NADFC) is responsible for determining the food additives that are allowed to be used for

a specified technical purpose and the maximum limits within certain food categories

Subsidiary regulations on food additives include:

- 1) Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives;
- 2) Minister of Health Regulation No. 1168/MENKES/PER/X/1999 amending Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives;
- 3) Decision of the Director-General for Drug and Food Control No. 02592/B/SK/VIII/91 on Use of Food Additives; and
- 4) Decision of the Head of the National Agency for Drug and Food Control No. HK.00.05.5.1.4547 on Conditions of Use for Artificial Sweetener Food Additives in Food Products

3.5.4.5.2 Food Additive Definition & Functional Classes

Food additives in Indonesia are defined in Government Regulation No. 28/2004 on Food Safety, Quality and Nutrition as follows:

“Food additives shall mean any materials added to food in order to affect the nature and form of the food.”

In the accompanying explanations to the Regulation, it is explained that food additives do not include contaminants or any materials added into food in order to maintain or increase the nutritional value of foods. Therefore, substances that may also nutrients are only considered to be food additives if they have a technological purpose (for e.g. ascorbic acid as an antioxidant).

The definition of food additives is further defined in subsidiary regulations in Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives as follows:

“Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional additional of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (direct or indirect) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods.”

Regulation No. 722/MENKES/PER/IX/88 also divides food additives into 11 functional classes in Indonesia, as follows:

- 1) Antioxidants
- 2) Anti-caking agents
- 3) Acidity regulators
- 4) Artificial sweeteners
- 5) Flour treatment agents
- 6) Emulsifiers, stabilizers and thickeners
- 7) Preservatives
- 8) Firming agents
- 9) Colours
- 10) Flavours and flavour enhancers; and
- 11) Sequestrants

Processing aids are not defined in the Regulation, however in Government Regulation No. 28/2004, they are mentioned in reference to genetically modified food products separately from food additives³⁹.

3.5.4.5.3 Permitted Food Additives and Maximum Limits

The positive list of permitted food additives together with the maximum permitted use levels are included in the appendixes of Regulation No. 722/MENKES/PER/IX/88 and have been updated once by Regulation No. 1168/MENKES/PER/X/1999.

However, these food additive standards are currently being revised by NADFC and have/will be issued as national standard by the National Standardization Agency (BSN). Currently, revised standards for artificial sweeteners (SNI 01-6993-2004, which has been adopted into regulation as Decision No. HK.00.05.5.1.4547) and flavours (SNI 01-7152-2006) are already adopted. Draft revisions for antioxidants and preservatives are being prepared and are expected to be adopted in the near future.

Although permitted to be used in food in general, such food additives must not however be used for the following purposes:

- 1) To mask the use of illegal ingredients or ingredients that are not compliant with regulations;

³⁹ Article 14 (1) of Government Regulation No. 28/2004 states “Any person who produces food or uses raw materials, food additives and/or any other processing aid in the activity or process of producing food obtained from genetically modified process shall have the safety of such food examined prior to distribution.”

- 2) To mask production practices that are against good manufacturing practices for food; and
- 3) To mask the presence of food spoilage.

3.5.4.5.4 Prohibited Substances as Food Additives

A negative list of substances prohibited to be used as food additives are included in Regulation No. 722/MENKES/PER/IX/88 and Regulation No. 1168/MENKES/PER/X/1999. These include:

- 1) Boric acid and its derivatives;
- 2) Salicylic Acid and its salts;
- 3) Diethylpyrocarbonate (DEPC);
- 4) Dulcin;
- 5) Potassium chlorate;
- 6) Chloramphenicol;
- 7) Brominated vegetable oils;
- 8) Nitrofurazon;
- 9) Formaldehyde; and
- 10) Potassium bromate

In addition, Regulation No. 239/MENKES/PER/V/85 on Colouring Substances that are Declared to be Hazardous Substances and Decision of the Director-General for Drug and Food Control No. 00386/C/SK/II/90 on Amendments to the Appendixes of Regulation No. 239/MENKES/PER/V/85 on Colourings that are Declared to be Hazardous Substances, also contain negative lists of colouring substances that are prohibited to be used as food additives.

3.5.4.5.5 Specifications for Food Additives

Food additives that are produced, imported and distributed within the country must follow the specifications and criteria laid out in the Indonesian Food Codex on Food Additives (Kodeks Makanan Indonesia). There are currently two editions of the Indonesian Food Codex, one from 1979 and the other from 2001. Both versions are still applicable, however the 2001 edition has revised some of the specifications in the earlier version for certain food additives.

3.5.4.5.6 Assessment of Food Additives

New food additives must first be evaluated and approved by the NADFC prior to use in food. The assessment procedures and data requirements are described by Decision of the Director-General for Drug and Food Control No. 02592/B/SK/VIII/91

on Use of Food Additives. Information and data required for the assessment include:

- 1) Trade name, type of packaging, manufacturer and manufacturer contact details for the food additive;
- 2) Chemical name, composition, specifications or purity criteria, physical and chemical properties and chemical formula of the food additive;
- 3) Method of production of the food additive as well as methods of analysis that are suitable to determine the concentration and purity of the food additive;
- 4) Purpose and intended use, guidance for use, physical effects, techniques and methods of use for the food additive, as well as the type of food and maximum levels intended to be used;
- 5) Safety evaluation of the food additive and its maximum residue in food products; and
- 6) Literature that supports the safety of use of the food additive including regulation/references that show that the food is also approved for use in other countries

3.5.4.5.7 Labelling of Food Additives

Labelling of food additives in foods shall be in accordance with existing regulations on food labelling and advertisement (Government Regulation No. 69/1999 on Labelling and Advertising of Food). Specifically, the food additive functional class must be included on the food label. For antioxidants, artificial sweeteners, preservatives, colours and flavour enhancers, the name of the food additive must also be included. For colours used as food additive in particular, the special index numbers also needs to be attached, as specified by Decision of the Director-General for Drug and Food Control No. 01415/B/SK/IV91 on Special Mark for Food Colours.

Regulation of the head of the Drug and Food Supervisory Agency HK.03.1.5.12.11.09955 on the registration of processed food was issued on December 12, 2011. Appendix 3 of this regulation, "Label Requirements of Processed Food" set several special labelling requirements for several special processed foods, for example, "Contains Artificial Sweeteners, recommended not to be consumed by children, pregnant women, and breastfeeding mothers" for processed food containing artificial sweeteners.

3.5.4.6 Case Study

(1) Instant Noodles (**Table 3.5-13**)

Standards for use of food additives in "Instant Noodles (Mi Instan)" (SNI 01-3551-2000) and "instant rice noodles (Bihun instan)" (SNI 01-3742-2000).

(2) Carbonated Soft Drinks (**Table 3.5-14**)

Standards for use of food additives in “Lemonade” (SNI 01-2972-1998) , “Diet lemonade” (SNI 01-3699-1995), “Soda water” (SNI 01-3708-1995) and “Energy drinks” (SNI 01-6684-2002).

(3) Prepared Frozen Foods (**Table 3.5-15**)

Standards for use of food additives in “Chicken nugget” (SNI 01-6683-200) and “Frozen breaded shrimp” (SNI 01-6163-1999).

(4) Cow’s Milk (**Table 3.5-16**)

Standards for use of food additives in “Pasteurized milk” (SNI 01-3951-1995).

Table 3.5-A4 Description/Definition (General)

	Description/Definition	Reference
Related legislation	Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products	http://www.pom.go.id/public/hukum_perundangan/pdf/Regulation_%20722.pdf http://agri.sucofindo.co.id/Extra/PDF/SNI_01-02-22-1995_Bahan_Tambahan_Makanan.pdf (in Indonesian) http://pustan.bpkimi.kemenperin.go.id/files/SNI_01-7152-2006.pdf
General Description/Definitions		
Definition of food additives	The definition of food additives is further defined in subsidiary regulations in Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives as follows: “Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional additional of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (direct or indirect) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods.”	Regulation No. 722/MENKES/PER/IX/88 Article 1, 1
Flavours	“Flavour” is classified under the food additive functional cases of “Flavour and flavour enhancer”, which means substances added to impart or help impart a taste or aroma in food. “Flavour” means a food additive in the form of concentrate, with or without flavouring adjunct that is used to give flavour, with the exception of salty, sweet and sour taste, that is not intended for direct consumption and not be treated as a food.	Regulation No. 722/MENKES/PER/IX/88 Article 1, 14 SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products
Processing aids	The term “Processing Aid” is mentioned in Government Regulation No. 28/2004 but no definition is provided.	Government Regulation of the Republic of Indonesia No. 28/2004 on Food Safety, Quality and Nutrition, http://www.pom.go.id/public/hukum_perundangan/pdf/PP28-in%20English_a.pdf

Carry-over	<p>“Carry-over” principle is defined for labelling purposes, as follows:</p> <p>“Carry-over additives are food additives that are normally found in the product formulation as a result of being an ingredient from another ingredient. Examples: Food colouring in orange concentrate; Monosodium glutamate in spices.”</p>	General Guidelines on Food Labelling
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Table 3.5-B4 Description/Definition (Specific)

	Description/Definition		Reference
Related legislation	<p>Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives</p> <p>Minister of Health of the Republic of Indonesia Regulation No. 1168/MENKES/PER/X/1999 on Amendments to Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives</p> <p>Decision of the Head of BPOM No. HK.00.05.5.1.4547 on Conditions of Use for Artificial Sweetener Food Additives in Food Products</p>		<p>http://www.pom.go.id/public/hukum_perundangan/pdf/Regulation_%20722.pdf</p> <p>http://agri.sucofindo.co.id/Extra/PDF/SNI_01-0222-1995_Bahan_Tambahan_Makanan.pdf (full text)</p> <p>http://www.pom.go.id/public/hukum_perundangan/pdf/PerubPermenkes.pdf (Indonesian only)</p> <p>http://www.pom.go.id/public/hukum_perundangan/pdf/Kep.Ka.BPOM-Pemanis.pdf (Indonesian only)</p>
Specific Descriptions/Definitions			
1	List of Designated Food Additives	Includes antioxidant; anticaking agent; acidity regulator; artificial sweetener; flour treatment agent; emulsifier, stabilizer, thickener; preservative; firming agent; colour; flavour, flavour enhancer; sequestrant.	Regulation No. 722/MENKES/PER/IX/88, Annex 1 Regulation No. 1168/MENKES/PER/X/99 Annex 1 Decision No. HK.00.05.5.1.4547, Annex 1
2	List of Existing Food Additives	There is no such list in Indonesia.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Indonesia.	

4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Indonesia.	
	Negative list (if any)	1) Boric acid and its compounds; 2) Salicylic acid and its salts; 3) Diethylpirocarbonate DEPC; 4) Dulcin; 5) Potassium chlorate; 6) Chloramphenicol; 7) Brominated vegetable oils; 8) Nitrofurazone; 9) Formaldehyde; 10) Potassium bromate SNI 01-7152-206 Food additives set conditions for use of flavouring materials in food.	Regulation No. 1168/MENKES/PER/X/99 Annex 2 SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products
	Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives	Indonesian Food Codex 2001	http://www.pom.go.id/public/hukum_perundangan/pdf/Kodeks_MakIndo2001.pdf (not full text)
	Official publication and/or gazette for food additives	Apart from regulations issued by the National Agency for Drug and Food Control (NADFC or Badan POM), standards for food additives are also published by the National Standards Body. Currently, up-to-date standards have only been published for two functional classes of additive – flavours and artificial sweeteners.	SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products SNI 01-6993-2004 Food additives – Artificial sweeteners - Conditions for use in food products

Table 3.5-13 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Instant noodles	SNI 01-3551-2000 Instant Noodles
Positive and/or Negative List	Food additives are permitted in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		

Scope and/or Description	Instant rice noodles	SNI 01-3742-1995 Instant rice noodles (Bihun instant)
Positive and/or Negative List	Food additives are permitted in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		

Table 3.5-14 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Lemonade	SNI 01-2972-1998 Lemonade
Positive and/or Negative List	Artificial sweeteners (e.g. cyclamates and saccharin) are prohibited.	
Use Limitation and/or Maximum Level, if any	Colours and preservatives are permitted in accordance to existing regulations*.	
Scope and/or Description	Diet lemonade	SNI 01-3699-1995 Diet lemonade
Positive and/or Negative List	Food additives are permitted in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Soda water	SNI 01-3708-1995 Soda water
Positive and/or Negative List	Food additives are not allowed except for mineral salts in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Energy drinks	SNI 01-6684-2002 Energy drinks
Positive and/or Negative List	Food additives are permitted in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		

Table 3.5-15 Case Study 3 Prepared Frozen Foods

	Description/Definition	Reference
Scope and/or Description	Chicken nugget	SNI 01-6683-2002 Chicken nugget
Positive and/or Negative List	Preservatives and colours are permitted in accordance to existing regulations*.	
Use Limitation and/or Maximum Level, if any		
Scope and/or Description	Frozen breaded shrimp	SNI 01-6163-1999 Frozen breaded shrimp
Positive and/or Negative List	Food additives used should not impair or change the composition and specific properties of the frozen breaded shrimp.	
Use Limitation and/or Maximum Level, if any	Food additives are permitted in accordance to existing regulations*.	

Table 3.5-16 Case Study 4 Cow's Milk

	Description/Definition	Reference
Scope and/or Description	Pasteurized milk	SNI 01-3951-1995 Pasteurized milk
Positive and/or Negative List	Flavourings and preservatives are permitted according to existing regulations*.	
Use Limitation and/or Maximum Level, if any		

* Existing regulations on food additives refer to the following:

1. Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives
2. Minister of Health of the Republic of Indonesia Regulation No. 1168/MENKES/PER/X/1999 on Amendments to Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives
3. Decision of the Head of BPOM No. HK.00.05.5.1.4547 on Conditions of Use for Artificial Sweetener Food Additives in Food Products

3.5.5 Thailand

3.5.5.1 Food Administration

In Thailand, the administrative agency responsible for the food safety, food standards and hygienic control is Ministry of Public Health and Ministry of Agriculture and Cooperatives.

3.5.5.2 Acts and Regulations related to Commodity Standards

A brief summary of food law in Thailand that relates to the elaboration and regulation of food commodity standards within the country is presented in **Figure 3.5-5** below.

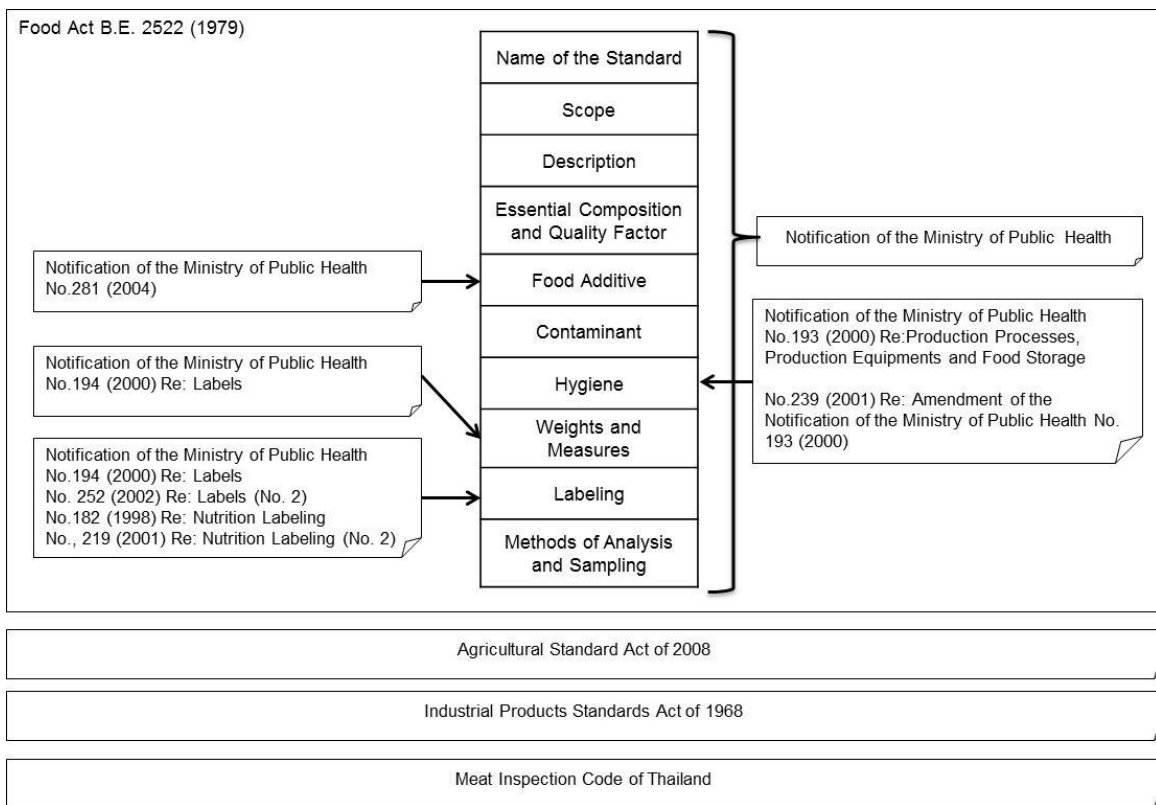


Figure 3.5-5 Food law in Thailand in relation to food commodity standards

3.5.5.3 Food Relevant Laws

(1) Food Act of B.E.2522 (1979)⁴⁰

In Thailand, the Food Act of B.E.2522 (1979) is the major law aimed at protecting and preventing consumers from health hazards occurring from food consumption. According to the Food Act, the Ministry of Public Health (MOPH) is designated to be in charge of the execution of this Act. The Act also empowered the Ministry of Public Health to promulgate ministerial regulations, to appoint the Food

⁴⁰ Food Act of B.E.2522 <http://www.thailawforum.com/database1/food-act.html>

Committee and competent officers, and to set up other activities in order to carry out the provisions of the Act.

The Act defines the word “Food” as edible items and those which sustain life, including:

- (A) Substances that can be eaten, drunk, dissolved in the mouth or induced into the body by mouth, no matter in what form, but not including medicine, psychotropic and narcotic substances.
- (B) Substances intended for use or to be used as ingredients in the production of food including food additives, colouring and flavouring materials.

The Food Act classifies food into four categories as follows:

- 1) Specifically-controlled food - the category for which registration is required. Legal provisions are established regarding standard quality, specifications, packaging and labelling requirements, as well as other aspects of good manufacturing practice. At present, 14 types of food have been listed in this category.
- 2) Standardized food - the category for which quality standards will be defined by regulations. Food in this category is mainly locally produced food from small-scale or household industry. The main objective is to facilitate and encourage food producers on upgrading or at least maintaining hygienic quality of their products. Standardized food does not require registration but its quality and labelling have to meet the standard requirements as specified in the Notification of the Ministry of Public Health. There are 39 types of food in this category.
- 3) Food required to bear standard labels - the category which needs less-restricted control than the first two categories, as food under this category exposes a low risk of hazard to consumers’ health. There are 13 items of food in this category.
- 4) General food - food either raw, or cooked, preserved or non-preserved, processed or non- processed, if they are not listed under category 1, 2, or 3 will be considered as general food. Although registrations are not required, general food products are controlled and monitored on hygiene, safety, labelling and advertisement.

The Ministerial Regulations describe the procedures for applications for manufacturing licenses, importation licenses, and registration including the rates of fees, the identification card of the competent officers and the labelling of food products for exports. There are 12 issues of Ministerial Regulation issued pursuant

to the Food Act B.E 2522 (1979). Notifications of the MOPH⁴¹ are listed in **Table 3.5-26** of the FY2010 report “Investigation of Commodity Food Standards and Analytical Methods in Asia” (II) (March, 2011).

(2) The Agricultural Standard Act B.E. 2551 (2008)⁴²

The Public Act known as “Agricultural Standard Act B.E. 2551 (2008)”, mandates the National Bureau of Agricultural Commodity and Food Standards (ACFS) to be “enforced on produce, product originated from agriculture, fishery, livestock or forestry and by-products”. The ACFS is a bureau established under the purview of the Ministry of Agriculture and Cooperatives. The responsibilities of the ACFS include:

- 1) Method, procedure or process for production management or characteristics of agricultural commodity pertaining to quality, safety on chemical, biological or physical aspects, sanitary and phytosanitary and related issues,
- 2) Pack, packing, marking or labelling,
- 3) Inspection, assessment, testing, experiment, analysis or research as related to 1) or 2), and
- 4) Other requirements as notified by the Minister of Agriculture and Cooperatives in the National Gazette

Establishment of Agricultural Standards

There are two types of Agricultural Standards, namely:

- 1) Mandatory Standards which are regulated under the Ministerial Regulations, and
- 2) Voluntary Standards which are regulated under the Ministerial Notifications

The technical committee will be assigned to draft standards on agricultural commodity for endorsement by the Committee on Agricultural Standards which will recommend further to the Minister for issuing either Mandatory or Voluntary Standards as it is deemed necessary and relevant to circumstances.

⁴¹ The Notifications of the Ministry of Public Health
http://iodinethailand.fda.moph.go.th/fda/new/web_cms/subcol.php?SubCol_ID=77&Col_ID=14
<http://newsser.fda.moph.go.th/food/Law%20Notification%20of%20Ministry%20of%20PublicHealth07.php>
(Thai version)

⁴² http://www.acfs.go.th/km/download/AGRICULTURAL_STANDARDS_ACT.pdf

Mandatory vs. Voluntary Standards

- The producer, exporter or importer of agriculture commodity regulated under Mandatory Standards issued by the Ministerial Regulations is required to get license from the ACFS prior to operation of its activity. Its license shall be valid for three years.
- They are also required to get inspection and certification for approval of Mandatory Standards from service provider for standard inspection.
- They are not required to get license for operation involving Voluntary Standards but they may apply for standard inspection and certification from service provider in accordance with criteria, procedure and condition thereof under the Ministerial Regulations.

Standard Certification Mark (Q-marks)

There are two types of standard certification mark, namely:

- 1) Certification mark for Mandatory Standards, and
- 2) Certification mark for Voluntary Standards,



Whereas, both standard marks shall be regulated by the Ministerial Regulations.

- The producer, exporter or importer of agricultural commodity regulated under Mandatory Standards is required to present standard mark prior to taking out of production unit or custom officer as the case may be.
- No one can apply certification mark unless producer, exporter or importer who receives certificate for either Mandatory or Voluntary Standards.

(3) The Industrial Products Standards Act B.E. 2511 (1968) ⁴³

The public Act known as “Industrial Product Standard Act B.E. 2511 (1968)”, mandates the Thai Industrial Standards Institute (TISI) to “undertake standardization with commitment to the promotion and development of the industry, maximizing the benefits for entrepreneurs, consumers and the nation as a whole”. The TISI was established in the Ministry of Industry as the national standard body of Thailand. The responsibilities of the TISI include:

- 1) Industrial Products Standards Act B.E. 2511 (1968)
- 2) Resolutions of the Cabinet
- 3) Policy and master plan of the Ministry of Industry
- 4) Policy of the government

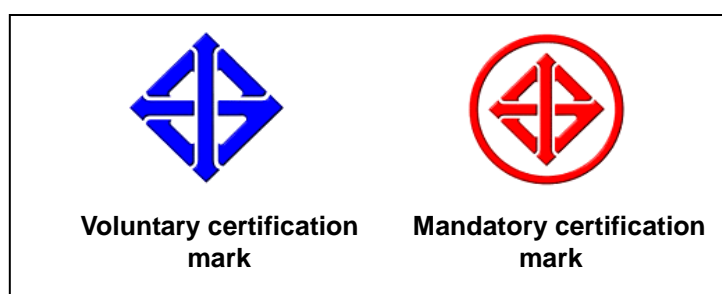
⁴³ http://www.tisi.go.th/eng/index.php?option=com_content&view=article&id=20&Itemid=6

5) The National Economic and Social Development Plan

TISI develops both mandatory and voluntary Thai Industrial Standards (TISs) to suit the need and the growth of industry, trade and economy of the country. Standards are developed according to the government policy in consumers protection, industrial promotion to be competitive in the world market, environmental protection and natural resources preservation. The standards cover all industrial products, food or non-food.

Product certification according to TISs.

The product certification scheme of TISI consists of two types with different certification marks. They are voluntary certification mark and mandatory certification mark



An example of mandatory standard is TIS 51-2530 (1987) Re: Canned pineapple (Effective Date 15 May 1988).

In 2002, the Ministry of Industry also appointed the Standard Committee of Community Products under the ministerial order number 400/2545 to be responsible for the followings.

- 1) To develop national standards and monitor quality of products and services to be in line with the requirements and international practices
- 2) To develop community product standards and provide certification service
- 3) To promote and develop national standardization activities
- 4) To cooperate with foreign standardization organizations both bilateral and multilateral levels
- 5) To provide information on standardization
- 6) To establish the national single network of standardization

The standards for community products were established to cover both food and non-food products. It is a voluntary standard aimed to upgrade the production and quality of merchandises from small and medium-size manufacturers.



(4) The Meat Inspection Code of Thailand

The Act known as “Control of Slaughtering and Selling Meat Act B.E. 2535 (1992)” mandates the Department of Livestock Development (DLD) as the “sole national controlling authority pertaining to meat and meat product inspection and meat hygiene”. The DLD is a department established under the Ministry of Agriculture and Cooperatives which is responsible for “establishing safety and quality standards for meat and meat products”. This Act excludes wildlife and includes cattle, goat, sheep and pigs. Subsequently in 2002 the Ministry had added chickens, ducks and geese. The relevant product standard in this case also includes the Notification of the Ministry of Public Health No. 243 B.E. 2544 (2001) Re: Meat Products.

(5) Hygienic Standards in the Production of Fishery Products

According to “The Fishery Act B.E. 2490 (1947)⁴⁴” there are insufficient data about standards of fishery products and sanitation. Nevertheless, there is the “Hygienic Standards in the Production of Fishery Products” issued by the National Institute of Coastal Aquaculture (NICA). The NICA is an institute established under the Department of Fisheries, Ministry of Agriculture and Cooperatives.

3.5.5.4 Laws and Regulations related to Food Additives

3.5.5.4.1 Overview

In Thailand, food additives are regulated by the Food and Drug Administration (FDA) of Thailand. They are regulated as “specifically controlled foods” and the main legal basis for regulation of food additives is found in the Notification of the Ministry of Public Health No. 281 B.E. 2547 (2004) on Food Additives, which also repealed earlier regulations on food additives.

3.5.5.4.2 Food Additive Definition & Functional Classes

Food additives are defined in the Notification No. 281 as follows:

“Food additives means articles which normally are not used as food or major ingredients of food, irrespective of their nutritional value, but are added to food for the purpose of manufacturing technology, food colouring, food flavouring, packaging, storage or transportation, which renders certain effects to the quality or standard or description of the food. However, it shall mean to include articles not added to food but are put in a specific container and packed within the food for the above-said purposes as well, such as desiccants, anti-oxidants, etc.”

⁴⁴ <http://faolex.fao.org/docs/pdf/tha4931.pdf>

Functional classes for food additives largely follow Codex Alimentarius General Standard for Food Additives (GSFA), and include:

- 1) Acid;
- 2) Acidity regulator;
- 3) Anticaking agent;
- 4) Antifoaming agent;
- 5) Antioxidant;
- 6) Bulking agent;
- 7) Colour;
- 8) Colour retention agent;
- 9) Emulsifier;
- 10) Emulsifying salts;
- 11) Firming agent;
- 12) Flavour enhancer;
- 13) Flour treatment agent;
- 14) Foaming agent;
- 15) Gelling agent;
- 16) Glazing agent;
- 17) Humectant;
- 18) Preservative;
- 19) Propellant;
- 20) Raising agent;
- 21) Stabilizer;
- 22) Sweetener;
- 23) Thickener

3.5.5.4.3 Permitted Food Additives and Maximum Limits

According to Notification No. 281⁴⁵, conditions of use for food additives in relation to their function, food categories and maximum limits follow:

- 1) The Codex Alimentarius General Standard for Food Additives (latest version);
- 2) Notifications issued by the FDA after approval of the Food Commission; and
- 3) Other food additives not covered by the above must be approved by the FDA

3.5.5.4.4 Prohibited Substances as Food Additives

⁴⁵http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Additives%20-%20Coloring%20Permitted%20in%20Thailand_Bangkok_Thailand_1-26-2011.pdf#search='MOPH%20Notification%20No.%20281%20Food%20Additives'

The following regulations prohibit certain substances to be used as food additives:

- 1) Notification of the Ministry of Public Health No. 247 B.E. 2544 (2001) Re: Prescribed Prohibited Substances to be Used in Foods (No. 2);
- 2) Notification of the Ministry of Public Health No. 261 B.E. 2545 (2002) Re: Prescribed Prohibited Food to be Produced, Imported or Sold (No. 2);
- 3) Notification of the Ministry of Public Health No. 292 B.E. 2548 (2005) Re: Prohibited foods to be produced, imported or sold;
- 4) Notification of the Ministry of Public Health No. 311 B.E. 2551 (2008) Re: Prescribed Prohibited Food to be Produced, Imported or Sold;

The negative list of prohibited additives includes:

- 1) Methyl alcohol or methanol (except for use as a food processing aid);
- 2) Stevia and stevia products that are non-water crude extractions and/or derivatives of substances from crude extraction;
- 3) Dulcin (para-phenetolcarbamide);
- 4) Cyclamic acid and its salts (sodium cyclamate);
- 5) Furylframide;
- 6) Potassium bromated;
- 7) Melamine and its analogues (cyanuric acid, ammelide and ammeline);
- 8) Brominated vegetable oil;
- 9) Salicylic acid;
- 10) Boric acid;
- 11) Borax;
- 12) Calcium iodate or potassium iodate;
- 13) Nitrofurazone;
- 14) Potassium chlorate;
- 15) Formaldehyde, formaldehyde solution or paraformaldehyde;
- 16) Coumarin (1,2-benzyopyrone or 5,6-benzo-alpha-pyrone or cis-o-coumaric acid, anhydride or o-hydroxycinnamic acid, lactone);
- 17) Dihydrocoumarin, benzodihydropyrone, 3,4-dihydrocoumarin or hydrocoumarin;
- 18) Diethylene glycol, dihydroxydiethyl ether, diglycol, 2,2'-oxybis-ethanol or 2,2'-oxydiethanol;
- 19) Daminozide or succinic acid 2,2-dimethylhydrazide

3.5.5.4.5 Specifications for Food Additives

According to Notification No. 281, specifications for food additives and purity criteria for food additives used in food in Singapore must conform to the

specifications as recommended by the Joint Expert Committee on Food Additives (JECFA); those published by the Thai FDA with approval from the Food Commission; as well as those approved by the Food Sub-Committee on a case-by-case basis.

3.5.5.4.6 Assessment of Food Additives

New food additives must first be evaluated and approved by the Food Sub-Committee and FDA prior to use in food. Information and data requirements for the assessment include:

- 1) Identification of ingredients and chemical characterization of the food additive;
- 2) Information on the identity and purity of the food additive;
- 3) Information on the reaction and fate of the food additive in food;
- 4) Toxicological studies that may indicate toxicity, such as on functional manifestations, morphological manifestations, neoplasms, reproductive and developmental toxicology, including *in vitro* studies;
- 5) Metabolic and pharmacokinetic studies on the additive, using appropriate animal species, which show the mechanism of toxicity, metabolic fate in the body, effect of the gut microflora on the chemical and effect of the chemical on the gut microflora;
- 6) Information on the influence of age, nutritional status, and health status in the design and interpretation of the scientific/toxicological studies;
- 7) Studies in humans such as epidemiological studies and food intolerance studies as a result of consumption of the food additive; and
- 8) Information on the derivation of the acceptable daily intake (ADI) including the no-observed-effect level (NOEL) that was used, safety factors applied, toxicological versus physiological responses considered, and estimates from exposure assessment of the population.

3.5.5.4.7 Labelling of Food Additives

Labelling of food additives should be in accordance with Notification of the Ministry of Public Health No. 194 B.E. 2543 (2000) on Labels.

3.5.5.5 Case Study

(1) Instant Noodles (Table 3.5-17)

MOPH Notification No. 210 B.E. 2543 is for “Semi-processed food”. Standard for use of food additives in “Semi-processed food” is regulated by MOPH Notification No. 281 B.E. 2547 for “Food additives”.

(2) Carbonated Soft Drinks (**Table 3.5-18**)

Conditions for use of several food additives in “Beverages in sealed container” are set in MOPH Notification No. 214 B.E. 2543 “Beverages in sealed container”. Conditions for use of other additives are in accordance with MOPH Notification No. 281 B.E. 2547 for “Food additives”.

(3) Prepared Frozen Foods

There is no standard for use of food additives in “prepared frozen foods” in Thailand.

(4) Cow’s Milk (**Table 3.5-19**)

Preservatives and artificial sweeteners are not permitted in “Cow’s milk” by MOPH Notification No. 265 B.E. 2545 “Cow’s milk”. Conditions for use of other additives are in accordance with MOPH Notification No. 281 B.E. 2547 for “Food additives”.

Table 3.5-A5 Description/Definition (General)

	Description/Definition	Reference
Related legislation	Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	
General Description/Definitions		
Definition of food additives	Food additives are defined in the Notification No. 281 as follows: “Food additives means articles which normally are not used as food or major ingredients of food, irrespective of their nutritional value, but are added to food for the purpose of manufacturing technology, food colouring, food flavouring, packaging, storage or transportation, which renders certain effects to the quality or standard or description of the food. However, it shall mean to include articles not added to food but are put in a specific container and packed within the food for the above-said purposes as well, such as desiccants, anti-oxidants, etc.”	
Flavours	Flavouring agents are classified as foods which are required to bear labels. “Flavouring Agents” mean substances used for flavour or taste of food. “Natural Flavouring Agent” means agent for enhancing taste or flavour which is physically derived from plant or animals normally used for human consumption. “Imitate of Natural Flavour Agent” means flavour agent derived from chemical extraction or synthesized flavouring agent in which the extracted substances or synthesized shall be of the same chemical properties as of the natural products normally used for human consumption and shall mean to include imitate of natural flavouring agent which contain natural flavouring agent as well. “Synthesized Flavouring Agent” means flavouring agent which is not discovered in natural products normally used for human consumption and means to include synthesized flavouring agent which contain natural flavour agent or imitate of natural flavouring agent.	Notification of the Ministry of Public Health No. 223 B.E. 2544 (2001) Re: Flavouring Agents http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148370158_223-44%281%29.pdf

Processing aids	“Processing Aid” means substances or any matters which are not for consumption in the manner of food compositions but are used in production of raw materials or food ingredients, by the used technology between qualities adjustment or processing, in which these substances or their derivatives may be unintentionally or inevitable left over, in this regard not to include production equipments.	Notification of the Ministry of Public Health No. 259 B.E. 2545 (2002) Re: Application of Methyl Alcohol as Processing Aid in Some Foods http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148399746_259-45%281%29.pdf
Carry-over	There is no definition of carry over principles in Thailand.	

Table 3.5-B5 Description/Definition (Specific)

	Description/Definition		Reference
Related legislation	Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives		http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Additives%20-%20Coloring%20Permitted%20in%20Thailand_Bangkok_Thailand_1-26-2011.pdf (contains unofficial translation)
Specific descriptions / Additional explanations			
1	List of Designated Food Additives	As per listed in the attachment to the Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	http://newsser.fda.moph.go.th/food/file/Laws/Notification%20of%20Ministry%20of%20PublicHealth/Law03P281.pdf (available only Thai)
2	List of Existing Food Additives	There is no such list in Thailand.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Thailand.	
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Thailand.	

<p>Negative list (if any)</p>	<p>1) Methyl alcohol or methanol (except for use as a food processing aid); 2) Stevia and stevia products that are non-water crude extractions and/or derivatives of substances from crude extraction; 3) Dulcin (para-phenetolcarbamide); 4) Cyclamic acid and its salts (sodium cyclamate); 5) Furfylframide; 6) Potassium bromate; 7) Melamine and its analogues (cyanuric acid, ammelide and ammeline); 8) Brominated vegetable oil; 9) Salicylic acid; 10) Boric acid; 11) Borax; 12) Calcium iodate or potassium iodate; 13) Nitrofurazone; 14) Potassium chlorate; 15) Formaldehyde, formaldehyde solution or paraformaldehyde; 16) Coumarin (1,2-benzopyrone or 5,6-benzo-alpha-pyrone or cis-o-coumaric acid, anhydride or o-hydroxycinnamic acid, lactone); 17) dihydrocoumarin, benzodihydropyrone, 3,4-dihydrocoumarin or hydrocoumarin; 18) diethylene glycol, dihydroxydiethyl ether, diglycol, 2,2'-oxybis-ethanol or 2,2'-oxydiethanol; 19) daminozide or succinic acid 2,2-dimethylhydrazide</p>	<p>http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148400006_261-45%281%29.pdf</p> <p>Notification of the Ministry of Public Health No. 292 B.E. 2548 (2005) Re: Prohibited foods to be produced, imported or sold http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1169705816_no.292.pdf</p> <p>Notification of the Ministry of Public Health No. 311 B.E. 2551 (2008) Re: Prescribed Prohibited Food to be Produced, Imported or Sold http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1224050701_Notification_No.311_B.E.2551.pdf</p> <p>Notification of the Ministry of Public Health No. 247 B.E. 2544 (2001) Re: Prescribed Prohibited Substances to be Used in Foods (No. 2) http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148399024_247-44.pdf</p> <p>Notification of the Ministry of Public Health No. 261 B.E. 2545 (2002) Re: Prescribed Prohibited Food to be Produced, Imported or Sold (No. 2)</p>
<p>Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives</p>	<p>Mainly follows JECFA and Codex specifications. However, can also be those published by Thai FDA or approved by the Sub-Committee for Studying and Analyzing Problems and Determining Food Technicality.</p>	<p>Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives</p> <p>Notification of the Food and Drug Administration of 3rd November B.E. 2547 (2004) Re: Principle of using food additives test methods different from requirements in Codex Advisory Specification for the Identity and Purity of Food Additives http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1169707498_different%20from%20prescription.pdf</p>

		<p>Notification of the Food and Drug Administration of 3rd November B.E. 2547 (2004) Re: Prescription of quality or standards of combined food additives http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1169707646_food%20add%20cpd.pdf</p> <p>Notification of the Food and Drug Administration of 17th June B.E. 2548 (2005) Re: Prescription of quality or standards of food additives that are used to prolong or maintain quality or standards of food http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1169707849_food%20add%20preserv%20type.pdf</p> <p>Notification of the Food and Drug Administration of 24th June B.E. 2548 (2005) Re: Prescription of quality or standards of single food additives http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1169710676_single%20food%20additive.pdf</p> <p>Notification of the Ministry of Public Health (No. 262) B.E. 2545 (2002) Re: Stevioside and Foods Containing Stevioside. http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148400098_262-45%281%29.pdf</p>
Official publication and/or gazette for food additives	There is no official publication and/or gazette for food additives. However, updates to food additive regulations are made through issuances of Notifications of the Ministry of Public Health.	http://iodinethailand.fda.moph.go.th/fda/new/web_cms/subcol.php?SubCol_ID=77&Col_ID=14

Table 3.5-17 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Semi-processed food in sealed container, including noodle, a sheet of rice noodle (Guay-Jub), wheat noodle, rice vermicelli and mug bean vermicelli	Notification of the Ministry of Public Health No. 210 B.E. 2543 (2000) Re: Semi-processed Food http://www.fda.moph.go.th/eng/eng_food/Notification/210-43.pdf
Positive and/or Negative List	Use of food additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	
Use Limitation and/or Maximum Level, if any		

Table 3.5-18 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Beverage in sealed container	Notification of the Ministry of Public Health No. 214 B.E. 2543 (2000) Re: Beverage In Sealed Container http://www.fda.moph.go.th/eng/eng_food/Notification/214-43.pdf
Positive and/or Negative List	Use of artificial sweeteners should follow Codex GSFA and/or as prescribed by the Thai FDA. Methyl alcohol is prohibited to be used in the production process. Preservatives including sulfur dioxide, benzoic acid and sorbic acid (including their salts) are permitted. Use of other additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives.	
Use Limitation and/or Maximum Level, if any	1. Sulfur dioxide: <70mg/kg 2. Benzoic acid (and salts): <200mg/kg 3. Sorbic acid (and salts): <200mg/kg If more than one preservative used together, total quantity of preservatives should not be more than least allowed quantity. When artificial sweeteners are used, the label should state "Usage of [...] to be an artificial sweetener" (where [...] refers to the artificial sweetener).	

Case Study 3 Prepared Frozen Foods

There is no standard for use of food additives in “prepared frozen foods” in Thailand.

Table 3.5-19 Case Study 4 Cow’s Milk

	Description/Definition	Reference
Scope and/or Description	Cow’s milk	Notification of the Ministry of Public Health No. 265 B.E. 2545 (2002) Re: Cow’s milk http://iodinethailand.fda.moph.go.th/fda/new/images/cms/top_upload/1148400308_265-45%281%29.pdf
Positive and/or Negative List	Preservatives and artificial sweeteners are not permitted.	
Use Limitation and/or Maximum Level, if any	Use of other additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives.	

3.5.6 Vietnam

3.5.6.1 Food Administration (Food safety management)

Responsibilities for the management of food safety in Vietnam are divided among several state-level ministries as well as the People's Committees at the provincial level. These ministries include the Ministry of Health (MOH), Ministry of Agriculture and Rural Development (MARD), as well as the Ministry of Industry and Trade (MIT).

According to the Law on Food Safety, the Ministry of Health has the leading role for food safety management at the national level, which includes the formulation of national policies on food safety and the coordinating of their implementation. At the provincial and local levels, these responsibilities are undertaken by the People's Committees. MOH is also responsible for the promulgation of national technical regulations related to food safety for food products (including raw and processed foods), food-packaging tools, food packaging and food containers. The Ministry has been given the authority to develop policies and manage food safety for the processed food sector, which includes food additives, food processing aids, bottled drinking water, natural mineral water, and functional foods. Within the purview of the Ministry of Health, these duties have been delegated to the Vietnam Food Administration (VFA). The Ministry of Health is also responsible for food quality according to the Law on Product and Goods Quality.

The Ministry of Agriculture and Rural Development is responsible for policy making and management of food safety for the primary production sector, which includes products such as cereals, meat and products thereof, aquatic animals and products thereof, vegetables, tuber and fruits and products thereof, eggs and products thereof, fresh milk, honey and products thereof, genetically modified food, salt and other farm products. Similarly to MOH, these duties have been delegated to the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD). It is worth noting that within its purview, MARD may also issue regulations that are normative in nature, which appear to be equivalent to technical regulations.

The Ministry of Industry and Trade is responsible for policy making and management of food safety for specific food sectors that manufacture products including liquor, beer, beverage, processed milk, vegetable oil, and powder and starch processed products. Apart from this, MIT is primarily responsible for food safety at markets and supermarkets, as well as for regulation of fake food and fraud in food trade.

In Vietnam, Laws are promulgated by the National Assembly (equivalent to an act of

parliament), which is the highest legislative authority in the country. Subsequently, Ordinances are issued by the Standing Committee of the National Assembly (second highest legislative body). This is followed by Presidential Orders and Decisions, Government Decrees and Resolution, Prime Minister’s Decisions and Directives, and finally Decisions, Directives, Circulars and Joint Circulars by the Ministers.

3.5.6.2 Acts and Regulations related to Commodity Standards

A brief summary of the food laws in Vietnam that relate to regulation and standards for food products/commodities are presented in **Figure 3.5-6** below.

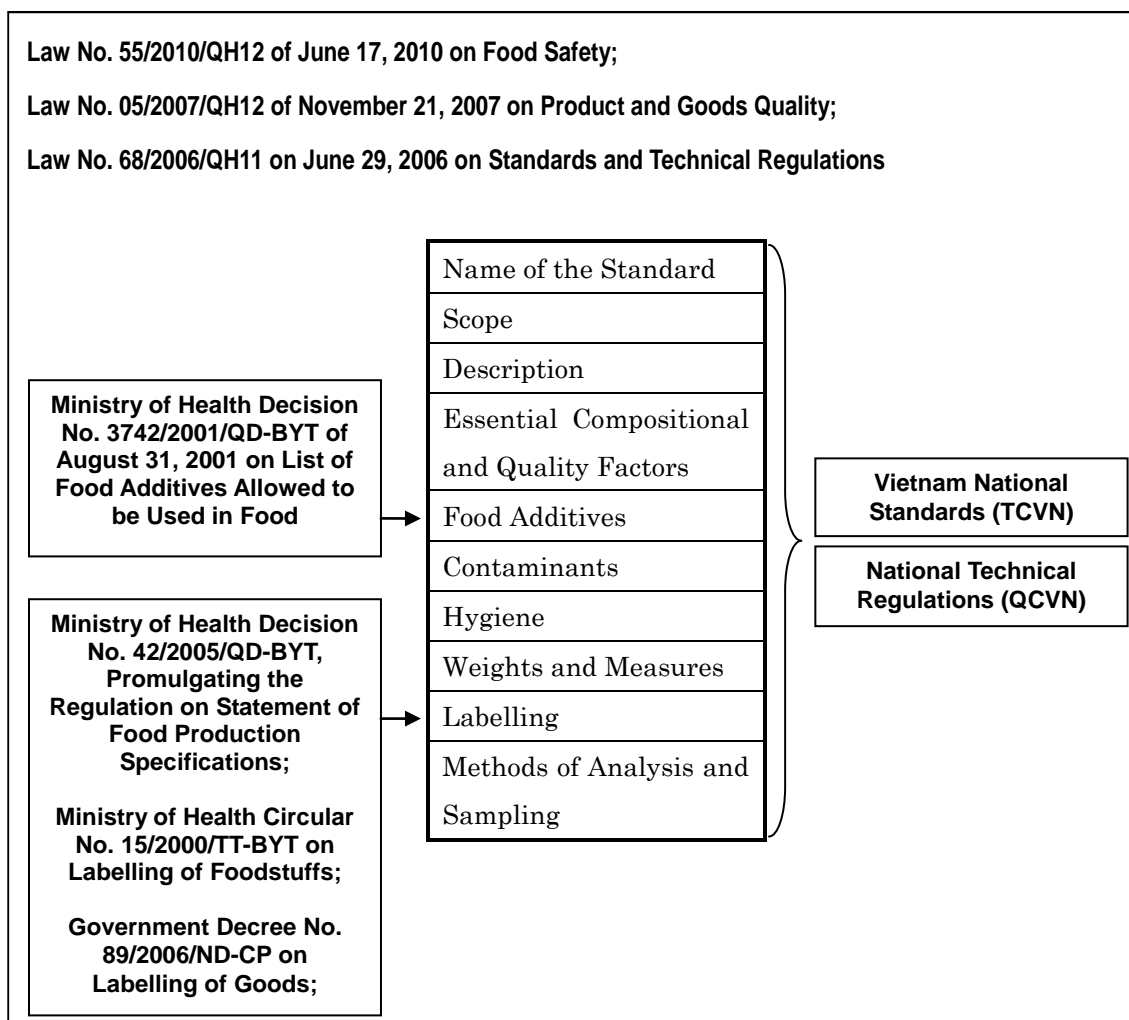


Figure 3.5-6 Food law in Vietnam in relation to food commodity regulations and standards

3.5.6.2 Food Relevant Laws

(1) Law No. 55/2010/QH12 of June 17, 2010 on Food Safety

Law No. 55/2010/QH12 of June 17, 2010 (herein known as the “Law on Food Safety”) is the “general food law” of Vietnam, replacing the earlier Ordinance on Hygiene and

Food Safety issued on November 31, 2003. It is divided into 11 chapters and outlines the general principles of food safety management and declares the state policies for food safety. It also touches upon the specific areas for food safety assurance, including:

- 1) General conditions;
- 2) Fresh and raw food;
- 3) Processed food;
- 4) Micronutrient-fortified food;
- 5) Functional food;
- 6) Genetically modified food;
- 7) Irradiated food;
- 8) Food additives and processing aids;
- 9) Food packaging tools, food packaging and food containers;
- 10) Small-scale food production;
- 11) Street food;
- 12) Imported foods;
- 13) Food advertisement and labelling;
- 14) Food testing;
- 15) Risk analysis;
- 16) Food safety incident management;
- 17) Traceability and recalls; and
- 18) Information, education and communication on food safety

(2) Law No. 05/2007/QH12 of November 21, 2007 on Product and Goods Quality Law No. 55/2010/QH12 of June 17, 2010 (herein known as the “Law on Product Quality”) serves the purpose of a consumer protection law and provides for the rights and obligations of organizations and individuals producing or trading in products as well as organizations and individuals conducting activities related to product and goods quality, as well as the principles for the management of product and good quality. In relation to food regulation, it assigns responsibility to the Ministry of Health for controlling product and goods quality for food, and Ministry of Agriculture and Rural Development (MARD) for plants, animals, animal feeds, plant protection products, veterinary drugs, and other bio-products related to agriculture or aquaculture.

(3) Law No. 68/2006/QH11 of June 29 2006 on Standards and Technical Regulations Law No. 68/2006/QH11 of June 29 2006 on Standards and Technical Regulations (herein known as the ‘Law on Standards and Technical Regulations’) provides for the

formulation, announcement and application of standards; the formulation, promulgation and application of technical regulations; and the assessment of conformity with standards and technical regulations. The law places the responsibility of leading and coordinating the standard setting process with the Ministry of Science and Technology, while ministries and ministerial agencies lead the process for development of technical regulations. Standards can be either mandatory or voluntary, while technical regulations are strictly mandatory.

Standards are defined in the Law as “regulation on technical characteristics and management requirements used as standards for classifying and appraising products, goods, services, processes, the environment and other objects in socio-economic activities with a view to improving the quality and effectiveness of these objects”; while technical regulations are defined as “regulation on the limits of technical characteristics and management requirements which products, goods, services, processes, the environment and other objects in socio-economic activities must comply with in order to ensure safety, hygiene and human health; to protect animals, plants and environment; to safeguard national interests and security, consumer interests and other essential requirements”.

3.5.6.3 Selected food regulations

Some food regulations that are relevant to the investigation of food commodity standards in Vietnam are as follows:

1) Food additives –

Ministry of Health Decision No. 3742/2001/QD-BYT of August 31, 2001 on List of Food Additives Allowed to be Used in Food

2) Hygiene –

Ministry of Health QVCN: 2010/BYT National technical regulation on the safety limits of Microbiological contaminants in food;

Ministry of Agriculture and Rural Development Circular No. 29/2010/TT-BNNPTNT on Promulgating the list of food safety criteria and maximum levels thereof in certain domestically-produced or imported foodstuffs of animal origin under the management of the Ministry of Agriculture and Rural Development

3) Labelling –

Government Decree No. 89/2006/ND-CP on Labelling of Goods

Ministry of Health Decision No. 42/2005/QD-BYT, Promulgating the Regulation on Statement of Food Production Specifications;

Ministry of Health Circular No. 15/2000/TT-BYT on Labelling of Foodstuffs;

3.5.6.4 Food standards

In Vietnam, there are two types of normative instruments used for standardization of safety and quality for food products and processes, which are the standards and technical regulations. As described in the “Law on Standards and Technical Regulations”, standards differ from technical regulations. Standards define technical characteristics of the products, goods, services, processes, environment, etc. while technical regulations define limits to these technical characteristics, which must be complied with the view of ensuring human, animal, plant and environmental health, as well as safeguard national interests, security and consumer interests.

For standards, there are two kinds including National Standards (symbolized by “TCVN”), which can be mandatory in nature (when used as the reference by regulatory agencies), and Local Standards (symbolized by “TCCS”), which are voluntarily adopted by manufacturers. Standards are developed by the Directorate for Standards, Metrology and Quality (STAMEQ) under the Ministry of Science and Technology. STAMEQ under the Ministry of Science and Technology leads and coordinates between different ministries, ministerial-level agencies and government-attached agencies in setting national standards.

National technical regulations (symbolized by “QCVN”) on the other hand, are promulgated by the respective ministries and ministerial agencies in consultation with the Ministry of Science and Technology. As mentioned in the previous section, the Ministry of Health is responsible for promulgating technical regulations for all food products, food-packaging tools, food packaging and food containers. Nevertheless, there also exist regulations (in the form of Decisions, Directives and Circulars) by other ministries that are equivalent to technical regulations. One example can be seen in Circular No. 29/2010/TT-BNNPTNT of the Ministry of Agriculture and Rural Development on Promulgating the list of food safety criteria and maximum levels thereof in certain domestically-produced or imported foodstuffs of animal origin under the management of the Ministry of Agriculture and Rural Development.

In Vietnam, the national standards (TCVN) appear to widely cover not only the food commodity standards but also food storage methods, methods of analysis, standards for food additives, practice standards for food hygiene, labelling methods for general processed foods (**FY2010 Report Table3.5-29**).

3.5.6.5 Laws and Regulations related to Food Additives

3.5.6.5.1 Overview

In Vietnam, food additives are regulated by the Vietnam Food Administration (VFA) under the Ministry of Health for processed foods, as well as the National Agro-Forestry-Fisheries Quality Assurance Department under the Ministry of Agriculture and Rural Development (MARD) for certain additives permitted in agricultural products.

The main legal basis for regulation of food additives is found in the Law No. 55/2010/QH12 on Food Safety, which provides the definition for food additives and allows only the use of food additives that are listed in technical regulations issued by the Ministry of Health.

3.5.6.5.2 Food Additive Definition & Functional Classes

Food additives are defined in the Law on Food Safety as follows:

“Food additive means a substance with or without nutritious value, which is intentionally added to food in the process of production in order to retain or improve particular characteristics of food.”

There are 23 functional classes for food additives in Vietnam that are based largely on Codex GSFA. Although defined separately in the Law on Food Safety, some of the classes include substances that are also used as processing aids. The functional classes include:

- 1) Acidity regulator;
- 2) Anticaking agent;
- 3) Antifoaming agent;
- 4) Antioxidant;
- 5) Artificial sweetener;
- 6) Bulking agent;
- 7) Colour;
- 8) Colour retention agent;
- 9) Emulsifier;
- 10) Enzyme;
- 11) Firming agent;
- 12) Flavour enhancer;
- 13) Flour treatment agent
- 14) Foaming agent;
- 15) Glazing agent;

- 16) Humectant;
- 17) Modified starch;
- 18) Preservative;
- 19) Propellant;
- 20) Raising agent;
- 21) Sequestrant;
- 22) Stabilizer;
- 23) Thickener;

3.5.6.5.3 Permitted Food Additives and Maximum Limits

Conditions for use of additives in food and the maximum permitted levels are found in Minister of Health Decision No. 3742/2001/QĐ-BYT on List of Additives permitted for Use in Food. Use of permitted food additives are based on the following conditions:

- 1) Must be used only in certain foods as specified and at levels that do not exceed the permitted levels;
- 2) Must meet the technical requirements, safety regulations for each additive according to existing regulations;
- 3) Must not alter the state or inherent nature of the food that it is added to

3.5.6.5.4 Prohibited Substances as Food Additives

There is no known negative list of substances prohibited to be used as food additives, as only permitted additives are allowed to be used in foods.

3.5.6.5.5 Specifications for Food Additives

Specifications and purity criteria for food additives are found in National Technical Regulations QCVN 4-1:2010 to QCVN 4-23:2010, issued by the Ministry of Health.

3.5.6.5.6 Assessment of Food Additives

There are no articulated procedures for the assessment and approval of new food additives found in the existing regulations.

3.5.6.5.7 Labelling of Food Additives

Labelling of food additives should be in accordance with Minister of Health Decision No. 15/2000/TT-BYT on Food Labelling. According to Decision No. 15/2000/TT-BYT, additives used in food must be listed in the ingredients list with the class name followed by the name of the additive, for example “Emulsifier: sodium polyphosphate”), or followed by the international code (with the code stated in

brackets), for example “Emulsifier (452i)”. Foods containing additives such as flavourings, sweeteners or colouring should be qualified by words such as “natural”, “artificial” or “synthetic” as appropriate, for example “Artificial colouring (160f)” or “Synthetic colouring: beta-apo-8-caretenoic methyl acid”.

3.5.6.6 Case Study

(1) Instant Noodles (Table 3.5-20)

TCVN 7879:2008 is for “Cereal products instant noodles”. Standard for use of food additives in “Cereal products instant noodles” is in accordance with CODEX STN/249:2006 on “Instant noodles”.

(2) Carbonated Soft Drinks (Table 3.5-21)

QCVN 6-2-2010/BYT is for “Soft drinks”. Standard for use of food additives in “Soft drinks” is in accordance with the Decision of the MOH No.3742:2001 QD-BYT.

(3) Prepared Frozen Foods

There is no food category for “prepared frozen foods” in Vietnam.

(4) Cow’s Milk (Table 3.5-22)

QCVN 5-1-2010/BYT is for “Fluid milk drinks”. Standard for use of food additives in “Fluid milk drinks” is in accordance with the Decision of the MOH No.3742:2001 QD-BYT.

Table 3.5-A6 Description/Definition (General)

	Description/Definition	Reference
Related legislation	Law No. 55/2010/QH 12 on Food Safety	http://www.vcalaw.com/legal-documents/law-a-or-dinance/29-2010lawonfoodsafedownload.html
General Description/Definitions		
Definition of food additives	Food additives are defined in the Law on Food Safety as follows: “Food additive means a substance with or without nutritious value, which is intentionally added to food in the process of production in order to retain or improve particular characteristics of food.”	Law No. 55/2010/QH 12 on Food Safety, Article 2 (13)
Flavours	Not described	
Processing aids	“Food Processing Aid” means a substance which is intentionally used in the processing of food materials or food ingredients in order to achieve a technological purpose and can be removed from or remains in foods.	Law No. 55/2010/QH 12 on Food Safety, Article 2 (3)
Carry-over	There is no definition of carry over principles in Vietnam.	

Table 3.5-B6 Description/Definition (Specific)

		Description/Definition	Reference
Related legislation		Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food	http://www.spsvietnam.gov.vn/Lists/VBPQ_VN/Attachments/147/3742-2001-%20QD-BYT_VIE.doc (in Vietnamese)
Specific Descriptions/Definitions			
1	List of Designated Food Additives	Includes acidity regulator, flavour enhancer, firming agent, preservative, anticaking agent, antioxidant agent, antifoaming agent, bulking agent, artificial sweetener, modified starch, enzyme, propellant, glazing agent, humectant, thickener, stabilizer, emulsifier, colour, foaming agent, sequestrant, raising agent, flour treatment agent	Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food
2	List of Existing Food Additives	There is no such list in Vietnam.	
3	List of Plant or Animal sources for Flavouring agents	There is no such list in Vietnam.	
4	List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Vietnam.	
Negative list (if any)		There is no negative list of food additives in Vietnam.	
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives		flavour enhancer, humectant, raising agent, anticaking agent, colour retention agent, antioxidant agent, foaming agent, artificial sweetener, firming agent, colours, acidity regulator, preservative, stabilizer, sequestrant, flour treatment agent, bulking agent, propellant, modified starch, enzyme, glazing agent, thickener, emulsifier, foaming agent	QCVN 4-1:2010/BYT – national technical regulations on food additives – flavour enhancer QCVN 4-2:2010/BYT – national technical regulations on food additives – humectant QCVN 4-3:2010/BYT – national technical regulations on food additives – raising agent QCVN 4-4:2010/BYT – national technical

		<p>regulations on food additives – anticaking agent</p> <p>QCVN 4-5:2010/BYT – national technical regulations on food additives – colour retention agent</p> <p>QCVN 4-6:2010/BYT – national technical regulations on food additives – antioxidant agent</p> <p>QCVN 4-7:2010/BYT – national technical regulations on food additives – foaming agent</p> <p>QCVN 4-8:2010/BYT – national technical regulations on food additives – artificial sweetener</p> <p>QCVN 4-9:2010/BYT – national technical regulations on food additives – firming agent</p> <p>QCVN 4-9:2010/BYT – national technical regulations on food additives – colours</p> <p>QCVN 4-11:2010/BYT – national technical regulations on food additives – acidity regulator</p> <p>QCVN 4-12:2010/BYT – national technical regulations on food additives – preservative</p> <p>QCVN 4-13:2010/BYT – national technical regulations on food additives – stabilizer</p> <p>QCVN 4-14:2010/BYT – national technical regulations on food additives – sequestrant</p> <p>QCVN 4-15:2010/BYT – national technical regulations on food additives – flour treatment agent</p> <p>QCVN 4-16:2010/BYT – national technical</p>
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		<p>regulations on food additives – bulking agent</p> <p>QCVN 4-17:2010/BYT – national technical regulations on food additives – propellant</p> <p>QCVN 4-18:2010/BYT – national technical regulations on food additives – modified starch</p> <p>QCVN 4-19:2010/BYT – national technical regulations on food additives – enzyme</p> <p>QCVN 4-20:2010/BYT – national technical regulations on food additives – glazing agent</p> <p>QCVN 4-21:2010/BYT – national technical regulations on food additives – thickener</p> <p>QCVN 4-22:2010/BYT – national technical regulations on food additives – emulsifier</p> <p>QCVN 4-23:2010/BYT – national technical regulations on food additives – foaming agent</p>
Official publication and/or gazette for food additives	There is no official publication or gazette for food additives in Vietnam.	

Table 3.5-20 Case Study 1 Instant Noodles

	Description/Definition	Reference
Scope and/or Description	Instant noodles	TCVN 7879:2008 Instant noodles
Positive and/or Negative List	Food additive usage in accordance with Codex Standard 249:2006 on Instant Noodles	
Use Limitation and/or Maximum Level, if any		

Table 3.5-21 Case Study 2 Carbonated Soft Drinks

	Description/Definition	Reference
Scope and/or Description	Soft drinks	QCVN 6-2: 2010/BYT National technical regulation for soft drinks
Positive and/or Negative List	Food additives usage in accordance with most current regulations –Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food	
Use Limitation and/or Maximum Level, if any		

Case Study 3 Prepared Frozen Foods

There is no food category for “prepared frozen foods” in Vietnam.

Table 3.5-22 Case Study 4 Cow's Milk

	Description/Definition	Reference
Scope and/or Description	Fluid milk products	QCVN 5-1:2010/BYT National technical regulation for fluid milk products
Positive and/or Negative List	Food additives usage in accordance with most current regulations –Decision of the Minister of Health No.	
Use Limitation and/or Maximum Level, if any	3742/2001QD-BYT on List of Additives Permitted for Use in Food	

3.6 Overall Report

3.6.1 Comparative Assessment of Regulations on Food Additives in Japan, Korea, and China

3.6.1.1 Survey Summary

ILSI (International Life Sciences Institute) Japan requested ILSI Korea, ILSI Focal Point in China, and ILSI Southeast Asia Region to report the current situation about food additives regulation in each country, and to fill in the questionnaire provided with the same items so that the comparison among these nations would be easy. ILSI Japan summarized the reports and questionnaire responses, as well as the situation in Japan and the Codex General Standard for Food Additives (GSFA), and made mutual comparison.

The southeast nations in the following report represent six nations we have surveyed this time: Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam.

3.6.1.2 Results of Survey in Each Nation

1) Japan

In Japan, food additives include both flavourings and nutrient supplements. It is a Japanese feature that food additives are extensively defined as the substances used in food manufacture and processing whether or not they remain in the final food products.

In 1996, there was a major change in the food additive regulations in Japan. Previously, only chemically synthesized substances had been controlled by the positive list system as designated additives; however, both natural and chemically synthesized additives were placed under the control of positive list system. Simultaneously, it became obligatory to describe a natural food additive on the label of the food product in which the additive was used, which had not been required before. At this change, the food additives which had been already manufactured and used were shown in the List of Existing Food Additives, and were approved for their manufacture and use; this list has been updated constantly and some additives were already eliminated.

Japan has these two positive lists, List of designated Additives and List of Existing Food additives, both of which are compiled according to the individual names of food additives. There is no list categorized by function or intended use. Processing aids and carry-over are not defined under the category of function or use, but are defined in the requirements when it is not obligatory to describe the food additive on the

label of the food product in which the additive is used.

In terms of the connection with the Codex standards, Japan might be most remotely connected compared with China and Southeast Asian nations, where Codex definitions and annexes are cited and referred to as discussed below. The fact that no other country has an equivalent of List of Existing Food Additives or List of Food Additives Generally Provided for Eating or Drinking also highlights Japanese uniqueness.

2) Korea

In Korea food additives are similarly defined as in Japan, and include the substances used in the processing but do not remain in the final food products, and nutrient enhancers. Processing aids and carry-over are similarly stipulated as not obligatory to be described on the label of the final food product following the regulations for labelling. However, there is no equivalent of Japanese List of Existing Food Additives.

Korean Industrial standards (KS) are also similar to Japanese Agricultural Standards (JAS) in the points that it is voluntary to obtain certification or not, and that to obtain the certification, the type and amount of food additives which may be used are limited in certain foods.

3) China

In China, Food Safety Act was established in 2009, based on which the food sanitation system is under steady development and organization.

Like in Japan and Korea, food additives include both natural and chemically synthesized substances, as well as flavourings, nutrition enhancers, and processing aids. Meanwhile, unlike in Japan and Korea, the food additives are numbered; food category system is stipulated in order to establish the use standards including the standard maximum use levels of food additives; and the list of food additives, foods in which the additives are used, and use standards specifying the category of function and intended use is stipulated. It is likely that these approaches have consulted the Codex system.

Other Chinese features which are not found in Japan or Korea are that the processing aids are listed, and that the processing aids which may be used without limited level of residue are listed, and the processing aids which may be used only in the designated foods for the designated functions and uses are listed as well.

3.6.1.3 Comparison of Survey Results on the Food Additives Regulations in Japan, Korea, and China

Table 3.6-1 tabulates the situation of these three nations.

Nutrition enhancers are excluded from the definitions of food additives in the Codex standard; but in Japan and Korea, no such description is found in the food additives definitions, and nutrition enhancers are handled as food additives. In Chinese definitions of food additives, it is clearly stipulated that the food additives include nutrition enhancers, flavourings, and processing aids.

In China, there are a list of food categories in which an additive may be used and the standard maximum use levels for each food additive, a list of food additives which may be used in all foods in accordance with the Good Manufacturing Practice (GMP), and a list of food categories as an exemption from these procedures; and these lists correspond to Table 1, Table 2, and Table 3 in the Annexes of GSFA provisions of food additives, respectively.

Neither Japan nor Korea has such a system.

3.6.2 Regulation and Harmonization regarding Food Additives in Southeast Asian Nations

3.6.2.1 Regulation of Food Additives in Southeast Asian Nations

In all the six nations surveyed, the Codex General Standard for Food Additives (GSFA) was cited unchanged or modified, or utilized in some other forms. Although the extent and degree of citations and utilizations vary from nation to nation, such as in definitions, functional and intended use categories, use standards, and/or new designations/registrations, it is most likely that GSFA would become the common platform when Southeast Asian nations would aim to harmonize the food additives regulations in the future.

When we deliberate the harmonization of food additives regulations in Japan, Korea, China, and Southeast Asian nations, on the basis that China is also trying to actively utilize GSFA, and that there is little possibility of Japanese system consulted or cited unchanged in other countries, it is predicted that how Japan would incorporate Codex system into the Japanese regulation of food additives would be an urgent task.

3.6.2.2 Comparison of Survey Results on Food Additives Regulation in Southeast Asian Nations (Table 3.6-2)

In all the six countries surveyed, most or a part of Codex definitions of food additives

are cited in the food additives definitions. Example are; “whether or not it has nutritive value,” “in the manufacture, processing, preparation, treatment, packing, packaging, transport or storage of food,” “intentional addition,” and “be reasonably expected to result in becoming a component of or otherwise affecting the characteristics of such foods.”

Although a part of the Codex definitions of flavourings, processing aids, and carry-over are cited in some countries, compared with the definition of food additives, these definitions are more varied and different from those of Codex.

There is no equivalent of List of Existing Food Additives or List of Food Additives Generally Provided for Eating or Drinking found in any nation, including in the Codex standards.

3.6.2.3 Harmonization of Food Additives Regulation in Southeast Asian Nations

In February 2012, the 10th Workshop on Harmonization of ASEAN Food Safety Standards was held in Jakarta by ILSI Southeast Asia Regional Office, who has been working as the organizer since 2001.

Extensive efforts have been made at this workshop such as establishing the guidelines for risk analysis and organizing the training programs for exposure assessment by the government employees of Southeast Asian nations in charge of food safety standards. Among the step-by-step progresses, ASEAN Food Safety Standards Data Base has accumulated data of 863 food additives so far, promoted by ILSI Southeast Asia Regional Committee.

In this effort for harmonization, the Codex standards are also utilized so that food additives are listed according to each category of function and use, and GMP approach is adopted for the use standards.

However, there are some remaining problems that it is difficult to entry data because the food categories in the custom code are different from those of GSFA in some countries, and that the database is not simultaneously and systematically updated when a country respectively amends its rules.

On December 12, 2011, the regulation of food labelling was revised in Indonesia, and a certain warning was required on the label of a food where an artificial sweetener was used (refer pages 92 – 93). Malaysia and Singapore also have regulations of labelling for certain food additives, but they are different from those in Indonesia. Meanwhile, Malaysia, Singapore, Philippines, Indonesia, and Thailand have lists of prohibited food additives, and they are different from country to country. No equivalent of them can be found in the Codex standards.

The Codex standards can be a dominant platform for harmonization, but it will not be an easy task to carry out real harmonization even for the Southeast Asian nations who utilize the Codex standards.

Table 3.6-1 General-C-J-K-C

	Codex	Japan	Korea	China
Related legislation	CODEX STAN 192-1995 CAC/GL 66-2008 CODEX STAN 107-1981	Food Sanitation Act, 1947	Korea Food Sanitation Act (KFSA), 2010 Korea Food Additive Code (KFAC), 2010, 2011 Korea Food Code (KFC), 2010	GB2760-2011 Standard for Use of Food Additives
General Descriptions / Definitions				
Definition of Food Additives	CODEX STAN 192-1995 Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.	"Food additives" means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.	Food additives is defined in Article 2.2 of KFSA as "materials added to or mixed with foods or materials used for wetting foods in the processes of manufacturing, processing, or preserving foods. In such cases, food additives shall include materials used in sterilizing or disinfecting apparatus, containers or packages, which may be transferred to foods in an indirect manner".	"Food additives" refer to the artificially or chemically synthetic or natural substances to be added to foods in order to improve food quality and colour, flavour and taste, and for the need of preservation and processing technology, including nutritional fortification substances, flavouring agents and processing aids.
Flavour	GUIDELINES FOR THE USE OF FLAVOURINGS CAC/GL 66-2008 (ア) Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings. (イ) Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients (Section 2.3) within the conditions as referred to in 3.5. They are not intended to be consumed as such.	Flavour is classified in the food additive category. "Natural flavouring agent" means food additives, intended for use for flavouring food, which are substances obtained from animals or plants, or mixtures thereof.	Flavourings is recognized as one category of food additives. There is no clear definition of "Flavourings" in KFSA, but from its standard of use in KFAC, it is assumed to be defined as "additives used (only) for adding flavourings for foods". There are two groups in food additives used for flavourings. One is 'synthetic flavouring substances' in synthetic additives. All of the permitted chemicals used for flavourings are classified in this group, but there are some substances that also appear in KFAC individually with their names because they have obligatory specifications. Another group is 'natural flavouring substances' in natural additives. It is defined as follows and listed by the name of raw materials. There also be a special limitation in career, extraction solvents, etc.: "These materials are obtained from the following origins by processes such as extraction and distillation. They are used to add or enhance aroma. There are refined oils, extracts, and Oleoresin (spice oleoresin whose specification is separately set is excluded). Water, ethanol, vegetable oil can be added for preserving quality".	The flavouring agents and flavouring essences are used in foods in order to create, change or improve the flavour of foods. The flavouring agents are usually made into flavouring essences for flavouring the food, but some of them may be directly added into the food. The flavouring agents and flavouring essences exclude the substances which only make the food sweet, sour or salty and the flavour enhancer. flavours are not used as a directly consumed ingredient.
Processing aid	CODEX STAN 107-1981 Processing aid means a substance or material not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.	Processing aid is classified in the food additive category. "Processing aids" means substances added to a food in processing the food, which are: 1) removed from the food before the completion of the food, 2) derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or 3) present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food.	There is no clear definition of 'Processing aids' in KFSA, but the glossary on KFSA WEB site (only in Korean) defines it as follows: "They are food additives that are not specified their function but are used in foods during manufacturing or processing, or used for other purposes. Representatively includes n-Hexane." The concept which is similar to its definition in Codex can be found in Article 1.A.7 c) (9) of "Detailed labelling Standard"(Attachment 1 to KFLS) as follows: "When a food additive is added during manufacturing but removed from the final product, declaration of such additive can be exempted."	Food processing aids refer to various kinds of substances to enable food processing to go with a swing smoothly, regardless of irrelative to food itself, for example, nutritional substances for filtration aids, clarification clarifiers, absorption absorbents, lubrication lubricants, decoating mold release agents, decolouring agents, peeling agents, solvents extraction solvents, and nutritional substances for fermentation, etc. Processing aids are not allowed to remain in the processed food (where they are used) unless other wise specified.
Carry-over	4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that: a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard; b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard; c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.	"Carry-over" is defined, but only for labelling purposes. "Carry-over" means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished product at levels less than those normally required to achieve any technical or functional effect in the food.	It is not defined in KFAC, but its principle is partially appeared in Article 2. 5. 3) (2) of KFC as follows: "If a food additive that cannot be used in a food is derived from a raw material for which the food additive can be used, the restriction on the use of food additives may not be applied within the range of such deriving the raw material."	Besides direct addition, the food additives can be brought introduced into the foods through the food ingredients in the following cases; 1. The use of the food additive in the food ingredients can only be allowed according to this standard; 2. The level of use of this additive in the food ingredients should not exceed the allowable maximum level; 3. These ingredients shall be applied in the normal production process. And the content of this additive in the food should not exceed the level that is carried over by the ingredients; 4. The content of this additive brought introduced into the food by the ingredients shall be obviously lower than the usually required level of it that which is directly added to this the food.

Table 3.6-1 Specific-J-K-C

	Japan	Korea	China
Related legislation	Food Sanitation Act, 1947	Korea Food Sanitation Act (KFSA), 2010 Korea Food Code (KFC), 2010 Korea Food Additives Code (KFAC), 2010, 2011	GB2760-2011 Standard for Use of Food Additives
Specific descriptions / Additional explanations			
List of Designated Food Additives	Food additive is listed as "Designated food additives" on the attached table 1 of the Food Sanitation Act Enforcement Regulations, 1948. There is no classification of function in these lists. As of March 2012, 423 additives are designated as approved by the MHLW.	As of November 2010 (Notification #2010-82), 602 food additives in total are approved with the permission to use in respectively designated food groups. Standard and specification of the synthetic additives (400 items), natural additives (195 items) and mixed additives (7 items) are listed in the current KFAC. The e-book of English version still contains those officially deleted which are summarized in the appendix 2 (33 synthetic additives and 12 natural additives deleted from KFAC). Flavouring agents of which synthetic ones are covered under the item No 424 of synthetic food additives list can be accessed separately in the KFAC.	There is no one list showing all the approved food additives and it is published as a notice whenever approved and later they will be listed as new approved additives in total as GB3760 or GB14880 is revised.
List of Existing Food Additives	Substances that were already marketed or used on the date of the amendment of the FSA in 1995 were listed on the Existing Food Additives. The MHLW is conducting continuous survey of marketing and use of food additives on the list. As of March 2012, there are 365 Existing Food Additives in the list.	Not applicable in Korea.	Not applicable in China.
List of Plant or Animal sources for Flavouring agents	"List of plant or animal sources of natural flavourings" is given in Appendix 2, the CAA Notice, No. 377, 2010. This list is for labelling of "Natural flavouring agents" and is NOT a positive list of source of flavouring agents.	Natural Flavourings are categorized as one of Natural additives, and raw materials of Natural flavourings are listed in a table of this item in KFAC. The list consists of 272 of each substances and general description "raw materials that are appropriate for 2. Requirements for Raw Materials. Common in Food Codes".	A list of natural flavouring agents is shown in Appendix B.2 of GB2760.
List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	Substances that are both generally provided for eating or drinking as foods and used as food additives have been excluded from the designation system. "List of substances which are generally provided for eating or drinking as foods and which are used as food additives" is given in Appendix 3, the CAA Notice, No. 377, 2010.	Not applicable in Korea.	Not applicable in China.
Negative list (if any)	There is no negative list of food additives under FSA.	In principle, the positive list of food additives are managed under the Korea Food Sanitation Act. However, for some individual food items (e.g. Instant noodles, carbonated beverages, etc.), negative list of food additives are described.	There is no negative list of food additives under GB2760
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives	The last 8 th edition is issued in 2007. English translation of 7 th edition, issued in 1999, is available on website.	General provisions of KFAC provides the information of [weight, volume and temperature], [tests], [container], and [definition of terms]. KFAC main text provides standards for manufacturing and preparation, general standards for food additive used in foods, food contact surface sanitizing solutions and general test methods as well.	The specifications of food additive, including analytical method, are part of National Food Safety Standards, which should be issued by Ministry of Health. Nevertheless, there are still some food additives that lack of specification, and MOH is working on that to cover the gap as soon as possible.
Official publication and/or gazette for food additives	Regarding additives for which the specifications and standards have been established pursuant to the provisions of Article 11, paragraph 1 and additives for which the labelling standards have been established pursuant to the provisions of Article 19, paragraph 1, the MHLW shall compile the Japanese Standards of Food Additives to contain such specifications and standards.	http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (KFCA)	

Table 3.6-2 General-C-M-S-P-I-

	Codex	Malaysia	Singapore	Phillipines	Indonesia	Thailand	Vietnam
Related legislation	CODEX STAN 192-1995 CAC/GL 66-2008 CODEX STAN 107-1981	Food Regulations 1985	Food Regulations	Department of Health Administration Order No. 88-A s.1984 on Regulatory Guidelines Concern Food Additives Department of Health, Food and Drug Administration Circular No. 2006-016 on Updated List of Food Additives	Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products	Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	Law No. 55/2010/QH 12 on Food Safety
General Descriptions /							
Definition of Food Additives	CODEX STAN 192-1995 Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.	Food additives are defined in the Food Regulations as follows: "Food additive means any safe substance that is intentionally introduced into or on a food in small quantities in order to affect the food's keeping quality, texture, consistency, appearance, odour, taste, alkalinity, or acidity, or to serve any other technological function in the manufacture, processing, preparation, treatment, packing, packaging, transport, or storage of the food, and that results or may be reasonably expected to result directly or indirectly in the substance or any of its by-products becoming a component of, or otherwise affecting the characteristics of, the food, and includes any preservative, colouring substance, flavouring substance, flavour enhancer, antioxidant and food conditioner, but shall not include added nutrient, incidental constituent or salt."	"Food additive includes – i) all substances, which are components of food, the intended use of which results or may reasonably be expected to result, directly or indirectly, in their affecting the characteristics of food but does not include any foreign substance mixed with food as a result of contamination, or improper handling of the food during the preparation, processing, packing or storage of the food; and ii) anti-caking agents, anti-foaming agents, anti-oxidants, sweetening agents, chemical preservatives, colouring matters, emulsifiers or stabilizers, flavouring agents, flavour enhancers, humectants, nutrient supplements, sequestrants and other general purpose food additives."	Food additives are defined in the Food, Drug and Cosmetic Act as follows: "Food additive means any substance the intended use of which results or may reasonably be expected to result, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of intended use."	The definition of food additives is further defined in subsidiary regulations in Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives as follows: "Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional additional of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (direct or indirect) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods."	Food additives are defined in the Notification No. 281 as follows: "Food additives means articles which normally are not used as food or major ingredients of food, irrespective of their nutritional value, but are added to food for the purpose of manufacturing technology, food colouring, food flavouring, packaging, storage or transportation, which renders certain effects to the quality or standard or description of the food. However, it shall mean to include articles not added to food but are put in a specific container and packed within the food for the above-said purposes as well, such as desiccants, anti-oxidants, etc."	Food additives are defined in the Law on Food Safety as follows: "Food additive means a substance with or without nutritive value, which is intentionally added to food in the process of production in order to retain or improve particular characteristics of food."
Flavour	GUIDELINES FOR THE USE OF FLAVOURINGS CAC/GL 66-2008 (7) Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings. (1) Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients (Section 2.3) within the conditions as referred to in 3.5. They are not intended to be consumed as such.	"Flavouring substance" means any substance that, when added to food, is capable of imparting flavour to that food and includes spices specified in regulation 286 to 333. "Natural Flavouring Substance" means any flavouring substance obtained exclusively by physical processes from vegetable, fruit or animal, either in their natural state or processed, for human consumption. "Nature Identical Flavouring Substance" means any flavouring substance chemically isolated from aromatic raw materials or obtained synthetically, and are chemically identical to substances present in natural products intended for human consumption, either processed or not.	"Flavour Agent" means any wholesome substance that when added or applied to food is capable of imparting taste or odour, or both, to a food. "Natural Flavouring Agents" shall include natural flavouring essences, spices and condiments. "Synthetic Flavouring Essences or Extracts" shall include any artificial flavour or imitation flavour which may resemble the sapid or odoriferous principles of an aromatic plant, fruit or vegetable or any other food, except that the flavouring principle shall be derived in whole, or in part, from either chemical synthesis or any other sources that does not involve extraction or isolation therefrom of the sapid or odoriferous principles present in an aromatic plant, fruit or vegetable or any other food.	"Flavouring Substances" refer to flavour preparations composed of substances derived from plant/animal products and/or chemically synthesized substances whose significant function in food flavouring rather than nutritional.	"Flavour" is classified under the food additive functional class of "Flavour and flavour enhancer", which means substances added to impart or help impart a taste or aroma in food. "Flavour" means a food additive in the form of concentrate, with or without flavouring adjunct that is used to give flavour, with the exception of salty, sweet and sour taste, that is not intended for direct consumption and not be treated as a food.	Flavouring agents are classified as foods which are required to bear labels. "Flavouring Agents" mean substances used for flavour or taste of food. "Natural Flavouring Agent" means agent for enhancing taste or flavour which is physically derived from plant or animals normally used for human consumption. "Imitate of Natural Flavour Agent" means flavour agent derived from chemical extraction or synthesized flavouring agent in which the extracted substances or synthesized shall be of the same chemical properties as of the natural products normally used for human consumption and shall mean to include imitate of natural flavouring agent which contain natural flavouring agent as well. "Synthesized Flavouring Agent" means flavouring agent which is not discovered in natural products normally used for human consumption and means to include synthesized flavouring agent which contain natural flavour agent or imitate of natural flavouring agent.	Not described
Processing aid	CODEX STAN 107-1981 Processing aid means a substance or material not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.	Processing aids are considered as food additives under the functional class of "food conditioner".	"Processing Aids" are considered as "General Purpose Food Additives", which means any substance which serves a useful and specific purpose during either the processing or packing of a food and shall include processing aid.	"Processing Aids" are additives that are used in the processing of food to achieve a specified technological purpose and which may or may not result in the presence of residues or derivatives in the final product.	The term "Processing Aid" is mentioned in Government Regulation No. 28/2004 but no definition is provided.	"Processing Aid" means substances or any matters which are not for consumption in the manner of food compositions but are used in production of raw materials or food ingredients, by the used technology between qualities adjustment or processing, in which these substances or their derivatives may be unintentionally or inevitable left over, in this regard not to include production equipments.	"Food Processing Aid" means a substance which is intentionally used in the processing of food materials or food ingredients in order to achieve a technological purpose and can be removed from or remains in foods.
Carry-over	4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that: a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard; b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard; c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.	"Carry-over" principle is described in general in the Food Regulations, with restricted list of additives allowed to be carried over for infant formula.	Food ingredients that are added to foods may also contain food additives for the types of additives permitted and in accordance with the levels specified for the food ingredients.	Defined in general according to BC 2006-16	"Carry-over" principle is defined for labelling purposes, as follows: "Carry-over additives are food additives that are normally found in the product formulation as a result of being an ingredient from another ingredient. Examples: Food colouring in orange concentrate; Monosodium glutamate in spices."	There is no definition of carry over principles in Thailand.	There is no definition of carry over principles in Vietnam.

Table 3.6-2 Specific-M-S-P-I-T-V

	Malaysia	Singapore	Phillipines	Indonesia	Thailand	Vietnam
Related legislation	Food Regulations 1985	Food Regulations	Department of Health Administration Order No. 88-A s.1984 on Regulatory Guidelines Concern Food Additives Department of Health Food and Drug Administration Circular No. 2006-016 on Updated List of Food Additives	Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives Minister of Health of the Republic of Indonesia Regulation No. 1168/MENKES/PER/X/1999 on Amendments to Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives Decision of the Head of BPOM No. HK.00.05.5.1.4547 on Conditions of Use for Artificial Sweetener Food Additives in Food Products	Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food
Specific descriptions / Additional explanations						
List of Designated Food Additives	Includes preservative, antimicrobial agent, colouring substance, flavouring substance, flavour enhancer, antioxidant, antioxidant and food conditioner.	Anti-caking agents, anti-foaming agents, anti-oxidants, sweetening agents, chemical preservatives, colouring matter, emulsifiers and stabilizers, flavouring agents, flavour enhancers, humectants, nutrient supplements, sequestrants, gaseous packaging agent, general purpose food additives	Follows Codex GSFA.	Includes antioxidant; anticaking agent; acidity regulator; artificial sweetener; flour treatment agent; emulsifier, stabilizer, thickener; preservative; firming agent; colour; flavour, flavour enhancer; sequestrant.	As per listed in the attachment to the Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	Includes acidity regulator, flavour enhancer, firming agent, preservative, anticaking agent, antioxidant agent, antifoaming agent, bulking agent, artificial sweetener, modified starch, enzyme, propellant, glazing agent, humectant, thickener, stabilizer, emulsifier, colour, foaming agent, sequestrant, raising agent, flour treatment agent
List of Existing Food Additives	There is no such list in Malaysia.	There is no such list in Singapore.	There is no such list in Philippines.	There is no such list in Indonesia.	There is no such list in Thailand.	There is no such list in Vietnam.
List of Plant or Animal sources for Flavouring agents	There is no such list in Malaysia.	There is no such list in Singapore.	There is no such list in Philippines.	There is no such list in Indonesia.	There is no such list in Thailand.	There is no such list in Vietnam.
List of substances which are generally provided for eating or drinking as foods and are used as food additives as well	There is no such list in Malaysia.	There is no such list in Singapore.	There is no such list in Philippines.	There is no such list in Indonesia.	There is no such list in Thailand.	There is no such list in Vietnam.
Negative list (if any)	There is a list of flavouring substances the use of which is prohibited or limited in Malaysia.	There is a list of prohibited substances for use as flavouring agents.	Cyclamates, dulcins and p-4000 (5-nitro-2-propoxyaniline) are prohibited from use in foods as sweeteners. Administrative Order No. 122 s.1970 on General Regulation Governing the Prohibition of the Use of Cyclamic Acid and its Salts Administrative Order No. 125 s. 1970 on General Regulation for Labelling Artificial Sweeteners in the Dietary Management of Disease in Man; Prohibited Artificial Sweeteners	1) Boric acid and its compounds; 2) Salicylic acid and its salts; 3) Diethylpirocarbonate DEPC; 4) Dulcin; 5) Potassium chlorate; 6) Chloramphenicol; 7) Brominated vegetable oils; 8) Nitrofurazone; 9) Formaldehyde; 10) Potassium bromate SNI 01-7152-206 Food additives set conditions for use of flavouring materials in food.	1) Methyl alcohol or methanol (except for use as a food processing aid); 2) Stevia and stevia products that are non-water crude extractions and/or derivatives of substances from crude extraction; 3) Duclin (para-phenetolcarbamide); 4) Cyclamic acid and its salts (sodium cyclamate); 5) Furylframide; 6) Potassium bromated; 7) Melamine and its analogues (cyanuric acid, ammelide and ammeline); 8) Brominated vegetable oil; 9) Salicylic acid; 10) Boric acid; 11) Borax; 12) Calcium iodate or potassium iodate; 13) Nitrofurazone; 14) Potassium chlorate; 15) Formaldehyde, formaldehyde solution or paraformaldehyde; 16) Coumarin (1,2-benzopyrone or 5,6-benzo-alpha-pyrone or cis-o-coumaric acid, anhydride or o-hydroxycinnamic acid, lactone); 17) dihydrocoumarin, benzodihydropyrone, 3,4-dihydrocoumarin or hydrocoumarin; 18) diethylene glycol, dihydroxydiethyl ether, diglycol, 2,2'-oxybis-ethanol or 2,2'-oxydiethanol; 19) daminozide or succinic acid 2,2-dimethylhydrazide	There is no negative list of food additives in Vietnam.
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives	Found in Malaysian Standard 1282 Parts 1-8 for acidity regulator; preservative; antioxidant; flavour enhancer; stabilizer, thickener and gelling agent; solvent; anticaking agent; and colouring substance.	Follows JECFA specifications.	Follow JECFA specifications.	Indonesian Food Codex 2001	Mainly follows JECFA and Codex specifications. However, can also be those published by Thai FDA or approved by the Sub-Committee for Studying and Analyzing Problems and Determining Food Technicality.	flavour enhancer, humectant, raising agent, anticaking agent, colour retention agent, antioxidant agent, foaming agent, artificial sweetener, firming agent, colours, acidity regulator, preservative, stabilizer, sequestrant, flour treatment agent, bulking agent, propellant, modified starch, enzyme, glazing agent, thickener, emulsifier, foaming agent
Official publication and/or gazette for food additives	No official publication and/or gazette for food additives. However, updates on food additives are announced on the FSQD, MOH, Malaysia website.	There is no official publication and/or gazette for food additives. However, official circulars are issued when food regulations are amended.	There is no official publication and/or gazette for food additives in the Philippines. However, additional food additive and functional classes by Codex are automatically added to the list of additives/ functional classes.	Apart from regulations issued by the National Agency for Drug and Food Control (NADFC or Badan POM), standards for food additives are also published by the National Standards Body. Currently, up-to-date standards have only been published for two functional classes of additive – flavours and artificial sweeteners.	There is no official publication and/or gazette for food additives. However, updates to food additive regulations are made through issuances of Notifications of the Ministry of Public Health.	There is no official publication or gazette for food additives in Vietnam.

Case Study Foods	Japan		Korea		China
	Food Sanitation Act	JAS Law (voluntary standards)	Food Sanitation Act	KS (voluntary standards)	Food Categories in GB2760
1. Instant Noodles	Standards for "Instant Noodles" is defined in Food Sanitation Act, but it only includes specification and standards of storage for oil-processed type Noodles. Limitation of use of some food additives to Instant Noodles (including their attached soup powder) are defined at JSFA.	Positive List (limitation in use)	<p>Specification of noodles are described in Korea Food Code.</p> <p>Positive /negative list of food additives for noodles should be complied in Korea.</p> <p>Below food additives should not be detected in the products :</p> <ul style="list-style-type: none"> - Prepared Tar Dyes (colour) - Preservatives - Titanium dioxide <p>Sodium Stearoyl Lactylate is permitted for use in noodles.</p>	<p>Fried Noodles (KS H 2508), Dried Noodles (KS H 2505), Raw Noodles (KS H 2506), and Cooked Noodles (KS H 2507)</p> <p>Noodles were specified as fried noodles and non-fried noodles.</p> <p>Tar colour should not be detected.</p>	<p>06.0 Cereals and cereal products</p> <p>06.03 Wheat flour and its product</p> <p>06.03.01 Wheat flour</p> <p>06.03.01.01 All-purpose wheat flour</p> <p>06.03.02 Wheat flour product</p> <p>06.07 Pre-cooked (instant) noodles and rice</p>
2. Carbonated Soft Drinks	<p>Maximum level of several food additives in "non-alcoholic beverage" is set in "the Standards for use of Food Additives "</p> <p>Standards of soft drinks are described in FSA.</p> <p>But no positive/negative list on food additives in it.</p> <p>In "the Standards for use of Food Additives", maximum level of several food additives in "non-alcoholic beverage" is set and some food additives are prohibited to be used in "non-alcoholic beverages".</p>	<p>-Preservatives: only sodium benzoate and p-hydroxybenzoic acid allowed</p> <p>-Antioxidants: only L-ascorbic acid and sodium L-ascorbate allowed</p> <p>-Emulsifiers: only sucrose fatty acid esters and glycerin fatty acid esters allowed</p>	<p>Specification of carbonated beverages are described in Korea Food Code- Carbonated beverages, Carbonated water.</p> <p>Positive/negative list on food additives (Korea Food Additives Code).</p> <p>Some food additives are allowed to use in carbonated beverages and maximum levels in soft drinks are set as below:</p> <ul style="list-style-type: none"> - Preservatives: Benzoic acid, sodium benzoate, potassium benzoate, and calcium benzoate less than 0.6g/kg are permitted to only carbonated beverages (excluding carbonated water). - Ester Gum less than 0.1/kg - Manganese gluconate (no maximum level specified) <p>Some food additives are not allowed to use in carbonated beverages:</p> <ul style="list-style-type: none"> -Food Red No.2 -Food Red No. 2 Aluminum Lake. 	<p>Carbonated soft drinks</p> <p>No positive/negative list included. It is recommended to follow the Korea Food Code.</p>	<p>14.0 Beverage</p> <p>14.04 Water-based flavoured beverage</p> <p>14.04.01 Carbonated drink</p> <p>14.04.01.01 Cola type carbonated drink</p> <p>14.04.01.02 Other carbonated drink</p>
3. Prepared Frozen Foods	<p>Specifications of prepared frozen foods are described in FSA.</p> <p>No positive/negative list on food additives in it.</p> <p>The restrictions in use of food additives are applied to the foods to be frozen, not to the frozen foods.</p>	Positive List (limitation in use)	<p>Food additive standards for frozen food should comply to those for respective food item as designated in the Korea Food Code and/or Food Additive Code.</p> <p>"Frozen food" means a food made by filling the manufactured, processed, cooked food into container and packaging materials after freezing treatment for the purpose of long-term storage.</p> <p>(1) Frozen food not requiring heat process before consumption: Frozen food that can be consumed without a separate heating process.</p> <p>(2) Frozen food requiring heating process before consumption: Frozen food that can be consumed only after a separate heating process.</p>	<p>Frozen prepared dumplings (KS H 4001), Frozen prepared croquet (KS H 4002), Frozen battered Shrimps (KS H 4003), Frozen Fried Pork (KS H 4004), and Frozen Fried Fish (KS H 6032)</p> <p>No positive/negative List is included. Generally, it should comply the Korea Food Code and/or Food Additive Code.</p>	<p>06.0 Cereals and cereal products</p> <p>06.03 Wheat flour and its product</p> <p>06.03.01 Wheat flour</p> <p>06.03.01.01 All-purpose wheat flour</p> <p>06.03.01.02 Special wheat flour</p> <p>06.03.02 Wheat flour product</p> <p>06.03.02.01 Fresh pasta</p> <p>06.08 Frozen rice and flour product</p> <p>06.1 Filling for grain product</p>
4. Cow's Milk	Use of food additives in milk is prohibited or restricted by FSA	No JAS Mark standard for Cow's Milk	<p>Milk is defined as the milk pasteurized or sterilized.</p> <p>Use of food additives in milk is prohibited or restricted under the Korea FSA.</p> <p>(Sanitary control for livestock products has designated milks for milk, fortified milk, reconstituted milk, and lactic acid bacteria added milk.)</p>	<p>There is no positive/negative list in KS.</p> <p>Milk was included in the milks (KS H 2195) in KS.</p>	<p>01.0 Milk and dairy product</p> <p>01.01 Pasteurized milk, sterilized milk and recombined milk</p> <p>01.01.01 Pasteurized milk</p> <p>01.01.02 Sterilized milk</p>

Case Study Foods	Malaysia	Singapore	Philippines	Indonesia	Thailand	Vietnam
1. Instant Noodles	<p>Pasta Should not contain any prohibited flavouring substances under the Food Regulations 1985. May contain Transglutaminase and sulphur dioxide or sulphites, as permitted food conditioner at < 200mg/kg.</p> <p>Instant wheat noodles Food additives are permitted in accordance with Food Regulations 1985.</p> <p>Instant rice noodles Preservatives are prohibited. Other additives are permitted in accordance with Food Regulations 1985.</p>	<p>Pasta Permitted flavouring agents and colouring matters according to Food Regulations.</p> <p>Dried noodles and pasta products Not specified.</p>	<p>Flour sticks (pancit canton) Usage of food additives in accordance with FDA Circular No. 2006-016 and Codex GSFA.</p> <p>Permitted additives include acidity regulators, antioxidants, colours, flour treatment agents, raising agents and stabilizers.</p> <p>Carry-over of other additives are allowed as approved by FDA and in accordance with Codex principles on carry-over of food additives.</p> <ol style="list-style-type: none"> 1. Sodium hydroxide: GMP 2. Butylated hydroxyanisole (BHA): <100mg/kg 3. Butylated hydroxytoluene (BHT): <200mg/kg 4. Tocopherol: GMP 5. Tartrazine: <300mg/kg 6. Sunset Yellow: <300mg/kg 7. Phosphates (as sodium or potassium phosphates): <2,200mg/kg 8. Sodium carbonate: <2,600mg/kg 9. Potassium carbonate: <2,600mg/kg 	<p>Instant noodles Food additives are permitted in accordance to existing regulations*.</p> <p>Instant rice noodles Food additives are permitted in accordance to existing regulations*.</p>	<p>Semi-processed food in sealed container, including noodle, a sheet of rice noodle (Guay-Jub), wheat noodle, rice vermicelli and mug bean vermicelli</p> <p>Use of food additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives</p>	<p>Instant noodles Food additive usage in accordance with Codex Standard 249:2006 on Instant Noodles</p>
2. Carbonated Soft Drinks	<p>Flavoured drink Should not contain any prohibited flavouring substances under the Food Regulations 1985. May contain permitted preservative, colouring substance and food conditioner in accordance with Food Regulations 1985.</p> <ol style="list-style-type: none"> 1. Ester gum: <150mg/l 2. β-cyclodextrin: <150mg/l 3. Caffeine-containing plant extract as flavouring substance: <200mg/l 4. Sulphur dioxide: <140mg/l 5. Benzoic acid: <350mg/kg 6. Agaric acid: <20mg/kg 7. Total hydrocyanic acid (free and combined): <1mg/kg 8. Pulegone: <100mg/kg (except peppermint or mint flavoured beverages) or 250mg/kg (for peppermint or mint flavoured beverages) 9. Quassin: <5mg/kg 10. Quinine: <85mg/kg 11. Thujones: <0.5mg/kg <p>Ready-to-drink beverages Permitted acidity regulators: citric acid, phosphoric acid, lactic acid, malic acid, acetic acid, fumaric acid, tartaric acid (including the sodium, potassium and calcium salts) Permitted colours, nutritive and non-nutritive sweeteners in accordance with Food Regulations 1985. Permitted mineral salts: sodium carbonate and sodium bicarbonate Permitted preservatives and flavouring agents</p> <ol style="list-style-type: none"> 1. Sulphuric acid: <140ppm 2. Benzoic acid: <350ppm 3. Sorbic acid: <350ppm 4. Caffeine: <150ppm 5. Quinine: 40-85ppm 6. Ascorbic acid: 10mg/100ml 	<p>Soft drinks Food additives are permitted in accordance with Food Regulations.</p> <ol style="list-style-type: none"> 1. Ester gum: < 100ppm 2. Sucrose acetate isobutrate: < 300ppm 3. Dimethyl polysiloxane: < 10ppm 4. Calcium disodium ethylenediaminetetraacetate: <33ppm 5. Sulphur dioxide: <60ppm 6. Benzoic acid: <160ppm 7. Methyl or propyl para-hydroxy benzoate: <160ppm 8. Sorbic acid: <300ppm 9. Dimethyl carbonate: <250ppm 10. Acesulfame-K: <350ppm 11. Saccharin: <80ppm 12. Cyclamates (as cyclamic acid): <250ppm 13. Neotame: 20ppm 14. Steviol glycosides (as steviol): < 160ppm 15. Sucralose: <300ppm <p>Carbonated and non-carbonated beverages Permitted acidity regulators including citric acid, tartaric acid, malic acid, phosphoric acid, ascorbic acid, acetic acid, adipic acid, fumaric acid, hydrochloric acid, dl-lactic acid, dl-malic acid, ortho-phosphoric acid and L(+)/tartaric acid</p> <p>Permitted food colours, clouding agents, foaming agents, emulsifying and stabilizing agents, and preservatives</p>	<p>Citrus beverage products Usage of food additives in accordance with FDA Circular No. 2006-016 and Codex GSFA.</p> <p>Permitted additives include:</p> <ol style="list-style-type: none"> 1. acidity regulator (citric acid, malic acid, calcium carbonate, adipates) 2. anticaking agent (calcium aluminium silicate – synthetic, microcrystalline cellulose; aluminium silicate, carnauba wax) 3. antioxidant (ascorbic acid, calcium ascorbate, erythorbic acid, potassium ascorbate, sodium ascorbate, sodium erythorbate) 4. colour (carotenoids, chlorophylls, chlorophyll copper complexes, sulphites, carbon dioxide, phosphates, ethylenediaminetetraacetic acid/EDTA) 5. stabilizer/thickener (calcium chloride, carob bean gum, carrageenan, gellan gum, guar gum, gum arabic, karaya gum, lactic and fatty acid esters of glycerol, pectins, potassium alginate, sodium alginate, tara gum, tragacanth gum, xanthan gum, agar, konjac flour, sodium carboxymethylcellulose) 6. sweetener (acesulfame potassium, aspartame, saccharin, sucralose) 7. Processing aids (antifoaming agents:- polydimethylsiloxane; clarifying agents/filtration aids/flocculating agents :- adsorbent clays, adsorbent resins, activated carbon – only from plants, bentonite, cellulose, chitosan, colloidal silica, diatomaceous earth, gelatin – from skin collagen, ion exchange resin – cation and anion, kaolin, perlite; enzyme preparations:- pectinases – for breakdown of pectin, proteinases – for breakdown of proteins, amylases – for breakdown of starch, cellulases – limited use to facilitate disruption of cell walls; packaging gas:- nitrogen, carbon dioxide) 	<p>Lemonade Artificial sweeteners (e.g. cyclamates and saccharin) are prohibited.</p> <p>Colours and preservatives are permitted in accordance to existing regulations*.</p> <p>Diet lemonade Food additives are permitted in accordance to existing regulations*.</p> <p>Soda water Food additives are not allowed except for mineral salts in accordance to existing regulations*.</p> <p>Energy drinks Food additives are permitted in accordance to existing regulations*.</p>	<p>Beverage in sealed container Use of artificial sweeteners should follow Codex GSFA and/or as prescribed by the Thai FDA.</p> <p>Methyl alcohol is prohibited to be used in the production process.</p> <p>Preservatives including sulfur dioxide, benzoic acid and sorbic acid (including their salts) are permitted.</p> <p>Use of other additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives.</p> <ol style="list-style-type: none"> 1. Sulfur dioxide: <70mg/kg 2. Benzoic acid (and salts): <200mg/kg 3. Sorbic acid (and salts): <200mg/kg <p>If more than one preservative used together, total quantity of preservatives should not be more than least allowed quantity.</p> <p>When artificial sweeteners are used, the label should state "Usage of [...] to be an artificial sweetener" (where [...] refers to the artificial sweetener).</p>	<p>Soft drinks Food additives usage in accordance with most current regulations –Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food</p>
3. Prepared Frozen Foods	<p>Meat frankfurters Food additives are permitted in accordance with Food Regulations 1985.</p> <p>Meat burgers Food additives are permitted in accordance with Food Regulations 1985.</p>	<p>There is no food category for "prepared frozen foods" in Singapore.</p>	<p>There is no food category for "prepared frozen foods" in the Philippines.</p>	<p>Chicken nugget Preservatives and colours are permitted in accordance to existing regulations*.</p> <p>Frozen breaded shrimp Food additives used should not impair or change the composition and specific properties of the frozen breaded shrimp. Food additives are permitted in accordance to existing regulations*.</p>	<p>There is no standard for use of food additives in "prepared frozen foods" in Thailand.</p>	<p>There is no food category for "prepared frozen foods" in Vietnam.</p>
4. Cow's Milk	<p>Milk, raw milk or fresh milk Food additives are prohibited according to Food Regulations 1985.</p>	<p>Milk Food additives are prohibited according to Food Regulations.</p>	<p>Fresh milk Usage of food additives in accordance with FDA Circular No.2006-016 and Codex GSFA.</p>	<p>Pasteurized milk Flavourings and preservatives are permitted according to existing regulations*.</p>	<p>Cow's milk Preservatives and artificial sweeteners are not permitted. Use of other additives are in accordance with Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives.</p>	<p>Fluid milk products Food additives usage in accordance with most current regulations –Decision of the Minister of Health No. 3742/2001QD-BYT on List of Additives Permitted for Use in Food</p>

* Existing regulations on food additives refer to the following:

1. Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives
2. Minister of Health of the Republic of Indonesia Regulation No. 1168/MENKES/PER/X/1999 on Amendments to Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives
3. Decision of the Head of BPOM No. HK.00.05.5.1.4547 on Conditions of Use for Artificial Sweetener Food Additives in Food Products

4. India

4.1 Preliminary Investigation on Indian Food Related Laws

Preliminary investigation was conducted on Indian food regulatory organizations and food laws, prior to the investigation on food standards and analysis methods.

4.2 Transition from the Old Food Legal Structures to the New Food Legal Structures

Indian food related laws consisted of Prevention of Food Adulteration Act, 1954 and Rules, 1955 which was established in 1954 and had been supervised by Ministry of Health & Family Welfare, and many other food related laws which were supervised by other multiple ministries and agencies (**Figure 4-1**).

Prevention of Food Adulteration Act and Rules had undergone repeated amendments since 1954, and there were many unclear points to interpret in the Act and Rules. Also there were many problems such as complexity resulted from supervision of many foods related laws by multiple ministries and agencies and inconsistency with international standards such as Codex. Thus since 2004 or so, movements toward the integration of such complicated food related legal structures and the transition to the food safety-based integrated food law based on international harmonization and risk analysis have started.

In January 2005, Food Safety and Standards Bill, which was the origin of the existing Food Safety and Standards Act, 2006, was proposed by Ministry of Food Processing Industries. This bill covered the following chapters: The establishment of Food Safety and Standards Authority of India (FSSAI) which was the new authority in charge of all food administrations, the establishment of Central Advisory Committee, the establishment of Scientific Committee and Scientific Panel as the organization for the risk assessment, general principles for food safety, basic regulations for food additives, contaminants, agrichemicals, labelling, genetically modified foods, organic foods, functional foods and advertisements, responsibilities of food producers, basic regulation for food analysis and implementation, basic regulation of imports and exports, rules of violations and penalties, regulations regarding adjudication and suits, regulations regarding finance and audit reports, and others. Also, the revision or repeal and integration of 15 laws including Prevention of Food Adulteration Act, 1954 and Rules, 1955 were described.

This bill was approved among ministers of related ministries in April, 2005. Then, there was jockeying between Ministry of Food Processing Industries which created the bill and Ministry of Health & Family Welfare which had jurisdiction over

Prevention of Food Adulteration Act and Rules. But finally Ministry of Health & Family Welfare became competent authority. After the revisions, Food Safety and Standard Act, 2006 came into force in August, 2006.

In 2009, draft Food Safety and Standards Rules & Regulation, which were detailed regulations of Food Safety and Standards Act, 2006, were announced and public comments were invited. However, new detailed regulations of Food Safety and Standards took over almost all the contents of the old Prevention of Food Adulteration Act and Rules only with the change of the composition. Thus, international harmonization, which was one of the purposes, was not achieved. After the revision in 2010, the draft Rules came into force in May, 2011 and the draft Regulations came into force in August, 2011, respectively (**Figure 4-1**).

For regulations for food additives, concept notes in which a positive list based on Codex was introduced for the purpose of harmonization with Codex and public comments were invited. Draft regulations for functional foods and for imported foods were announced and public comments were invited. Now the work for revision is ongoing.

Indian Food Regulations

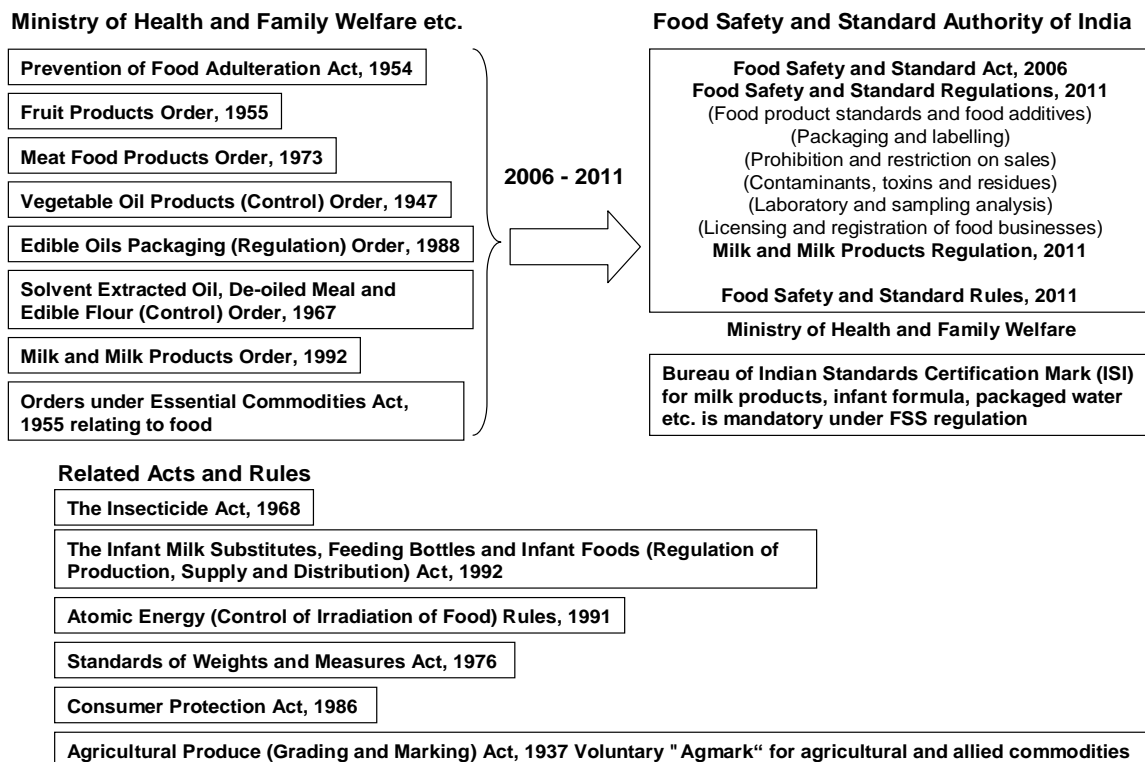


Figure 4-1 Transition to new legal structures of Indian food related laws

4.3 Outline of Food Safety and Standards Authority of India

The Food Safety and Standards Authority of India (FSSAI), which has been

established under the Food Safety and Standards Act, 2006, has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The Act also aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command (**Figure 4-2**).

Establishment of Food Safety and Standards Authority of India

Food Safety and Standards Authority of India (FSSAI), which was supervised by Ministry of Health & Family Welfare, was established as an independent administration. The Chairperson and Chief Executive Officer of FSSAI are appointed by the Government of India. The Chairperson is or was in the position of not below the rank of Secretary to the Government of India.

Important Roles of Food Safety and Standards Authority of India

- Framing of regulations to lay down the standards and guidelines for food.
- Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
- Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
- To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
- Contribute to the development of International technical standards for food.
- Promote general awareness about food safety and food standards.

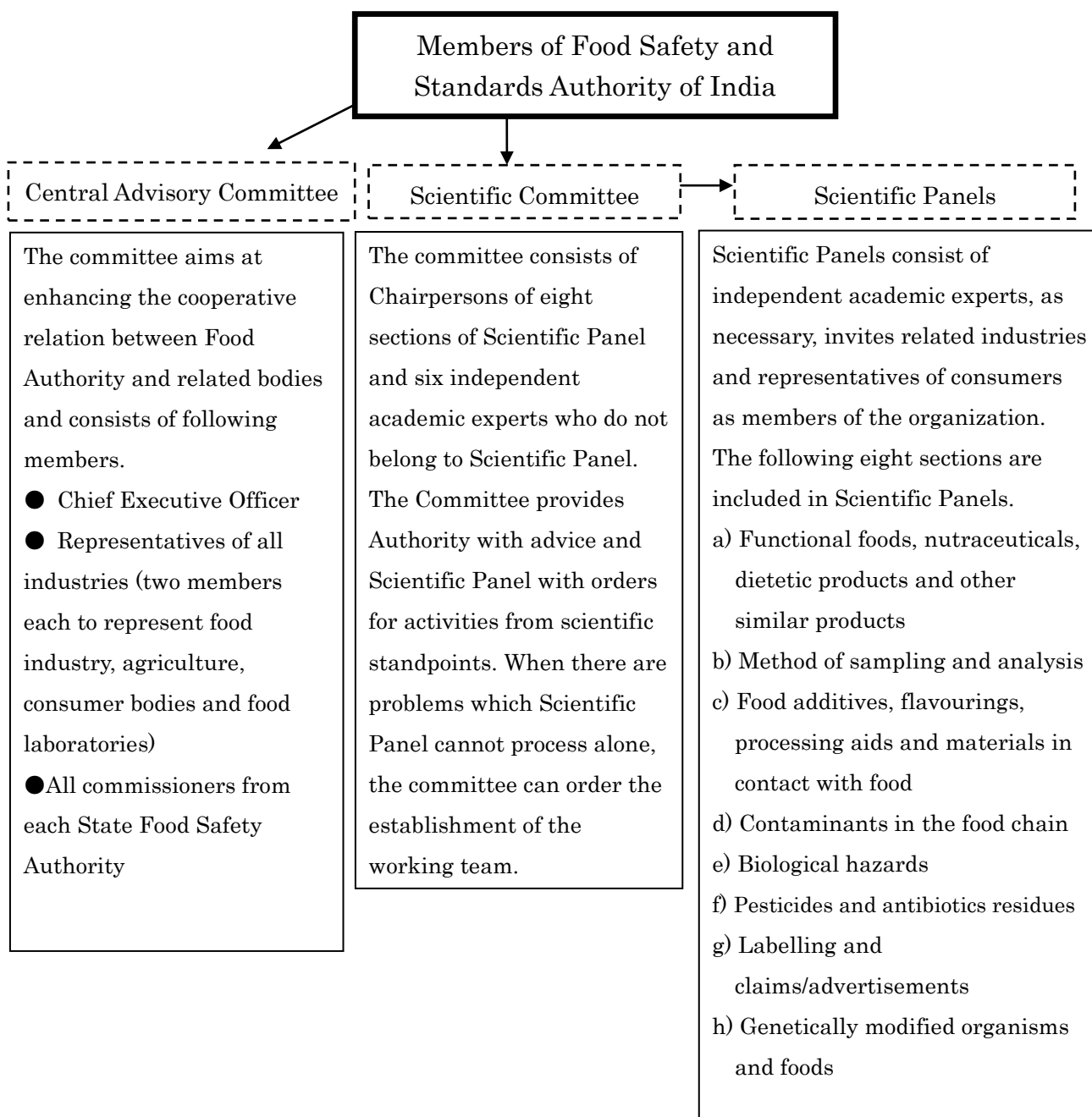


Figure 4-2 Outline of Food Safety and Standards Authority of India

4.4 Outline of Food Safety and Standards Act, Rules and Regulations of India

As described earlier, Prevention of Food Adulteration Act and Rules and standards for some food categories such as dairy products had functioned as regulations for foods for a long time. In 2006, Food Safety and Standards Act was enacted and the structure which can almost unify the management of the food related laws was established. For the implementation of the above-mentioned laws such as the inspection, Food Safety and Standards Rules, 2011 (publication in May, 2011 and enforcement three months after the publication) determining the details of the parts under the jurisdiction of the Central Government of India and the following

regulations determining detailed parts under the jurisdiction of newly established Food Safety and Standards Authority of India were established and enforced (as of March, 2012: Note that some corrections of these some regulations were published in December, 2011. It is necessary to keep it in mind when referring these regulations on the website). At the same time, regulations, established for some specific food categories, were consolidated into one regulation

- Food Safety and Standards (Procedures for Scientific Committee and Scientific Panel) Regulation, 2011 (published and enforced in March, 2011)
- Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011 (published and enforced in August, 2011)
- Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 (published and enforced in August, some of them were enforced 6 months after the first enforcement in August)
- Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011 (published and enforced in August, 2011)
- Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011 (published and enforced in August, 2011)
- Food Safety and Standards (Packaging and Labelling) Regulation, 2011 (published and enforced in August, 2011)
- Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011 (published and enforced in August, 2011)

Besides the above-mentioned regulations, public comments were invited on the draft regulations for food import and for food recall last year. It is considered that these regulations will be put in order accordingly.

Outline of Food Safety and Standards Act, 2006

Food Safety and Standards Act 2006 consists of twelve chapters. The definition and enforcement date are set forth and the outlines of the following items are established.

- Establishment of Food Safety and Standards Authority of India
- General principles of food safety (In addition to the protection of human health, the followings such as the protection of the interests of consumer including fair food trade, appropriate risk management based on scientific evidence and preventive measures at appropriate level are set forth.)
- General rules regarding articles of foods (keywords: additives and

processing aids, contaminants, pesticides, veterinary drugs residues, antibiotic residues and microbiological counts,, genetically modified foods, organic foods, functional foods, packaging and labelling of foods, Restrictions of advertisement and prohibition as to unfair trade practices)

- Provisions relating to import
- Responsibilities of the food business operators, food recall procedure
- Implementing sectors and their administrations, penalties, appeal organizations
- Analysis and inspection

Items with already-published regulations are underlined. The remaining items are drafted and under call for public comments.

Outline of Food Safety and Standards Regulation, 2011

The above regulation was published under Food Safety and Standards Act 2006 in August, 2011. Here, the outlines are described on four regulations directly related to foods themselves such as "food product standards and food additives", "contaminants, toxins and residues", "packaging and labelling" and "prohibition and restriction on sales."

1) Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011

The regulation consists of three chapters and two appendixes. The first chapter describes the title of the regulation, the enforcement date and the definition. The second chapter describes the regulations related to standards for some food categories and irradiation of food. (For further details, refer to "Regulations for Food Standards" later described). The third chapter describes items regarding food additives. First, the concept of "GMP" is defined. Then, the following items are described. Food additives: Described contents are general principles in use of additives, colouring matter, artificial sweeteners, preservatives, antioxidants, emulsifying and stabilizing agents, anticaking agents, antifoaming agents in edible oils and fats, release agents in confectionery, flavouring agents and related substances, principles in use of flavour enhancers, sequestering and buffering agents (acids, bases and salts), use of glycerol esters of wood resins, use of Sucrose Acetate Isobutyrate, use of lactulose syrup, use of dimethyl dicarbonate, other substances which can be used under the specific restrictions, and carry-over concept of additives. Standards of use in foods are also included in some individual categories. Standards of additives: Standards for sweeteners and colours

are described. These standard items contain maximum limit of contaminants such as heavy metal.

Appendix A is "List of food additives" and "food products may contain additives as specified in the Regulations and in the following tables." There are Tables 1 to 15, which describe additives usable in some food categories, with their use levels (including "GMP"). There are two types of tables: In one type of tables such description is set for each food categories. In another type of tables, such description is described by each items set for by each additive category. Further, tables themselves are not divided by each food category. So it should be done carefully when checking the use and use levels of food additives.

Appendix B covers items related to microbiological standards. One table is set for each of following four categories: sea foods, milk and milk product, spices and others. Especially, for milk and milk products, in addition to the description of parameters and maximum limits, methods of sampling and recommended analysis methods are also footnoted.

Also, for the reference of the Codex additives, a list sorted by INS number and a list sorted in alphabetical order of the name of additives are attached in the last part. But there are some additives of which INS numbers do not exist in the Codex.

2) Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011

The regulation consists of two chapters. The first chapter describes the general rules as same as the regulation described in 1). The second chapter consists of the following three items.

1. Metal contaminants: limitations are set on lead, copper, arsenic, tin, zinc, cadmium, mercury, methyl mercury, chromium and nickel. The maximum limit is described for each food category.
2. Crop contaminants and naturally occurring toxic substances: As crop contaminants, limitations are set on aflatoxin (total aflatoxin and aflatoxin M1), patulin and ochratoxin A. As naturally occurring toxic substances, limitations are set on Agaric acid, Hydrocyanic acid, Hypericine and Safrole.
3. Residues: Limitation on residues of insecticides and of antibiotic substances and other pharmacologically active substances are described. The latter provision is for sea foods and fishery products.

3) Food Safety and Standards (Packaging and Labelling) Regulation, 2011

This regulation consists of two chapters. The main part is the second chapter consisting of the following items.

1. Packaging: General requirements (reference standards for containers, requirements for canned products) and product-specific requirements (for milk and milk products, edible oil/fat, fruit and vegetable products, canned meat products and drinking water)
2. Labelling: General requirements (language of description, prohibition of labelling causing false, misleading or deceptive situation or errors, prohibition of separation between labelling and the product and labelling legible by the consumer), labelling of pre-packaged foods (the name of the product, the list of ingredients, nutritional information, veg/non-veg mark, declaration regarding food additives, name and complete address of the manufacturer, net quantity, ID numbers (such as the lot), date of manufacture or packing, best before and use by date, country of origin(imported food only), and instructions for use), Manner of declaration (legible label, display panel and size of letters), specific requirements/restrictions on labelling (infant milk substitute and infant food, edible oils and fats, permitted food colours, irradiated foods, specific labelling requirements of other products and restrictions on product labels), restriction on advertisement, exemptions from labelling requirements and notices (regarding addition, admixture or deficiency)

4) Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011

The regulations consist of two chapters. The main body is the second chapter including the following two items.

1. Sales of certain admixtures prohibited (adulterated milk products, edible oil and fat mixture, and coffee mixture with other than chicory, turmeric containing any foreign substance, etc.)
2. Restriction in use of certain ingredients (restriction in use of the followings in foods, such as some types of grass peas and their products, flours, admixtures, etc.)
3. Prohibition and Restriction on sales of certain products (ex. prohibition on sale of food articles coated with mineral oil, prohibition on use of carbide gas for fruits ripening purpose, prohibition on use of tobacco and nicotine as food ingredients, special rules regarding milk and milk products, special rules regarding vegetable oil and edible oil, etc.)

Regulations related to Food Standards

There are several regulations that relate to food standards in addition to Food Safety and Standards (Food Product Standards and Food Additives) Regulation, Standards for contaminants are set forth in Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011. Some prohibition and restriction items regarding some food categories such as milk products and edible oil are set forth in Food Safety and Standard (Prohibition and Restriction on Sales) Regulation, 2011.

1) Food standards in Food Safety and Standards Regulation

(a) Standards for each food category: Following categories are set forth in Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011. Standard items vary on each category.

1. Dairy products and analogue
2. Fats, oils and fat emulsions
3. Fruit and vegetable products
4. Cereals and cereal products
5. Meat and meat products
6. Fish and fish products
7. Sweets and confectionery
8. Sweetening agents including honey (containing food additives permitted in these Regulations and Appendices)
9. Salts, spices, condiments and related products
10. Beverages, (other than dairy and fruits and vegetables based but including water)
Its categories include only coffee (including substitutes), tea, carbonated beverages, mineral water and packaged drinking water.
11. Other foods products and food ingredients: Baking powder, edible catechu (the heart wood of acacia), gelatin, silver leaf, pan masala, cocoa powder, carob powder are described.
12. Proprietary Food: Food that has not been standardized under above-mentioned regulations.

(b) Items related to food additives: Usable food additives and its amount in specific food categories are described in each food standard in the text of Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 or in articles related to additives. In addition, Appendix A of the regulation has the equivalent list.

- (c) Items related to microorganisms: Some food categories separately have microbiological standards in Appendix B to Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011.
- (d) Items related to contaminants: In Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011, standards are set mainly on fresh foods. Regulations for heavy metal and others are set forth on some processed foods. When the item is described as "all food", the regulation is considered to be applied to all foods.
- (e) Prohibition and restriction items: In Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011, items under which sales are not permitted for some food categories in case of non-compliance are described. This is also a kind of food product standards.
- (f) Others: Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 has standards for irradiation of foods. Rules are set for the followings such as irradiation accepted food categories, dose of irradiation, requirement for the process of Irradiation (approval of facilities, prohibition of re-irradiation unless otherwise permitted, prohibition of carry out of foods/irradiated foods from irradiation facility without appropriately irradiated), restrictions (compliance to approved contents, identification for the prevention from re-irradiation, irradiation by the personnel with the minimum qualifications and training specified under the related rule, prohibition of re-irradiation unless otherwise permitted), records of irradiation, standards for irradiated foods, and provisions on storage and sales, restrictions on sales.

2) Other Standards

The obtainment of ISI mark certified by Bureau of Indian Standards (BIS) is mandatory on milk products, infant milk foods, packaged drinking water, mineral water, etc. Other BIS standards such as for additives are now on voluntary base although some standards of food additives are integrated in the regulations.

<Referential websites>

<http://www.fssai.gov.in/> Food Safety and Standards Authority of India

<http://www.mohfw.nic.in/> Ministry of Health & Family Welfare

<http://mofpi.nic.in/default.aspx> Ministry of Food Processing Industries

<http://www.bis.org.in/> Bureau of Indian Standards

<http://www.cifti.org/> Confederation of Indian Food Trade and Industry

<http://foodsafetynews.wordpress.com/> Food Safety News

5. Halal

5.1 Background

When Japanese food industry tries to expand their businesses in East Asia including Association of Southeast Nations (ASEAN), they need to know “Halal” in addition to the survey on standards, analysis methods and other items of local foods. “Halal” is clearly stated as one of the requirement items for import and export of foods and others within the ASEAN area toward the ongoing harmonization within ASEAN.

Various information about “Halal” is available from the Muslim (people who embrace Islam, i.e. worshippers of Allah) organizations within Japan.

In addition, surveys on “Halal” have been conducted by Japan External Trade Organization (JETRO), Japan Food Industry Center and local governments such as Nagasaki-city office in recent years and various reports have been published.

Many of these reports describe detailed information of the system and market of the countries such as Malaysia and Indonesia, which systematize or address “Halal” at nation level. In case of Malaysia, Malaysian governmental organizations hold seminars and lectures on Malaysian Halal system in Japan and try to attract Japanese food industry to Malaysia.

When Japanese food industry thinks of its business expansion to overseas countries, many Japanese food companies think about exporting their own products. In that case, they are at loss what they should do at first and consider where they will be able to receive advice on “Halal” in Japan. Or when they conduct survey on “Halal” in advance, they find “Halal” might be something difficult. Thus they are hesitant to make inquiries about “Halal” from the beginning. Furthermore, some raw material manufacturers provide domestic food business operator with raw materials and do not think of the expansion of their businesses to overseas countries. Thus, such manufacturers consider that “Halal” has nothing to do with them. Other manufactures have some knowledge on “Halal”, and when domestic partners request raw materials of “Halal”, they do not understand why “Halal” is required for raw materials which may not have problems.

5.2 Purpose of the Survey

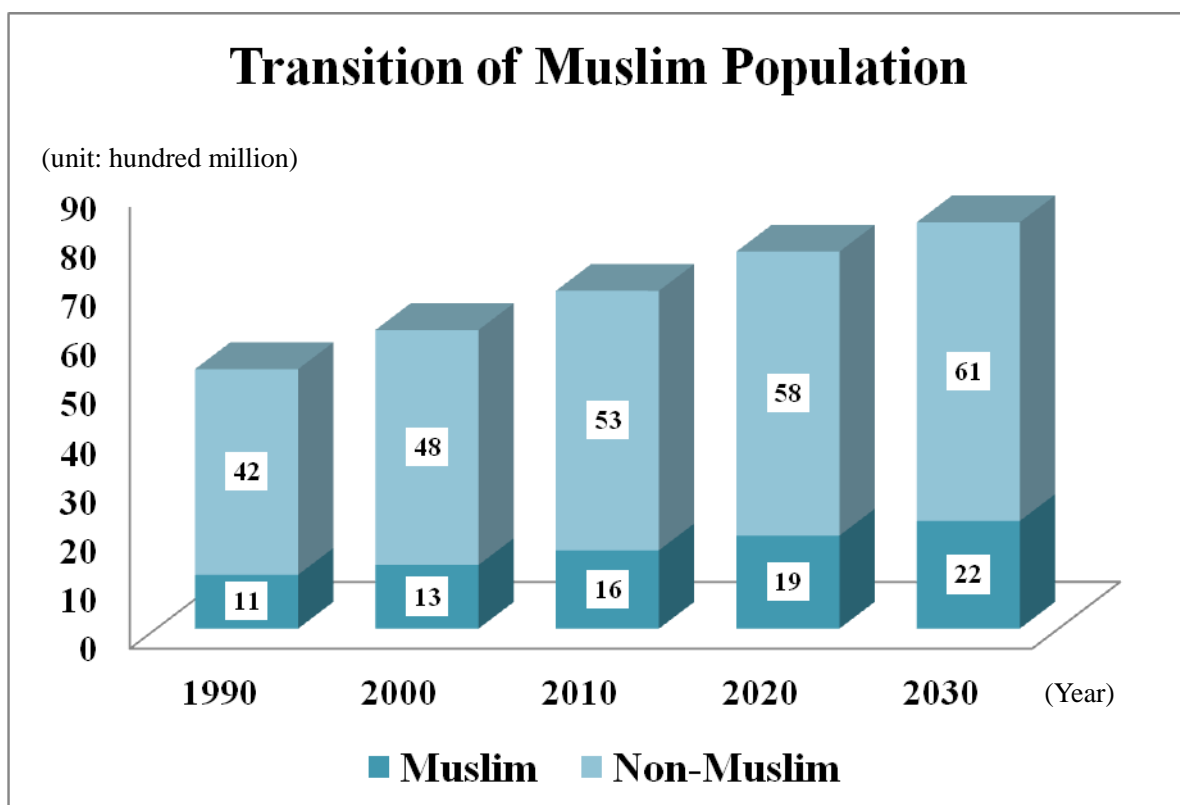
To make Japanese food business operator with hesitation and questions understand “Halal” and lower the first barrier for them, this project integrate thoughts and materials which various organizations publish for “Halal” to the general public. Especially the project covers in detail the integrated information about contact points regarding “Halal” and the occasions when they obtain the certification in Japan. As this project addresses “Halal” once again, whether or not the food industry

has the expansion plan of its businesses to overseas areas, it is expected that the provision of the basic information through this report will enable food business operator to understand “Halal” more deeply, promote their businesses to East Asia, and will enhance the environment where they smoothly enter the local market and expand their businesses.

5.3 Outline of Global “Halal” Market

5.3.1 Current and Future Status of Global Muslim Population

According to Pew Research Center, the total population of Muslims worldwide was about 1.62 billion in 2010. Twenty years later, in 2030, it is expected that the global population of Muslims will increase by about 35% and reach 2.19 billion. Muslims accounted for 24.3% of the world population in 2010 and will account for 26.4% in 2030, when more than one in every four people will be a Muslim. It is also expected that the annual rate of increase for Muslims will be 1.5 %, which is about double the rate for non-Muslims (0.7%).



5.3.2 Distribution of Muslims worldwide

By region, the largest number of Muslims live in Asian countries where the Muslim population is 1.1 billion, accounting for 68% of all Muslims worldwide. Next is Africa with 460 million Muslims, followed by Europe with 50 million. By nation, Indonesia is the world’s most populous Muslim country where 200 million Muslims live. It

accounts for 12% of all Muslims worldwide. The next country is Pakistan with 160 million Muslims, followed by India with 150 million and Bangladesh with 130 million Muslims. These four countries are all in Asia and have a total of more than 600 million Muslims.

This report will hopefully be useful in helping Japanese food business operators identify and prepare for potential present and future demand.

5.4 Basic Knowledge regarding “Halal”

Professor Hideomi Muto (Muslim name: Tayeb El-Mokhtar H. MUTO, Al-Azhari), Chief, Shariah Committee of Shariah Research Institute, Takushoku University explains the basic knowledge of “Halal”, focusing on "Islamic thought", "certification" and "procedure for Halal certification."

About “Halal”

Hideomi Muto (Tayeb El-Mokhtar H. MUTO, Al-Azhari),
Chief, Shariah Committee,
Sharia Research Institute, Takushoku University

1. Halal and Shariah (Islamic law)

“Halal” is the Arabic word, which means “lawful” or “permissible”. The opposite word is “Haram”, which means “forbidden” or “prohibited” in Arabic. In Japan, “Halal” and “Haram” is pronounced and described as “Halalu” and “Haramu” in Japanese katakana, because these words are pronounced in English pronunciation. In Arabic, there are three long vowels such as a, i, u. “la” of “Halal” and “ra” of “Haram” have long vowels, which are pronounced with long duration. Thus, they are pronounced as “laa” and “raa” with long vowel. Therefore, by reflecting these pronunciations, “Halaal” and “Haraam” described in Japanese is almost similar to the original words.

In Islam, the legislator is only God (Allah). The way human beings should follow which God showed to human beings is called “Shariah”. “Shariah” came from the following origins, Allah's revelations set forth in the Holy Quran and words and deeds of the prophet Muhammad (s.a.w.) who conveyed Allah’s revelations.

“Shariah” includes not only the religious practice for “Allah”, bringing human mind into question, but also standards for all secular deeds such as human interaction. “Halal” is the legal and/or lawful habit acceptable for Shariah, while “Haram” is the forbidden and/or prohibited habit. Also, doubtful habit is called “Shubhah”. Such doubtful habit is not included in the scope of “Halal”.

“Quran”, which is called “Koran” in Japan, is a collection of the words Allah revealed the prophet Muhammad (s.a.w.) in Arabic. In the Holy Quran, no word from the prophet Muhammad (s.a.w.) was included. “Hadith” (records of deeds and words) is the edited collection of deeds and words of the prophet Muhammad (s.a.w.). “Hadith” was clearly distinguished from “the Holy Quran”.

2. Grounds of Halal (from the Holy Quran)

2.1 Consumption of Halal Foods

Human beings are ordered to eat Halal foods by Allah. The Holy Quran states the following.

[Then eat of what Allah has provided for you (which is) lawful and good. And be grateful for the favor of Allah, if it is (indeed) Him that you worship.] (16:114, means the Chapter 16 : Verses 114, from the Holy Quran, here in after)

In the Holy Quran, the term “Halal” always comes with “Tayyib”, and so you can see the words “Halalan Tayyiban” (Lawful and good thing). This Tayyib means “good in purity, cleaning, health and environmental preservation”. In other words, it should be understood that God (Allah) orders human beings to eat “good foods for purity, cleaning, health and environmental preservation”.

Also, the prophet Muhammad (s.a.w.) told the following. “O Sa’d, consume lawful things and your supplications will be heard, when a man puts into his stomach a morsel of what is forbidden his prayers are not accepted for forty days.”

2.2 Passages Related to Foods

Thus, Muslims - people who embrace Islam, i.e. worshippers of Allah - should be sensitive about foods. Passages about foods in the Holy Quran are as follows.

○ Taboo foods

[Prohibited to you are dead animals, blood, the flesh of swine, and that which has been dedicated to other than Allah , and (those animals) killed by strangling or by a violent blow or by a head-long fall or by the goring of horns, and those from which a wild animal has eaten, except what you (are able to) slaughter (before its death)] (5:3)

“Dead animals” include animal meat which is not slaughtered in Islamic lawful manner. “Blood” means blood circulated from the animals, not blood which is left within the slaughtered animal body. “The flesh of swine” is regarded unclean and includes all the extraction from the swine body such as fat, skin and hair. Also,

anything in contact with the swine and anything of swine origin is regarded unclean.

○ **Prohibition of Alcohol (KHAMR)**

[O you who have believed, indeed, intoxicants, gambling, (sacrificing on) stone alters (to other than Allah), and divining arrows are but defilement from the work of Satan, so avoid it that you may be successful.] (5:90)

○ **Lawfulness of Seafood**

[Lawful to you is game from the sea and its food as provision for you and the travelers,] (5:96)

Foods caught in the sea which is not harmful to human beings, thus, sea weeds and fishes are Halal.

2.3 Why Halal Certification Is Required?

Muslims believe that they will be able to become successful in the present life and get a lot of rewards from the legislator after life by having a life acceptable to Shariah. Thus, it is very important to know whether their daily consumed foods are “Halal” or not. The reason lies in not only “food safety” but also the most immediate religious expression for God (Allah) they believe in. Thus, certification authorities of each country make Muslim consumers reassure and help them in their religious expression.

3. Halal Certification in Major Islamic Countries

[Middle-East Islamic Countries]

In Middle-East Islamic countries, each country decides Islam as the national religion set forth in the basic law. There are two main streams in those countries.

- (1) Governmental administrative agencies do not approve production and import of foods except Islamic foods (i.e. Halal foods).
- (2) Administrative agencies approve limitless production and import of such foods.

The former countries are Saudi Arabia, Libya and Kuwait as such well known as oil producing countries. It is well known that alcohol and anything of swine origin are prohibited to bring in those countries.

The latter countries are Tunisia, Egypt and others which coexist with non-Muslims. Those countries have a legislative distinction, but make their people judge for

themselves. Thus, their administrative agencies avoid intervening in Halal marks and Halal certification. Within these countries, non-Halal foods are allowed to produce, but the production is conducted only by non-Muslims. Furthermore, dealers clearly divide Halal products and non-Halal products.

[Malaysia]

Malaysia defines Islam as its national religion. In 1968, Malaysia Department of Islamic Development (JAKIM) was established by Prime Minister's Office of Malaysian Federal Government. As for Halal articles added in Trade Description (Use of expression 'Halal') Order 1975, the issues of Halal was pointed out. To producers who wish to file the Halal certificate, the guideline for Halal certification system is published. In 1982, the policy was announced, in which the Halal certification was required for all types of edible meat imported to Malaysia. In April, 2008, the authority for issuing the Halal certificate was moved from JAKIM to Halal Industry Development Corporation (HDC). But in 15 months, again the authority for issuing the Halal certificate was returned to JAKIM.

JAKIM had stopped the inspection and audit for foreign corporations since July, 2003. But JAKIM announced that it would resume the inspection and audit from July, 2010 and that would strengthen the cooperation with overseas Halal certification bodies. As of January 1, 2012, the number of the Halal certification bodies worldwide which JAKIM admits is 57 in 31 countries.

[Indonesia]

In Indonesia, about 90% of its people are Muslims. The population of Muslims reaches to 2.2 hundred millions. Indonesia has the largest population of Muslims among Islamic countries. The Indonesian Council of Ulama (MUI), which is the organization of Islamic leaders in Indonesia, established the Assessment Institute for Food, Drugs and Cosmetics - the Indonesian Council of Ulama (LPPOM-MUI) as the affiliated institute in January, 1989 to address Halal issues. As of May 1, 2011, the number of MUI's Approved Foreign Halal Certification Bodies is 44. The certification objects are classified into three product-by-product categories : 1. Slaughtering category (including poultry), 2. Food Processing category, and 3. Flavour category.

4. Basic Process of Certification Procedure

4.1 Products of Halal Certification Objects and Certification Standards

All products which Muslims consume are objects of "Halal certification". Obtaining the certification is required not only for marketed foods but also for the raw

materials used for the marketed foods with the confirmation of their nature of Halal. Besides foods, the objects of “Halal certification” are all products to be absorbed in the body through consuming or applying them from the mouth, eyes and skins in the form of drugs and cosmetics.

Fruits, vegetables and products of plant origin as natural they are, petroleum, chemical compositions and inorganic compounds themselves are basically regarded as Halal. But attention should be taken also on additives and auxiliary agents, support agents, apparatus, furniture and catalysts used in the transportation, storage, purification, process, production and others and preserving agents, anticaking agents and freshness-keeping agents added after the filling and packing.

In Europe and the United States, it is considered, due to the expansion of Muslim market, that they should obtain Halal certificate for the products whose certificate can be easily obtained. For example, look at the petroleum products. As Halal certification is easily obtained for products of petroleum processing and petrochemical corporations, obtaining Halal certification is highly recommended for the support of clients' overseas expansion. On the contrary, in Japan, most petroleum processing and petrochemical corporations refuse filing Halal certification. They say that their products are petroleum products, which have nothing to do with swine and alcohol. Thus Halal certification is not necessary, they think. Petroleum processors who use petroleum processed products as raw materials and auxiliary agents, will face difficulty later. If there is no Halal certification for raw materials and auxiliary agents, Islamic countries regard them as “faulty products without Halal traceability”. Even if non-Muslims insist that this is Halal, Muslims will not believe in their remarks. The existence value of certification bodies exists here.

Fungi and microorganisms useful for human beings are basically regarded as Halal. Attention should be taken in cases where fungi and microorganisms are extracted from the non-Halal objects, the extraction method, the collection of starter culture and cases where anything doubtful about the nature of Halal is used or possibly contacted through storage method and place, culture media and methods, etc.

Some countries where strict Halal standards are applied, put the factories or corporations producing Halal products under the obligation of the participation of a Muslim in their management and two Muslims in their Halal committee. The cooperated certification by Shariah Research Institute, Takushoku University and Japan Muslim Association of religious juridical institute has a positive impact on these requesting countries.

4.2 Procedures and Steps for Obtaining Halal Certification in Japan

Corporations who wish to obtain Halal certification should submit (1) the application for contract research to President of Takushoku University. The university responds to the filing corporations with (2) the written approval for accepting the contracted research. Then, (3) the contract for the contracted research is concluded based on the handling rules of the contracted research. The contracting parties are President from the corporation and President from the university.

After the conclusion of the contract, Shariah Research Institute invites the person in charge from the corporation to the institute and enters into the substantial research and survey. The Institute makes the corporation submit their written intention to the institute. That is (4) the request for obtaining Halal certificate. At the same time the institute receives (5) the detailed data relating the products of the corporation. Science Committee belonging to Shariah Committee of Shariah Research Institute investigates such materials.

Shariah Committee sometimes entrusts scientific experiments and laboratory analysis to specialized agencies.

Not less than two inspectors entrusted from Shariah Committee (each of them is a Shariah expert or an engineer) conduct the factory and on-site inspection. They have to inspect and investigate the storages of raw materials and products, the production site and process of the corporation and the supplier of raw materials, if necessary, the production site of original raw materials. After the on-site inspection and investigation, Shariah Committee considers the nature of Halal. When there is no problem, the institute (TSRI) recommends Japan Muslim Association (JMA) to issue the Halal certificate.

Above-mentioned is the simple flow of contracted research and research and investigation.

What is remarkable here is that confidentiality articles, which are common for the corporation, are described within (3) the contract for the contracted research. If the corporation does not disclose all information about such products, it will be impossible to judge the nature of Halal under Islamic laws. Thus, the corporation should disclose their strictly secret information in order that the institute may judge the nature of Halal. If the corporation is hesitant to disclose such information, it would be better for the corporation not to think of filling Halal certification.

Furthermore, the corporation is obliged to keep “Shariah compliance” and “maintenance of the nature of Halal”. Concretely, the corporation is obliged to “establish Halal Committee”, and “establish and implement Halal Assurance

System (HAS)". Furthermore, every quarter, the corporation is obliged to submit the minutes of "Halal Committee" and "review records of Halal Manual".

Regarding handling of Halal, when doubts arise on reports and actual condition of the corporation, Shariah Committee is obliged, according to Islamic laws, to conduct strict re-examination, cancel the Halal certificate and notice the invalidity of such Halal certificate to Islam-related organizations worldwide which exchange the information with Shariah Research Institute.

5. Relation between the Religious Juridical Institute, Japan Muslim Association (JMA) and Shariah Research Institute, Takushoku University (TSRI)

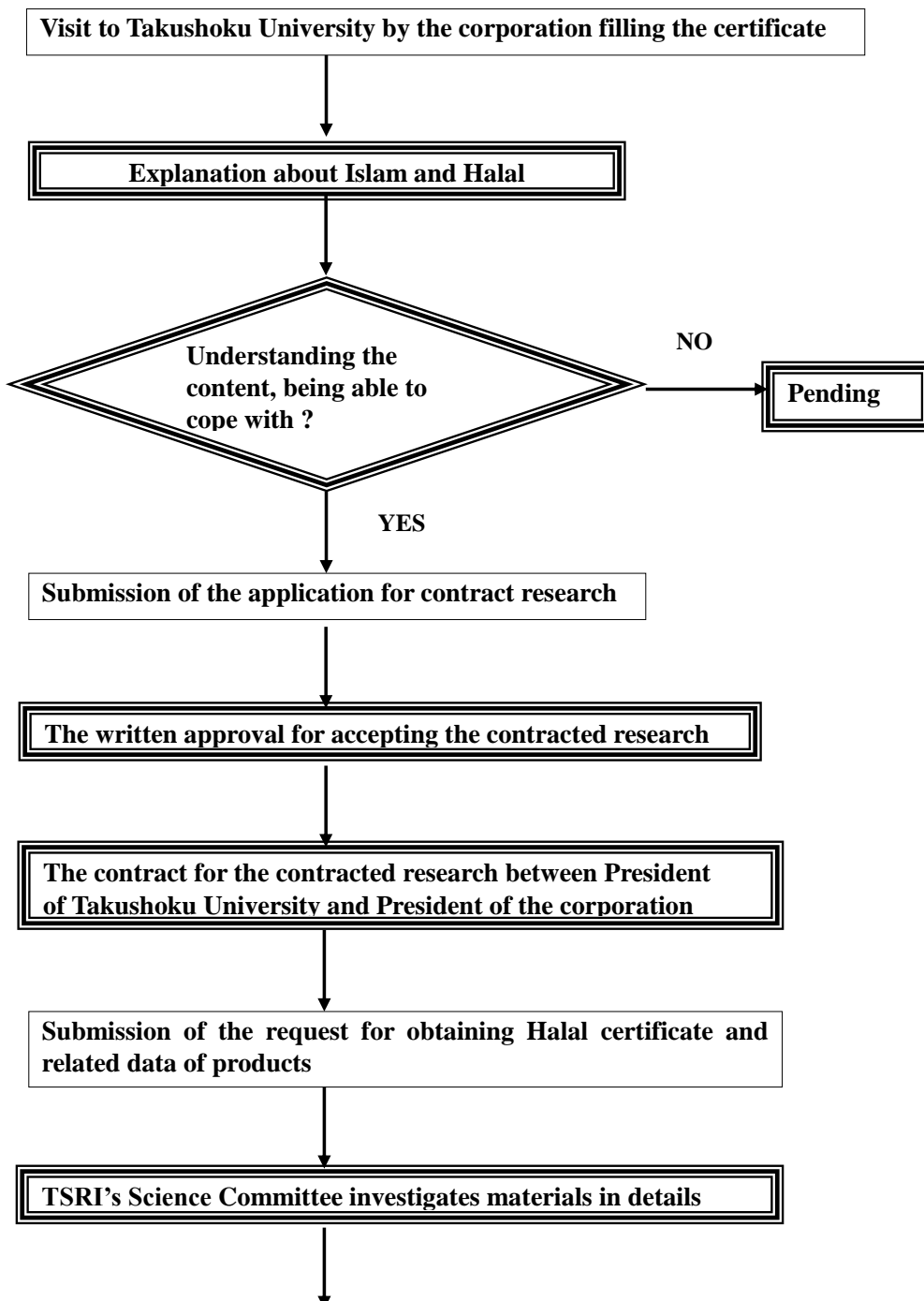
When TSRI investigates the nature of Halal and judges no doubt in the nature, JMA issues "Halal Certificate" based on TSRI's recommendation according to the survey report. The valid duration of the certificate is a year.

End of Prof. Muto's Description

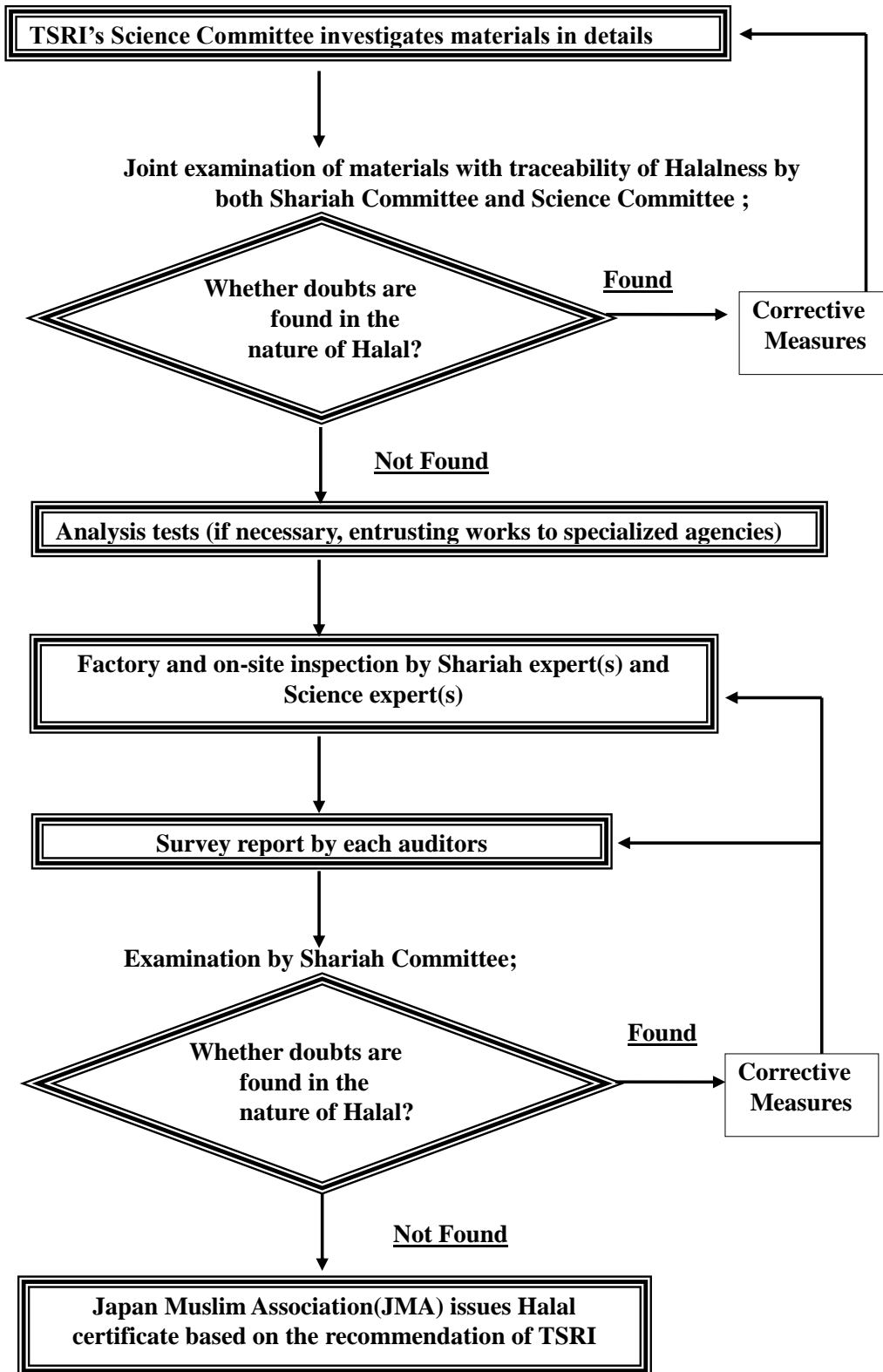
[Flowchart of Japan's Certification Work Procedure]

□ : Work at a corporation wishing to file the certificate

▭ : Work at Shariah Research Institute, Takushoku University or Japan Muslim Association (JMA)



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5.5 Conclusion

When looking at the increase of global Muslim population, we realize the expansion and growth of “Halal” market.

As described in the paragraph of obtaining Halal certificate, we can recognize the important role of raw material suppliers because Halal certificate cannot be obtained only through the efforts of the manufactures of final products. In the future, Japanese business operators who have thought of the business within Japan will foresee the possibility to directly or indirectly get involved in the needs of “Halal”.

Japanese food business operators will easily understand and address Halal not by regarding Halal as a “religious” matter, but by watching their operation in line with the customers' needs or local requirements, that is to say, by regarding Halal as the matter of compliance.

6. Report of the International Conference

As a part of reports of the research on “Sharing Information on Food Standards and Methods of Analysis in East Asia”, which were conducted for the FY2009~2011 Overseas Business Support Project for Japanese Food Industry in East Asia supported by Ministry of Agriculture, Forestry and Fisheries (MAFF), the following international conference was held at Hotel Mulia Senayan in Jakarta, Indonesia, on February 21, Tuesday, 2012.

International Conference for Sharing Information on Food Standards in Asia

Background of the Conference:

The Second ASEAN+3 (inter-governmental) Roundtable Conference on Food Security Cooperation Strategy was held in May 2010 in Tokyo. At the conference, the participating countries shared the recognition of the necessity of dialogues for promotion of agriculture and food industries within the region. Further, the APEC Ministerial Meeting on Food Security was first held in October 2010 in Niigata, Japan, where “dialogues of food industries on quality management and resource and environment conservation” was established as an action plan. Further, this program was also endorsed by the 11th Meeting of the ASEAN Ministers on Agriculture and Forestry plus Three (11th AMAF+3) held in October 2011 in Jakarta.

In line with the above agreement and in accordance with the Overseas Business Support Project for Japanese Food Industry in East Asia by the MAFF, in order to expand distribution of foods and food materials in the region, product standards, methods of analysis, and conditions for use of food additives for foods and food materials are desired to be standardized or harmonized in the region.

Purposes of the International Conference:

In order to strengthen food industries’ capacity of quality and safety control of foods in the region for enhancement of their international competitiveness, it is of key importance for the food industries in the region to understand the food standards and methods of analysis in the countries in the region. Thus, this international conference was held for the following purposes: 1) To investigate the commodity food standards and methods of analysis in the region and to contribute to the mutual understanding. 2) To contribute to future possibility of integration or harmonization of the commodity food standards and methods of analysis in the region. 3) To contribute to the mutual understanding in the region for sharing information on food safety issues (risk communication) mentioned in 1) and 2), and to further contribute to fair trade and business opportunities for foods in the region through those activities.

At this international conference, after starting with “Promoting Harmonization of Food Standards in ASEAN” as a Keynote Speech, the following 3 sessions were reported: 1) the outline and progress of the regulatory authorities and food industries toward harmonization of food standards, and the importance of the risk evaluation about the food consumption in ASEAN countries (Session 1), 2) the results of the research of food standards and analytical methods, and the regulation for food additives by ILSI Japan and ILSI Focal Point in China and ILSI Korea (Session 2), and 3) the risk recognition and communication for food safety, the food safety control system and topics for food safety in Japan, and the activities of Yakult in Indonesia (Session 3). The Conference was attended by total 127 participants from 9 ASEAN countries (Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam), plus Australia, China, Korea, Japan, UK and USA, from those Governments (47 participants) as well as food industries (80 participants). The interests of the administrators and food industries in harmonization of the standards for foods and agricultural products in the ASEAN countries were very high and the topics were actively discussed.