

FY 2012 Financial Supports for Promoting the “Sixth Industry”
in Agriculture, Forestry and Fisheries in Rural Areas
Export Promotion of Agricultural & Marine Products and Food
Overseas Business Support Project for Japanese Food Industry in East Asia

**"Investigation of Commodity Food Standards and
Methods of Analysis in East Asia" (IV)**

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International Life Sciences Institute (ILSI) Japan

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**"Investigation of Commodity Food Standards and Methods of Analysis
in East Asia" (IV)**

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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 through the international ILSI network, the results were shared in the workshops and international meetings to promote further understanding of the issues.

In the preceding projects in the fiscal years (FYs) 2009, 2010, and 2011 of this proposed project in FY 2012, we had investigated Codex, Korea, China, as well as Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam in ASEAN. The results of these investigations were released at the Workshop for "Sharing Investigation and Results on Food Standards in East Asia" in March 2010, in Tokyo; the International Conference for "Sharing Information on Food Standards and Resource and Environmental Conservation for Food Industries in Asia Pacific" in March 2011, in Bangkok, Thailand; and the International Conference for "Sharing Information on Food Standards in Asia" in February

2012, in Jakarta, Indonesia; for as many as 163, 115, and 127 participants, respectively, to confirm the considerable need and expectation for such information on investigation.

Based on these investigations, the FY 2012 survey aimed India where further expanding market is expected, with the surrounding Bangladesh, Nepal, and Sri Lanka to a maximum extent, to investigate regulatory framework on food, specifications and standards and methods of analysis of food, and conditions of use of food additives. The debriefing session of “Regularity Framework and Case Studies of Food and Food Additives in India, Bangladesh, Nepal, and Sri Lanka” was held on February 22, 2013 in Tokyo to share the information of investigation reports.

The investigations on Codex, Korea, China, and ASEAN countries were continued for updating with additional information, as well as for establishing data base of the previous results in the FYs 2009, 2010, 2011, and 2012.

The previous and latest investigations are outlined below.

Fiscal Year	Investigation Contents	Countries and Organization Investigated	Workshop / International Conference	Date and Place Held	Participants
2009 (I)	Legal Framework of Foods; Specification & Standards of Instant Noodles, Carbonated Soft Drinks, and Prepared Frozen Foods	Codex, Korea, China, Malaysia, Singapore, and Philippines	“Sharing Investigation Results on Food Standards in East Asia”	March 29, 2010, Tokyo Japan	163
2010 (II)	Legal Framework of Foods; Specifications & Standards and Methods of Analysis for Instant Noodles, Carbonated Soft Drinks, Prepared Frozen Foods, and Cow’s Milk	Codex, Korea, China, Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam	“Sharing Information on Food Standards and Resource and Environmental Conservation in Asia Pacific”	March 4, 2011, Bangkok Thailand	115
2011 (III)	Legal Framework of Foods and Food Additives; Conditions of Use of Food Additives in Instant Noodles, Carbonated Soft Drinks, Prepared Frozen Foods, and Cow’s Milk; and Halal System	Codex, Korea, China, Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam	“Sharing Information on Food Standards in Asia”	February 21, 2012, Jakarta Indonesia	127
2012 (IV)	Legal Framework of Foods and Food Additives; Specifications & Standards and Methods of Analysis for Instant Noodles, Carbonated Soft Drinks, Prepared Frozen Foods, and Cow’s Milk; and Regulatory System and Conditions of Use of Food Additives	India, Bangladesh, Nepal, and Sri Lanka; Codex, Korea, China, and ASEAN countries	Regulatory Framework and Case Studies of Food and Food Additives in India, Bangladesh, Nepal, and Sri Lanka	February, 22, 2013, Tokyo	80

2.1 Countries and Organization 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 FY 2009 project: Korea, China, Malaysia, Singapore, and Philippines. In FY 2010, we added 3 countries: Indonesia, Thailand, and Vietnam; in the FY 2011 project, we surveyed India, as well as the surrounding Bangladesh, Nepal, and Sri Lanka.

As mentioned above, we continued to investigate Codex, Korea, China, and ASEAN countries in FY 2012.

2.2 Food(s) Covered by the Investigation

In addition to the investigations for instant noodles, carbonated soft drinks, and prepared frozen foods in FY 2009, we mainly surveyed specifications & standards and methods of analysis of foods including cow's milk and milk products in the FY 2010 project considering the needs of the food companies. In the FY 2011 project, we added investigations focusing on the regulatory system and conditions for use of food additives in these countries.

In the FY 2012 project, we investigated the legal framework, specifications & standards and methods of analysis for food including instant noodles, carbonated soft drinks, prepared frozen foods, and cow's milk and its products, and conditions for use of food additives as before.

2.3 Procedures of the Investigation

This project was conducted by International Life Sciences Institute (ILSI) Japan, a specified non-profit organization, with the cooperation of its international network, especially ILSI India, as well as ILSI Korea, ILSI Focal Point in China and ILSI Southeast Asia Region (ASEAN countries), following the procedures below:

- (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 held a debriefing session of "Regulatory Framework and Case Studies of Food and Food Additives in India, Bangladesh, Nepal, and Sri Lanka" on February 22, 2013, in Tokyo.
- (7) ILSI Japan published the reports and disseminated them on the ILSI Japan website simultaneously.

2.4 Project Team

ILSI Japan set up a project team within its "International Cooperation Committee." The member represented each field of investigations including Indian market, food specifications & standards, methods of analysis, and food additives. The team designed the program, proposed the items to be investigated, discussed with ILSI branch offices of India, Korea, China, and Southeast Asian Region, and finally determined them.

The project team conducted the investigation using the above mentioned network of ILSI branches.

Host	Responsible ILSI Branch	Countries Investigated
ILSI Japan (which investigated Japan and Codex, and controlled all the program)	ILSI India	India, Bangladesh, Nepal, and Sri Lanka
	ILSI Korea	Korea
	ILSI FP China	China (except Hong Kong and Taiwan)
	ILSI Southeast Asian Region	Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam (major 6 countries of ASEAN)

2.5 Investigation Schedule

This proposed project was conducted according to the following schedule in FY 2012.

- Preliminary investigations, investigation program design, and development of investigation forms: August to September, 2012 (2 months)
- Investigations and filling in the investigation forms in each country: October to December, 2012 (3 months)
- Collection and analysis of the data, and extraction of future tasks: January to February, 2012 (2 months)
- Debriefing session/international conference: February 22, 2013, Tokyo
Preparation of the report: March, 2013 (1 month)
- Duration of the whole program: 8 months

3. Investigation Results of Each Country

3.1 Republic of India · · · 7

3.2 Democratic Socialist Republic of Sri Lanka · · · 28

3.3 Federal Democratic Republic of Nepal · · · 59

3.4 People's Republic of Bangladesh · · · 84

3.1 Republic of India

1. FOOD ADMINISTRATION

In India, The Food Safety and Standards Authority of India (FSSAI), which has been established under the Food Safety Standard Act, 2006, is responsible for food standards, safety and hygiene control. FSSAI 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.

On the other hand, product certification system, including a lot of kinds of food standards, is conducted by the Bureau of Indian Standards (BIS). The BIS is supervised by Ministry of Consumer Affairs, Food and Public Distribution, which is concerned in the food administration through several laws. In addition to that, some kinds of laws concerning the food regulation are controlled by Ministry of Women and Child Development, Ministry of Agriculture, Department of Atomic Energy and Atomic Energy Regulatory Board. The Ministry of Food Processing Industries, set up in July 1988, is the main central agency of the Government responsible for developing a strong and vibrant food processing sector; with a view to create increased job opportunities in rural areas, enable the farmers to reap benefit from modern technology, create surplus for exports and stimulating demand for processed food. Several personnel have been dispatched to FSSAI from this Ministry. All administrative bodies of food safety are summarized in Table 1.

Table 1: Food Administrative Bodies in India

Administrative Bodies	Responsible Divisions	Related Laws^(a)
Ministries of		
Health and Family Welfare	FSSAI ^(b)	<ul style="list-style-type: none"> • Food Safety and Standards Act, 2006 • Food Safety and Standards Regulations, 2011 • Food Safety and Standards Rules, 2011
Consumer Affairs, Food and Public Distribution	BIS ^(c)	<ul style="list-style-type: none"> • The Bureau of Indian Standards Act, 1986 • The Standards for Weights and Measures Act, 1976 • The Standards for Weights and Measures Rules, 1977
Women and Child Development		<ul style="list-style-type: none"> • The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003
Agriculture		<ul style="list-style-type: none"> • Agricultural Produce (Grading and Marking) Act, 1937

		<ul style="list-style-type: none"> • The General Grading and Marking Rules, 1988
	Food Processing Industries	<ul style="list-style-type: none"> • (The origin of the existing “Food Safety and Standards Act, 2006” was proposed by this Ministry.)
	Atomic Energy Commission	<ul style="list-style-type: none"> • The Atomic Energy Act, 1962
		<ul style="list-style-type: none"> • Atomic Energy (Control of irradiation of Food) Rules, 1996

(a) All laws related to the administrative bodies are detailed in “1.3. Laws and Regulations related to Foods” of this report.

(b) FSSAI: The Food Safety and Standards Authority of India.

(c) BIS: The Bureau of Indian standards.

(d) DAE: Department of Atomic Energy.

(e) AERB: Atomic Energy Regulatory Board.

1.1 Establishment of Food Safety and Standard Authority of India

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

1.2 Important Roles of Food Safety and Standards Authority of India

FSSAI conducts following important roles (Figure 1).

- 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.

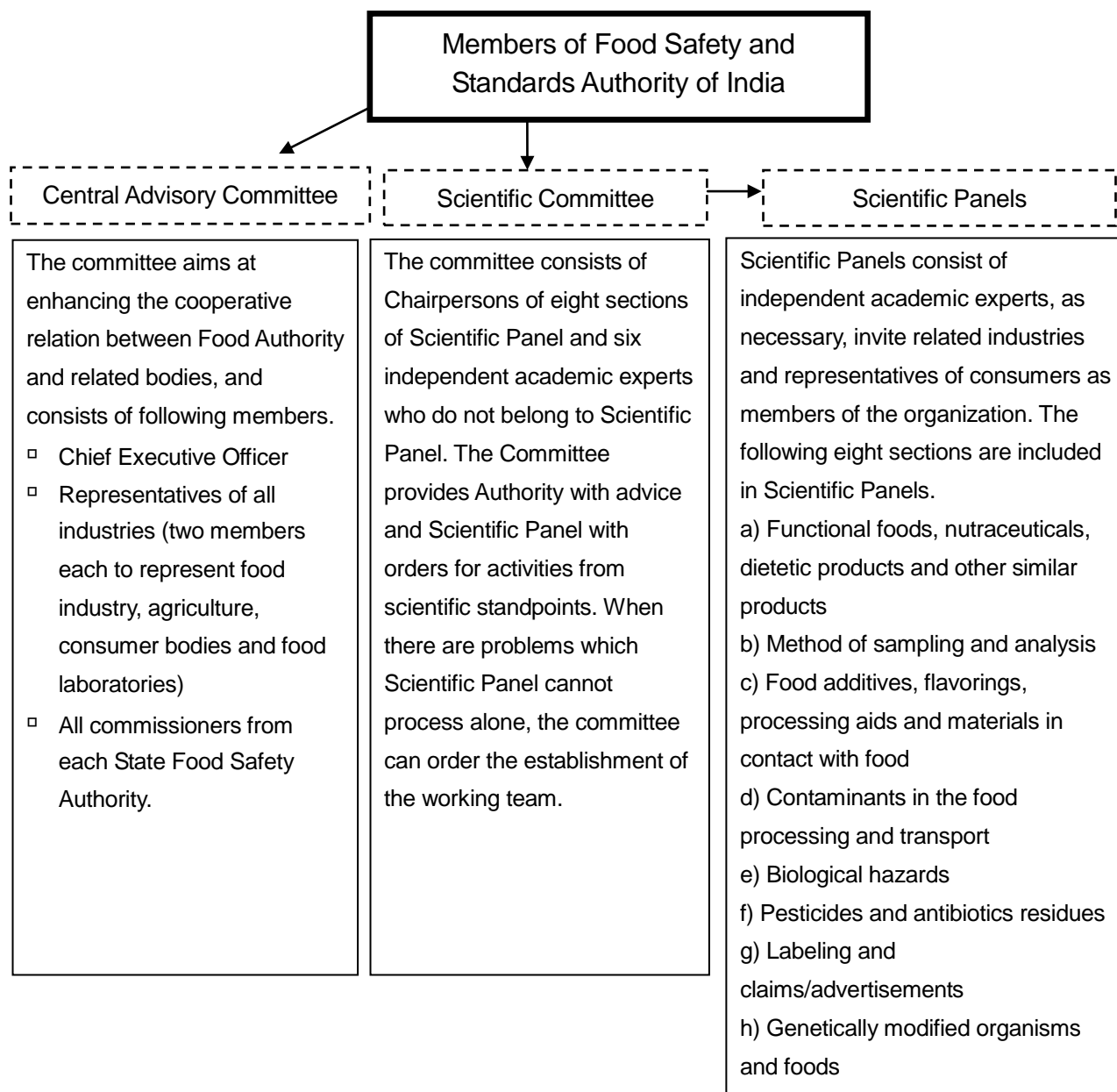


Figure 1: Outline of Food Safety and Standards Authority of India

2. SUMMARY OF RELATIONSHIP BETWEEN FOOD REGULATORY SYSTEM AND COMMODITY FOOD STANDARDS

Major acts and regulations related to Commodity Standards in India are presented in Figure 2.

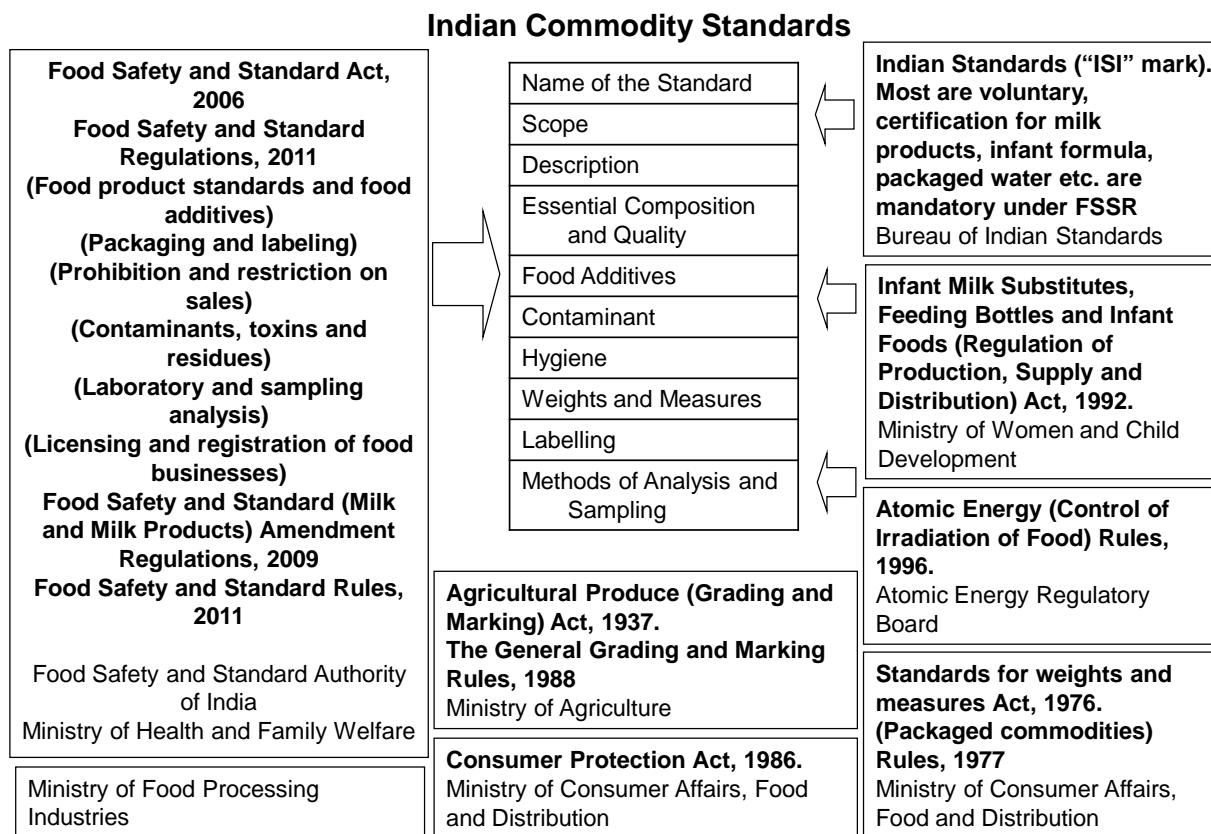


Figure 2: Summary of Food Standards and Relevant Laws in India

3. LAWS AND REGULATIONS RELATED TO FOODS

Indian food related laws had undergone repeated amendments since establishment of Prevention of Food Adulteration (PFA) Act, 1954 and Rules, 1955, 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. Therefore, from early 2000s, 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.

3.1 Food Safety and Standards Act, 2006

In January 2005, Food Safety and Standards Bill, which was the origin of the existing Food Safety and Standards Act, 2006 (FSS Act), was proposed by Ministry of Food Processing Industries. An inter-ministerial Committee headed by the Minister for Food Processing Industries prepared the draft. It was passed by the Parliament in 2006. FSS

Act came into force in August, 2006. However, Food Safety Authority was established in 2007 as an independent Authority with Ministry of Health and Family Welfare as the administrative ministry. FSS Act consists of twelve chapters. The following items are established.

- Establishment of Food Safety and Standards Authority of India (composition, functions, procedure and duties)
- General principles of food safety (not only the protection of human health, but also the protection of consumers' benefit including fair food transaction, appropriate risk management based on scientific reasons and preventive measures at appropriate level are set forth)
- General provisions as to articles of food
 - Use of food additive or processing aid
 - Contaminants, naturally occurring toxic substances, heavy metals, etc
 - Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts
 - Genetically modified foods, organic foods, functional foods, proprietary foods, etc
 - Packaging and labelling of foods
 - Restrictions of advertisement and prohibition as to unfair trade practices
- Provisions relating to import
- Special responsibilities as to food safety (responsibilities of the food business operators, food recall procedure)
- Analysis of food (laboratories, auditors, analysts, procedure)
- Implementing sectors and their administrations, penalties, appeal organizations

Based on the enforcement of FSS Act, the structure which can almost unify the management of the food related laws was established. The following regulations and rules are detailed laws of FSS Act.

3.2 Food Safety and Standards Regulations, 2011

Food Safety and Standards Regulations, 2011 (FSS Regulations, 2011) was released under FSS Act in August, 2011. Because some words and clauses in FSS Act should be amended, corrigenda were published in December, 2011. At the same time, regulations which were established for some specific food categories were consolidated into one regulation. FSS Regulations, 2011 was divided into 6 parts that were listed as below.

- Contaminants, Toxins and Residues
- Food Product Standards and Food Additives
- Laboratory and Sampling Analysis
- Licensing and Registration of Food Businesses
- Packaging and Labelling
- Prohibition and Restriction on Sales

With regard to the milk and milk product, although it had been regulated by the Milk and Milk Products Order, 1992 previously, the Regulations have been amended to “FSS (Milk and Milk Products) Amendment Regulations, 2009”. The Regulations, which are

conducted by FSSAI, can be applied as same as FSS Regulations, 2011 under FSS Act.

The standards for food products and additives have been prescribed in the FSS (Food Product Standards and Food Additives) Regulations, 2011. These standards are substantially the same as were notified under the PFA Rules 1955 which was repealed in 2011. Although the standards have evolved over a period of time on the basis of contemporary data, scientific development and various other factors, many of the standards have not been reviewed for a long time. Thus, FSSAI has decided to review the existing standards and invited comments for the modification of existing, or inclusion of new standards of food products or additives in 2012. In addition, draft Food Authority's Food Recall Procedures Regulations, 2009, draft Regulations for Food for Special Nutritional or Dietary Uses 2010, revised draft on Regulation of Energy Drinks, and Caffeine, revised draft on Regulation of Trans Fatty Acids, TFAs, in Partially Hydrogenated Vegetable Oils, PHVOs, draft on Operationalizing the Regulation of Genetically Modified Foods in India and draft outline of FSS (Food Import) Regulation, 2011 were announced and public comments were invited. On December 27, 2012 draft regulation on labelling (claims) has been issued for public comments. It proposes general principles for making claims on pre-packed foods, defines general and specific condition for nutrition and health claims, and provides for claims related to dietary guidelines or healthy diets.

Now the works for reviewing standards and making new regulations are on-going.

3.3 Food Safety and Standards Rules, 2011

Food Safety and Standards Rules, 2011 (FSS Rules) was released under FSS Act in January, 2011. FSS Rules consists of following chapters and shows the procedures for execution of FSS Act.

- Definition
- Enforcement structure and procedures
- Adjudication and appeal to tribunal

3.4 Indian Standards (“ISI” mark)

In India, the Bureau of Indian Standards (BIS), which is supervised by Department of Consumer Affairs of Ministry of Consumer Affairs, Food and Public Distribution, conducts Product Certification Scheme based on The Bureau of Indian Standards Act, 1986 and its related laws. BIS licenses suppliers, including agriculturists, textile and electric equipment manufacturers and other wide variety of producers, to use certification marks, so called ISI marks (Figure 3). Food & Agriculture Department of BIS has 1800 kinds of standards in the various fields of foods. BIS, which was called Indian Standards Institution (ISI) before 1986, has been using ISI marks yet. Although Product Certification Scheme is basically on voluntary system, some kinds of products are compulsorily required to obtain ISI mark certified by BIS. In the mandatory certification list of BIS, there are 14 kinds of food related products as described below, among 83 kinds of products of all industry. All standards of mandatory certification have already been integrated in the FSS (Prohibition

& Restriction on sales) Regulations, 2011, Solvent Extracted Oil, Deoiled Meals and Edible Flour (Control) Order, 1967 or The Infant Milk Substitutes, Feeding Bottles and Infant Foods (regulation of production, supply and distribution), Act 1992 and Rules 1993. Each law provides following items.

- FSS (Prohibition & Restriction on sales) Regulations, 2011
 - Milk powder
 - Condensed milk, partly skimmed and skimmed condensed milk
 - Milk-cereal based weaning foods
 - Processed cereal based complementary foods for infants
 - Sweetened ultra-high temperature treated condensed milk
 - Skimmed milk powder, standard grade
 - Skimmed milk powder, extra grade
 - Partly skimmed milk powder
 - Infant milk substitute, Milk protein based
 - Packaged Natural Mineral Water
 - Packaged Drinking Water (Other than Packaged Natural Mineral Water)
 - Follow-up-formula-Complimentary Food-Specification
- Solvent Extracted Oil, Deoiled Meals and Edible Flour (Control) Order, 1967
 - Hexane, Food grade
- The Infant Milk Substitutes, Feeding Bottles and Infant Foods (regulation of production, supply and distribution), Act 1992 and Rules 1993
 - Plastic Feeding Bottles



Figure 3: ISI mark

3.5 The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003 (IMS Act)

The Act provides for the regulations of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto. It prohibits anyone to advertise, or take part in the publication of any advertisement, for the distribution, sale or supply of infant milk substitutes feeding bottles or infant foods; or give an impression or create a belief in any manner that feeding of infant milk substitutes and infant foods are equivalent to, or better than, mother's milk; or take part in the promotion of infant milk substitutes, feeding bottles or infant foods. It also prohibits that or the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods. No person shall supply or distribute

samples of infant milk substitutes or feeding bottles or infant foods gifts of utensils or other articles; or contact any pregnant woman or the mother of an infant; or offer inducement of any other kind. The BIS mandatory certifications, which are related to infant milk and feeding bottles, are mentioned in particular clauses of the Act. Ministry of Women and Child Development is responsible for the administration of the act.

3.6 The Standards for Weights and Measures Act, 1976, and Rules, 1977

Inter-state trade and commerce and commodities sold, distributed or supplied by weights and measures are regulated by The Standards for Weights and Measures Act, 1976. The Act also conducts pre-packed commodities sold or intended to be sold in the course of inter-state and commerce. The application of the Act is not only to Inter-state of India but also to export and import. The specification of the Act, which are given in the Standards of Weights and Measures (General) Fourth Amendment Rules, 2005, and the Standard Weights and Measures (Packaged commodities) Rules, 1977, provides to prescribe specification of measuring instruments used in commercial transaction, industrial production a measurement involved in public health and human safety. The responsibility in relation to weights and measures is shared between the States and the Central government, Ministry of Consumer Affairs, Food and Public Distribution.

3.7 Agricultural Produce (Grading and Marking) Act, 1937, and the General Grading and Marking Rules, 1988

Agricultural Produce (Grading and Marking) Act, 1937 as amended up to 1986 is an act to provide for the grading and marking of agricultural and other produce. According to the above Act, the General Grading and Making Rules, 1988 have been notified in which the detailed procedures of licensing, setting up of laboratories, consumer protection measures etc. have been given. The Ministry of Agriculture is vested with the responsibility to enforce and implement this Act. To carry out the provisions of the Act, the Central Government makes rules and such rules may provide for all or any of the following matters; namely:

- Fixing grade designation to indicate the quality of any scheduled article,
- Defining the quality indicated by every grade designation,
- Specifying grade designation marks to represent particular grade designations,
- Authorizing a person or a body of persons, subject to any prescribed conditions, to mark with a grade designation mark any article in respect of which such mark has been prescribed or any covering containing or label attached to any such article,
- Specifying the conditions referred to in previous clause including in respect of any article conditions as to the manner of marketing, the manner in which the article shall be packed, the type of covering to be used and the quantity by weight, number or otherwise to be included in each covering.
- Providing for the payment of any expenses incurred in connection with the manufacture or use of any implement necessary for the reproduction of a grade designation mark or with the manufacture or use of any covering or label marked with a grade designation mark or with measures for the control of the quality of articles marked with grade designation marks including testing of samples and

inspection of such articles or with any publicity work carried out to promote the sale of any class of such articles.

- Providing for the confiscation and disposal of produce marked otherwise than in accordance with the prescribed conditions with a grade designation mark,
- Any other matter which required to be, or may be, prescribed.

3.8 Microbial Food Safety Regulations

In India, microbial food safety has been enforced through various regulatory mechanisms, such as The Prevention of Food Adulteration Act, 1954 and Rules, 1956, The Fruit Products Order, 1955, The Meat Food Products Order, 1973 and Vegetable Oil Products (Control) Order, 1947. However these regulations prescribe food standards but do not seek to identify and prevent source of contamination. Therefore, India has reoriented its food regulations to emphasize and ensure food safety, food hygiene and food quality as a holistic approach, and then, FSSAI has been established based on FSS Act, 2006.

As far as microbiological food safety, BIS has formulated many standards. BIS has formulated standards on test methods for detection and enumeration of pathogenic microorganisms in food and specifications for ingredients used in media for microbiological work. Limits of microbiological parameters for processed food products are specified in respective Indian Standards. BIS has also formulated code of hygienic conditions for various food industries, and has adopted Codex HACCP, Food Hygiene guidelines and ISO 22000 as Indian Standards. Important codes for good practices to guide food business operators at all levels of the food chain such as Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP), Good Retail Practices (GRP) and Good Agricultural Practices (India GAP) are now under formulation.

3.9 Regulatory Framework for Nuclear and Radiation Facilities

In India, the basic law of activities regarding atomic energy is The Atomic Energy Act, 1962. The top organization of the system is Atomic Energy Commission (AEC) which makes the atomic energy policy. And a lot of regulations and rules are enacted to conduct the atomic energy by branch institutions, such as Department of Atomic Energy (DAE) and Atomic Energy Regulatory Board (AERB). DAE is directly administered by prime minister and has affiliated the research institutes, industries and power generations of the atomic energy. AERB, which was provided in The Atomic Energy Act, 1962 and established in 1983, is independently responsible for the safety control and regulatory function and has the authority to make safety regulations and rules and to supervise each section of DAE and radiation dealers. The chief laws are listed as below.

- The Atomic Energy Act, 1962
- Atomic Energy (Arbitration Procedure) Rules, 1983
- Atomic Energy (Working of the mines, minerals and handling of prescribed substances) Rules, 1984
- Atomic Energy (Safe disposal of radioactive wastes) Rules, 1987
- Atomic Energy (Factories) Rules, 1996
- Atomic Energy (Control of irradiation of Food) Rules, 1996

- Atomic Energy (Radiation Protection) Rules, 2004
- Civil liability for Nuclear Damage Act, 2010

3.10 The Consumer Protection Act, 1986 and Rules, 1987

The Consumer Protection Act, 1986 seeks to provide for better protection of the interests of consumers and for the purpose, to make provision for the establishment of Consumer Protection Councils and other authorities for the settlement of consumer disputes and for matter connected therewith. In addition, The Consumer Protection Rules, 1987 came into force in April, 1987. The laws are conducted by Department of Consumer Affairs of Ministry of Consumer Affairs, Food and Public Distribution. The following rights of consumers were defined in The Consumer Protection Act, 1986.

- To be protected against marketing of goods which are hazardous to life and property
- To be informed about the quality, quantity, potency, purity, standard and price of goods to protect the consumer against unfair trade practices
- To be assured, wherever possible, access to an authority of goods at competitive prices
- To be heard and to be assured that consumers interests will receive due consideration at appropriate forums
- To seek redressal against unfair trade practices or unscrupulous exploitation of consumers
- Consumer education

Based on The Consumer Protection Act, 1986, these objects are sought to be promoted and protected by the Consumer Protection Council to be established at the Central and State level. To provide speedy and simple redressal to consumer disputes, a quasi-judicial machinery is sought to be setup at the district, State and Central levels. These organizations are generally called Consumer Court which includes Consumer Disputes Redressal (CDR) Forum for districts and CDR Commission for States and for Central, respectively.

4. FOOD ADDITIVE REGULATIONS

4.1 Food Additive Definitions and their Categories

'Food Additive' is defined in the CHAPTER I PRELIMINARY Article 3 of FSS ACT, 2006 as below.

(k) "food additive" means any substance not normally consumed as a food by itself or 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 by-products becoming a component of or otherwise affecting the characteristics of such food but does not include "contaminants" or

substances added to food for maintaining or improving nutritional qualities.

Also, in FSS Regulations, 2011, the following additive categories exist under Chapter 3. Most of these categories also include their definition in each section respectively:

Colouring Matter, Artificial Sweeteners, Preservatives, Anti-oxidants, Emulsifying agents, Stabilising agents, Anticaking Agents, Antifoaming agents in edible oils and fats, Release agents, Flavouring Agents, Flavour Enhancers, Sequestering Agents and Buffering Agents.

‘Flavours’ are described in Article 3 of the same FSS Regulations, 2011.

1) Flavouring agents include flavour substances, flavour extracts or flavour preparations, which are capable of imparting flavouring properties, namely taste or odour or both to food. Flavouring agents may be of following three types:-

(i) Natural Flavours and Natural Flavouring substances means flavour preparations and single substance respectively, acceptable for human consumption, obtained exclusively by physical processes from vegetables, for human consumption.

(ii) Nature-Identical Flavouring Substances means substances chemically isolated from aromatic raw materials or obtained synthetically; they are chemically identical to substances present in natural products intended for human consumption, either processed or not.

(iii) Artificial Flavouring Substances means those substances which have not been identified in natural products intended for human consumption either processed or not.

‘Processing Aid’ is expressed in the FSS ACT, 2006, CHAPTER IV GENERAL PROVISIONS AS TO ARTICLES OF FOOD Article 19. It reads as below.

Use of food additives or processing aids: No article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of this Act and regulations made thereunder. “Processing aid” means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, 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 unintentional but unavoidable presence of residues or derivatives in the final product.

4.2. Approved Food Additives and their Standards of Use

Approved Food Additives are described and defined in FSS (Food Product Standards and Food Additives) Regulations, 2011 and some of their standards of use are also described there. In its Chapter 3: SUBSTANCES ADDED TO FOOD reads,

3.1: Food Additives:

3.1.1: 1) Use of Food Additives in Food Products: The food products may contain food additives as specified in these Regulations and in Appendix A.

In addition, Appendix A includes list of food additives with their limitations/restrictions of use in food categories. There also are some restrictions/limitations of use of food additives described in standards of some food categories. For example, there is a special list of additives that can be used for infant formula. Further, some sections of food additive

categories have their limitations/restrictions of use for some food categories.

4.3 Prohibited Substances for Use in Foods as Food Additives

As mentioned above, only the permitted additives can be used in food in India, but food additives may have some restriction or standards of use for specific food categories one another.

There is a list of food additives (flavourings) that shows their prohibition of use in all foods in 3.1.10 of FSS (Food Product Standards and Food Additives) Regulations, 2011 as follows:

4) Restriction on use of flavouring agents:

The use of the following flavouring agents are prohibited in any article of food, namely:-

- (i) Coumarin and dihydrocoumarin,*
- (ii) Tonka bean (Dipteryl adorat),*
- (iii) β -asarone and cinnamyl anthracilate,*
- (iv) Estragole,*
- (v) Ethyl methyl ketone,*
- (vi) Ethyl-3-phenylglycidate,*
- (vii) Eugenyl methyl ether,*
- (viii) Methyl β naphthyl ketone,*
- (ix) P.Propylanisole,*
- (x) Safrole and Isosafrole,*
- (xi) Thujone and Isothujone or α - and β -thujone.*

4.4 Food Additive Specifications

In the section 3.2: Standards of Additives of FSS (Food Product Standards and Food Additives) Regulations, 2011, so far only the specifications of colorants are described under 3.2.1.

There are some specifications for sweeteners such as saccharin sodium in Food Product Standard (section 2.8), and for others are not available. On the other hand, the Bureau of Indian Standards (BIS) set standards for 91 food additives.

In the current regulatory frame work for food and food additives, BIS certification is voluntary; however, importer of specific food additives shall register to BIS.

4.5 Application and Approval of New Food Additives

A new food additive or food additives that are not described in any FSS regulations are required to get its approval from FSSAI. Specifying the limits for use of food additives and processing aids is a responsibility of Food Authority.

Application format and summary sheet for approval of food additives were announced by the Scientific Panel on food additives, flavouring, processing aids and materials in contact

with food on April 4th, 2012. It explains that

“Applicants should apply for the approval of food additives/enhancement of permitted food additives in other food products as well as increase the existing quantity of permitted food additives in the food product in the enclosed prescribed format. The application should be addressed to Director (PA), Food Safety and Standards Authority of India.”

Application format and summary sheet for approval of food additives:

([http://www.fssai.gov.in/Portals/0/Pdf/Note_for_FSSAI_website\(04-04-2012\).pdf](http://www.fssai.gov.in/Portals/0/Pdf/Note_for_FSSAI_website(04-04-2012).pdf))

4.6 Labelling of Food Additives Used in Foods

Labelling of food additives that are used in foods is defined in FSS (Packaging and Labelling) Regulations, 2011. In 2.2.2 (*Labelling of Pre-packaged Food*) it reads,

2.(d) Where an ingredient itself is the product of two or more ingredients, such compound ingredients shall be declared in the list of ingredients, and shall be accompanied by a list, in brackets, of its ingredients in descending order of weight or volume, as the case may be. Provided that where a compound ingredient, constitutes less than five per cent of the food, the list of ingredients of the compound ingredient, other than food additive, need not to be declared;

Regarding the functional classifications of food additives, it is described in “Article 5. Declaration regarding Food Additives” of FSS (Packaging and Labelling) Regulations, 2011, as follows:

5. Declaration regarding Food Additives-

(i) For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific names or recognized international numerical identifications:

Acidity Regulator, Acids, Anticaking Agent, Antifoaming Agent, Antioxidant, Bulking Agent, Colour, Colour Retention Agent, Emulsifier, Emulsifying Salt, Firming Agent, Flour Treatment Agent, Flavour Enhancer, Foaming Agent, Gelling Agent, Glazing Agent, Humectant, Preservative, Propellant, Raising Agent, Stabilizer, Sweetener, Thickener

There require specific declarations for foods in which colorants and/or flavourings are added just beneath the ingredient declaration. These requirements are described in 2.2.2.5(ii) of these Regulations.

Further, there are specific requirements relating to food additives for labelling of infant milk substitute and infant food (2.4.1), permitted food colours (2.4.3), salt containing permitted anticaking agent (2.4.5.20), flavoured tea (2.4.5.23), flavour emulsion and flavour paste meant for use in carbonated or noncarbonated beverages (2.4.5.35), and foods added monosodium glutamate (2.4.5.18), artificial sweeteners (2.4.5.24-29), caffeine (2.4.5.38) and enzyme from GMO used for specific variety of cheeses (Table 15).

4.7 Carry Over of Food Additives

FSS (Food product standards and Food Additives) Regulations, 2011 defines “Carry Over” at the Article of ‘3.1.18.’ as follows:

For the purpose of the standards specified in chapter 2 of these regulations the "Carry Over" principle applies to the presence of additives such as colours, flavouring agents, anti-oxidants anti-caking agents, emulsifying and stabilising agents, and preservatives in food, as a result of the use of raw material or other ingredients in which these additives were used. The presence of contaminants is not covered by this purpose.

The presence of an additive in food through the application of the carry over principle is admissible in general unless otherwise specifically prohibited in the regulations provided the total additive including the carry over through the raw material or other ingredients does not exceed the maximum amount so permitted.

4.8 Official Compilation of Food Additives in India

There is no official book like Japan's Specifications and Standards, and specifications and standards of use for some food additives are described or defined in each FSS regulation.

5. CASE STUDIES

In order to compare the contents of food standards set in India, (1) Instant Noodles, (2) Carbonated Soft Drinks, (3) Prepared Frozen Foods and (4) Cow's Milk were chosen.

Regarding the foods which are not prescribed in the FSS Regulations, 2011, the summary is shown in the *Reference: Proprietary Food, as it is described that the proprietary foods shall conform to the requirements prescribed in "2.12: Proprietary Food" in FSS Regulations, 2011.

(1) Instant Noodles

There is no food standard for "instant noodles" in both FSS Regulations, 2011 and Indian Standards. Therefore, Instant Noodles shall comply with the requirements set on "2.12: Proprietary Food" in FSS (Food product standards and Food Additives) Regulations, 2011. Standards related to "Instant Noodles" are described below.

	FSS Regulations, 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) Regulations, 2011 See the section of *Reference: Proprietary Food at the end of this chapter.	NA
Labelling	FSS (Packaging and Labelling) Regulations, 2011 2.2: Labelling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food See the section of **Reference: Labelling of Pre-packaged Food at the end of this chapter.	
Food Additives	FSS (Food product standards and Food Additives) Regulations, 2011	

	3.1: Food Additives	
Contaminants	FSS (Contaminants, Toxins and Residues) Regulations, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene		

(2) Carbonated Soft Drinks

There are two standards relevant to the “Carbonated Soft Drinks” in FSS Regulations, 2011 as follows:

- 2.3.30 Carbonated Fruit Beverages or Fruit Drinks,
- 2.10.6 Beverages Non-Alcoholic-Carbonated.

Also, there are two standards relevant to the “Carbonated Soft Drinks” in Indian Standards as follows:

- IS 2346-1992 Carbonated Beverages,
- IS 12544 1988 Carbonated Beverages - Non-alcoholic Beer.

Standards related to “Carbonated Soft Drink” are described below.

	FSS Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) Regulations, 2011 2.3.30: Carbonated Fruit Beverages or Fruit Drinks 2.10.6: Beverages Non-Alcoholic-Carbonated	
Labelling	FSS (Packaging and Labelling) Regulations, 2011 2.2: Labelling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food See the section of ** Reference: Labelling of Pre-packaged Food at the end of this chapter.	IS 2346: 1992 Carbonated Beverages Specifications IS 12544: 1988 Carbonated Beverages - Non-alcoholic Beer - Specifications
Food Additives	FSS (Food product standards and Food Additives) Regulations, 2011 3.1: Food Additives Appendix A: List of Food Additives	
Contaminants	FSS (Contaminants, Toxins and Residues) Regulations, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene	FSS (Food product standards and Food Additives) Regulations, 2011 Appendix B: Microbiological Requirements	

Standards and methods of analysis of “Carbonated Soft Drinks” are shown below.

Regulations Applied	Items	Specifications	Methods of Analysis	References
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FSS Regulations, 2011 IS 2346: 1992 Carbonated Beverages	Arsenic	Max. 0.1 mg/kg		IS 11124: 1984
	Lead	Max. 0.5 mg/kg		IS 6854: 1973
	Copper	Max. 1.5 mg/kg		IS 6854: 1973
	Iron	Max. 0.5 mg/kg		IS 6854: 1973
	Total plate count	Not more than 50 cfu/mL		IS 5402: 1969
	Coliform count	Absent in 100 mL		IS 5401: 1969
	Yeast and mould count	Not more than 2 cfu/mL		IS 5403: 1969
	Saccharin	-	HPLC method, etc.	IS 2346: 1992
	Gas volume	-		IS 2346: 1992

(3) Prepared Frozen Foods

There is no food standard for “Prepared Frozen Foods” in both FSS Regulations, 2011 and Indian Standards. Therefore, “Prepared Frozen Foods” shall comply with the requirements set on “2.12: Proprietary Food” in FSS (Food product standards and Food Additives) Regulations, 2011. Standards related to “Prepared Frozen Foods” are described below.

	FSS Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) Regulations, 2011 See the section of *Reference: Proprietary Food at the end of this chapter. Depending on type of food products, refer to following standards; 2.1.7: Dairy Based Desserts/Confections 2.5.2: Meat and Meat Products 2.6: Fish and Fish Products	NA
Labelling	FSS (Packaging and Labelling) Regulations, 2011 2.2: Labelling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food See the section of **Reference: Labelling of Pre-packaged Food at the end of this chapter.	
Food Additives	FSS (Food product standards and Food Additives) Regulations, 2011 3.1: Food Additives	
Contaminants	FSS (Contaminants, Toxins and Residues) Regulations, 2011 2.1: Metal Contaminants 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene		

(4) Cow's Milk

There is the standard relevant to the "Cow's Milk" in FSS Regulations, 2011 as follows;

2.1.1 Milk

Also, there are two standards relevant to the "Cow's Milk" in Indian Standards as follows;

IS 4238: 1967 Sterilized Milk

IS 13688: 1999 Packaged Sterilized Milk

Standards related to "Cow's Milk" are described below.

	FSS Regulations, 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) Regulations, 2011 2.1: Dairy Products and Analogues 2.1.1: Milk	IS 4238: 1967 Sterilized Milk Specifications IS 13688: 1999 Packaged Pasteurized Milk -Specifications
Labelling	FSS (Packaging and Labelling) Regulations, 2011 2.2: Labelling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food	
Food Additives	FSS (Food product standards and Food Additives) Regulations, 2011 3.1: Food Additives Appendix A: List of Food Additives Table 14. List of Food Additives for Use in Milk products	
Contaminants	FSS (Contaminants, Toxins and Residues) Regulations, 2011 2.1: Metal Contaminants 2.2: Crop contaminants and naturally occurring toxic substances 2.3: Residues	
Hygiene	FSS (Food product standards and Food Additives) Regulations, 2011 Appendix B: Microbiological Requirements Table 2. Microbiological Parameter for Milk products	

Standards and methods of analysis related to "Cow's Milk (Sterilized Milk)" are shown below.

Regulations Applied	Items	Specifications	Methods of analysis	References
FSS (Milk and Milk Products Regulations), Amended in 2009	Creaming index	Max. 20	Centrifugation	IS 4238: 1967 Sterilized Milk Specifications
	Turbidity test	To conform to specifications		
	Confirmation of Sterility (a)	pH variation on Incubation Day		

		7: Max 0.3		
	Confirmation of Sterility (b)	Titrateable acidity variation on Incubation Day 7: Max. 0.02 g	Titration	
	Bacterial Spores, aerobic	Max. 5 colonies/mL		

***Reference: Proprietary Food and New Product Approval Procedures**

The foods which are not prescribed in FSS Regulations, 2011 shall conform to the requirements prescribed in “2.12: Proprietary Food” in FSS Regulations, 2011.

Followings are the description regarding “Proprietary food.”

- 1) “Proprietary food” means a food that has not been standardized under the FSS Regulations, 2011.
- 2) In addition to the provisions including labelling requirements specified under the FSS Regulations, 2011 the proprietary foods shall also conform to the following requirements, namely:-
 - (1) The name, nature or composition of food and/or category of the food under which it falls in the FSS Regulations, 2011 shall be mentioned as clearly as possible on the label.
 - (2) The proprietary food product shall comply with all other regulatory provisions specified in the FSS Regulations and in Appendices A and B. Appendix A is on Use of Food Additives in Food Product and Appendix B is on Microbiological Requirements.

Recently, Food Safety Authority Procedure for New Product Approval has been issued by FSSAI (11/12/2012). This includes **Proprietary Foods**. The purpose is to further streamline the product approval procedure and the licensing of these foods in a timely manner with due consideration to the safety of foods and public health as well as for the smooth continuance of trade. The following procedure shall be followed:

- a. All advisories and clarifications regarding Product Approval issued previously will be superseded with the new procedure referred as “New Product Approval Procedure.”
- b. This shall come into force from the date of notification on the FSSAI website (www.fssai.gov.in).
- c. The following guidelines given below shall apply.

1. Foods or Food Categories Covered under the NPA Procedure and Required to Obtain Product Approval

- 1a. Proprietary Foods that have been granted license under previous Acts/Orders (PFA, MMPO, MFPO etc.) and have been in the market prior to 31st March 2011, or new food products intended to be placed on the market and do not contain Novel Foods, Functional Foods, Food Supplements, Irradiated Foods, Genetically Modified Foods, Foods for Special Dietary Uses or Foods which do not contain Extracts or Concentrates of Botanicals, Herbs or of Animal sources shall be granted product approval under the following condition.
 - I. The FBO (Food Business Operator) has provided a complete list of ingredients and food additives as mentioned on the label (copy of label to be attached for products in market) and
 - II. The FBO has provided the category number as applicable under the Indian Food Category Code.

III. Where the application is in accordance to conditions as shown in 1a above and in the format (Format 1a), FSSAI shall grant Product Approval and the FBO may proceed to obtaining a license as provided under paragraph (2) below.

1b. Foods labelled as proprietary foods, whether licensed under previous Act/Orders or are intended to be placed on the market, and contain Novel Foods, Functional Foods, Food Supplements, Irradiated Foods, Genetically Modified Foods, Foods for Special Dietary Uses or Foods which contain Extracts or Concentrates of Botanicals, Herbs or of Animal Sources shall be apply for product approval and grant of provisional NOC as provided under paragraph 2. Licensing Conditions below.

1c. Foods products requiring product approval shall be made in the application form as provided by FSSAI (Format 1b). Further,

I. Safety documentation is required for all ingredients except for vitamin and minerals or food additives approved under FSS Regulations, 2011 or Codex (JECFA).

II. The FBO shall also declare the category under which he intends to market the product as specified under Section 22, - namely, Food Supplements, Food for Special Dietary Uses, Functional Food, etc. or any other recognized under international regulations.

2. Licensing Conditions

2a. All licenses granted under the Product Approval Procedure shall be issued under Central Licensing Authority for a period of 1 year, and thereafter they will be considered for migrated to the respective State Licensing Authority in accordance with the rules and regulations there under.

2b. Products falling under Clause 1(a) of this advisory shall apply for license as per the general requirements as applicable to the food product under FSS (Licensing and Registration of Food Business) Regulations, 2011.

2c. Products falling under Clause 1(b) shall be considered for issuance of a Provisional No Objection Certificate (PNOC) only after grant of Product Approval and subject to the conditions as under:

I. For new products which are yet to be placed on the market a No Objection Certificate (NOC) will be issued for application of license under conditions of the FSS (Licensing and Registration of Food Business) Regulations, 2011 as applicable. Where the safety data is insufficient to make the determination the FBO will be called upon to submit the (additional) safety data prior to grant of an NOC.

II. In the case of products currently in the market both domestic and imports and licensed under previous Act/Orders, shall be granted a provisional NOC (PNOC) for a period not exceeding one year (from date of granting of the PNOC), on the condition that the FBO obtains the required Food/Ingredients/additives approval in the stipulated time.

III. In case of rejection of application under the Approval Procedure, the product under reference shall be as per provisions laid down FSS Regulations, 2011.

**** Reference: Labelling of Pre-packaged Foods**

FSS (Packaging and Labelling) Regulations, 2011 have various general and specific labelling requirements. Among them, the labelling for Vegetarian Food and Non-Vegetarian Food are one of the most unique general labelling requirements.

1.2: Definitions- 1.2.1: In these regulations unless the context otherwise requires:

7. “Non- Vegetarian Food” means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient.

11. “Vegetarian Food” means any article of Food other than Non-Vegetarian Food as defined in regulation 1.2.1 (7).

2.2.2: Labelling of Pre-packaged Foods

4. Declaration regarding Veg or Non veg –

(i) Every package of Non Vegetarian food shall bear a declaration to this effect made by a symbol and colour code as stipulated below to indicate that the product is Non-Vegetarian Food. The symbol shall consist of **a brown colour filled circle** having a diameter not less than the minimum size specified in the Table mentioned in the regulation 2.2.2 (4) (iv), inside **a square with brown outline** having sides double the diameter of the circle as indicated below :

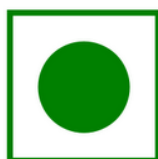
(Brown Colour)



(ii) Where any article of food contains egg only as Non-Vegetarian ingredient, the manufacturer, or packer or seller may give declaration to this effect in addition to the said symbol.

(iii) Every package of Vegetarian Food shall bear a declaration to this effect by a symbol and colour code as stipulated below for this purpose to indicate that the product is Vegetarian Food. The symbol shall consist of **a green colour filled circle**, having a diameter not less than the minimum size specified in the Table below, inside **the square with green outline** having size double the diameter of the circle, as indicated below.

(Green colour)



3.2 Democratic Socialist Republic of Sri Lanka

1. ADMINISTRATIVE AUTHORITIES

Administrative authorities in Sri Lanka as shown below are responsible for Food Administration of food categories and related stage of production. The Chief Food Authority (Director General of Health Services) is the apex body responsible for the country's food control administration.

Sectors	Products	Imported Foods	Domestic Foods
Ministry/Department of Agriculture (MOA)	Primary products of agriculture	Food Control Administration of *MoH (FCA)	MOA and FCA
Department of Animal Production & Health (DAP&H)	Animal Husbandry Milk Products	DAP&H and FCA	DAP&H and FCA
Coconut Development Authority (CDA)	Coconuts & their products	FCA and CDA	FCA and CDA
Tea Board (TB)	Manufactured Tea	FCA and TB	FCA and TB
Ministry/Department of Fisheries (MDF)	Fish and Fish Related products	FCA	MDF and FCA
Sri Lanka Standards Institution (SLSI)	Setting voluntary & mandatory standards for all food products	FCA and in limited cases SLSI	FCA
Excise Department (ED)	Alcoholic Beverages	ED/Customs	ED
Ministry of Local Government (MoLG)	General Food Safety and Standards (implementation)		
Sri Lanka Standards Institution (SLSI) established under Sri Lanka Standards Institution Act No. 6 of 1984	Formulation of General National Standards of consumer and industrial products including food	SLSI	SLSI
Consumer Affairs Authority (CAA) established under the Consumer Affairs Authority Act No. 9 of 2003	Promotion of effective completion and protection of consumers: regulation of internal trade	FCA	CAA

- Note: SLSI plays an integral role with the FCA and FAC in formulation of National Standards under the Food Act. The Standards of the SLSI are mostly voluntary. Some of them are declared mandatory for verification of standard parameters at the point of import. The SLSI has mutual agreements with standards setting bodies of the exporting countries that certify the products exported from selected countries. Based on the certification of those bodies and verification checks carried out at national level the SLSI releases those products for further inspection and verification of FCA as far as food products are concerned
- Consumer Affairs Authority (CAA) was established replacing the Consumer Protection Authority (CPA). The main functions of the CAA are regulating internal trade, control of prices of consumer products, investigation of complaints relating to trade, goods and services.
- **MoH** - Ministry of Health. The Food Control Administration (FCA) comes under the purview of the Ministry of Health.

2. RELATED LAWS AND REGULATIONS

2.1 The Food Act No. 26 of 1980

The Food Act No. 26 of 1980 came into being replacing the Food & Drugs Act (Chapter 216) and an amendment titled Food (Amendment) Act No. 20 of 1991 came into operation. The main features of the Food Act are:

Part I – Prohibition in respect of food related to

- a) Additives,
- b) Fitness for human consumption,
- c) Cleanliness,
- d) Adulteration,
- e) Sanitary conditions

Part II – Administration providing for

- a) Establishment of a Food Advisory Committee (FAC);
- b) Designating Director General of Health Services as the Chief Food Authority (CFA);
- c) Providing for the Director (Environment & Occupational Health) to be in charge of the Food Control Administration;
- d) Providing for Approved Analysts;
- e) Providing for Food Authorities under the Food Act, viz. Director General of Customs for imported foods, chief Medical Officer of Health (CMOH) for the Colombo Municipal area, and Local Authorities (Urban Councils and Pradheshiya Sabhas, etc.);
- f) Constituting members from various disciplines for the effective function of the FAC;
- g) Providing for duties and responsibilities of the FAC;
- h) Action in respect of default of local authorities;
- i) Duties and Responsibilities of the CFA;
- j) Powers of Authorized Officers;
- k) Procedures in respect of articles seized, etc.

Part III

- a) Nature of offenses under the Food Act,
- b) Punishment of offenders on conviction,
- c) Defences of the accused,
- d) Institution of proceedings,
- e) Reports of approved analysts as evidence,
- f) Production of samples to courts,
- g) Presumptions

Part IV

- a) Protection for action taken in good faith,
- b) Certain fines to be paid to the funds of local authority,
- c) Notification of Food Poisoning,
- d) Application of other written laws to food,
- e) Minister of Health to make regulations under the Food Act

2.2 Regulations made under section 32 of the Food Act by the Minister of Health

- 1) Food Miscellaneous Regulations 1985
- 2) Food (Hygiene) Regulations 1988
- 3) Food (Standards) Regulations 1991
- 4) Food (Non-nutritive sweeteners) Regulations
- 5) Food (Standards) Regulations - Milk
- 6) Additional Approved Analyst Regulations
- 7) Food (Iodization of Salt) regulations 1993
- 8) Amendment of Food (Standards) Regulations - Maize Starch
- 9) Additional Microbiological Analyst Regulations
- 10) Food (Labelling & Miscellaneous) Regulations - Traditional Names
- 11) Food (Preservative in Milk) Standards Regulations

- 12) Food (Iodization of Salt) Regulations - Correction
- 13) Notification Additional Approved Analyst
- 14) Food (Sweeteners) Regulations 1999
- 15) Food (Genetically Modified Foods) Provisional Regulations 2003
- 16) Food (Sweeteners) Regulations 2004
- 17) Food (Bread Standards) Regulations
- 18) Food (Labeling & Advertising) Regulations 2005
- 19) Food (Iodization of Salt) Regulations 2005
- 20) Food (Vinegar) Regulations 2007
- 21) Food (Irradiation) Regulations 2005
- 22) Food (Colouring Substances) Regulations 2006
- 23) Food (Bottled or Package Water) Regulations 2005
- 24) Food (Adoption of SL Standards) Regulations 2008
- 25) Food (Appointment of Additional Approved Analyst CMC) Notification
- 26) Food (Hygiene) Regulations 2011

3. FOODS UNDER THE FOOD STANDARDS

Commodities covered under the Food Standards as per Regulations of 1991 are given below. It may be noted that these composite regulations are being gradually divided into separate categories such as Oils and Fats, Cereals, Pulses and Legumes, Spices and Condiments, etc., keeping in line with the Codex Guidelines and Standards. Most of these Regulations are in formulation stages and the delay is on account of the fact that they need to be published in Sinhala, Tamil and English languages and they need to be finalized by the Department of Legal Draftsman.

1. Baking Powder	2. Sugar confectionery
3. Margarine	4. Vegetable fat Hydrogenated Vegetable Oil
5. Bakery shortening	6. Edible Coconut Oil
7. Gingelly Oil / Sesame Oil	8. Corn oil
9. Olive oil	10. Groundnut oil
11. Soy bean oil	12. Palm kernel oil
13. Palm Oil	14. Lard
15. Dripping	16. Paddy
17. Rice, Polished Rice, Unpolished Raw Rice, Parboiled Rice	18. Corn or Maize
19. Kurakkan (<i>Eleusine coracana Gaertn</i>)	20. Barley
21. Green Gram	22. Cow Pea
23. Cow Pea Dhal	24. Myshore Dhal / (Mashoor Dhal) / Red Split Lentils
25. Toor Dhal	26. Black Gram
27. Soy	28. Rice Flour
29. Whole wheat flour	30. Wheat flour
31. Corn flour	32. Kurakkan flour
33. Arrow root starch	34. Manioc Sago
35. Custard Powder	36. Semolina
37. Macaroni/Spaghetti/Vermicelli/Noodles	38. Caraway Whole
39. Caraway Powder	40. Cardamom Whole
41. Chillies Whole	42. Cinnamon Whole
43. Cinnamon Powder	44. Cloves Whole
45. Cloves powder	46. Coriander Powder
47. Cumin Whole	48. Cumin Powder
49. Dill Whole	50. Dill Powder
49. Fennel Whole	50. Fennel Powder

51. Fenugreek Whole	52. Fenugreek Powder
53. Ginger Whole	54. Ginger Powder
55. Mace Whole	56. Mace Powder
57. Mustard Whole	58. Mustard Powder
59. Nutmeg Whole	60. Nutmeg Powder
61. Black Pepper Powder	62. Black Pepper Whole
63. White Pepper Whole	64. White Pepper Powder
65. Turmeric Whole	66. Turmeric Powder
67. Curry Powder/Condiment Powder	68. Asafoetida

4. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

4.1 Overview

Uncontrolled use of Food Additives is deemed to pose danger to public health, for most food additives of modern days are synthetically derived chemicals used by many food manufacturers. According to Food Additives (General) Regulations yet to be published (currently in draft form) "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 manufacturing, processing, preparation, treatment, packing, packaging, transport or storage of 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, emulsifying and stabilizing agent, sweetener and food conditioner, but shall not include nutrient supplement, incidental constituent or common salt.

4.2 Food Additive Definitions

1) Flavours

- (1) **"Natural aromatic raw material"** means a substance of vegetable or animal origin, either in its natural form or after processing by physical methods other than heat treatments, possessing flavouring properties.
- (2) **"Natural flavouring concentrate"** means a concentrated preparation obtained by physical, microbiological or enzymatic process from materials of vegetable or animal origin either in its raw state or after processing by traditional food preparation processes, including drying, roasting and fermentation.
- (3) **"Natural flavouring substance"** means a single chemical unit obtained by physical, microbiological or enzymatic processes from materials of vegetable or animal origin either in its raw state or after processing by traditional food preparation processes including drying, roasting and fermentation.
Natural flavouring shall include "natural flavouring concentrate," "natural flavouring substance" and "natural aromatic raw materials." Natural flavouring shall not contain any nature-identical flavouring substance or artificial flavouring substance.

- (4) **“Nature-identical flavouring substance”** means a substance which is chemically identical to a natural flavouring substance, obtained either by synthesis or by chemical processes from material of vegetable or animal origin either in its raw state or after processing by traditional food preparation processes including drying, roasting and fermentation. Nature-identical flavouring may contain one or more of the followings:
- a. a natural flavour concentrate,
 - b. a natural flavouring substance, or
 - c. a natural aromatic raw material.

- (5) **“Artificial flavouring substance”** means a flavouring substance not identified in a natural aromatic raw material or natural flavour concentrate and one that is not prohibited under these regulations and accepted as safe to be used in food, generally recognized as safe in the GRAS list of Flavouring Substances published by the Flavour and Extract Manufacturers Association of the United States.

An artificial flavouring may contain one or more of the followings:

- a. a natural flavour concentrate,
- b. a natural flavouring substance,
- c. a nature-identical flavouring substance, or
- d. a natural aromatic raw material.

2) Processing Aids

The Inventory of Processing Aids compiled and adopted by the Codex Alimentarius Commission (CAC) is consulted in preparing the National Regulations although currently there is no regulation in place. The inventory contains the following

- Category: functional effect classification.
- Processing Aid: the chemical name and description of the substance used.
- Area of Utilization
- Level of Residues
- Interaction with food
- JECFA evaluation

3) Carry Over

“Carry Over” is defined as the presence of food additives in food as a result of the use of raw material or other ingredients in which these additives were used.

4.3 Functional Classes of Food Additives

The following functional classes of Food Additives per the Table below provided by the CAC are considered in the Sri Lankan standards with the relevant INS numbers.

Acid	Acidity regulators	Anti-caking agents
Anti-foaming agents	Anti-oxidants	Bulking agents
Colours	Colour retention agents	Emulsifiers
Emulsifying salts	Firming agents	Flavour enhancer

Flour treatment agents	Foaming agents	Gelling agents
Glazing agents	Humectants	Preservatives
Propellants	Raising agents	Stabilizers
Sweetener	Thickener	

4.4 Permitted Food Additives and Maximum Limits

Permitted Food Additives are prescribed with their Maximum Limits under the Food Additives Regulations in Sri Lanka. They are invariably based on the Codex Limits prescribed.

(1) List of designated Food Preservatives and Maximum Limits that could be applied on designated food products

SCHEDULE 1

Column 1		Column II	
Permitted Preservative	INS No.	Alternative form in which the permitted preservative may be used (to be calculated as the permitted preservatives shown in Column I)	INS No.
1. Sorbic acid	200	Sodium sorbate Potassium sorbate Calcium sorbate	201 202 203
2. Benzoic acid	210	Sodium benzoate Potassium benzoate Calcium benzoate	211 212 213
3. Sulphur dioxide	220	Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Potassium sulphite Potassium hydrogen sulphite Calcium sulphite Calcium hydrogen sulphite	221 222 223 224 225 228 226 227
4. Biphenyl, Diphenyl	230		
5. Orthophenylphenol	231	Sodium orthophenylphenate	232
6. Nisin	234		
7. Potassium nitrite	249		
8. Sodium nitrite	250		
9. Sodium nitrate	251		
10. Potassium nitrate	252		
11. Propionic acid	280	Sodium propionate Calcium propionate Potassium propionate	281 282 283

(2) Articles of Food which may contain permitted preservative and quantity of the permitted preservatives in each case

SCHEDULE II

Column I Specified Foods	Column II Permitted Preservatives	Column III Maximum Permitted Level (mg/kg)
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1.0 Dairy Products		
(a) Dairy based drinks, flavoured, and/or fermented	Sorbic acid and Sorbates, or Propionic acid and Propionates	300 GMP
(b) Cheese, pre-packed, sliced	Sorbic acid and Sorbates	1000
(c) Cheese, ripened Cheese, processed Cheese spread and Cheese paste	Sorbic acid and Sorbates, or Propionic acid and Propionates Nisin	1000 GMP 12.5
(d) Desserts, dairy based non heat treated (e.g. curd, fruit or flavoured yoghurt)	Sorbic acid and Sorbates, or Propionic acid and Propionates	1000 GMP
2.0 Fat Emulsions of Type Water-in-Oil		
(a) Margarine and similar products (containing at least 80% fat)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates	1000 1000
(b) Emulsions containing less than 80% fat	Sorbic acid and Sorbates, or Benzoic acid and Benzoates	2000 1000
(c) Vegetable and nut purees & spreads (e.g. peanut butter)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates	2000 1000
3.0 Fruits, Vegetables and Artificially Flavoured Drinks		
3.1 Fruits and fruit products		
(a) Surface treated fresh fruits	Sorbic acid and Sorbates, or Sulphites, or Biphenyl, Diphenyl, or Orthophenyphenol and Sodium orthophenyphenate	1000 50 70 12 12
(b) Peeled or cut fresh fruit	Sorbic acid and Sorbates	1000
(c) Dried fruits	Sorbic acid and Sorbates, or Sulphites	2000 1000
(d) Frozen fruit	Sorbic acid and Sorbates, or Sulphites	1000 300
(e) Candied, crystallized or glazed fruits and citrus peel	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 1000 100
(f) Fruits, canned or bottled (pasteurised)	Sorbic acid and Sorbates, or Sulphites	1000 350
(g) Fruits in vinegar, oil or brine	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 1000 100
(h) Fruit based spreads e.g. chutney, excluding jams, jellies and marmalades	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 250 100
(i) Fruit preparations, including pulp, puree, fruit toppings	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 1000 500
(k) Jams, jellies, marmalades	Sorbic acid and Sorbates, or Sulphites	500 100
(l) Jams, jellies and marmalades, low in sugar or sugar free	Sorbic acid and Sorbates, or Benzoic acid and Benzoates,	500 500
(m) Fruit juices	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(n) Fruit juice concentrates (as served to consumer)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(o) Fruit nectar (as served to consumer)	Sorbic acid and Sorbates, or	300

	Benzoic acid and Benzoates, or Sulphites	120 50
(p) Concentrates for fruit nectar (as served to consumer)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(q) Fruit cordials and squashes containing not less than 25% fruit juice and not less than 25% sugar (calculated as sucrose) for consumption after dilution.	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1500 600 250
(r) Fruit squash concentrates containing not less than 45% Benzoates or fruit juice and not less than 45% sugar (calculated as sucrose) for consumption after dilution	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	2500 1500 450
(s) Fruit drinks for consumption without dilution containing not less than 10 % fruit juice and not less than 5 % sugar (calculated as sucrose)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(t) Fruit wines	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1500 600 250
3.2 Water based flavoured drinks		
(a) Artificially flavoured cordials, containing not less than 25% Benzoates or sugar (calculated as sucrose) for consumption after dilution	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1500 600 250
(b) Artificial flavoured drinks ready for consumption without dilution, containing not less than 5% sugar (calculated as sucrose)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(c) Water based flavoured drinks, carbonated	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 120 50
(d) Artificially flavoured syrup concentrates	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1500 600 250
3.3 Vegetables (including mushrooms, roots, tubers, pulses, legumes and nuts) and Vegetable Products		
(a) Peeled, cut or shredded fresh vegetables including mushrooms, roots, tubers, pulses, legumes and nuts	Sulphites	50
(b) Frozen vegetables including mushrooms, roots, tubers, pulses, legumes and nuts	Sulphites	50
(c) Dried Vegetables including mushrooms, roots, tubers pulses, legumes and nuts	Sulphites	500
(d) Canned or bottled Vegetables (pasteurised) or retort pouch	Sorbic acid and Sorbates, or Sulphites	1000 50
(e) Vegetables in vinegar, oil, brine or soy sauce	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 1000 100
(f) Vegetable including mushrooms, roots, tubers, pulses, legumes and nut pulps and preparations (e.g.	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	300 250 100

vegetable desserts and sauces, candied vegetables)		
(g) Fermented vegetables, including mushrooms, roots, tubers, pulses, legumes and nuts except fermented soybean products	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 1000 500
(h) Culinary pastes	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	500 250 100
(i) Pickles	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	1000 250 100
4.0 Carbohydrates, Cereals and their Products		
4.1 Carbohydrates		
(a) Starches (excluding starches for weaning foods, follow on formula and infant formula)	Sorbic acid and Sorbates, or Sulphites	1000 50
(b) Flours	Sorbic acid and Sorbates, or Sulphites	1000 200
(c) White sugars, fructose, glucose, icing sugar, powdered dextrose	Sulphites	15
(d) Plantation and mill white sugar	Sulphites	70
(e) Brown sugar	Sulphites	40
(f) Sugar solutions and syrups, also (partially) inverted sugars including treacle and molasses	Sulphites	70
(g) Other sugars and syrups, (e.g. xylose, maple syrup, sugar toppings)	Sorbic acid and Sorbates, or Sulphites	1000 40
(h) Glucose syrup and dried glucose syrup	Sulphites	20
(i) Glucose syrup for manufacturing purposes	Sulphites	400
(j) Dried Glucose syrup for manufacturing purposes	Sulphites	150
4.2 Cereals and cereal products		
(a) Whole, broken or flaked cereal grain including rice	Sulphites	400
(b) Breakfast cereals	Propionic acid and Propionates	GMP
(c) Cereal and starch based desserts	Sorbic acid and Sorbates, or Propionic acid and Propionates	1000 GMP
(d) Pastas and noodles and like products	Sorbic acid and Sorbates, or Propionic acid and Propionates	1000 2000
(e) Precooked and processed rice products	Propionic acid	GMP
(g) Bread and other bakery products	Sorbic acid and Sorbates, or Propionic acid and Propionates	2000 GMP
4.3 Confectionery		
(a) Confectionery, flour based and sugar based and mixes	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates	2000 1500 GMP
(b) Confectionery, glucose syrup based	Sulphites or Propionic acid and Propionates	50 GMP
(c) Chewing gum and bubble gum	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites or	1500 1500 2000

	Propionic acid and Propionates	GMP
(d) Cocoa powders and mixes	Sorbic acid and Sorbates	1500
(e) Cocoa based spreads including fillings	Sorbic acid and Sorbates, or Sulphites or Propionic acid and Propionates	1500 2000 GMP
(f) Chocolate and chocolate products	Sorbic acid and Sorbates, or Sulphites or Propionic acid and Propionates	1500 150 GMP
5.0 Egg, Fish, Poultry, Meat and their Products		
5.1 Egg, fish and their products		
(a) Egg products, concentrated, dehydrated, or frozen	Sorbic acid and Sorbates	1000
(b) Egg based desserts	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates	1000 1000 GMP
(c) Crustaceans, mollusks and echinoderm. fresh	Sulphites	100
(d) Crustaceans, mollusks and echinoderm, cooked	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	2000 2000 50
(e) Fish, fish fillets and fish products including mollusks, crustaceans and echinoderm, frozen	Sorbic acid and Sorbates, or Sulphites	2000 100
(f) Fish products, minced and creamed, frozen, cooked	Sorbic acid and Sorbates, or	2000
(g) Fish and fish products, including mollusks, crustaceans and echinoderms, smoked, dried, fermented and/or salted	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites, or Nitrites	2000 200 200 125
(h) Fish and fish products, including mollusks, crustaceans and echinoderms, semi preserved. (e.g. marinated and/or in jelly, pickled and/or in brine, fish paste)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates, or Nitrites	2000 2000 GMP 125
5.2 Poultry and meat and their products		
(a) Meat and poultry, fresh whole pieces or cuts	Nitrates or Nitrites	125 125
(b) Meat and poultry, fresh, comminuted	Sulphites or Nitrates or Nitrites	450 125 125
(c) Ham and bacon	Nitrates or Nitrites	125 125
(d) Meat and poultry products, heat treated, processed, comminuted including meat balls, sausage, burger, chicken roll, luncheon meat	Sulphites or Nitrates or Nitrites	500 125 125
(e) Canned corned beef	Nitrites	50
6.0 Sauces, Soups and Miscellaneous Items		
6.1 Sauces and like products		
(a) Emulsified sauces (e.g. salad dressings, mayonnaise)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites or Propionic acid and Propionates	1000 250 100 GMP
(b) Non emulsified sauces (e.g. ketchup, cheese sauce, cream	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or	1000 250

sauce, brown gravy), mixes for sauces and gravies and clear sauces (e.g. fish sauce)	Sulphites or Propionic acid and Propionates	100 GMP
(c) Sandwich spreads, excluding cocoa based spreads and vegetable and nut spreads	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates	1500 1500 GMP
6.2 Soups		
(a) Soup Mixes	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites or Propionic acid and Propionates	500 500 1000 GMP
6.3 Miscellaneous		
(a) Herbs and spices	Sulphites	500
(b) Seasonings and condiments (e.g. seasoning for instant noodles)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites or Propionic acid and Propionates	1000 1000 200 GMP
(c) Dietetic foods and food supplements except for infants and young children	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates	1500 1500 GMP
(d) Soybean products (e.g. tofu, soy sauce)	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Propionic acid and Propionates	1000 250 GMP
(e) Coffee, coffee substitutes, tea, herbal infusions and other hot cereal and grain beverages excluding cocoa	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or	300 120
(h) Spice pastes	Sorbic acid and Sorbates, or Benzoic acid and Benzoates, or Sulphites	500 250 100

(3) List of Existing Food Additives under Colouring Substances Regulations)

Colours	Common Names	Colour Index	INS Numbers
Red	Carmosine	14720	122
	Ponceau 4R (Food Red 102)	16255	124
	Erythrosine (Food Red 3)	45430	127
Yellow	Sunset Yellow FCF (Food Yellow 5)	15985	110
	Tartrazine (Food Yellow 4)	19140	102
Blue	Indigo Carmine (Food Blue 2)	73015	132
	Brilliant Blue FCF (Food Blue 1)	42090	133
Green	Green S	44090	142

- **Synthetic dyes specified in Table above shall conform to the following standards:**

Pure dye minimum	85.0%
Water insoluble matter maximum	0.1%
Subsidiary dye maximum	4.0%
Ether extractable matter maximum	0.2%
Intermediates maximum	0.5%

(4) Other colouring substances permitted to be used in food

INS Number	Natural Colouring Substance	Colour Index
100	Curcumin	75300
120	Cochineal (Carminic Acid)	75470
140	Chlorophyll	75810
150b	Caramel	
160a	Carotenes (alpha, beta or gamma)	75130
160b	Annatto	75120
160c	Capsanthin or capsorubin	
160d	Lycopene	75125
160e	Beta-apo-8'-carotenal carotenoic acid	
161a	Flavoxanthin	75135
162	Beetroot red (betanin)	
163	Anthocyanins	
171	Titanium dioxide	77891

(5) List of plant or animal sources for flavouring agents

No such classification has been made in any of the regulations of Sri Lanka although the following provision has been made in the Food (Additives - Flavouring and Flavour enhancers) Regulations (Draft):

“The label on or attached to a package of a natural flavouring shall include the statement ‘NATURAL (here insert description of flavour) FLAVOURING’ or a similar statement.”

4.5 List of substances which are generally provided for eating or drinking as foods and used as food additives as well:

There is no such list in any of the regulations although in practical terms this happens.

4.6 List of Substances which are prohibited to be used in food

No negative list other the list furnished under the Food (additives - flavouring) Regulations.

Negative List of Flavours

- i) Aloin;
- ii) Beberine;
- iii) Beta-Azarone;
- iv) Cade oil;
- v) Calamus oil;
- vi) Coumarin and dihydrocoumarin;
- vii) Diethylene glycol;
- viii) Monoethyl ether;
- ix) Ethyl methyl ketone;
- x) Ethyl-3-phenylglycidate;
- xi) Eugenol methyl ether;
- xii) Methyl naphthyl ketone;
- xiii) Safrole and Isosafrole;
- xiv) Santonin;
- xv) Sassafras oil;
- xvi) Thujone, Isothujone, alpha and beta thujone;
- xvii) Tonka bean.

4.7 Specifications for food additives

The General Principle for the use of food additives specify that Food Additives should at all times conform to an approved specification, for example, the Specification of Identity and Purity recommended by the Codex Alimentarius Commission. For this reason the recommended list of the Codex and evaluations carried out by Joint Expert Committee on Food Additives (JECFA) is consulted before approval of any Food Additive in Sri Lanka.

4.8 Assessment of new food additives

Assessment of food additives as such is not carried in Sri Lanka and there had been no need for such assessments.

4.9 Labelling of food additives

The labelling of food additives is governed by the Food (Labelling & Advertising) Regulation 2005 in Sri Lanka.

4.10 Specifications of food additives, Weights and measures, Contaminants, Methods of analysis and sampling, Standards for manufacturing of food additives:

General Principles for the use of Food Additives (advisory text: paragraph 295, ALINORM 72/35) and related texts are used. No exclusive guidelines or texts for Sri Lanka have been published.

4.11 Official Publications and/or Gazette for food additives

- Gazette Notification 1323/1 on Sweeteners
- Gazette Notification No. 615/11 on Preservatives

Most of the regulations relating to food additives are either under draft stage or with the Department of Legal Draftsman.

5. CASE STUDIES

In order to compare the contents of food standards set in Sri Lanka, (1) Instant Noodles, (2) Carbonated Soft Drinks, (3) Prepared Frozen Foods and (4) Cow's Milk were chosen as examples.

(1) Instant Noodles

There is no SLS standard for Instant noodles under the Food Act; this is not even considered as a possibility in the near future. Reference can only be given to CODEX STAN 249-2006 which would be taken into consideration as a benchmark standard if and when such a standards framed.

(2) Carbonated Soft Drinks

There is no standard under the Food Act for Carbonated Soft Drinks. However there is a standard under the purview of the SLSI which becomes the de facto standard under the Food Act until such time a standard under Food Act is published. Given below is the copy of the standard (Draft) of the SLSI.

Sri Lanka Standard SPECIFICATION FOR CARBONATED BEVERAGES (draft) (Third Revision) SLS 183

1. SCOPE:

This standard prescribes the requirements and methods of sampling and testing for carbonated beverages and formulated caffeinated beverages.

2. REFERENCES

- i) SLS 79 Edible common salt
- ii) SLS 102 Rules for rounding off numerical values
- iii) SLS 143 General principles for food hygiene
- iv) SLS 191 White sugar
- v) SLS 291 Glass bottles aerated water
- vi) SLS 398 Crown closures
- vii) SLS 428 Random sampling methods
- viii) SLS 427 Labelling of pre-packaged food
- ix) SLS 464 Bees Honey
- x) SLS 516 Microbiological test materials
- xi) SLS 614 Potable water
- xii) SLS 772 Treacle
- xiii) SLS 883 Brown sugar
- xiv) SLS 1332 Methods of test for fruits and vegetable products

3. DEFINITIONS

For the purpose of this standard, the following definitions shall apply:

3.1 Caffeinated beverages: all caffeine present from whatever source.

3.2 Carbonated beverage: A non-alcoholic, water-based beverage which contains dissolved carbon dioxide and may contain one or more of the ingredients given in 5.2

3.3 Formulated caffeinated beverages: A non-alcoholic, water-based, flavoured beverage which contains caffeine and dissolved carbon dioxide and may contain carbohydrates, amino acids, vitamins and one or more of the ingredients given in 5.2

3.4 One day quantity: In relation to formulated caffeinated beverage, means the maximum amount of that food that shall be recommended to be consumed in one day in accordance with the directions specified in the label.

4 TYPES

The product shall be of the following types:

4.1 Carbonated beverages

4.2 Formulated caffeinated beverages

5 INGREDIENTS

All ingredients used shall comply with the Sri Lanka Food Act No. 26 of 1980 and the regulations framed thereunder (as amended from time to time). The limits set for the use of ingredients by the regulations in the said Food Act shall be adhered to.

5.1 Basic Ingredients

5.1.1 Potable water: conforming to SLS 614.

5.1.2 Carbon dioxide: purity not less than 19 per cent;

5.2 Optional Ingredients

In addition to the ingredients given in 5.1, one or more of the following may be used.

5.2.1 Sweeteners

5.2.1.1 Sugars: see SLS 191

White sugars: see SLS 883

5.2.1.2 Non-nutritive sweeteners: only for products labelled as in 8.2(b). The limits given are for the beverage at the point of consumption.

Aspartame	600 mg/L (max)
Acesulfame-I	350 mg/L (max)
Sucralose	300 mg/L (max)
Neotame	20 mg/L (max)

5.2.2 Syrups: liquid glucose, invert sugar syrup, fructose, dextrose, liquid cane sugar, isoglucose, high fructose. Syrup: see SLS 464. Treacle: see BSL 772.

5.2.3 Fruit juice: comminuted fruit and fruit bases, fresh or preserved.

5.2.4 Flavouring substances: natural, nature-identical, artificial or a combination of such flavouring substances.

5.2.5 Emulsifying/Stabilizing agents

INS NUMBER (1)	ADDITIVE (2)	MAXIMUM LEVEL IN 1 LITRE OF PRODUCT (3)
440	Pectins	Limited by GMP
403	Alginates	do
466	Sodium carboxymethyl cellulose	do
407	Carrageenan	do
414	Gum Arabic (Acacia gum)	do
418	Gellan gum	do
415	Xanthan gum	5000 mg
452(i)	Sodium hexametaphosphate (Sodium polyphosphate)	1000 mg
445(iii)	Glycerol ester of wood resin	100 mg
444	Sucrose acetate isobutynalol	500 mg
480	Diocetyl sodium sulfosuccinate	10 mg

5.2.6 Foaming Agents

999(i)	Quillaia extract type I	50 mg
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5.2.7 Preservatives: Sulphites, benzoates, sorbates and/or their sodium, potassium or calcium salts.

5.2.8 Colouring substances

5.2.9 Caffeine (see 6.5)

5.2.10 Quinine salts (see 6.6)

5.2.11 Sodium bicarbonate (Food grade)

5.2.12 Edible common salt (see SLS 79)

5.2.13 Ascorbic acid

5.2.14 Acidulants: Acetic acid, citric acid, tartaric acid, malic acid, fumaric acid, lactic acid and/or their sodium, potassium or calcium salts (GMP). Orthophosphoric acid: maximum 0.06 per cent by mass.

5.2.15 Vitamins and minerals

5.2.16 Herbal extracts/Tea extracts

5.2.17 Inositol

5.2.18 Amino acids

5.2.19 Carbohydrates/Malt extracts

5.2.20 Glucuronolactone

6 REQUIREMENTS

6.1 Hygiene

The product shall be processed, packed, stored and distributed under hygienic conditions as prescribed in SLS 143.

6.2 Appearance

Clear product shall have a sparkling clarity under normal conditions of storage. Cloudy beverages shall be stable. Surface film or scum shall not be present in the product. There shall be no rust at the mouth of the bottle.

6.3 Flavour and odour

The flavoured products shall have the pleasant and characteristic flavour. The flavour of the product shall be in accordance with any claim made or implied on the label. The product shall be free from off flavours.

6.4 Carbonation

The product shall have the following carbonation values, when tested in accordance with the Appendix H:

- a) Soda water/Soda 3.0 gas volumes, (min.)

b) Other beverages 1.0 gas volume, (min.)

Note: The gas volume being the amount of carbon dioxide the water would absorb at normal atmospheric pressure at 15.6° C

6.5 Caffeine

6.5.1 The carbonated beverage shall not contain more than 150 mg/L of caffeine when tested in accordance with the method prescribed in AOA 979.08.

6.5.2 The formulated caffeinated beverage shall contain not less than 100 mg/l of caffeine when tested in accordance with the method prescribed in AOA 979.08.

6.6 Quinine salts

Tonic beverage shall no contain more than 100 mg/l quinine salts calculated as quinine sulphate when tested in accordance with the method prescribed in Appendix B.

6.7 Other requirements

6.7.1 Carbonated beverages and formulated or caffeinated beverages shall conform to the requirements given in Table 1, when tested according to the method given in Column 4 of the Table.

TABLE 1 – Other requirements

SI No (1)	Characteristic (2)	Requirement (3)	Method of Test (4)
i)	Total soluble solids per cent by mass, (max.)	16	Appendix C
ii)	Sulphur dioxide content, mg/L, (max.)*+	50	Appendix D
iii)	Benzoic acid content, mg/L, (max.)*	120	Appendix E
iv)	Sorbic acid content, mg/L, (max.)*	300	Appendix E

Note: * When a product contains more than one preservative, the quantity of each preservative expressed as a percentage of the maximum permitted limit of the preservative shall be calculated. The sum of the percentage shall not exceed 100.

+ Products packed in metal containers shall not contain sulphur dioxide.

6.7.2 The formulated caffeinated beverages shall also conform to the requirements given in Table 2, when tested according to the methods given in column 4 of the Table.

TABLE 2 – Only for formulated caffeinated beverages

SI No. (1)	Substance (2)	Maximum amount per one-day quantity (3)	Method of Test (4)
i)	Thiamine	40 mg	Appendix F
ii)	Riboflavin	20 mg	do
iii)	Niacin	40 mg	do
iv)	Vitamin B ₆	10 mg	do
v)	Vitamin B _{1, 2}	10 µg	do
vi)	Pantothenic acid	10 mg	do
vii)	Taurine	2000 mg	do
viii)	Glucuronolactone	1200 mg	do
ix)	Inositol	100 mg	do

6.8 Microbiological requirements

The product shall conform to the limits given in Table 3, when tested according to the methods given in Column 4 of the Table.

TABLE 4 – Limits for heavy metals

SI No.(1)	Heavy metal (2)	Limit (3)	Method of test (4)
i)	Arsenic, (as As), mg/l, max.	0.01	Appendix G
ii)	Cadmium, (as Cd), mg/l max.	0.003	do
iii)	Lead, (as Pb), mg/l, max.	0.01	do
iv)	Tin, (As Sn), mg/l, max.*	150	do

*Only for canned beverages

7 PACKAGING

7.1 The product shall be filled in glass bottles conforming to SLS 291. It may also be filled in cans, food grade plastic containers and dispensing units.

7.2 All containers shall be clean and free from chips, cracks and any other defects and appropriately sealed. Glass bottles shall be properly sealed with gas tight crown closures conforming to SLS 398. Crown closures shall be lined internally with a suitable liner of food grade material. Plastic containers shall not leak after they are filled and capped. All bottles shall be

subjected to cleansing/sanitizing process before filling.

8 MARKING AND/OR LABELLING

8.1 The marking and labelling of the containers shall be done either by printing or lithographing on the label of the containers themselves or attaching labels printed on paper or printed on the crown/closure.

8.2 The following shall be marked legibly and indelibly on the label of the container:

- a) A product with carbohydrate sweeteners reduced by a minimum of 30% of the comparable product may be named as "Low Sugar" (Lite/Light) or "Sugar Reduced" or "Sugar Free" (percentage of sugar level shall be declared on the label).
- b) When non-nutritive sweeteners are added as substitutes for sugar, the statements "with Non-nutritive Sweetener(s)" and "Energy Reduced" or "with No Added Sugar" or "Sugar Free" as the case may be, shall be included in conjunction with or in close proximity to the product name.
- c) Brand name or trade mark, if any;
- d) Name and address of the manufacturer;
- e) Name and address of the packer or distributor in Sri Lanka;
- f) Food additive's name or class and INS number if added;
- g) Complete list of ingredients;
- h) Net volume in "mL" or "L";
- i) Date of manufacture;
- j) Date of expiry;
- k) Batch number and code number;

Note 1: *Date of manufacture and/or Date of expiry and/or Batch number may be marked on the surface of the bottle.*

Note 2: *For formulated carbonated beverages, no other description shall be made under the common name.*

- l) A pictorial representation on the label shall not mislead with respect to the ingredients used;
- m) Country of origin, in case of imported products; and
- n) Instructions for storage if any.

8.3 In addition to above (8.2), the following information shall be marked legibly and indelibly on the label of formulated caffeinated beverages only:

- a) The average quantity of caffeine per 100 ml, expressed in milligrams.
- b) The substances listed in Column 2 of Table 2, where present, expressed in the units included in Column 3 of the Table.
- c) The declarations under a) and b) may be adjacent to or follow a nutrition information panel on the label, provided that the declarations are clearly distinguished from the nutrition information.
- d) Cautionary statements to the effect that
 - (i) The food "is not recommended for children under 12 years and pregnant and lactating women";
 - (ii) The food "contains caffeine" and "not recommended for individuals sensitive to caffeine";
- e) When formulated caffeinated beverage contains one or more the substances in the Table 2 shall include an advisory statement to the effect that "consume no more than [amount of one-day quantity (as cans, bottles of mL)] per day."
- f) The label on a package of formulated caffeinated beverage shall not include declaration of the quantities of vitamins present in the food expressed as proportion or multiple of the "Recommended Daily Allowance" or "Estimated Safe and Adequate Daily Dietary Intakes" or "Recommended Daily Intake" of that vitamin.

8.4 The marking and labelling shall also be in accordance with SLS 467.

9. SAMPLING: Representative samples of the product for ascertaining conformity to the requirements of this standard shall be drawn as prescribed.

(3) Prepared Frozen Foods

No standard relating to prepared frozen foods either under the Food Act or under the SLSI has been prepared and published so far.

(4) Cow's Milk

Descriptions/Definitions under Food Act
<p>1. Milk/Liquid Milk Milk/Liquid Milk means the normal, clean, fresh mammary secretion obtained by milking of one or more healthy cows or buffaloes or a combination of them, or goat milk, without the addition of any substance or extraction of fat or any other constituents. All milk shall satisfy the standards.</p>
<p>2. Raw or Fresh Liquid Milk Raw or fresh liquid milk means cow milk, buffalo milk or goat milk in its natural form and such milk may have been cooled, but should not have been subjected heat, irradiation or any other physical treatment.</p>
<p>3. Standardized Milk Standardized Milk means cow milk and/or buffalo milk or a combination of any of them that has been standardized to fat and milk solids other than milk fat, as set out in Schedule I hereto.</p>
<p>4. Semi-Skimmed Milk or Low-Fat Milk Semi-skimmed Milk or Low-Fat Milk means a product prepared by the partial removal of milk fat from cow milk and/or buffalo milk or a combination of any of them so as to satisfy the standards set out in Schedule I hereto.</p>
<p>5. Skimmed Milk or Non-Fat Milk Skimmed Milk or Non-Fat Milk means a product prepared from cow milk and/or buffalo milk or a combination of any of them from which almost all the milk fat has been removed so as to satisfy the standards set out in Schedule I hereto.</p>
<p>6. Pasteurized Milk Pasteurized Milk means milk that has been heated in such a way that every particle of milk is heated to at least 63⁰C and not more than 65⁰ C and held continuously at that temperature for at least 30 minutes or heated to at least 71.5⁰ C and held at that temperature continuously for at least 15 seconds or any other approved temperature time combination equivalent thereto, that will serve to give a negative phosphatase test, and cooled immediately to a temperature of 4⁰C and kept at a temperature of not more than 10⁰C until sale. Pasteurized milk shall, when subjected to the reductase test, not completely decolourize any methylene blue solution in less than 2½ hours.</p>
<p>7. Sterilized Milk Sterilized Milk means the milk that has been filtered, homogenized and thereafter heated to and maintained at a temperature of not less than 100⁰ C for a length of time, without appreciable loss of volume, sufficient to render it commercially sterile and shall be packed in hermetically sealed containers. For the purpose of these regulations, "commercially sterile" means any condition which is free of viable microorganisms, including spores, of public health significance and microorganisms capable of reproducing in the food under normal conditions of storage and distribution.</p>
<p>8. Ultra Heat Treated Milk Ultra Heat Treated Milk (Ultra High Temperature Milk) or U.H.T. Milk means the milk that has been heated, without appreciable loss of volume, to a temperature of 135⁰- 150⁰C for not less than 4 seconds and then be filled and sealed aseptically into sterile containers.</p>
<p>9. Flavoured Milk Flavoured Milk means the product prepared from milk, recombined milk, milk powder or condensed milk and suitable ingredients, or other permitted flavouring, with or without permitted food colours, acidity regulators, stabilizers and buffering agents and effectively heat treated by one of the methods given in section 5, 6 and 7 above. It shall comply with the standards set out in Schedule I hereto.</p>
<p>10. Recombined Milk Recombined Milk means the product prepared from the constituents of milk combined with water or</p>

milk or both and shall be subjected to pasteurization, sterilization or ultra-high temperature. It shall comply with the standards set out in Schedule I hereto.

11. Reconstituted Milk

Reconstituted Milk means the liquid product prepared by the addition of water to full cream milk powder and shall be subjected to pasteurizations, sterilization or ultra-high temperature. It shall comply with the standards set out in Schedule I hereto.

12. Reconstituted Skimmed Milk

Non-Fat Milk Reconstituted Skimmed Milk (Non-Fat Milk) means the liquid product prepared by the addition of water to skimmed milk powder (non-fat milk powder) and shall be subjected to pasteurization, sterilization or ultra-high temperature. It shall comply with the standards set out in Schedule I hereto.

13. Toned Milk

Toned Milk means the product prepared by admixture of cow or buffalo milk or both with fresh skimmed milk, or by admixture of cow or buffalo milk or both that has been standardized to fat and solids-not-fat percentage set out in Schedule I hereto by adjustment of milk solids. It shall be pasteurized and shall show a negative Phosphatase Test. When fat or dry non-fat milk solids are used, it shall be ensured that the product remains homogeneous and no deposition of solids take place on standing.

14. Lactose Hydrolysed Milk

Lactose Hydrolysed Milk means the product made from milk treated with the enzyme lactase to give low lactose milk, containing glucose and galactose. It shall not contain more than 1.25 % m/m lactose and shall comply with the standards set out in Schedule I hereto.

Voluntary or Quality Standards, If Any	Currently, Draft Food (milk and milk products) Regulations with the Legal Draftsman's Department. Mandatory when published in the Govt. Gazette
Positive and/or Negative list	See Schedule I and II below
Use Limitation and/or Maximum Level, If Any	See Schedule I and II below

**SCHEDULE 1
STANDARDS REQUIRED OF MILK AND LIQUID MILK**

Classes of Milk	Definitions	Minimum Milk Fat %m/m	Minimum Milk Solids-Not-Fat %m/m
1. Buffalo	Raw, Pasteurized, Sterilized, Boiled or UHT	5.0	9.0
2. Cow	Raw, Pasteurized, Sterilized, Boiled or UHT	3.5	8.0
3. Milk (combination of Cow and Buffalo)	Raw, Pasteurized, Sterilized, Boiled or UHT	3.5	8.5
4. Goat	Raw, Pasteurized, Sterilized, Boiled or UHT	3.0	8.5
5. Standardized	Pasteurized, Sterilized or UHT	3.25	8.25
6. Semi-skimmed / Low-fat	Pasteurized, Sterilized or UHT	2.0 (max)	8.5
7. Skimmed/Non-Fat	Pasteurized, Sterilized or UHT	0.5 (max)	8.5
8. Flavoured	Pasteurized, Sterilized or UHT	2.0	7.2
9. Recombined	Pasteurized, Sterilized or UHT	3.25	8.25
10. Reconstituted	Pasteurized, Sterilized or UHT	3.25	8.25
11. Reconstituted (Non-Fat)	Pasteurized, Sterilized or UHT	0.5 (max)	8.25
12. Toned	Pasteurized, Sterilized or UHT	2.0	8.5
13. Lactose hydrolysed	Pasteurized, Sterilized or UHT	3.25	8.25

SCHEDULE II
FOOD ADDITIVES FOR UHT STERILIZED FLAVOURED MILK
WITH OVER 3 MONTHS SHELF LIFE
Regulation 4

Classes	INS Numbers	Names	Maximum levels
1.Acidity regulators	331 332 500(ii) 501(ii) 339(ii) 339(iii) 331(ii)	Sodium citrate Potassium citrate Sodium hydrogen carbonate Potassium hydrogen carbonate Disodium hydrogen phosphate Trisodium phosphate Trisodium citrate	limited by GMP
2.Emulsifiers/stabilizers	407 401, 402, 404 ---- 322 440 460(i) 471 415 412	Carrageenan Alginates Gelatine Lecithins Pectins Microcrystalline cellulose Mono- and diglycerides of fatty acids Xanthan gum Guar gum	limited by GMP

6. FOOD REGULATIONS (SHELF LIFE OF IMPORTED FOOD ITEMS)

REGULATIONS made by the Minister of Health under section 32 of the Food Act, No. 26 of 1980 in consultation with the Food Advisory Committee.

**MAITHRIPALA
SIRISENA,
Minister of Health**

**Ministry of Health,
Colombo,
31st January 2011.**

Regulations

1. These regulations may be cited as the Food (Shelf Life of Imported Food Items) Regulations 2011 and shall come into effect on 01st August 2011.
2. All items of food imported into Sri Lanka shall at the point of entry into Sri Lanka, possess a minimum period of sixty *per centum* (60%) of unexpired shelf life ;

Provided that the shelf life period specified above, shall not be enforced in respect of imported fresh fruits and vegetables and potatoes which have not been peeled or cut.

3. The period of shelf life of an item of imported food shall be determined on the basis of the date of manufacture and the date of expiry as declared by the manufacturer of the product and which is depicted on the label attached thereto
4. For the purposes of these regulations, the expression “end of shelf life” shall be identified by the use of the words “date of expiry”, “best before” , “use by” or “use before” or other similar words which convey this meaning and which are used by a manufacturer of any food item being imported into Sri Lanka.
5. For the purpose of these regulations “shelf life” means the period of time between the date of manufacture and its usability by the consumer, during which time the product is safe for human consumption and is of satisfactory quality in terms of nutritional value, flavour, texture and appearance.

FOOD ACT, No. 26 of 1980
Food (Packaging Materials and Articles) Regulations 2010

REGULATIONS made by the Minister of Health in consultation with the Food Advisory Committee in terms of Section 32 of the Food Act, No. 26 of 1980.

**MAITHRIPALA
SIRISENA,
Minister of Health**

**Ministry of Health,
Colombo,
09th June, 2010**

REGULATIONS

1. These Regulations may be cited as the Food (Packaging Materials and Articles) Regulations 2010 and shall come into operation from 01st July, 2011.

2. (1) No person shall import, manufacture, transport, advertise for sale, expose for sale, sell, package, store, use or distribute any food packaging material or article which under normal and foreseeable conditions:

- (a) is injurious to human health ;
- (b) deteriorates the organoleptic characteristics of food; or
- (c) changes the nature, substance and quality of food.

(2) Every person who manufactures or imports any material or article intended to be used for the packaging of food shall ensure that there is printed thereon:

- (a) the words "FOR FOOD USE" or any relevant words or the designated symbol as indicated in Schedule I;
- (b) any special condition to be observed in the use thereof; and
- (c) the name and address or registered trade mark of the manufacturer.

(3) Every person who manufactures or imports any material or article intended to be used for the packaging of food shall be certified by the manufacturer to the effect that the raw material used in the manufacture of the packaging materials or articles meets the required quality or grade in compliance with international standards and that the packaging material or article is of food grade quality.

(4) Where plastic laminates are used for packaging food, all components of the laminate, including adhesives and inks, shall be certified by the manufacturer of each individual component, to be of required food grade quality, in compliance with international standards.

3. (1) No person shall import, manufacture, prepare or advertise for sale, expose for sale, sell, package, store, use, deliver or distribute any food:

- (a) which is packed in any packaging material or article made of enamel or glazed earthenware if such material or article is capable of imparting lead, antimony, arsenic, cadmium or any other toxic substance to any food prepared, packed, stored, delivered or exposed in such material or article which is not resistant to acid unless the leachate from the packaging material or article, satisfies parameters of the test results prescribed in Schedule II hereto.
- (b) for sale which is packed, stored, delivered or exposed for sale in any rigid or semi-rigid packaging material or article or any vessel made of polyvinyl chloride which contains more than 1mg/kg of vinyl chloride monomer
- (c) if such food contains more than 0.05 mg/kg of vinyl chloride monomer; or
- (d) packed, stored, delivered or exposed for sale in any damaged package or container.

(2) For the purpose of subparagraph (d) of paragraph (1) of this regulation, the term “damaged” includes:

- (a) chipping or distortion that affects integrity of the package or container or the wholesomeness of the product or both; or
- (b) perforation or corrosion or leakage, or a combination of these.

4. No person shall use or cause or permit to be used:

- (a) any vinyl chloride plastics in coatings applied to fresh fruits in order to retain freshness; or
- (b) any bottle, box or other container made of or containing acrylonitrile plastics as a container for the packaging, storing, delivering or exposing of food for sale.

5. (1) No person shall use or cause or permit to use in the preparation, packaging, storage, delivery or exposure for sale of:

- (a) any food in any package, appliance, container or vessel that had been used or intended to be used for any non-food product;
- (b) any sugar or flour in any sack that has previously been used for any other purpose;
- (c) any edible fat or any edible oil, in any bottle or metal container that has previously been used for any other purpose; however silos and tankers used for the storage of edible fat and edible oil are exempted;
- (d) any plastic container that has previously been used for any other purpose unless the food has been packed in any extra wrapper of food grade material;
- (e) any rice in any gunny bag or polysack that has previously been used for any other food;
- (f) bottled drinking water in any containers of not less than eighteen (18) liters in size that has previously been used for any other purpose; and
- (g) any food in any package, appliance, container or vessel that has been made from recycled plastic.

(2) Any box or crate that has previously been used for storage or packaging of vegetables

may be used for the packaging or storage of fruit and *vice-versa*.

6. For the purpose of regulation 5, where a packaging material or article containing food bears any mark or label belonging to another food it shall be presumed that such packaging material or article has been used for that particular food as shown by such mark or label.

7. (1) No person shall place any toy, coin or other article in food exposed for sale or in the package containing such food.

Provided that any person may however place with any food or in packages of such food:

- (a) any article for measuring the recommended quantity of food to be consumed, provided that such article is sterile;
- (b) the label placed inside a package of clear, transparent material if it is completely enclosed in an interior wrapper in such a manner that it has no direct contact or is not likely to come in contact with the food ready for direct consumption; and
- (c) any sachet of reduced iron powder for the purpose of absorbing oxygen.

(2) The reduced iron powder specified in sub-paragraph (c) of paragraph (1) of this regulation shall be enclosed in a sachet in such a manner that the oxygen absorber will not contaminate, taint or migrate into the food.

(3) Where the sachet of reduced iron powder is in direct contact with the food, the sachet itself and its label shall compose of material that will not contaminate, taint or migrate into the food.

(4) The sachet of reduced iron powder may contain one or more of the items specified in Schedule III to these regulations.

(5) The sachet of reduced iron powder shall be labeled with the words "OXYGEN ABSORBER" or word or words having the same or similar effect and shall be followed by the words "DO NOT EAT CONTENTS " and "CONTAINS IRON POWDER".

8. No person who is engaged in the business of packaging or storing food shall package or store such food except in a package or container which is labeled in accordance with the Food (Labeling and Advertising) Regulations 2005 made under the Food Act, No. 26 of 1980 published in *Gazette Extraordinary*, No. 1376/9 of 19th January, 2005 and any subsequent amendments or replacements.

9. The Food (Labeling and Miscellaneous) Regulations - 1993 made under the Food Act, No. 26 of 1980 published in *Gazette Extraordinary*, No. 788/7 of 14 October, 1993 are hereby amended by the repeal of regulation 25 of such regulation.

10. In these regulations, unless the context otherwise requires, "Packaging material or article" includes any packing, appliance, container or vessel.

SCHEDULE I
Regulation 2(2)

SCHEDULE II
Regulation 3.(1) a)
TEST FOR PACKAGES

(A) TEST FOR PACKAGES, APPLIANCES, CONTAINERS AND VESSELS USED FOR STORAGE OF FOOD

1. Preparation:

The article of the ware to be tested shall be washed in water containing detergent and rinsed with clean water. The surface to be tested shall not be handled thereafter. All remnant of water shall be removed from the washed ware by rinsing it with leaching solution that comprises 4 percent of acetic acid in water v/v.

2. Test:

The ware shall be filled with the leaching solution at room temperature to the maximum capacity of the ware. The ware shall be covered to minimize contamination and shall be left at room temperature for 24 hours. After the period of 24 hours, the leaching solution shall be thoroughly stirred and a portion shall be removed for analysis. The leachate shall not contain antimony, arsenic, cadmium or lead above the following limits expressed in ppm; Sb: 0.2, As: 0.2, Cd: 0.2, Pb: 0.2

(B) TEST FOR PACKAGES, APPLIANCES, CONTAINERS AND VESSELS USED FOR COOKING

1. Preparation:

As in (A) above.

2. Test:

The ware shall then be heated to 1200 C and filled to two-thirds of its effective volume with boiling leaching solution (4 percent of acetic acid in water v/v). The vessels shall be covered by its own lid, if any, and the leaching solution shall be kept boiling gently for 2 hours. Leaching solution shall be added periodically to ensure that the area of contact is not diminished, the vessel shall then be left at room temperature for 22 hours. After 22 hours, the volume of the leaching solution shall be restored to two-third of the effective volume of the vessel. After thorough stirring, a portion of the leaching solution shall be removed for analysis. The leachate shall not contain antimony, arsenic, cadmium, or lead above the following limits, expressed in ppm; Sb: 0.7, As: 0.7, Cd: 0.7, Pb: 0.7

SCHEDULE III
Regulation 7(4)

CONTENTS OF SACHET OF REDUCED IRON POWDER:

- (a) calcium chloride,
- (b) calcium hydroxide,
- (c) activated carbon,
- (d) gypsum,
- (e) iron oxide
- (f) magnesium hydroxide,
- (g) magnesium stearate,
- (h) perlite,
- (i) common salt,
- (j) talc,
- (k) zeolite.

Source FCAU /Ministry of Health, Govt. Gazette Extraordinary No.1456/22 of 03.08.2006

Food Regulations
(Control of Import, Labeling and Sale of Genetically Modified Foods)

REGULATIONS made by the Minister of Healthcare and Nutrition in consultation with the Food Advisory Committee under section 32 of the Food Act No. 26 of 1980.

NIMAL SIRIPALA DE SILVA,
Minister of Healthcare and
Nutrition

Colombo,
02nd August, 2006.

Regulations

1. These regulations may be cited as the Food (Control of Import, Labeling and Sale of Genetically Modified Foods) Regulations 2006 and shall come into operation on 1st January 2007.
2. No person shall, import, store, transport, distribute, sell or offer for sale:
 - (a) any genetically modified organism as food for human consumption;
 - (b) any food containing or consisting of genetically modified organisms;
 - (c) any food produced from or containing ingredients produced from genetically modified organisms;
without the approval of the Chief Food Authority (hereinafter referred to as the "Authority").
3. Any food or ingredients used in the preparation of food as is referred to in regulation 2, shall not:
 - (a) be injurious to the health of the consumer;
 - (b) differ nutritionally to the disadvantage of the consumer as opposed to the nutritional value of food or food ingredients consumed normally by such consumer.
4. Any person (hereinafter referred to as the 'applicant' who intends to import store, sell or offer for sale the food or the ingredients used in the preparation of food as is referred to in regulation 2 shall submit an application to the Authority in the form specified in the Schedule hereto.
5. (1) The application referred to in regulation 4 shall:
 - (a) contain the necessary information, including copies of the studies which have been carried out;
 - (b) contain the modification done on the Deoxyribonucleic acid (DNA) and protein, the process, the countries where these products are sold and any other materials

which are available to demonstrate that the food or ingredients used in the preparation of food, complies with the criteria laid down in regulation 3;

- (c) indicate the manner of presentation and labeling in accordance with the requirements under regulation 11.

(2) The application referred to in regulation 4 shall be accompanied by such information relating to the food or ingredient used in the preparation of food, compiled in a readily comprehensive manner.

6. The Authority shall acknowledge receipt of the application in writing, within fifteen days of receiving. The acknowledgement shall include the date of receipt of the application. The Authority shall forthwith submit the application for a scientific risk assessment report to a Technical Evaluation Committee (hereinafter referred to as the “TEC”), appointed by the Authority on the recommendation of the Food Advisory Committee (hereinafter referred to as the “FAC”).

7. Where the TEC is satisfied with the information furnished in the application, a scientific risk assessment report shall be issued by TEC within a period of three months from the date on which the application was received by it. The TEC may request the applicant to provide supplementary information in support of the application. This information shall be provided within a period of three months from the date of receipt of the request. The time period of three months for the preparation of the report shall not apply until the information is provided by the applicant by way of oral or written explanation.

8. The Authority shall charge a processing and assessment fee which shall be determined by the Authority in consultation in the FAC from time to time to be a non-refundable deposit be paid by the applicant.

9. The Authority shall forward the report of the TEC to the FAC and shall communicate the decision on the recommendations of the FAC to the applicant.

10. Where the application has been approved and permission granted in accordance with these regulation the applicant shall be permitted to place the product in the market subject to appropriate labeling of the product.

11. The label on or attached to a package of genetically modified food or food ingredients used in the preparation of good must include the statement ‘genetically modified’ in conjunction with the name of that food or ingredients used in the preparation of food, or processing aid irrespective of the size of the label or package.

Example 1: for single ingredient genetically modified foods “Soy flour - Genetically Modified” or “Soy flour – from genetically modified soya beans”

Example 2: for genetically modified ingredients: “Ingredients; Soy Protein Isolate

(genetically modified), Maltodextrin, Vegetable Oil, Emulsifier (INS 471)”

12. Where genetically modified food is displayed for retail sale other than in a package, any information that would have been required under regulation 11, shall, where it is attached to the food, be considered sufficiently labeled.

13. Food which contains or has genetically modified organisms less than naught decimal five per centum (0.5%), are exempted from the provisions of these regulations:

Provided that the presence of such genetically modified organisms are considered technically unavoidable and the organisms have been subjected to a scientific risk assessment and considered to be safe.

14. (i) Where new information or a reassessment of the existing information reveals that the use of food or genetically modified food approved by these regulations endangers human health, the Authority shall immediately suspend the sale of such food.

(ii) The Authority shall require the person who submitted the application for approval to import, store, transport, distribute or sell such food, as the case may be, to withdraw the product from the market and such person shall immediately comply with the requirement.

15. In the event of refusal of an application, the applicant may appeal within one month of such refusal to the Authority, along with any further information in support of the application.

16. Any Appeal received under regulation 15 shall be referred by the Authority to the TEC. The TEC shall within thirty working days from the receipt of such appeal prepare a report which shall be forwarded to the FAC for further consideration of the application.

17. There shall be only one appeal made in respect of a food or ingredients used in the preparation of food. The Authority shall not accept more than one appeal in respect of the same food or ingredient.

18. The FAC shall communicate its response to the Authority within one month of receiving the decision from the TEC, and the Authority shall communicate the decision of the FAC to the applicant, stating reasons for the decision. The decision of the FAC shall be final.

19. Notwithstanding the provisions of regulation 17, any applicant may make a fresh application in respect of the same food or ingredients used in the preparation of food in accordance with regulation 4.

SCHEDULE

**Director General of Health Services,
(Chief Food Authority)**

APPLICATION FOR A PERMIT TO IMPORT GENETICALLY MODIFIED FOOD/FOOD INGREDIENTS OR MATERIALS CONNECTED THERE TO

I/We wish to import genetically modified food/import and sell genetically modified food/import genetically modified substances to be used as food ingredients/ prepare/process / manufacture and sell genetically modified food, the details of which are furnished below as required in terms of regulation 4.1

1. Name and address of the applicant/s and other relevant information of the organization/trade;
2. Description of the food or food ingredient intended for import and specifications:
3. Detailed description of method or production/manufacturing of the food:
4. Detailed description of the host organism or the food:
5. Description of donor organism:
6. Information of changes such as nutrients, toxicants or allergic reaction etc. in the product.
7. Copies of the studies which have been carried out and any other material that is available to demonstrate the safety of the food:
8. Support by analysis report as data determining the fact that the food is not different from conventional food:
9. Where appropriate, the conditions for placing in the market, foods produced from it, including specific conditions for use and handling:
10. Method for detection, including sampling and identification of the transformation event. Where applicable method for detection and identification of transformation event in the food and / or in the food produced from it:
11. Samples provided of modified food and their controls;
12. Documents relating to the approvals and marketing of the same/identical food in any other country or countries:
13. Proposed scheme for post-marketing monitoring
14. Any other material relevant to the application to facilitate and expedite the process of assessment

1. Strike off inapplicable words

I/We hereby confirm that the information furnished by me/us are true and accurate to the best of my/our knowledge and that I/We would promptly notify the Chief Food Authority in the event of any information furnished are subsequently found to be inaccurate or requires revision in the light of new information provided by scientific research. I/we also undertake to provide any further information relating to the application and the relevant

product whenever required by the Chief Food Authority. I/We further undertake to abide by all the conditions stipulated by the Chief Food Authority in respect of import, manufacturing/processing, packaging, labeling, storing, transport and sale of the products in the event of approval being granted.

Signature/s of Applicant/s

Date:.....

Note: *Applicants are expected to provide all the information requested above in detail. Reference should be made in the respective columns to documents or materials attached to the application. If, for any special reasons, they are unable to provide the information in respect of certain issues, they should explain why they are unable to do so:*

3.3 Federal Democratic Republic of Nepal

Note: Nepal follows Hindu calendar (Bikram Sambat) which is approximately 57 years ahead of international calendar. Year 2027 in Nepali calendar would be 1970 in International calendar.

1. ADMINISTRATIVE AUTHORITIES

Inception of food control system in Nepal goes back to sixties, when Government of Nepal (GoN, then HMG Nepal) decided to open one new department in 1960 in the name of Department of Food which was put structurally under the Ministry of Food, Agriculture and Irrigation. The department endeavoured to establish a regulatory set up in the country for food control. As a result, Food Act enacted in Nepal for the first time in 1966. The opening of an institutional set up for food regulation in the country was also inspired by the international trends, because even before sixties, there were already established systems in operation in many countries in the world including India. At the beginning, it was generally realized in this region that the threats to the quality of food is mainly intentional which is nothing but malpractices and adulteration guided by the profit motive. It could also be observed from the fact that the first food act enacted in India was given the name as Prevention of Food Adulteration Act 1954.

During the decade while Nepal was initiating the process of formulation food regulatory frameworks, very few operational models of food control authorities were existing around few developed countries of the world including India (PFA, 1954). Hence, in the course of formulating food regulatory framework in Nepal, many of the technical aspects were referred from PFA which was rather reasonable because consumers in both the neighbouring countries have been sharing the same pattern of food habits and there has been cross boarder exchange of foods between the two countries in substantial numbers and quantity. These days, the trend of updating of regulation is mainly guided by the codex guidelines.

1.1 Efforts for Updating Regulatory Framework

Food Act was initially proclaimed in 1966. With the change in time, different methods of food processing and preservation came into existence. The pattern of food trade has changed dramatically. Accordingly the existing Food Act has gone through different amendment. It covers: (1) Short Title and commencement; (2) Amendment in Section 2 of the 1966 Food Act; (3) Amendment in Section 3 of the Principal Act; (4) Amendment in Section 1 of the Principal Act; (5) Amendment in Section 5 of the Principal Act; (6) Amendment in Section 8 of the Principal Act; (7) Amendment in Section 9 of the Principal Act; (8) Amendment in Section 13 of the Principal Act; and (9) Conversion.

The original Food Act does not cover the mandatory requirements and regulation mechanisms for functional foods, nutraceuticals, GM foods and many other dimensions

of newer food processing technologies. To address these issues, the existing Food Act has to be replaced with newer version, which has already been drafted and is under the process of promulgation by legislature.

With consumer awareness and changed pattern of food trade in Nepal, food quality control and food safety has become the much prioritized sector of government. The structural extension of the department and changing it into the Food Safety Authority has been advocated.

Besides Department of Food Technology and Quality Control, Nepal Bureau of Standards and Metrology has been also working in the field of food quality assurance. It provides voluntary quality certification marks.

1.2 Nepal Bureau of Standards and Metrology (NBSM)

Nepal Bureau of Standards and Metrology (NBSM) is the National Standards Body of Nepal. It is one of the departments under Ministry of Industry, Government of Nepal. NBSM has formulated 862 Standards (as of 19.07.2011 Ref: www.nbsm.gov.np), approved by National Council for Standards.

The standards cover various industrial and consumer products, test methods, management system, basic standards etc. The standards are formulated based on internationally adopted practices. Majority of the standards published by NBSM are voluntary standards, however it could be mandatory to those who apply and comply the provisions as laid down in Nepal Standards (Certification Mark) Act, 2037 (1980). So long the proponent maintains the quality criteria and comply the law, he is eligible to use NS mark in the product for which he had applied for.

Categorization of NBSM Standards

A. Total number of standards published (as of 19.07.2011)	862
B. Standards for food products	106
C. Standards for food testing methods	90
D. Standards for systems related to food	29
E. Standards for food packaging materials	13
F. Standards for animal feed	4
G. Total standards related to food (B to F)	242
H. Standards for other products and systems (A-G)	620

1.3 National Council of Standards

Under the "Nepal Standard (Certification Mark) Act 2037", Nepal Council for Standards (NCS) was formed as the governing body for Quality, Standards, Testing and Metrology (QSTM) activities in Nepal. NBSM is to act as the secretariat to this Council.

- **Functions, Duties and Responsibilities of Nepal Council of Standards (NCS)**

- To establish, name and revise national standards.
- To adopt and or to recognize standards so established by other national bodies and International Standardization Institutions.
- To determine the fees for granting license to use quality certification Marks (NS Mark).
- To form committees, sub-committees as per future need in the field of formulation of standards and related matter.
- Other activities as directed by the Act.

1.4 Legislations and Agencies - Food Safety

Laws and regulations as well as agencies and ministries related to food safety are shown below.

Acts/Rules and Implementing Departments	Related Ministries
Food Act 1966 DFTQC	MoAD
Food Regulation 1970 DFTQC	MoAD
Consumer protection Act 1998 DoC	MoCS
Consumer protection Rules 2000 DoC	MoCS
Slaughterhouse and Meat Inspection Act 1998 DLS	MoAD
Slaughterhouse and Meat Inspection Rules 2000 DLS	MoAD
Local self-governance Act 1999 Local Govts	MoLD
Local self-government Rules 2000 Local Govts	MoLD
Nepal Standards (Certification mark) Act 1980 NBSM	Mol
Nepal Standards (Certification mark) Rules 1983 NBSM	Mol
Standard weights and Measures Act 1968 NBSM	Mol
Standard weights and Measure Rules 1978 NBSM	Mol
Animal health and livestock service act 1998 DLS	MoAD
Animal health and Livestock service Rules 2000 DLS	MoAD
Breast feeding substances (Sales & Distribution control) Act 1992 DH/DFTQC	MoHP/MoAD
Breast feeding substances (Sales & Distribution control) Rules 1994 DH/DFTQC	MoHP/MOAD
Iodized Salt (Production Sale and Distribution) Act 1999DH/DFTQC	MoH/MoAD
Feed Act 1976 DFTQC	MoAD
Pesticide Regulation Act 1991 DoA	MoAD

DFTQC: Department of Food Technology & Quality Control.

MoAD: Ministry of Agriculture Development.

MoCS : Ministry of Commerce and Supplies.

MoLD: Ministry of Local Development.

Mol: Ministry of Industries.

MoHP: Ministry of Health & Population.

DH: Department of Health.

1.5 Central Food Laboratory

The Central Food Laboratory (CFL) is authorised to investigate the quality and safety of food products in accordance with the Food Act and Regulations. The laboratory has the capability to analyse all major food commodities; has facilities for monitoring pesticide residues, heavy metals, mycotoxins and undertake microbiological analysis. The laboratory has equipment and manpower to carry routine analysis and testing of chemical residues. CFL is now the only accredited food testing laboratory in Nepal.

1.6 Related Laws and Regulations (Years are as per International calendar)

● Excise Act & Excise Rates for 2011 15/02/2011

The first 14 pages are the Excise Act, with the remainder of the pages covering excise rate for a range of products: Juices, All kinds of non-alcoholic beverages, Beer, Wine, Cider, Spirits, and Raw Materials for making Spirits, Liquors, and Over-Proof beverages, along with a range of other items not related to food.

● Plant Protection Rules 22/03/2010

Covers (1) Preliminary; (2) Provisions relating to functions, duties and powers of Committee and Organization; and (3) Provisions relating to entry permit. Schedule 1 - Format of application for entry permit. Schedule 2 - Format of entry permit of plants or plant products. Schedule 3 - Format of entry permit of biological control agents, beneficial organisms. Schedule 4 - Format of entry permit of soil, moss, peat and other plant growing means. Schedule 5 - Format of entry permit of germplasm / living modified organism / genetically modified organism / transgenic substance. Schedule 6 - Format of information to be given in the case of inappropriateness to issue. Schedule 7 - Format of application for the renewal of entry permit. Schedule 8 - Format of application to be made at entry point for entry permit. Schedule 9 - Format of clearance slip. Schedule 10 - Format of application for phytosanitary certificate. Schedule 11 - Format of phytosanitary certificate. Schedule 12 - Plant re-export phytosanitary certificate. Schedule 13 - Format of information to be given in the case of inappropriateness to issue Phytosanitary certificate. Schedule 14 - Format of application for permit to carry consignment in transit. Schedule 15 - Format of entry permit to carry consignment in transit. Schedule 16 - Format of charge sheet.

● Plant Protection Act 01/07/2002

The present Law repeals the former one, Act No. 2029 (1972), and institutes of the Plant Quarantine Check Post, whose powers and areas of influence shall be determined by the Government via notification in the Nepal Gazette. All importation and exportation of plants, seeds and related items must be licensed by the Plant Quarantine Check Post and fees paid accordingly. Under this Act, it is furthermore instituted the National Plant Quarantine Committee, whose functions and tasks shall be the protection of plants from whatever harmful occurrence (pests, diseases, infections).

● Prohibitions and Restrictions Regarding the Import of Plants or Plant Products 07/04/1975

For the purpose of implementing section 3 of the Plant Protection Act, 2029, and for the purpose of preventing certain plant diseases, the present document contains a list of countries from which the importation of specified plants and plant products is prohibited.

- **Nepal Agricultural Research Council Act 21/01/2010**

To establish and manage the Nepal Agricultural Research Council in order to enhance the economic standards of the general public by doing study and research works on the problems of the agricultural sector and finding out solutions to the problems. First issued 7 April, 1992 / this document amended 21 January, 2010.

- **Seeds Act 21/01/2010**

To maintain the convenience and economic interest of the general public by providing the Seeds of quality-standards in a well-planned manner upon producing, processing and testing the Seeds of high quality-standards to have the production of different crops increased. First issued: 26 October, 1988 / Last amended: 21 January, 2010.

- **Iodized Salt (Production, Sale and Distribution) Act 21/01/2010**

To make provision for the production, import, supply, sale, distribution of iodized salt in a proper quantity and for mixing iodine with salt in order to prevent and eradicate extensive and serious effects caused to public health from iodine deficiency. First issued 15 January, 1999 / Last amendment 21 January, 2010.

- **Animal Health & Livestock Services Rules 00/00/2007**

Covers: (1) Preliminary; (2) Provisions relating to animal quarantine; (3) Provisions relating to Letter of Recommendation; (4) Miscellaneous. Schedule 1 - Method of disinfection. Schedule 2 - Format of Quarantine Certificate. Schedule 3 - Format of the Health Certificate for Dog and Cat / Format of Health Certificate for Domestic or Wild Animal / Format of Health Certificate for Semen of Animal / Format of the Sanitary Certificate for Meat of Domestic Animal / Format of the Sanitary Certificate for Product of Animal Origin destined for use in Animal Feeding, Industrial or Pharmaceutical Use / Format of the Animal Health Certificate for Equines / Format of the Animal Health Certification for Avian / Format of the Health Certificate for Eggs, Day-Old Chicks, Other Newly-hatched Avian Species and Hatching Eggs. Schedule 4 - Format of the Application for Letter of Recommendation. Schedule 5 - Format of the Application for Letter of Recommendation. Schedule 6 - Format of the Application for Letter of Recommendation. Schedule 7 - Format of the Application for Letter of Recommendation. Schedule 8 - Format of the Application for License. Schedule 9 - Format of the License. Schedule 10 - Particulars of the disease to be enlisted. Schedule 11 - The Particulars to be Made Available While Making Application for the Production, Sale and Distribution or Import of Biological Product. First issued 2000 / Last amended 2007.

- **Animal Health & Livestock Services Regulation 21/02/2000**

The Regulation provides for regulation on animal, products of animal origin and livestock product materials, the document comprises four Chapters: Chapter I, Preliminary; Chapter II, Provisions relating to Animal Quarantine; Chapter III, Provisions relating to letter of recommendation, license and quality standard; Chapter IV, Miscellaneous. Extensive forms, related to the provisions, are listed in the Annexes.

- **Animal Slaughterhouse & Meat Inspection Act 22/03/1999**

To establish slaughterhouse and arrange for meat inspection to safeguard the health and welfare of the people in general and to control adulteration in meat and meat products and to maintain reasonable standard of meat by protecting the wholesomeness, quality and adequacy of meat.

- **Slaughter & Meat Inspection Regulation 00/00/2001**

Covers: Establishment of Slaughter house in Non-governmental sector; Establishment & Operation of a Slaughterhouse; Meat Seller to Obtain License; To Slaughter Animal in Other Places; To Keep Suspected Meat Safely; Meat Seller to Comply with Terms & Conditions; Procedure for Ante-mortem Examination of Animals; Procedure for Post-mortem Examination; Functions, Duties & Powers of the Meat Inspector; Functions, Duties & Powers of Meat Supervisor; Conveyance of Meat; To Disinfect; To Stamp or Mark; Charges for Inspection; etc.

- **Aquatic Animal Protection Act 20/02/1997**

To make provisions on the protection of aquatic animals and other matters pertaining thereto in order to maintain peace and order as well as convenience and economic interests of the general public. First issued: 13 December 1960 / Last amended: 20 February, 1997.

- **National Dairy Development Board Act 10/08/1998**

To establish and manage the National Dairy Development Board in order to maintain the health and convenience of the general public by producing much milk within the country through public participation and bringing about coordination among the programme on dairy production launched by the governmental and private sectors. First issued: 29 April, 1992 / Last amended: 10 August, 1998.

- **Consumer Protection Act 28/01/1998**

The aim of this Act is to protect consumers from irregularities concerning the quality, quantity and prices of consumer goods or services, ensuring that no one lowers or removes the attributes or usefulness of consumer goods or services, preventing circumstances in which monopolies and unfair trade practices may lead to an increase in prices, as well as false and misleading propaganda regarding the use and usefulness of consumer goods or services, selling, supplying, importing, exporting and storing safe and quality consumer goods or services, and protecting the rights and interests of consumers through the establishment of an agency for redressing the hardships of consumers, and thus maintaining the health, convenience and economic welfare of consumers.

- **Mother's Milk Substitutes (Control of Sale & Distribution) Rules 14/08/1994**

1. For the protection and promotion of breastfeeding, the committee may itself or through sub-committees or inspectors supervise or cause to be supervised as to whether the health care system, health worker and the manufacturer or distributor have observed the provisions required to be observed under the Act and these Rules.

2. This Regulation further implements provisions of the Mother's Milk Substitutes (Control of Sale and Distribution) Act, 1992. The Regulation, among other things, provides for applications for the certification of infant food products; applications for the approval of labels; and powers of inspectors.

- **The Mother's Milk Substitutes (Control of Sale & Distribution) Act (17pages) 13/08/1992**

This Act aims at promoting breast feeding and controlling the sale and distribution of infant food. The Act provides for the establishment of a breastfeeding protection and promotion committee, defines its internal organization and lays down its duties and powers which include: to supervise the compliance with this Act; to review and approve the labels submitted by the manufacturers and distributors which are in conformity with the provisions of this Act; and to formulate a national policy for the protection and

promotion of breastfeeding. The Act further specifies the acts prohibited by manufacturers and distributors and makes provision for: the certification of products from the central food laboratory; the labelling of products; and the conformity to the standards of the Nepal Bureau of Standards.

2. CURRENT LEGAL FRAMEWORK

2.1 Food Act 2023 (1966) The main features as provisioned in Food Act are:

- Definition of food
- Prohibition for production and distribution of adulterated and low quality foods
- Power for seal and confiscation
- Punishment for violated cases
- Provision for licence to be obtained
- Provision for Food Standards and Standardization Committee
- Bans the production, sale and distribution of substandard, contaminated or hazardous food items (Article 3).
- Regulates the misbranding of sales by false statement.
- Provision for the detention of food products
- Provision for licensing of food establishments
- Provision for enforcement and penalties
- Provision for analysis of food in specified laboratories (Article 8)
- Establishes the Food Standardisation Board (Article 9).
- Establishes the Nepalese government as a plaintiff, with authority to hear cases (Article 10).
- Sets out the process for appeal (Article 12).
- Provision for research and analysis laboratories (Article 13); and
- Sets out the functions of the Department of Food Technology and Quality Control (DFTQC) and the Food Standardization Board.

2.2 Food Rules 2027 (1970)

As already mentioned above, in 1966 the promulgation of Food Act took place first time in the history of Nepal, its procedural part for actual implementation had to be worked out which took additional four years till 1970. As a result, food regulation based on the mandate given by Food Act came into existence in 1970 that incorporated many essential regulatory and technical aspects as listed below.

- Provisions for food additives
- Contaminants
- Inspections
- Licensing
- Analysis of food

- Right and duties of public analyst
- The working procedure of the Dept. of Food Technology and Quality Control (DFTQC) as food quality control authority
- Food Inspector; basic qualification required to be food inspector and his right and duties
- Method of sampling and evidential documents to be prepared at sampling
- Detention of food if found decomposed or rotten at production or sale
- Filing of cases
- Food standardization committee and its working procedure
- Food labelling
- Matters to be observed by food seller
- Use of colour and preservative in food
- Licence to be obtained by food business operator and its procedure

Altogether food regulation comprises with 9 chapters and 14 schedules. The detailed formatting of the following aspects are given in the schedules:

- Food inspectors' licence
- Sampling procedure and documents thereof
- Mention on quantity of samples for various food products
- The limits of permitted coal tar dyes and natural dyes to be used in foods
- List of class 1 and class 2 preservatives

2.3 Department of Food Technology and Quality Control (DFTQC)

Website: www.dftqc.gov.np/

The Department of Food Technology and Quality Control (DFTQC) functioning under Ministry of Agriculture Development (MoAD), Government of Nepal is the agency responsible for administering the food control programme in Nepal.

1) DFTQC delivers its activities through three Divisions and two sections as given below:

- Quality Control Division
- Central Food Laboratory
- Food Technology and Training Division
- National Nutrition Programme
- SPS Enquiry Point

2) The functions of DFTQC, as specified in Section 7.2 (Part II) of the Food Act, are as follows:

- To analyse appeal (requested) samples
- To assist the Food Standardisation Board in generating scientific data to set Standards for food.
- To conduct food inspector training program and issue licenses for food inspectors
- To regulate imports of food products from the perspective of quality control
- To facilitate export of food products from the perspective of food safety and quality

- To provide laboratory services to food quality control programmes including industries and import export trades as requested

3) Quality Control Division

This is the division responsible to execute the functions and activities specifically focused to food quality control (implementation of Food Act & Regulation). Within this division there are sections and respected activities like:

- Food inspection
- Industry licensing
- Consumer awareness
- Food standardization and compliance

4) More details of DFTQC's responsibilities are given in Annex I

2.4 Food Standard Fixation Committee

The major function of the Food Standardisation Committee is to make recommendations to the Government on the development of, or amendment to standards taking account of Codex practices, scientific justification and production practices. The Board is chaired by the Secretary of the Ministry of Agriculture Development and consists of representatives from several ministries, industry and consumer association.

● Structure of Food Standard Fixation Committee

(1) A Food Standard Fixation Committee is hereby formed as follows so as to carry out the functions as specified in the Act and this Regulation:

(a) Secretary, Ministry of Agriculture Development	Chairperson
(b) Representative, Ministry of Law and Justice	Member
(c) Representative, Ministry of Industries	Member
(d) Representative, Ministry of Commerce	Member
(e) Representative, Ministry of Supplies	Member
(f) Representative, Ministry of Home	Member
(g) Representative, Ministry of Health	Member
(h) Representative, Kathmandu Municipal Council	Member
(i) One food industry entrepreneur nominated by Federation of Industries and Commerce	Member
(j) One nominated by the Ministry of Supplies from amongst the food consumers	Member
(k) Chief, Central Food Laboratory	Member Secretary

(2) The Ministry level representative member shall be of at least under-secretary level. The term of the member nominated under clauses (i) and (j) of sub-rule (1) shall be of two years.

3. MANDATORY FOOD STANDARDS

3.1 General Standards

The standards of food commodities either common staple or their products, are included in the generic standards. Standards of milk and milk products, grains and grain products, edible oils and fats, fruits and vegetable products, spices, sugar and sweetener, bakery and confectionery products, tea and coffee etc. come under this category.

The number of food commodities included in **Mandatory Standards** in Nepal is shown below.

S. N.	Food Groups	No. of Food Commodities
1	Milk & Milk Products	18
2	Fats & Oils	16
3	Fruits & Vegetable Products	17
4	Spices & Condiments	22
5	Tea, Coffee, Cocoa and their Products	3
6	Salt	2
7	Cereal, Pulses & their Products	23
8	Processed Drinking Water	1
9	Non-Alcoholic Beverage	1
10	Sweetening Agent	3
11	Sweets and Confectionaries	3
Total		109

3.2 Food Safety Standards (Horizontal Standards)

As the trend of adding more chemicals in the forms of fertilizers, pesticides and veterinary drugs increased in agriculture chain it has increased the risk of their residues in food. Likewise food processing technology as developed world over in fast pace also created wider ground of adding more and more chemicals in the form of processing aids, colours, preservatives and so on. As a response to these increasing risk on food safety situation, food safety standards are being reviewed in developed countries and it is in increasing pace in developing countries. As a result, newer frameworks and quantitative standards and limits are coming up as horizontal food safety standards. In this context, Nepal has moved few step forward in preparing horizontal food safety standards. But there is long way to go to have a significant work in this regard. Some of the works done so far in this direction are:

- Food safety has been also duly emphasized as food quality in food rules wherever deemed necessary.
- The safety limits as MRLs have been established and published for 29 pesticides that is applicable to food products belonging to group: Cereal, Pulse and their Products (total products 23).

- Maximum residue limits (MRL) have been established for heavy metals like Lead, Copper, Arsenic, Tin, Zinc, Cadmium, Mercury, Chromium, and Nickel which is applicable to various food products like Beverages, Baking Powder, Edible Oils and Fats, Spices Powders, Yeast and Yeast products, Carbonated Water and Other foods.
- The limit for mycotoxin including aflatoxin has been established (which should not be more than 20 ppb). This is stated at the end of generic standards for each of Whole Green Gram, Split Green Gram, Dehusked Split Green Gram, Red Gram, Whole Black Gram, Split Black Gram, Whole Bengal Gram, Split Bengal Gram, Whole Lentil, Dehusked Lentil, Bengal Gram Flour, Wheat, Maize, Corn Flakes and Rice.
- The limit of Aflatoxin B1 should not exceed 50 ppb in the feed of milking cattle prepared by feed industries.

3.3 The prevailing food regulatory framework has not mentioned about functional foods and nutraceuticals.

4. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

For those additives and processing aids which are not yet established and published in food standards of Nepal, reference is made in Codex and PFA (now FSSAI). During the course of standard development, whether it is for generic standard, or for other additives, the frequently referred standard used to be the standard published by PFA (now FSSAI) and CODEX. This has also facilitated the efforts toward the process of harmonization of standards.

4.1 Food Additive Definitions and Functional Classes

- 1) **Flavours:** Natural and artificial flavours in processed foods are referred in Codex and PFA publication. No detail on qualitative and quantitative is given in Nepalese food standard.
- 2) **Processing Aids:** No specific definitions and quantitative limits are available in the existing Food Act and Regulation regarding processing aids.
- 3) **Carry Over:** No specific requirements available but generally guided by Codex requirements.
- 4) **Functional Classes:** There are many Additives coming up in internal and external markets with specific claims as per their functional role. This has been one of the important sectors for food regulation. However in the present context, only few classes such as food colours (natural and artificial), preservatives (class I and Class II) and few vitamins and minerals are given with quantitative limits in Food Regulation and Standards in Nepal. Details are given below.

4.2 Use of Colours in Foods (Clause 22)

No person shall, in a manner contrary to the provisions contained in Schedule-10,

produce, sell, distribute or export a food mixed with a colour, or keep such mixed substance for any of such purposes. "Colour" means any natural or artificial colour to be mixed in a food.

- 1) Coal Tar Colours (Synthetic Dyes) Allowed To Be Used In Food:** No coal tar colour (dye) except the following coal tar colours synthetically produced or a mixture thereof shall be used in any food:

List of Coal Tar Colours Permitted to Be Used in Food

Type	Colour Index No. 1956	Common Name	Other Name
Red	16185	Amaranth	Food Red 9
Red	16255	Ponceau 4R	
Red	45430	Erythrosine	Food red 14
Red	14720	Carmoisine (Azo Rubin)	
Red	16045	Fast red E	
Yellow	19140	Tartrazine	Food yellow 4
Yellow	15985	Sunset yellow FCF	
Blue	73015	Indigo carmine	Food blue 1
Blue	42090	Brilliant blue FCF	
Green	44090	Wool green B.S.	
Green	42053	Fast green FCF	

- 2) Maximum Limit of Permitted Colours:** The above-mentioned Coal Tar Colours may be added to any food that is ready for consumption not in excess of 200 milligram per kilogram.
- 3) Coal Tar Colours to Be Pure:** The Coal Tar Colours specified in 1) above to be used in any food shall not contain any substance that is injurious to health.
- 4) Restriction on the Use of Coal Tar Colours:** The Coal Tar Colours specified in 1) above shall be used only in the following food:
- (1) All kinds of ice-cream
 - (2) Cheese
 - (3) Different preparations from egg
 - (4) Biscuit, cake, pastry, and other sweets
 - (5) Non-alcoholic beverages except tea, coffee, coca cola
 - (6) Custard powder
 - (7) Jelly powder
 - (8) Processed or preserved fruits and green vegetables
 - (9) Soup powder
 - (10) Flavouring agents
- 5) Prohibition of the Use of Coal Tar Colours:** Even the Coal Tar Colours specified in clause (a) are not allowed to be used in any food to be eaten after cooking.
- 6) Natural Colours allowed to Be Used in Food:** Natural colours other than those mentioned below are not allowed to be used in any food:

List of Permitted Natural Colours

Type	Colour Index	Common Name
Yellow	75.120	Annatto
-do-	75.130	Carotene or β -carotene
-do-	75.100	Saffron
-do-	-	Riboflavin or lactoflavin
-do-	75.150	Turmeric or curcumin
-do-	-	Lentophil
Gray	-	Caramel
Red	75.470	Cochineal, carmine or carmine acid
-do-	-	Ratanjot, haematoxylin
-do-	-	Arrayal (atsin)
-do-	75.520	Alkanet, alkaline
Green	75.810	Chlorophyll

- 7) Restriction on Use of Inorganic Colours and Pigments:** No inorganic colours or pigments are permitted to be used in food preparations

4.3 Use of Preservatives in Food (Clause 22)

No person shall, in a manner contrary to the provisions contained in Schedule-11, produce, sell, distribute or export a food mixed with a preservative, or keep such mixed substance for any of such purposes. "Preservative" means any substance used to prevent, suppress or retard fermentation or acidification in, or any other process of decomposition of, any food.

- 1) First Class Preservatives:** The following preservatives shall be deemed to be the first class preservatives, and these preservatives may be added in any quantity to any food.

- (1) Common salt
- (2) Sugar/sugar candy
- (3) Dextrose
- (4) Glucose
- (5) Wood smoke
- (6) Spices
- (7) Vinegar or acetic acid
- (8) Honey
- (9) Hops
- (10) Alcohol

- 2) Second Class Preservatives:** The following substances shall be deemed to be the Second Class Preservatives. These preservatives have to be used in the foods shown in the following table in the quantity not exceeding the limits shown in the following table:

- (a) Sodium or potassium nitrites
- (b) Benzoic acid and salts thereof

(c) Sulphurous acid and sulphur dioxide

● List of Foods and Permitted Levels of Preservatives

Description of Foods		Parts per million (ppm)	
		Sulphur dioxide	Benzoic acid
1	Sausages and spices and sausage meat containing raw meat	450	
2	Fruit pulp or juice (for conversion into jam, crystallized glaze or cured fruit etc.) (a) Cherries (b) Strawberries and raspberries (c) Other fruit juice	3000 2000 1000	
3	Fruit juice concentrate	1500	
4	Dried fruits (a) Peaches, apples, pears, apricots and other fruits (b) Raisins, Kissmis	2000 750	
5	Non-alcoholic drinks including fruit drinks, lemon juices	350	600
6	Jam, marmalade, fruit jelly and pickles etc.	40	200
7	Fruit pulps not mentioned in this list	350	
8	Sugar, glucose, <i>Gur</i> and <i>Khandsari</i> etc.	70	
9	Corn flour or starchy food	100	
10	Liquid Glucose	450	
11	Gelatine	350	
12.	Beer	70	
13.	Cider apple juice	200	
14.	Wine	450	
15.	Brewed ginger beer		120
16.	Sweet soda water	70	120
17.	Coffee extract		450
18.	Pickles and chutneys made from fruits or Vegetables		250
19.	Tomato and other sauces		750
20.	Tomato pulps (puree and paste)		250
21.	Syrup and sherbets	600	600
22.	Dehydrated vegetables (a) Tomato (b) Cabbage (c) Beans, peas, carrot, <i>Palungo</i> , <i>Salgam</i> etc.	550 3000 2000	
23.	Dried Ginger	2000	
24.	Processed meat (cooked pickled) including ham and bacon	Sodium or potassium nitrite not exceeding 200 ppm	
25.	Danish tinned caviar (salt added fish)		50

Explanation:

(1) Parts per million (ppm) means one part of one million parts.

- (2) Sodium or potassium nitrites shall be used only in the meat of any other types which may be used to preserve hams or bacons.
- (3) Prohibition on the use of more than one second class preservative: The use of more than one Second Class Preservative in any food is prohibited.

4.4 Prohibition of Sale of Contaminated, Sub-Standard or Harmful Foods

- 1) No person shall him/herself or through his/her representative produce, sell, or hold for the sale of, the following food:
 - (a) Contaminated or sub-standard food
 - (b) Brominated vegetable oil (BVO) mixed food
 - (c) *Khesari, Kshesari* pulse, *Khesari* flour, and food containing *Khesari*
 - (d) Fruits cooked artificially from carbide (acetylene) gas
 - (e) Such other food as Government of Nepal may, by a Notification in the Nepal Gazette, specify.
- 2) No person shall sell the flesh of any animal having died a natural death or a food containing such flesh or keep such flesh or food for sale.

4.5 Specifications for Food Additives

- **List of Permitted Food Additives**

(a)	Vitamin A or Carotene	By the proportion of the international unit of vitamin "A" (in doing so, 0.6 microgram is to be considered as an international unit of beta carotene or vitamin A).
(b)	Vitamin D Vitamin D ₂ Calciferol and Vitamin D ₃	By the proportion of the international unit of vitamin "D".
(c)	Other vitamins: Thiamine (Vitamin B ₁) Riboflavin (Vitamin B ₂) Niacin or nicotinic acid Pyridoxine (vitamin B ₆) Folic acid Pantothenic acid Inositol Biotin Parasavini benzoic acid Choline	Milligram, by the proportion of the vitamin concerned.
(d)	Alpha Raibazil phosphate (Vitamin B ₁₂) Ascorbic acid (Vitamin C) Tocopherol (Vitamin E) Vitamin K	Milligram, by the proportion of the nutritional minerals concerned.
(e)	Nutritional minerals: Calcium Iodine Iron	Milligram, by the proportion of the nutritional minerals concerned.

5. CASE STUDIES PART 1: COMMODITY FOOD STANDARDS

The standard development process, at its beginning during seventies and eighties, mainly focused to prepare standards for common primary products like cow milk, buffalo milk including the standards for whole grains of rice, wheat, maize and few of commonly used primary products. In addition to these, the standard making process gradually covered milled products like whole wheat flour, refined wheat flour, milled pulses including pasteurized milk and some spices, whole and grind. Then so far officially published standards were mainly confined to compositional parameters with some permissible limits for objectionable components like damaged grains, insect fragments, etc.

Towards the end of eighties and beginning of nineties, the trend of trade liberalization created conducive environment for trade expansion which brought new momentum in trade. As a result, importation of refined oils and other processed food products significantly increased in Nepalese markets. Further the trend of establishment of agro food industries in the sector of vanaspati, refined flour mill, biscuit and confectionery, and instant noodle took in an increasing pace. Thus the production, trade and consumption of processed foods urged the need of standards for varieties of processed food products. In this connection, the efforts for preparing new standards for processed food were emphasized. As a result, new standards prepared and published. Some of the processed foods covered by the standards are:

- Refined vegetable ghee and oils
- Biscuits and confectionery
- Sugar boiled confectionery
- Ordinary noodles and instant noodles
- Bread.
- Corn flakes, etc.
- Processed dairy products like processed milk, evaporated milk, condensed milk, infant milk food
- Luncheon meat
- Processed drinking water
- Tea and coffee (roasted, ground and instant)
- Fruits and vegetable products like juices, squashes, fruit beverages, jam, jelly, marmalade, chutneys and canned products, etc.

Most of the standards so far prepared and published are mainly generic standards (refer to 3.1). The total of each food group as given in the table comprise both primary products and processed products. Some published standards for colours, preservatives are discussed earlier. Now the effort is focused to prepare food safety standards aiming to cover horizontally, more and more products, processed and unprocessed, coming into the practice of production, processing, marketing and consumption.

However, the standards so far prepared and executed up to now are published in Nepali Language. For specific compositional and technical parameters the English version is also

given in the brackets. The need is felt by the concerning stakeholders to have an authentically translated version of standards in English. Food safety and quality document being a regulatory document needs to be translated by authorized institutions. Some efforts could be expected towards this direction in near future.

5.1 Labelling Requirements for Food

Labelling requirement for food commodities has been described in Food Rules, 1970. The label is defined as "Label" means a description or sign written, printed or marked on a container and/or on a cover containing any food which is put for sale or being conveyed. The chapter 6 of the Food Rules, 1970 describes, in detail, the labelling requirement as mentioned below:

- (1) No packed food shall be sold or kept for sale unless and until a label is put on the wrapper of container of that food specifying the following fact or description:
 - (a) The description of the food shall be so specified on the label that it may be easily and clearly seen, and where such food is kept in more than one container or cover, the label shall also be put on such inner container or cover.
 - (b) The name and address of the entrepreneur who has packed the food stuff or put the label thereon for sale shall be clearly specified on the label; and where such packing or labelling is carried out at the direction of or on behalf of an entrepreneur carrying on a business in the Nepal, the name and address of that entrepreneur shall also be specified on such label.
 - (c) The label shall specify the real (usual) name of a food in case the food is made from only one food substance, the usual name; if any, of a mixed food, the real or usual name(s) of the different contents mixed to the food if the food is made from two or more food substances, and in the case of a means substance, the name and quantity thereof, in an order of the applied weight or volume thereof. Provided that, where the water is used as a means, it is not required to specify its quantity and measure on the label.
 - (d) Both the net weight and measurement of the packed food shall be clearly specified, and the measurement or quantity so specified shall not be lesser in any case. If the food is allowed to be sold on the basis of weight and quantity of its container or wrapper thereof, the minimum weight and quantity of the packed container and its wrapper shall also be clearly mentioned.
 - (e) Where a colour or a preservative is added to a food, any statement or any kind of symbol or sign indicating such addition shall be mentioned on the label.
 - (f) The label of a container containing a packed food shall compulsorily specify the batch number, date of production and expiry date.
- (2) The description to be specified in a label shall be in the Nepali or English language. The description may also be specified in another language, in addition to these two languages, if one so wishes.

- (3) Where a preservative is added to a food, its label shall not contain words such as "pure", "chokho", "bisuddha" and "sudda" or another description mentioned in such label shall not contain any false or misleading claim or sign or symbol.
- (4) A retailer of packed food shall not be required to put on the label to sell it after opening the packet.
- (5) The label of a food claimed to contain vitamins, minerals or other nutritional substances shall specify the matters required to be specified as mentioned below:
- (a) One shall not claim that a food sold by him/her contains such vitamins and/or other nutritional substances without specifying the same on the label of that food.
 - (b) An advertisement or publicity statement shall not mention that a food contains such vitamins and/or other nutritional substances without specifying the quantity of such vitamins and/or other nutritional substances.
- Note: (The label of a food claimed to contain vitamins, minerals or other nutritional substances shall clearly specify each of such vitamins, minerals or nutritional substances in the unit.)
- (6) Notwithstanding anything, it shall not be required to put a label on the following packed food:
- (a) Fruits or green leaves kept fresh through the use of gas or cold storage or freezing or any other provision, provided that, the exemption as referred to in these Rules shall not be available to any food canned, bottled or subject to other processing system, except in cases where it is kept fresh as mentioned above.
 - (b) Milk in liquid state other than condensed milk.
 - (c) Whole egg.
 - (d) Various kinds of fishes, meat other than the fish or food containing meat sealed in a can or bottle, provided that, in the case of meat, it shall clearly indicate in writing the meat of which animal.
 - (e) Where the concerned trader sells or distributes through his/her own people the dish prepared in any hotel or any portion of the dish so prepared.
Provided that, in the case of the ghee and oil used in the preparation of a dish, it shall clearly indicate in writing that the dish has been prepared with the use of such ghee, oil or fatty substance.
- (7) A person who has a duty to act in accordance with these Rules shall not overwrite, alter or deface or erase the label put in accordance with these Rules.

Schedule 6 describes that the label of the container containing a sample to which a preservative is so added has to specify that the sample contains the preservative as mentioned above.

There is no specific mention regarding the following aspects of label of packed foods:

- (a) Method of consumption and any side effects of the product
- (b) Price of product
- (c) Registration number of manufacturer
- (d) Composition of products
- (e) Standard mark of certification if given to the product

- (f) Products guarantee and guarantee time limit of products like electric, electronics hardware and machinery parts
- (g) Preventive and security measures necessary for any inflammability and hazard

The labelling requirements are same for domestic and imported food commodities. The label must be either in Nepali or in English language and the products labelled in other languages must be labelled either in English or in Nepali by the importing agency.

The packaging and labelling requirements for import certification are as mentioned below:

- Weights, shape and size of the retail pack
- Type of the packaging material
- Certifying agency for the packaging material to be of the food grade and quality
- Whether or not the copy of quality certificate of packaging material attached with the application
- The labelling detail of the product
 - Languages used for labelling
 - Net weight
 - Composition
 - Date of manufacturing
 - Expiry date
 - Other important information

5.2 Packaging Requirements for Foods

For very few products, specific packaging requirements are given as part of the product standards in the respective place. Otherwise there are no detailed packaging specifications published. However, the issue is getting attention in the concerning institutions. In certain cases, if reference has to be made, literature published from regional and international institutions are cited.

5.3 Sanitation and Food Safety Situation at Different Settings

● Food Catering Business

The rapid pace of migration of people from rural areas to towns has created markets for food catering business as street foods, school catering and highway side dhawa (Kiosks or street foods) and restaurants. There are also tea stalls, breakfast and snack sellers serving ready to eat prepared foods in the big cities and local markets. This sector has been one of the sensitive areas requiring thorough monitoring for assuring the safety and quality of food served in place. Kathmandu valley itself is holding around four millions consumers. The eating outside homes trend is increasing. Altogether there are fifty eight municipalities all over the countries in almost all municipalities, there is rapidly increasing numbers of small food catering centres.

● Fruits and Vegetables Chain

Another important area from the stand point of food safety is fruits and vegetable chain.

The increasing use of pesticides in vegetable production and the use of chemical (carbide) in ripening in some fruits has been threatening to consumers health.

● **Meat and Milk Chain**

The more traditional mode of animal slaughter and meat consumption pattern is one of the vulnerable sectors to be improved. Even in Kathmandu, no well-organized slaughter house is in operation. In near future a few slaughter houses with adequate facilities could be expected in Kathmandu.

Other important chain is milk chain. Few relatively bigger size dairies are operating in some big towns. In Kathmandu valley itself around ten medium to big dairies are in operation. However, several small dairies are emerging at rapid pace where intervention is needed to adopt good hygienic practice in the chain.

● **Need of Food Epidemiological Database**

Gastrointestinal cases are frequently being reported in big hospitals and local health centres. Food poisoning and infections are among the complaints coming. However, a systematic data collecting mechanism is lacking. It is important to collect data on problems due to consumption of unsafe food.

In the organizational setup of Ministry of Health and Population, food epidemiology structure is lacking. Department of Food Technology and Quality Control (DFTQC) is also lacking the mechanism for the collection of food epidemiological data. Thus an institutional arrangement to have a mechanism of food epidemiological data collection and prompt intervention in case of outbreak is needed.

6. CASE STUDIES PART 2:

(1) Instant Noodles

Instant noodle means the product prepared from refined wheat flour which is cooked in the shape of curled or twisted thread or in any other shape. The product may contain vegetable oil, seasonings, eggs, mushrooms, vegetables, chicken or its extract, shrimp etc., and may be added with permitted flavour. The product shall not contain any mould and insect infestations, parts or whole, and shall meet the following requirements:

Items		Maximum Levels
(a) Moisture		Not more than 5.0 %
(b) Total ash		Not more than 4.0 %
(c) Ash insoluble in dilute Hcl		Not more than 0.1 %
(d) Protein		Not less than 10.0 %
(e) Extracted fat	(i) Acid value of extracted fat	Not more than 1.0 %
	(ii) Peroxide value	Not more than 10 mg equivalent peroxide oxygen per kg oil

(f) Monosodium glutamate	Not more than 1.0 %
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- If the noodle is prepared for the baby below the age of 12 months, it shall not contain monosodium glutamate.
- The type of oil which is provided in the sachet shall meet the quality standards as fixed for that particular type of oil.

Note: 1. Whether the product is vegetarian or non-vegetarian should be clearly mentioned in the label.

2. Calculation of above mentioned parameters from (b) to (d) is done in dry basis.

(2) Carbonated Beverages (Carbonated Water)

Carbonated water (non-alcoholic beverage) means the beverage prepared by mixing one or more ingredients which are packed and sealed in bottle or can impregnated with carbon dioxide under pressure.

- The following ingredients can be added in the product.
Sugar, liquid glucose, dextrose monohydrate, invert sugar, fructose, honey, fruits and vegetable extractive; and permitted flavouring, colouring and preservatives and emulsifying and stabilizing agents; citric acid, fumaric acid, sorbitol, tartaric acid, phosphoric acid, lactic acid, ascorbic acid, malic acid, edible gums a such as guar, karaya, arabic, carob bean, furcellaran, tragacanth, gum ghatti, gelatine, albumin, liquorice and its derivatives, salts of calcium and magnesium and vitamins.
- It shall conform to the following standards.
 1. The following additives shall not exceed the quantity as given below.

Caffeine	Not more than 200 mg/liter
Ester gum (glycerol ester of wood resin)	Not more than 100 mg/liter
Quinine salt as quinine sulphate	Not more than 100 mg/liter
Saccharine-Na	Not more than 100 mg/liter
or Acesulfame – K	Not more than 300 mg/liter
or Aspartame as methyl ester	Not more than 700 mg/liter
or Sucralose	Not more than 300 mg/liter

2. It shall absent with microorganisms or shall not be exceeded in numbers as given below.

Total plate count	Not more than 50
Coliform count /100 ml	Absent
Yeast and mould count/ml	Not more than 2

3. Carbonation: Carbonated water shall be subjected to carbonation and depending upon the type of beverage, at least one volume of carbon dioxide shall be present with suitably adjusting the temperature.

- The product if added with sugar, the quantity thereof shall be mentioned in the label. And if the product is not added with sugar, it shall be mentioned in the label. In case the product is packed in a recycle bottle, the information for sugar added or not added can be given in the crown.
- The carbonated beverage produced, as mentioned, shall be labelled with all information as per food rules. In case of preservatives, the requirements given in schedule-11 of food rules shall be followed. In addition to the requirements as mentioned here, the product shall meet the quality standards for processed drinking water.

(3) Fruit Juice

Fruit juice means the unfermented and un-concentrated liquid expressed from fresh, wholesome and ripe fruit and with or without:

- (a) Sugar, dextrose, invert sugar, or liquid glucose, either singly or in combination
- (b) Water, peel-oil, fruit essences and flavour, common salt, ascorbic acid, citric acid, and permitted colours and preservatives
- (c) The acidity of the finished product calculated as citric acid shall not be less than 4 per cent in the case of pure lemon juice, 5 per cent in the case of pure lemon juice but shall not exceed 3.5 per cent in the case of other juices.
- (d) The total soluble solids (except added sugar), measured by refract meter, must be not less than as mentioned below in different fruit juices:

(1) Orange	10.5 per cent (by weight)
(2) Lemon	7.5 per cent (by weight)
(3) Pineapple	10.0 per cent (by weight)

- (e) Fill of the container must be not less than 90 per cent of the total capacity of the container

(4) Processed Milk

Processed milk means the liquid milk containing not less than 3.0 per cent milk fat and 8.0 per cent milk-solid-not-fat (SNF) by adjusting either or not by the partial removal of milk fat and either or not by the solubilization of skimmed milk powder and processed by pasteurization or sterilization. The milk processed by pasteurization process can be labelled as "pasteurized milk" and that processed by sterilization can be labelled as "sterilized milk".

(5) Luncheon Meat

Luncheon meat means the product prepared from edible portion of meat of mammalian animal, or bird slaughtered in an abattoir, which have been subjected to anti-mortem and post-mortem inspection. Above mentioned edible meat shall be uniformly cured with edible common salt and permitted amount of sodium and/or potassium nitrite.

The luncheon meat may be with or without binders such as cereal flour/starch, bread,

biscuits or bakery products, milk powder, whey powder, egg protein, vegetable protein products, glucose, invert sugar, dextrose, lactose, maltose, glucose syrup, including corn syrup, spices, seasoning and condiments and water soluble hydrolyzed protein. The product may be smoked and flavoured with natural and natural identical flavours and permitted flavour enhancer.

It may contain ascorbic acid/isoascorbic acid and its sodium salts (sodium isoascorbate singly or in combination) not exceeding 500 mg/kg expressed as ascorbic acid as antioxidant, and sodium and/or potassium mono- and di- polyphosphates singly or in combination not exceeding 3000 mg/kg (expressed as P₂O₅) as water retention agents.

The quality requirements of luncheon meat must be as mentioned below in the table:

1.	(A) Minimum Meat content (1) Product without binder (2) Product with binder	Not less than 90 per cent Not less than 80 per cent
	(B) Total Fat content (1) Product without binder (2) Product with binder	Not more than 30 per cent Not more than 35 per cent
2.	Microbial count	
	(1) Total Plate Count	Not more than 1,000 per gram
	(2) <i>E. coli</i>	Absent in 25 gram
	(3) <i>Salmonella</i>	Absent in 25 gram
	(4) <i>Staphylococcus aureus</i>	Absent in 25 gram
	(5) <i>Clostridium perfringens</i>	Absent in 25 gram
	(6) <i>Clostridium botulinum</i>	Absent

The product must be packed in a hermetically sealed container and subjected to heat treatment followed by rapid cooling to ensure that the product is shelf stable.

The sealed container shall not show any change on incubation at 35⁰C for 10 days and 55⁰C for 5 days.

The product shall be safe, clean and the can shall be substantially free from stains from the foreign matter. It shall be capable of being sliced.

ADDITIONAL RESPONSIBILITIES OF DFTQC

DFTQC as Codex Contact Point

DFTQC has been entrusted with the responsibility of Codex Contact Point (CCP) for more than two decades. Government officials, especially from DFTQC have been participating in the meetings of different Codex committees relevant to the Nepalese context. Recently, National Codex Committee has been instituted to suggest the GoN. in food safety and quality control issues. Necessary provision has been made for the participation of private sector in the committee. DFTQC is functioning as National Codex Committee Secretariat and it is also providing the opportunity of sharing Codex publications to the concerned stakeholders within the country.

DFTQC as SPS Enquiry Point

Nepal obtained WTO membership in April 23, 2004. As one of the prerequisite for WTO members to establish Sanitary and Phytosanitary (SPS) enquiry point, DFTQC was given with the mandate to work as SPS enquiry point.

DFTQC as INFOSAN Contact Point

The Department of Food Technology and Quality Control (DFTQC) of the Ministry of Agriculture Development has been appointed the national INFOSAN focal point in Nepal. Its major activities are the dissemination and communication of information on various food safety issues to all the stakeholders concerned. The important activities that have been undertaken so far include addressing the melamine contamination of milk from China and radionuclide contamination of food products from Japan. Action has also been taken on issues raised by the European Commission's Rapid Alert System for Food and Feed (RASFF) pertaining to mould-infested cheese spread from France, the presence of erucic acid in lemon pickle from Nepal and India, and the presence of gluten of wheat flour (an allergen) in buckwheat from Nepal. More work is required to develop the INFOSAN information centre for effective management of information.

DFTQC's Role on Technology and Nutrition

In addition to the functions mandated by Food Act as mentioned above, other technical programmes conducted by DFTQC are:

- R & D on food product development and dissemination thereof through training.
- Nutrition programme through which community level nutritional status surveys are conducted and based on the nutritional problems of the community and locations studied some of the interventions are implemented. National Nutrition Program under this department also develops nutritionally rich food based commodities and carries out the nutritional quality analysis of the agro-industrial products.

DFTQC as Quality Control Authority for Feed (Cattle Feed & Poultry Feed)

DFTQC has also been mandated for the quality control of feed products. In this connection the Feed Act was proclaimed in the country in the year 1976. Subsequently feed regulation came into effect by the year 1984. Altogether there are mandatory standards for six different types of feed products. Within the structure of DFTQC, most of the food inspectors also hold the right as feed inspectors thereby simultaneously taking role for the quality control of cattle feed and poultry feed.

3.4 People's Republic of Bangladesh

1. FOOD REGULATORY SYSTEM

Bangladesh is yet to develop a unified Food Safety Administration System and to formulate a Food Safety Policy. But it has a National Food and Nutrition Policy where attention has been given on food safety. There are significant activities in food safety and quality control are going on in the country. A number of Ministries, Departments and Agencies are involved in these activities with a major responsibility of the Ministry of Health and Family Welfare (MOHFW) which has a unique infrastructure to deliver its services throughout the country. Under this Ministry, Management Information System on food safety and food borne illnesses is some extent integrated with the Primary Health Care Program. It may be mentioned here that Bangladesh has signed the WTO Agreement.

The Govt. of Bangladesh is well committed to ensure safe and quality food to its people. In Bangladesh, the food safety and quality control framework consists of Laws, Regulations & Standards; Administration & Inspection and Laboratory analytical services. Considering the alarming Food safety and quality situation, the Govt. has enacted the Bangladesh Pure Food (Amendment) Act, 2005. The Govt. through MOFDM has just completed a program of "Strengthening National Food Safety and Quality System" under FAO TA. The Govt. is also strengthening the Bangladesh Standard Testing Institution (BSTI), an Institute which is responsible for the standardization, testing, metrology, quality control, grading and marking of goods.

The Government has also enacted "The Iodine Deficiency Disorders Prevention Act, 1989 for universal salt iodization & banned non-iodized salt from market, aimed at virtual elimination of IDD from the country. Other Acts like the Radiation Protection Act, 1987, the Essential Commodity Act, 1990, Fish and Fish product (Inspection and Quality Control) Rules, 1997 etc. There are also a number of policies National Agricultural Policy, 1999, Integrated Pest Management Policy, 2002 etc., are linked with the country's food safety and quality control initiatives. The present anti-adulteration drive is highly appreciated by all corners of the society.

1.1 Administrative System

Food safety has become an important topic as consumers in Bangladesh have become victim of serious adulteration in food. Article 15 of the Bangladesh Constitution states that it shall be a fundamental responsibility of the State to secure provision of the basic necessities of life including food. Article 18 of the Constitution states that the State shall raise the level of nutrition and improve public health as its primary duties. Both the

Articles imply food safety requirements for consumers and the State must be ensured through enactment of appropriate laws. The following Ministries, Departments, Agencies are directly or indirectly responsible for enforcement of food laws, rules and regulations.

- **Ministry of Health and Family Welfare (MOHFW):** As per the Bangladesh Pure Food Ordinance, 1959 and the Bangladesh Pure Food Rules, 1967, the MOHFW having the major responsibility for the enforcement of food control legislation to ensure safe food. The MOHFW is responsible for monitoring of food quality and safety situation including collection of food samples. Inspection of food manufacturing/processing and selling premises as well as to collect food samples.
- **Ministry of Local Government, Rural Development and Co-operatives (MOLGRD):** MOLGRD is responsible for the food safety and quality of food in City corporations and Municipalities.
- **Ministry of Law, Justice and Parliamentary Affairs:** On the basis of the Certificate of Tested Food Samples, prosecution is done under "The Pure Food Ordinance, 1959" conducted by this Ministry. Besides, this Ministry having the responsibility for revision of existing rules/ordinance or to formulate, vetting and Parliamentary approval etc. for new ordinance or rules, as per request of or recommendation from the concerned sectors etc.
- **Ministry of Food and Disaster Management:** Directorate General of Food having Food Inspectors at the Upazila and District level and usually deal with the Food security aspects. Besides, they are also responsible for quality of imported and locally procured food grains and other food items including sugar, edible oil etc. as well as responsible for the quality of the storage food grains etc.
- **Ministry of Industry:** Ministry of Industry is responsible for the Standardisation, Certification Marks and Monitoring quality control of food items through its BSTI. BSTI is responsible for implementing food regulations in Bangladesh.
- **Ministry of Agriculture:** Ministry of Agriculture is also involved in maintaining safety and quality of food through good agricultural practices like optimum use of chemical fertilizers, pesticides, preservation and supply of seeds. Approval of pesticides is a responsibility of this Ministry. Directorate General of Extension (DAE) Service of this Ministry is working together with the Bangladesh Atomic Energy Commission to perform a survey to monitor for residues of pesticides in agricultural products all over the country. Furthermore, the Ministry is also implementing Integrated Pest Management in 201 Upazillas.
- **Ministry of Environment and Forest:** Presently, the Department of Environment of the ministry along with the Department of Agricultural Extension and Bangladesh Power Development Board is implementing a project on Persistent Organic Pollutants (POPS) under Stockholm Convention aimed to protect human health and environment.
- **Ministry of Fisheries and Livestock:** Of this Ministry, the Department of Fisheries is responsible for prevention and control of diseases in fishes & aquatic animals and safety and quality of fish and aquaculture products. The seafood quality and safety programme is based on GMP and sanitation Standard Operating Procedures (SSOP) and HACCP principles. Fish Inspection and Quality Control (FIQC) wing mandatorily introduced and implemented HACCP in Fish processing industries. The FIQC carry out regular inspection of hygiene (raw materials handling, process operations, plant hygiene) and sanitation of plant premises, verify HACCP related documents and records to satisfy the Codex guidelines and directives of EU & USFDA. The Directorate of Livestock is responsible for animal health and quality and safety of product of animal origin.
- **In addition,** the ministries like **Ministry of Home Affairs, Ministry of Science and Technology, Ministry of Energy and Mineral Resources, Ministry of Commerce, Ministry of Education, Ministry of Defence** are also responsible for food safety and quality control.

1.2 Laws & Regulations

There are several laws in Bangladesh for maintaining health and safety standards.

- **The Bangladesh Pure Food Ordinance, 1959:** This is an ordinance to provide better control of the manufacture and sale of food for human consumption. Now, this

Ordinance is under revision as 'The Bangladesh Pure Food (Amendment) Act'. Under this Act, it has been proposed to constitute a National Food Safety Council, headed by the Ministry of Health and Family Welfare as well as to establish Food Courts.

- **The Bangladesh Pure Food Rules, 1967:** In this Rule, there are generic standards for 107 food products. Now, this 'Rules' is under revision.
- **The Food Grain Supply (Prevention of Prejudicial activity) Ordinance, 1956 (Ord. xxvi of 1979):** This ordinance provides special measures for prevention of prejudicial activity relating to the storage, movement, transshipment, supply and distribution of food grains. It provides basis for the protection of false statement or information.
- **The Radiation Protection Act, 1987:** The Institute of Food and Radiation Biology (IFRB) of Bangladesh Atomic Energy Commission is primarily involved in food irradiation research and development in the country.
- **The Iodine Deficiency Disorders (IDD) Prevention Act, 1989:** The Government has enacted "The Iodine Deficiency Disorders Prevention Act, 1989 for universal salt iodisation and banned non-iodised salt from market, aimed at virtual elimination of IDD from the country.
- **Fish and Fish Product (Inspection and Quality Control) Rules, 1997:** Under the Fish and Fish products (Inspection and Control) Ordinance 1983 (Ord. xx of 1983) and in conjunction with fish and fish products Inspection and Quality Rules 1989, and other related provisions made thereunder, the government has made the Rules: Fish and Fish product (Inspection and Quality Control) Rules, 1997. These Rules are basically meant to develop quality improvement to promote export trade. The quality control of fish and fish products in the country has earned reputation among the importing countries.
- **Other Laws and Regulations:** In addition, a number of other laws and regulations exist in the country to ensure the safe and quality food viz., the Animal Slaughter (Restriction) and Meat Control (Amendment) Ordinance, 1983 (it is under revision); the Pesticide Ordinance, 1971 & the Pesticides Rules, 1985; Destructive Insects and Pests Rules (Plant Quarantine), 1966, amended up to 1989; Agricultural Products Market Act, 1950 (revised in 1985); Fish Protection and Conservation Act, 1950 (amended in 1995); Marine Fisheries Ordinance 1983 and Rules, 1983; Procurement Specifications, Ministry of Food, Rice Mill Control Order etc.
- **The Bangladesh Standards and Testing Institution Ordinance, 1985:** This ordinance relates to establishment of an institution for standardisation, testing, metrology, quality control, grading and marking of goods. Within the framework of this ordinance, the government has established **the Bangladesh Standards and Testing Institution (BSTI)**. One important task of this organisation is to certify the quality of commodities, materials, whether for local consumption or for export and import. The Ordinance has been amended as **the Bangladesh Standards and Testing Institution (Amendment) Act, 2003**.

● **Related Laws and Regulations**

- **Bangladesh New Food Safety Laws - 17 Jan 2010:** The parliament is expected to frame the Fish and Poultry Feed Act and the Hatchery Act to regulate fish and animal feed production, prevent contamination and deal with other compliance issues.
- **The Cantonments Pure Food Act - 19/07/1966:** The purpose of this Act is to prevent the adulteration of food in all cantonments in Bangladesh and to regulate the sale and manufacture of food.
- **The Pure Food Ordinance - 14/10/1959:** This Ordinance provides norms for processing products to be consumed as food in order to avoid any adulteration that could harm consumers. The Ordinance further provides for prohibition of manufacture or sale of food which does not meet quality standards; prohibition of sale or use of poisonous or dangerous chemicals and intoxicated food colour; standards of purity of milk, butter, ghee, wheat flour, mustard or any other rape seed oil and of any article of food; prohibition of sale of diseased animals and unwholesome food intended for human consumption; prohibition of use of false labels; analysis of food and certificates of analysis; inspection and seizure of food; offences and penalties; etc.
- **The Animal Slaughter (Restriction) and Meat Control Act - 23/04/1957:** This Act provides for the restrictions applied to the slaughter of animals and the consumption of meat.
- **The Food (Special Courts) Act - 13/11/1956:** An Act to provide for setting up of courts for speedy trial of offences in relation to foodstuffs.
- **The Seed Rules - 08/03/1998:** The Seeds Rules provides for the institution of the National Seeds Board, its function and tasks, and all the related procedures dealing with the registration of seed varieties and seeds dealers.
- **Protection and Conservation of Fish Rules / Act - 17/10/1985:** This document covers two (2) Notifications: (1) The Protection and Conservation of Fish Rules, 1985; (2) Protection and Conservation of Fish Act, 1950.
- **The Breast Milk Substitutes (Regulation of Marketing) Ordinance - 24/05/1984:** The Ordinance aims at protection and encouragement of breastfeeding, banning advertising, import, distribution and sale of breast milk substitutes.
- **The Marine Fisheries Rules - 05/09/1983:** Rules pertaining to fishing, licences for domestic and foreign fishing vessels, fishing operations and related activities.
- **The Marine Fisheries Ordinance - 19/07/1983:** (1) Preliminary, (2) Administration, (3) General Provisions Governing Licences, (4) Local Marine Fishing Operations, (5) Foreign Marine Fishing Operations, (6) Appeal, (7) Prohibited Fishing Methods, (8) Marine Reserves, (9) Powers of Authorized Officers, (10) Offences & Legal Procedures, and (11) Rules.
- **The Fish & Fish Products (Inspection & Quality Control) Ordinance - 17/05/1983:** An Ordinance to provide for inspection and quality of fish and fish products.
- **The Importers, Exporters and Indentors (Registration) Order - 22/10/1981:** All companies and / or person who indent, import or export goods are required to be registered in Bangladesh.
- **The East Pakistan Fisheries (Protection) Ordinance - 24/03/1959:** It covers: (1) Short title; (2) Definitions; (3) Declaration of a fishery to be a Khas managed fishery; (4) Bar to unauthorised fishing in Khas managed fisheries; (5) Carrying of valid licence of fishing and production of the same; (6) Bar to unauthorised fishing in other fisheries; (7) Authorisation by Provincial Government to question illegal fishing; (8) Exemption; (9) Penal clauses; (10) Rule making power.
- **Other Laws and Regulations:** A number of other laws and regulations are existed in the country to ensure the safe and quality food, viz., The Animal Slaughter (Restriction) and Meat Control (Amendment) Ordinance, 1983 (it is under revision); The Pesticide Ordinance, 1971 & the Pesticides Rules, 1985; Destructive Insects and Pests Rules (Plant Quarantine), 1966, amended up to 1989; Agricultural Products Market Act, 1950 (revised in 1985); Fish Protection and Conservation Act, 1950 (amended in 1995); Marine Fisheries Ordinance, 1983 and Rules, 1983; Procurement Specifications, Ministry of Food, Rice Mill Control Order, etc.

- **In addition**, to protect the consumers' rights and privileges a new Act i.e. Consumers' Protection Act, 2004 is to be passed soon. There are also a number of policies i.e. Bangladesh Food and Nutrition Policy, 1997; and National Plan of Action on Nutrition, National Agricultural Policy, 1999; Integrated Pest Management Policy, 2002, etc., are linked with the country's food safety and quality control.

1.3 Bangladesh Standards and Testing Institution (BSTI)

This institution is a corporate body made under the law, "the Bangladesh Standards and Testing Institution Ordinance, XXXVII of 1985." Since its establishment, it is the sole body to look after the quality of the products in Bangladesh. Among its many functions, the most important one is, as exemplified below, "To certify the quality of commodities, materials, produces, products and other things including food materials, whether for local consumption, or for export or import". (<http://www.bsti.gov.bd/about.html>)

- Surprise inspections of the licensee's factory are being carried out periodically by qualified inspecting officers of the institution and random samples are being taken and tested at the BSTI Laboratory
- Products bearing the standard mark are collected by the surveillance team of the institution directly from the open market and tested in the BSTI Laboratory. Representatives from the Consumers Association of Bangladesh (CAB) and the respective chamber of commerce and industries help the surveillance team in performing its function.
- Bangladesh Government is considering the health and safety of the consumers in the right earnest and has brought so far 145 items of mass consumption under the mandatory certification marks scheme by issuing statutory regulatory orders (SROs) from time to time under the provisions laid down in clause 24 of the BSTI Ordinance 1985.
- BSTI is committed to provide legal framework for standards, metrology, testing and quality (SMTQ) in line with the international norms and practices.
- All standards issued under Pure Food Rules are mandatory in nature and are enforced by BSTI.
- BSTI is the legal entity for certification of products and services under its Marks certification scheme.
- The legal metrological testing facility is under the BSTI management.
- BSTI has firmed more than 3000 standards for various products including food and agriculture. 151 standards are under mandatory requirement and require Marks certification. BSTI has adopted 153 Codex standards for food testing.
- Carbonated water standards have been formulated and enforced under BSTI. These standards are based on Indian as well as CODEX guidelines.
- BSTI has already initiated work on adoption of CODEX guidelines in formulating quality as well as safety standards for food products. More than 150 codex standards have been adopted by Y 2010.

- Most of the imports and exports requirements are covered under BSTI mandate. For specific inquiries BSTI need to be consulted. BSTI has provided regional testing facilities in the ports as well main business centres.

1.4 Major Stakeholder Ministries and Departments for Food Control

	Ministry	Department/ Organization	Major Activities
1	Ministry of Agriculture	Plant Protection Wing, DAE	<ul style="list-style-type: none"> ▫ Phytosanitary certificate for Import/Exported plants/plant products ▫ Pesticide Use Control ▫ Fertilizer Use Control ▫ Quality Control of PFDS, Stock, Procured Food grains/Food Stuff, Imported food, etc. ▫ Food Control in the Market (not doing at present)
2	Ministry of Food	Directorate General of Food (DGF)	<ul style="list-style-type: none"> ▫ Food Control in the Market (not doing at present)
3	Ministry of Health & Family Welfare	Directorate General of Health; District & Upazila Health Administration and Institute of Public Health.	<ul style="list-style-type: none"> ▫ Food Quality and Sanitation Control in Upazila/District level ▫ Testing
4	Ministry of LGRD	City Corporation & Pourashava Health Units	<ul style="list-style-type: none"> ▫ Have Sanitary Inspector, Labs and Public Analyst for food quality control in their command areas.
5	Ministry of Fisheries & Livestock	A) Department of Fisheries (FIQC Wing) B) Department of Livestock	<ul style="list-style-type: none"> ▫ Fish Quality Control & Certification for export ▫ Same for the domestic market ▫ Animal Health ▫ Animal Product ▫ Imported Animal ▫ Frame Standards of Food Products ▫ Testing & Certification Marks and Surveillance. ▫ Test Radiation level of Imported Food items; Pesticides Residues ▫ Testing of Food Items; Research and Development
6	Ministry of Industries	BSTI	<ul style="list-style-type: none"> ▫ Testing & Certification Marks and Surveillance. ▫ Test Radiation level of Imported Food items; Pesticides Residues ▫ Testing of Food Items; Research and Development
7	Ministry of Science, Information and Communication Technology	BAEC	<ul style="list-style-type: none"> ▫ Test Radiation level of Imported Food items; Pesticides Residues ▫ Testing of Food Items; Research and Development
8	Ministry of Education	IFST, BCSIR DG, Primary, DG, Secondary, Text Book Board, Universities	<ul style="list-style-type: none"> ▫ Food safety, Nutrition & Environmental issues in the text book of all level of education
9	Ministry of Information	PIB BTV Radio Bangladesh	<ul style="list-style-type: none"> ▫ Broad cast issues for awareness building
10	Ministry of Home	Bangladesh Police	<ul style="list-style-type: none"> ▫ Assist the Inspection Agencies
11	Ministry of Law, Justice & Parliamentary Affairs		<ul style="list-style-type: none"> ▫ Formulation, Vetting, Parliamentary Approval etc.

- Coordinating Mechanisms

- **Policy Structure:** Cabinet is the only universal coordinating and controlling infrastructure. No separate coordinating mechanism exists in respect of food safety in the policy structure.
- **Food Control (Management and Inspection):** No single organization exists in Bangladesh to oversee/coordinate food control activities.
- **Mandatory Minimum Standard Formulation:** There is no structure of Food Safety Advisory Committee or Minimum Standard Fixing Committee.
- **Auxiliary Standard Making:** Standard Wing of BSTI formulated about 365 food & agricultural product standards and services among those only 190 are Food Standards. BSTI has right to adopt International Standards (ISO, IEC, Codex, etc.) as Bangladesh Standards. Till now 150 International Standards have been adopted as Bangladesh Standards. Standards Wing of BSTI is being assisted by 6 (six) Divisional Committee and 70 Sectional/Technical Committees. 17-sectional committees under Agricultural & Food Divisional Committee are working for Food Standards. The members of the committee include representatives from stakeholder Ministries and departments, universities/research organizations, CAB, Business and trade associations/chambers etc.
- **Lab Activities and Research:** Coordinating mechanism among the laboratories should be strengthened in terms of research and routine test methods.
- **Accreditation Body:** A draft act has been prepared and sent to different ministries for comments.

2. BANGLADESH FOOD STANDARDS

- Under the Bangladesh Pure Food Ordinance, 1959 and the Bangladesh Pure Food Rules, 1967, there are 107 different generic, mandatory food standards.
- BSTI is the Standardization body in the country. There are 50 mandatory generic food standards of BSTI. In addition, there are some 250 optional standards for different foodstuff. BSTI is also adopting Codex standards.
- 190 food standards by BSTI of which 52 should have compulsory certification marks.
- 28 Codex standards adopted as Bangladesh standards.

2.1 Qualitative and Quantitative Assessment of Food Items

The following Laboratories are responsible for qualitative and quantitative assessment of food items:

- 1) Public Health Laboratory of the Institute of Public Health, Dhaka under the MOHFW. Some 5000 food samples are tested here annually, sent by the Sanitary Inspectors from different Upazilas and Municipalities. Results are indicated that there are as many as 50% of the samples are found unsatisfactory. But this does not reflect the real picture of the food quality of the country. Because, most of these samples are biased i.e. suspected as unsatisfactory food items by the Sanitary Inspectors, not collected randomly.

- 2) Laboratory of the Institute of Public Health Nutrition under the MOHFW dealing with the monitoring of the quality of Iodized salt and others.
- 3) Bangladesh Standard Testing Institution (BSTI) under the Ministry of Industries. In 2008-10, BSTI performed more than 500 mobile courts, samples collected from open market, issued show cause notice issued to manufacturers, some licenses were cancelled and legal actions were taken.
- 4) Food Testing Laboratory, Directorate of Food under the Ministry of Food and Disaster Management. In 2002-03, this laboratory tested 242 rice samples, 291 wheat and 6 oil which were respectively 3, 20 and 49 in 2000-01.
- 5) Institute of Food Science Technology, Dhaka; Bangladesh Council of Scientific and Industrial Research (BCSIR) as well as its Branches at Chittagong and Dhaka under Ministry of Science and Information & Communication Technology.
- 6) Food Testing Laboratory of Dhaka City Corporation under the MOLGRD. In 2003, a total 960 samples were tested in the Public Health Laboratory of the Dhaka City Corporation, which were 430 in the year 2000.
- 7) Laboratory of Plant Protection Wing of DAE of Ministry of Agriculture. This lab also tests both imported and exported vegetables and fruits. During the year 2002-03, 7007.6 metric tons vegetables and 2262.6 metric tons fruits were exported and of them 1500 samples were collected and tested. It was 5554 metric tons, 1885 metric tons and 1000 samples respectively in 2000-01. It was found that 100% samples were satisfactory in both years.
- 8) Quality Control Laboratories for frozen fish at Khulna and Chittagong under the Ministry of Fisheries and Livestock. In 2002-03, a total 3940 lots were exported. 49 and 8 lots were rejected in the country and outside of the country respectively. Under this Ministry, there is also Lab at Fisheries Research Institute, Mymensingh.
- 9) Laboratory of Department of Livestock under the Ministry of Fisheries and Livestock.
- 10) Institute of Food Radiation Biology, Atomic Energy Commission under the Ministry of Energy and Mineral Resources.
- 11) Institute of Nutrition and Food Science, University of Dhaka under the Ministry of Education.
- 12) Central laboratory and Lab of Postharvest Technology of Bangladesh Agricultural Research Institute and Lab. of Bangladesh Rice Research Institute under the Ministry of Agriculture.
- 13) Armed Forces Food and Drug Testing Laboratory, Dhaka Cantonment, Dhaka under the Ministry of Defence.

14) Laboratories of Department of Food Technology & Rural Industry, Department of Dairy Science and Department of Biochemistry of Bangladesh Agricultural University.

15) Chemical Examination Laboratory of CID under the Ministry of Home Affairs.

16) Environment Laboratory, Directorate of Environment under the Ministry Environment and Forests.

2.2 Food Safety Program

A collaborative program of Govt. of Bangladesh and WHO is being implemented in Bangladesh since 1994. Under the Food Safety Program. The major activities are

- 1) Strengthening of Public Health Laboratory of the Institute of Public Health, Dhaka.
 - a. Procurement of instruments, equipment and chemicals
 - b. Training of the laboratory personnel (in home and abroad)
- 2) Training on Food safety for Health Managers and Sanitary Inspectors of MOHFW and MOLGRD.
- 3) Training on HACCP for Quality Control personnel of Food industries.
- 4) Orientation on food safety for School teachers, Community leaders, Religious leaders and Hotel Restaurant Managers/Owners, Street food vendors and others.
- 5) National and Regional seminars on food safety.
- 6) Information, Education and Communication activities on food safety for School children, Managers/owners of Hotel restaurants, Food vendors, Mass people and others.
- 7) Research works: on quality of different food items, epidemiology of food borne diseases etc.

3. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

3.1 Definitions and Functional Classes of Food Additives

1) Flavours Under Bangladesh Pure Food Rules: Clause 21

An article of food to which has been added a flavouring compound in contravention of this rule shall be deemed to be adulterated.

- (1) No food shall contain any flavouring compounds which are by themselves toxic or which contain contaminants which are toxic.
- (2) Any food which contains any added natural flavouring compounds shall be labelled in the legend with 'NATURAL FLAVOUR' or 'CONTAIN NATURAL FLAVOURING' provided that only those flavouring compounds which have been obtained from fruits or plants by extraction with suitable harmless solvents or by distillation or by expression, or by any other suitable process are used.
- (3) Any food which contain any artificial flavouring compound shall be labelled with the legend 'ARTIFICIAL FLAVOUR' or 'IMITATION FLAVOUR' provided that where a food contains a mixture of both natural and artificial flavouring compounds it shall be labelled as 'ARTIFICIAL FLAVOUR' provided further that those flavouring

compounds which have been obtained by chemical synthesis shall be considered as artificial.

- 2) **Processing Aids:** No description available under the Bangladesh Pure Food Laws, 1967.
- 3) **Carry Over:** No description available under the Bangladesh Pure Food Laws, 1967.
- 4) **Functional Classes:** Under Bangladesh Pure Food Laws, 1967, the following functional classes of foods additives have been listed:

Food Categories	Food Additive Functional Classes
Milk and Milk Products	Flavouring Agents
Edible Oils and Oil Products	Colouring Matters
Tea, Coffee, Roasted Coffee and Grounded Coffee	Class I And Class II Preservatives
Sugars and Sugary Products Honey	Antioxidants
Food Grains, Cereals and Their Products	Stabilizers
Starchy Products	Non-nutritive Constituents
Non Alcoholic Beverages	Common Salt
Spices	Baking Powder
Fruits, Vegetables and Miscellaneous Products	Edible Gelatine
Edible Fats	
Biscuits, Bread and Confectionery Product	
Dried Fish	
Ice	

3.2 Permitted Food Additives and Maximum limits

Colouring matter in food: Any article of food to which has been added any colouring matter in contravention of this rule shall be deemed to be adulterated.

- 1) Coal-tar dyes: No Coal-tar dyes or mixtures thereof except the following shall be used in the preparation of any food, namely:

Colour Index No.	Colour Index Names	Common Names	Chemical Classes
73015	Food Blue 1	Indigo Carmine	Indigoid
42090	Food Blue 2	Brilliant Blue F.C.F.	Triarylmethane
69800	Food Blue 4	Indanthrone	Anthraquinone
42051	Food Blue 5	Patent Blue V	Triarylmethane
42640	Food Violent 2	Violet 6b	Triarylmethane
42580	Food Violent 3	Violets B.N.P.	Do
42085	Food Green 1	Sulpho Green 2 B.A.	Do

42095	Food Green 2	Acid Brilliant Green	Do
42053	Food Green 3	A.F. Green No. 3	Do
15985	Food Yellow 3	Sunset Yellow F.C.F.	Monoazo
19140	Food Yellow 4	Tartrazine	Do
.....	Food Brown 1	Brown F.K.	Disazo
.....	Food Brown 2	Chocolate Brown F.B.	Monoazo
20285	Food Brown 3	Chocolate Brown H.T.	Disazo
14700	Food Red 1	Ponceau S.X.	Monoazo
16185	Food Red 9	Amaranth	Do
45430	Food Red 14	Erythrosine B.S.	Xanthene
28440	Food Black 1	Black P.N.	Disazo

*The colour index, second edition, 1956, Society of Dyers and Colourists, England.

- 2) The maximum limit of permissible colour which may be added to any food shall be one grain (0.0648g) per pound (0.4536kg) of food.
- 3) The following natural colouring matters may be used in or, upon any article of food: cochineal, carmine, caramel, Carotenes, chlorophyll, curcumin, lactoflavin, annatto, ratanjot, saffron.
- 4) Inorganic colouring matters or pigments shall not be added to any article of food.
- 5) The use of artificial or synthetic colouring matters in raw foodstuffs which are consumed after cooking in the usual way is prohibited.
- 6) No person shall sell a coal-tar colour or a mixture of coal-tar colours unless the label on the package carries
 - (a) The common name(s) of the coal-tar colour(s),
 - (b) The lot number of coal-tar colour, and
 - (c) The words "Food Colour".
- 7) Use of permitted coal-tar dyes in or upon any food other than those shown below is prohibited:
 - (a) Ice-cream
 - (b) Dairy products except milk, dahi, butter, ghee, chhana, condensed milk, cream, and baby food
 - (c) Smoked fish
 - (d) Egg preparation
 - (e) Sweets including pastry and other confectionaries
 - (f) Fruit Products
 - (g) Non-alcoholic beverages except tea, cocoa and coffee
 - (h) Custard powder
 - (i) Jelly crystals
 - (j) Soup powder and
 - (k) Luncheon meat
 - (l) Processed or preserved vegetables
 - (m) Flavouring agents

3.3 Preservatives

An article of food to which has been added any preservative in contravention of Bangladesh Food Laws, 1967 shall be deemed to be adulterated (Clause 19).

1) Classification of preservative: Preservative shall be divided into following classes.

Class I Preservatives	Class II Preservatives
(a) Common salt	(a) Benzoic acid including salts thereof
(b) Sugar	(b) Sulphurous acid including salts thereof
(c) Dextrose	(c) Nitrites of sodium or potassium in respect of food like ham, pickle, meat
(d) Glucose	(d) Sorbic acid including salts thereof.
(e) Wood smoke	
(f) Spices	
(g) Vinegar or acetic acid	
(h) Honey	
(i) Hops	
(j) Commercial saltpetre	
(k) Alcohol or potable spirit	

2) Use of more than one class II preservative: No person shall use in or upon a food more than one class II preservatives.

3) Use of class II preservatives: The use of Class II preservatives shall be restricted to the following group of foods in concentration not exceeding the proportions given against each.

Article of Foods	Preservatives	ppm
i) Sausages and sausages meat containing raw meat, cereals and condiments	Sulphur Dioxide	450
ii) Fruit, fruit pulp or juice (not dried) for conversion into jam or crystallized, glace or cured fruit or other products		
(a) Cherries	Do.	3,000
(b) Strawberries and raspberries	Do.	2,000
(c) Other fruits	Do.	1,000
iii) Fruit juice concentrate	Do.	1,500
iv) Dried Fruits		
(a) Apricots, peaches, apples, pears and other fruits	Do.	2,000
(b) Raisins and sultanas	Do.	750
v) Other non-alcoholic wines, cordials, fruits, juices, and beverages sweetened and unsweetened	Do. Benzoic acid	350 600
vi) Jam, marmalade preserve, canned cherry and fruit jelly	Sulphur Dioxide Benzoic acid	40 200
vii) Crystallized glace or cured fruit (including candied peel)	Sulphur Dioxide	150
viii) Fruit and fruit pulp not otherwise	Do.	350

specified in this schedule		
ix) Sugar, Glucose, Gur and Khandsari	Do.	70
x) Corn flour or similar starch	Do.	100
xi) Gelatine	Do.	350
xii) Corn Syrup	Do.	450
xiii) Beer	Do.	70
xiv) Cider	Do.	200
xv) Alcoholic Wines	Do.	450
xvi) Sweetened Mineral Water	Sulphuric dioxide Benzoic acid	70 120
xvii) Brewed Ginger Beer	Benzoic acid	120
xviii) Coffee extract	Do.	450
xix) Pickles and chutney made from fruit or vegetables	Do.	250
xx) Tomato and other sauces	Do.	750
xxi) Cooked pickle meat including ham and bacon	Sodium or Potassium Nitrite	Not more than 200 ppm (calculated as Sodium nitrite)
xxii) Danish tinned Caviar	Benzoic acid	50
xxiii) Dehydrated Vegetables	Sulphuric dioxide	2,000
xxiv) Tomato purees and paste	Benzoic acid	250
xxv) Syrups and sherbets	Sulphur Dioxide or Benzoic acid	600
xxvi) Dried ginger	Sulphur Dioxide	2,000

Note:

- Sulphur dioxide shall not be added to meat or to any food recognizable as a source of Vitamin B, except as provided in sub-rules under this rule.
- No food shall contain compounds of boron, salicylic acid or formaldehyde
- No food shall contain sorbic acid or its compounds in excess of 0.1 per cent by weight.
- No food shall contain any preservative other than those specified in this rule unless it is approved by notification by the provincial Government.

4) Labelling of food which contains preservatives

Container of food which contains preservative shall not be marked "pure".

The word "pure" shall not be used on the label of the container of any food which contains preservative.

No preservative shall be sold for use in food unless the label carries

- The common name,
- The chemical name,
- The net weight,
- Adequate direction for use in accordance with the limits prescribed for such preservatives, and
- The name and address of the manufacturer.

3.4. Antioxidants in Foods

- 1) Any article of food to which has been added any antioxidant in contravention of this rule shall be deemed, unless the contrary is proved, to be adulterated.

- 2) Antioxidants shall not be added to any food other than edible oils and fats from animal, vegetable and fish, vitamin oils or concentrates and products consisting essentially of fat such as margarine or the like.
- 3) The addition of the following antioxidants to edible oils, fats and essential oils in quantities not exceeding those stated below is permitted, namely:

Antioxidant	Edible Oil and Fats %	Essential Oils %
i) Propyl, octyl or dodecyl gallate or a mixture thereof	0.01	0.1
ii) Gum guaiac	0.01	
iii) Nordihydroguaiaretic acid (NDGA)	0.01	
iv) Thiopropionic acid	0.01	
v) Butylated hydroxyanisole (BHA)	0.02	0.01
vi) Dilauryl thiodipropionate	0.02	
vii) Tocopherol	0.03	
viii) Ascorbic acid and its harmless derivatives	any quantity	

- 4) Compound foods shall be permitted to contain such amount of antioxidant as is necessarily introduced by the use of ingredients specified in sub-rule (3).

3.5. Stabilizers in Foods

The use of the following substances as stabilisers or emulsifying agents, singly or in combination is permitted:

- i) Agar-agar,
- ii) Carob bean,
- iii) Irish moss or carrageen or chondrus,
- iv) Guar gum,
- v) Sodium alginate,
- vi) Monoglycerides or diglycerides of fatty acids,
- vii) Brominated vegetable oils, and
- viii) Gum acacia.

Provided that where a standard for the nature, substance and quality of a food prescribes a limit, that shall not be exceeded by the stabilizer.

Note: Ice-cream shall not contain a stabiliser more than 0.5 per cent of the ice cream.

3.6. Non-nutritive Constituents in Foods

- 1) Any article of food to which has been added a non-nutritive constituent, that is to say, a constituent which is not utilized in normal metabolism, in contravention of this rule, shall be deemed to be adulterated.

- 2) Any food which purports to be or provides for any special dietary use by man for reason of the presence of any constituent which is not utilized in normal metabolism shall bear on its label a statement of the percentage of such constituent along with the name of such constituent and the word, 'Non-nutritive'.
- 3) If the non-nutritive constituent is saccharin or a saccharin salt, the label shall bear, in line of the statement prescribed in sub-rule (3) the statement contains saccharin (or saccharin salt, as the case may be), non-nutritive artificial sweetener which should be, used only by persons who must restrict their intake of ordinary sweets.
The blank is to be filled in with the percentage of saccharin or saccharin salt in such food.
- 4) The following non-nutritive sweeteners may be used in place of saccharin or its salts subjects to the same conditions regarding the statements on the label.
 - a) Calcium cyclohexyl-sulphate, and
 - b) Sodium cyclohexyl-sulphate.
- 5) The label statement of foods containing non-nutritive sweeteners shall also conform to the requirement of other rules.
- 6) Non-nutritive sweeteners and sugar shall not be used in combination in any food.
- 7) Saccharin, Saccharyl or any other non-nutritive sweeteners shall not be sold, unless the package carries a label showing
 - a) The common name,
 - b) The chemical name,
 - c) The net weight,
 - d) Adequate directions for use in foods, and
 - e) The address of manufacturer.

3.7 Negative List for Food Additives_

Not clearly specified Under Bangladesh Food Laws, 1967. Following description exists (Clause 22).

“Unsound or unwholesome food and food unfit for human consumption. Subject to the limitations prescribed under SI. No. 47 of the schedule, any article of food shall be considered injurious to health and unfit for human consumption within the meaning of section 17 of the Ordinance, if it is putrefied or decayed or it emits a bad smell.” That is,

- The food is infested with insects;
- The food has evidence of fifth or of infestation with parasites such as rodent excretion or hair;
- The food contains chemicals known to be toxic or it contains bacteria which are likely to cause food poisoning; or
- The food contains the following metal or metalloids in excess of the tolerance limit showing against each;

Metal	Maximum Limit, ppm	Metal	Maximum Limit, ppm
Aluminium	250	Copper	10
Antimony	2.0	Tin	100
Arsenic liquid	0.1	Fluorine	1.5

Arsenic solid	2	Silver	1
Boron	80	Lead liquid	2
Cadmium	6	Lead solid	20
Zinc	100		

or

- The food contains acidity in excess of the limit.

3.8 Assessment of New Food Additives

There are no specific directions in the existing Bangladesh Pure Food Regulations, 1967.

3.9 Labelling of Food Additives

The BSTI Ordinance, 1985 has been amended as The Bangladesh Standards and Testing Institution (Amendment) Act, 2003. Currently, BSTI is developing a 'Policy on Labelling'. BSTI is the Codex Focal Point for Bangladesh.

Most of the labelling requirements are in conformity to regional requirements and are guided by general principles of Codex Labelling norms. The labels are in Bangla and English dialects with general information on Brand Name, Manufacture details, weight/volume, price and date of manufacture. Labelling of additives is as per generic guidelines.

Container of food which contains preservative shall not be marked "pure"; the word "pure" shall not be used on the label of the container of any food which contains preservative (Bangladesh Pure Food Laws, 1967).

No preservative shall be sold for use in food unless the label carries:

- The common name,
- The chemical name,
- The net weight,
- Adequate directions for use in accordance with the limits prescribed for such preservatives, and
- The name and address of the manufacturer.

3.10 Summary of Food Additives

The definitions of food additives such as flavours, processing aids, carry overs, as well as designated food additives, existing food additives, and materials prohibited for use are summarised below.

1) Summary of Food Additives/Definition (General)

Related Legislation	Bangladesh Pure Food Laws, 1967.	
General Description / Definitions	Description / Definition	Voluntary or Quality Standards
Definition of food additives	No definite description exists under Bangladesh Pure Food Laws 1967.	BSTI standards for additives
Flavourings	Definitions on Natural flavourings,	

	Artificial Flavours and Imitation flavours is available	
Processing aids	No description available	
Carry Over	No details available under Bangladesh Food laws.	

2) Summary of Food Additives/Definition (Specific)

Related Legislation	Bangladesh Pure Food Laws, 1967.	
Specific Description / Definitions	Description / Definition	Voluntary or Quality Standards
List of Designated Food Additives	Colouring matters and Coal tar dyes Flavouring chemicals Class I and Class II preservatives. Antioxidants Stabilizing agents Non-nutritive constituents. Starches	
List of substances which are generally provided for eating or drinking as foods and are used as food additives as well.	No description available	
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis, Sampling, Standards of manufacturing of food additives	Edible salt Baking powder, Edible gelatine, Ice, Sugars, Jaggery, Honey and Sugar products, Cereal powders and processed products, Skimmed milk, Condensed milk, Butter and Clarified fat, Margarine and Hydrogenated fats, Vegetable oils, Spices, Dried fish, Bottled meat, Vinegar and Pickles.	BSTI standards for food products, ingredients and additives. Some of them are based on Codex guidelines.
Official publication and/or gazette for food additives	Details provided above under specific additives and foods.	BSTI standards.

4. CASE STUDIES

(1) Instant Noodles

Under Bangladesh Pure Food Laws, 1967, no specific standard for Instant noodles are prescribed. However, standards for cereal powder, local products and vermicelli are provided as given below:

● Food Grains, Cereals and Their Products:

Sl.	Articles of	Standards
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No	Foods	
47	Food Grains	<p>Food grains shall include rice, wheat, gram (chick peas), barley, oats, maize, jawar, bajra. Food grains for human consumption shall be clean, dry and free from moulds. They shall be free from damage (by insect or otherwise) bad smell, discolouration, and admixture with deleterious and toxic materials. Food grains shall conform to the following standards</p> <ol style="list-style-type: none"> a) Colour: The grains shall have its normal colour as far as possible, but slight discolouration shall not make it unfit for use, if it has not developed any unpleasant smell or taste. b) Smell: It shall be free from persistent bad smell. c) Taste: It shall not possess any taste uncharacteristic of the grain. d) Foreign matter: It includes sand, gravel, dirt, stones, pebbles, straw, stems, chaff, cockles, oilseeds and other non-poisonous seeds. It shall not exceed 3 per cent by weight. e) Damaged grain: Grains which are damaged, touched or mouldy or shrivelled shall not exceed a total of 10 per cent; and the mouldy grain, after superficial cleaning, shall not be more than 1.5 per cent. f) Insect: Damaged grain shall not exceed the limit of 5 per cent. g) Sound grain: Notwithstanding the permissible limits stated in "Foreign matter" and "Moisture content," the percentage of normal and sound grains shall in no case be less than 85 per cent of the total, including the small percentage of "foreign food grains". h) Moisture Content: The moisture content at any time of the year irrespective of climate shall not exceed 13 per cent.
48	Atta	<p>Atta means the product obtained by milling or grinding wheat which shall be effectively cleaned preferably by through washing. It shall be free from lumps, rancidity, insect and fungus, infestation, rodent contamination, and fermented, musty or other objectionable odour. It shall not have grit, adulterant and other extraneous material. The material shall be prepared in premises maintained under hygienic condition. The coarser particles of the bran shall be sifted out through sieve of 32 meshes per linear inch. It shall contain no more than 2.0 per cent of ash, or no less than 8.0 per cent of gluten (both calculated dry substance). It shall contain no more than 0.35 per cent of acidity, expressed as lactic acid (extractable with water) and its moisture content shall not exceed 13 per cent.</p>
49	Wheat Flour or Maida	<p>Maida means the fine product made by milling or grinding, cleaned wheat and bolting or dressing the resulting wheat meal. It shall contain no more than 0.7 per cent of ash and not less than 8 per cent of gluten. It shall contain no more than 0.7 per cent of acidity expressed as lactic acid (extractable with water) with moisture content not exceeding 13 per cent.</p>
50	Suji	<p>Suji means the purified middling of wheat obtained by grinding and bolting cleaned and washed wheat and freeing it from bran, germ, etc., to the desired extent. The material shall be obtained from sound and clean wheat. It shall be white to creamy in colour and shall have a characteristics state and smell. It shall be free from musty off odour, insect or fungus infestation, rodent contamination, grit and other extraneous matters. It shall pass through a No. 20 mesh sieve, with no more than 3 per cent of it passing through a No. 100 mesh sieve. It shall contain no more than 1 per cent of total ash (dry basis), no more than 13.0 per cent of moisture, no more than 0.05 per cent acid insoluble ash (on dry basis), no more than 0.35 per cent of acidity expressed as lactic acid, and no less than 7.5 per cent of gluten dry.</p>

51	Corn Flour	It means the starch powder derived from any variety of corn or grain with or without harmless colouring and flavouring matters. It shall be of such fineness that no less than 98 per cent of it passing through a No.50 mesh sieve, with no less than 50 per cent passing through 70 mesh sieve. It shall contain no more than 0.7 per cent of ash, no more than 13 per cent of moisture, and no more than 0.35 per cent acidity expressed as lactic acid (extractable with water).
52	Besan, Vasan	It means the product obtained by milling or grinding cleaned gram (chick peas) and by sieving it. It shall contain no more than 3 per cent of ash, and no more than 0.5 per cent acidity expressed as lactic acid (extractable with water).
53	Vermicelli or Semai	It means the material prepared from Suji or Maida obtained preferably from hard or semi hard wheat. It shall conform to the following specifications a. Moisture shall not be more than 13 per cent b. Total ash shall not be more than 1.0 per cent c. Total protein (NX6.25) shall not be less than 8 per cent d. Acid insoluble ash shall not be more than 0.05 per cent e. Acidity shall not be more than 0.35 per cent (expresses as lactic acid).

● **Starchy Food:**

54	Arrowroot	It means the separated and purified starch from the rhizomes of the plant known as Maranta arunidinacea. It shall have the characteristics appearance under microscope.
55	Sago or Sagodana	It means the starch obtained from the pitch of the sago palm. It shall have the characteristics appearance under microscopic, and shall conform to the following specifications a. Moisture shall not be more than 12 per cent b. Total ash shall not be more than 0.2 per cent c. Carbohydrates shall not be less than 87 per cent (calculated on dry substance).
56	Shoti or Shoti Food	It means the starch obtained from rhizomes of various Shoti plants. The material shall be white fine powder or pellets. It shall conform to the following standards a. Moisture shall not be more than 15.0 per cent b. Total ash shall not be more than 1.0 per cent (calculated on dry substance) c. Acid insoluble ash shall not be more than 0.2 per cent.

(2) Carbonated Soft Drinks

Under The Bangladesh Pure Food Rules, 1967, Standards for Non-alcoholic Beverages, which include Aerated water and Soda water, are prescribed. These are mandatory and enforced by government agencies.

● **Non Alcoholic Beverages:**

57	Aerated Water	It means potable water other than soda water sweetened with sugar or with saccharin or Sucaryl, but not in combination. It shall be impregnated with carbon dioxide or oxygen, or with both, under pressure, with or without admixture of salts of sodium, potassium, lithium, magnesium, or calcium, singly or in combination, with or without citric acid and of the permitted flavouring and colouring matters if any, and shall not contain tartaric acid except where grape juice has been used as an ingredient, and shall not contain more than 0.1 per cent of phosphoric, and aerated water shall not contain any other mineral acid. It shall not contain any bad and other poisonous metals or any other added substances. Provided that aerated water shall be deemed to be below the standard of purity if it is manufactured from water which is unfit for drinking purposes, or if the ice manufactured from such water is inserted in it. It shall conform to the standard of drinking water which are as follows
		a. pH-7 to be 8.3
		b. Total hardness shall not be more than 25 ppm.
		c. Chloride (as NaCl) shall not be more than 6 ppm.
		d. Free ammoniacal nitrogen shall not be more than 0.005 ppm
		e. Albuminoidal ammoniacal nitrogen shall not be more than 0.005 ppm.
		f. Oxygen absorbed (Tidy's process) shall not be more than 0.1 ppm.
		g. Nitrates (as Nitrogen) shall not be more than 0.005 ppm.
		h. Sulphate shall not be more than 4 ppm.
		i. Iron shall not be more than 0.03 ppm.
		j. Nitrites, Copper, Zinc, Lead, or Sulphureted hydrogen shall be absent.
		k. Total colonies on agar at 37 degrees C shall not be more than 10.
		l. Presumptive coli in 100 cc shall not be more than 2.
		m. Bact. Coli (faecal type) in 100cc shall be absent.
58	Soda Water	It means potable water impregnated with carbon dioxide or oxygen or with both, under pressure, with or without admixture of salts of sodium, potassium, lithium, magnesium or calcium, singly or in combination, and shall not contain any lead or other poisonous metal or any other added substance. Soda water shall be deemed to be below the standard of purity if it is manufactured from water which is unfit for drinking or if the ice manufactured from such water is inserted in it. The standard of purity of water is same as in No. 57.

(3) Prepared Frozen Foods

There are no standards under the Bangladesh Pure Food Laws, 1967, for Frozen foods. For reference, the standard for bottled meat is shown.

● Standard for Bottled Meat:

94	Bottled or Canned meat	It means a food prepared from clean, fresh, wholesome meats, free from infecting agents, contamination, filth, with or without water, vegetables, salt, condiments, spices, and permitted preservatives or colouring or flavouring substances. It shall be processed by heat in such a manner as to produce a sterile condition and packed in a hermetically sealed container.
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(4) Cow's Milk

Under The Bangladesh Pure Food Rules, 1967, Milk and Products standardization have been prescribed. These standards include cow milk along with other local processed milk products manufactured and traded in the country. All these standards are mandatory and enforced by government agencies.

The standard prescribes a number of milk products such as condensed milk, skimmed milk, ghee (clarified butter), butter, cheese, yogurt, ice-cream, sweets, and Chhana, etc.

● **Milk and Milk Products:**

1	Cow Milk	Cow milk shall contain no less than 3.5 per cent of milk fat, no less than 8.5 per cent of milk solid other than milk fat, and shall be with a specific gravity from 1.028 to 1.032 at 15.5 degrees C. Lactose content shall not be less than 4.4 per cent.
2	Buffalo Milk	Buffalo milk shall contain no less than 6.0 per cent of milk fat, and no less than 9.0 per cent of milk solid other than milk fat, and shall be with a specific gravity from 1.028 to 1.032 at 15.5 degrees C. The amount of lactose shall not be less than 4.4 per cent.
3	Milk or Mixed Milk (Cow and Buffalo)	The mixture in any proportion should approximate to the specification of cow milk (SL No. 1)

4. Investigation Results of Each Organization and Country (FY 2009-2012 Reports, Integrated and Revised)

4.1 Codex Alimentarius Commission . . . 106

4.2 Japan . . . 128

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4.1 Codex Alimentarius Commission

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 report as a standard.

1. ELABORATION OF CODEX COMMODITY STANDARDS

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

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.

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

2. CODEX COMMODITY STANDARDS

As of October 2012, Codex Alimentarius Commission has defined commodity standards for 212 food items and local standards for 13 food items³ presented in Table 1.

These standards (Table 1) are 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

¹ Codex Alimentarius Commission is an intergovernmental body established in 1963 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.

² <http://www.codexalimentarius.org/>

³ http://ftp.fao.org/codex/Publications/ProcManuals/Manual_20e.pdf

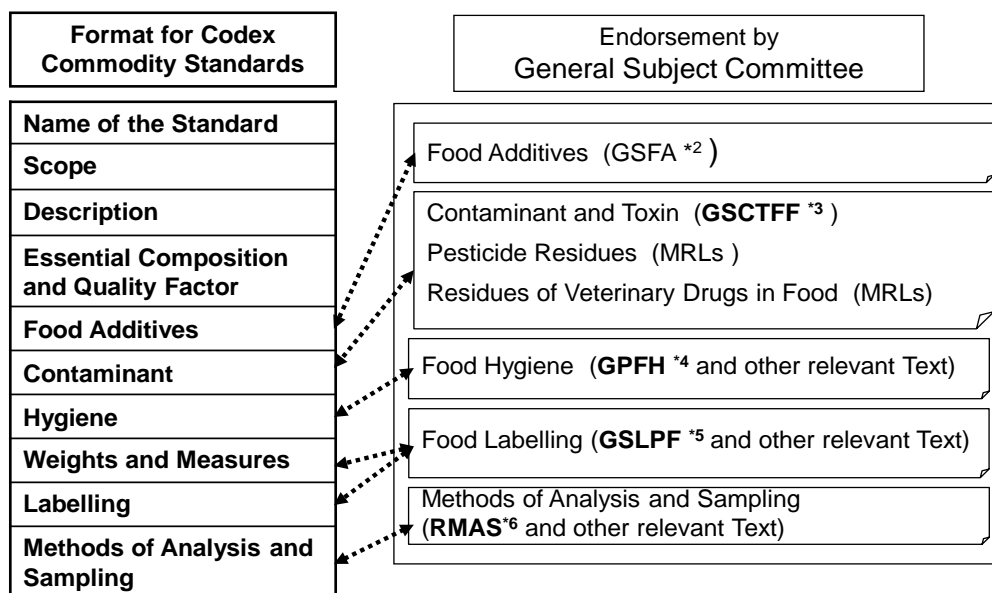
⁴ http://www.codexalimentarius.net/web/standard_list.do?lang=en

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

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.

Table 2 shows ANNEX B and Table 3 provides cross-reference list between the FCS and commodity standards shown in ANNEX C.

Elaboration of Codex Commodity Standards*1



*1 Procedural Manual : Section III Elaboration of Codex Standards and Related Text

*2 Codex Stan 192-1995 General Standard for Food Additives

*3 Codex Stan 193-1995 General Standard for Contaminants and Toxins in Foods and Feeds

*4 CAC/RCP1-1969 General Principles of Food Hygiene

*5 Codex Stan 1-1985 General Standards for the Labelling of Prepackaged Foods

*6 Recommended Methods of Analysis and Sampling

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Figure 1: Commodity Standards developed by Codex Alimentarius Commission

Table 1: List of Codex Commodity Standard

Stan No.	Title	Year of Adoption		Foods	
1	General Standard for the Labelling of Prepackaged Foods	1985	74	Standard for Processed Cereal-Based Foods for Infants and Young Children	1981
3	Standard for Canned Salmon	1981	75	Standard for Quick Frozen Peaches	1981
12	Standard for Honey	1981	76	Standard for Quick Frozen Bilberries	1981
13	Standard for Preserved Tomatoes	1981	77	Standard for Quick Frozen Spinach	1981
17	Standard for Canned Applesauce	1981	78	Standard for Canned Fruit Cocktail	1981
19	Standard for Edible Fats and Oils not Covered by Individual Standards	1981	86	Standard for Cocoa Butter	1981
33	Standard for Olive Oils and Olive Pomace Oils	1981	87	Standard for Chocolate	1981
36	Standard for Quick Frozen Finfish, Eviscerated or Uneviscerated	1981	88	Standard for Corned Beef	1981
37	Standard for Canned Shrimps or Prawns	1981	89	Standard for Luncheon Meat	1981
38	Standard for Edible Fungi and Fungus Products	1981	90	Standard for Canned Crab Meat	1981
39	Standard for Dried Edible Fungi	1981	92	Standard for Quick Frozen Shrimps or Prawns	1981
40R	Standard for Fresh Fungus "Chanterelle"	1981	94	Standard for Sardines and Sardine-Type Products	1981
41	Standard for Quick Frozen Peas	1981	95	Standard for Quick Frozen Lobsters	1981
42	Standard for Canned Pineapple	1981	96	Standard for Cooked Cured Ham	1981
52	Standard for Quick Frozen Strawberries	1981	97	Standard for Cooked Cured Pork Shoulder	1981
53	Standard for Special Dietary Foods with Low-Sodium Content	1981	98	Standard for Cooked Cured Chopped Meat	1981
57	Standard for Processed Tomato Concentrates	1981	99	Standard for Canned Tropical Fruit Salad	1981
60	Standard for Canned Raspberries	1981	103	Standard for Quick Frozen Blueberries	1981
61	Standard for Canned Pears	1981	104	Standard for Quick Frozen Leek	1981
62	Standard for Canned Strawberries	1981	105	Standard for Cocoa powders (cocoas) and dry mixtures of cocoa and sugars	1981
66	Standard for Table Olives	1981	106	General Standard for Irradiated Foods	1983
67	Standard for Raisins	1981	107	General Standard for the Labelling of Food Additives when sold as such	1981
69	Standard for Quick Frozen Raspberries	1981	108	Standard for Natural Mineral Waters	1981
70	Standard for Canned Tuna and Bonito	1981	110	Standard for Quick Frozen Broccoli	1981
72	Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants	1981	111	Standard for Quick Frozen Cauliflower	1981
73	Standard for Canned Baby	1981	112	Standard for Quick Frozen Brussels Sprouts	1981

113	Standard for Quick Frozen Green and Wax Beans	1981
114	Standard for Quick Frozen French Fried Potatoes	1981
115	Standard for Pickled Cucumbers	1981
117	Standard for Bouillons and Consommés	1981
118	Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten	1981
119	Standard for Canned Finfish	1981
130	Standard for Dried Apricots	1981
131	Standard for Unshelled Pistachio Nuts	1981
132	Standard for Quick Frozen Whole Kernel Corn	1981
133	Standard for Quick Frozen Corn-on-the-Cob	1981
140	Standard for Quick Frozen Carrots	1983
141	Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake	1983
143	Standard for Dates	1985
145	Standard for Canned Chestnuts and Chestnut Purée	1985
146	General Standard for Labelling of and Claims for Prepackaged Foods for Special Dietary Use	1985
150	Standard for Food Grade Salt	1985
151	Standard for Gari	1985
152	Standard for Wheat Flour	1985
153	Standard for Maize (Corn)	1985
154	Standard for Whole Maize (Corn) Meal	1985
155	Standard for Degermed Maize (Corn) Meal and Maize (Corn) Grits	1985
156	Standard for Follow-up formula	1987
159	Standard for Canned Mangoes	1987
160	Standard for Mango Chutney	1987
163	Standard for Wheat Protein Products	1987
165	Standard for Quick Frozen Blocks of Fish Fillets, Minced Fish Flesh and Mixtures of Fillets and	1989

	Minced Fish Flesh	
166	Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets - Breaded or in Batter	1989
167	Standard for Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes	1989
169	Standard for Whole and Decorticated Pearl Millet Grains	1989
170	Standard for Pearl Millet Flour	1989
171	Standard for Certain Pulses	1989
172	Standard for Sorghum Grains	1989
173	Standard for Sorghum Flour	1989
174	General Standard for Vegetable Protein Products	1989
175	Standard for Soy Protein Products	1989
176	Standard for Edible Cassava Flour	1989
177	Standard for Grated Desiccated Coconut	1991
178	Standard for Durum Wheat Semolina and Durum Wheat Flour	1991
180	Standard for Labelling of and Claims for Foods for Special Medical Purposes	1991
181	Standard for Formula Foods for Use in Weight Control Diets	1991
182	Standard for Pineapple	1993
183	Standard for Papaya	1993
184	Standard for Mangoes	1993
185	Standard for Nopal	1993
186	Standard for Prickly Pear	1993
187	Standard for Carambola	1993
188	Standard for Baby Corn	1993
189	Standard for Dried Shark Fins	1993
190	General Standard for Quick Frozen Fish Fillets	1995
191	Standard for Quick Frozen Raw Squid	1995
192	General Standard for Food Additives	1995
193	General Standard for Contaminants and Toxins in Food and Feed	1995

196	Standard for Litchi	1995
197	Standard for Avocado	1995
198	Standard for Rice	1995
199	Standard for Wheat and Durum Wheat	1995
200	Standard for Peanuts	1995
201	Standard for Oats	1995
202	Standard for Couscous	1995
203	Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction	1995
204	Standard for Mangosteens	1997
205	Standard for Bananas	1997
206	General Standard for Use of Dairy Terms	1999
207	Standard for Milk Powders and Cream Powder	1999
208	Standard for Cheeses in Brine (Group Standard)	1999
209	Maximum Level and Sampling Plan for Total Aflatoxins in Peanuts Intended for Further Processing	1999
210	Standard for Named Vegetable Oils	1999
211	Standard for Named Animal Fats	1999
212	Standard for Sugars	1999
213	Standard for Limes	1999
214	Standard for Pummelos (Citrus grandi)	1999
215	Standard for Guavas	1999
216	Standard for Chayotes	1999
217	Standard for Mexican Limes	1999
218	Standard for Ginger	1999
219	Standard for Grapefruits (Citrus paradisi)	1999
220	Standard for Longans	1999
221	Group Standard for Unripened Cheese including Fresh Cheese	2001
222	Standard for Crackers from Marine and Freshwater Fish, Crustaceans and Molluscan Shellfish	2001
223	Standard for Kimchi	2001
224	Standard for Tannia	2001
225	Standard for Asparagus	2001

226	Standard for Cape Gooseberry	2001
227	General Standard for Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters)	2001
228	General Methods of Analysis for Contaminants	2001
230	Lead: Maximum Levels	2001
231	General Codex Methods for the Detection of Irradiated Foods	2001
232	Aflatoxin M1 in Milk: Maximum Level	2001
234	Recommended Methods of Analysis and Sampling	1999
235	Patulin in Apple Juice and Apple Juice Ingredients in other Beverages : Maximum Level	2003
236	Standard for Boiled Dried Salted Anchovies	2003
237	Standard for Pitahayas	2003
238	Standard for Sweet Cassava	2003
239	General Methods of Analysis for Food Additives	2003
240	Standard for Aqueous Coconut Products: Coconut Milk and Coconut Cream	2003
241	Standard for Canned Bamboo Shoots	2003
242	Standard for Canned Stone Fruits	2003
243	Standard for Fermented Milks	2003
244	Standard for Salted Atlantic Herring and Salted Sprat	2004
245	Standard for Oranges	2004
246	Standard for Rambutan	2005
247	General Standard for Fruit Juices and Nectars	2005
248	Maximum Levels for Cadmium	2005
249	Standard for Instant Noodles	2006
250	Standard for a Blend of Evaporated Skimmed Milk and Vegetable Fat	2006
251	Standard for a Blend of Skimmed Milk and Vegetable Fat in Powdered Form	2006
252	Standard for a Blend of	2006

	Sweetened Condensed Skimmed Milk and Vegetable Fat	
253	Standard for Dairy Fat Spreads	2006
254	Standard for Certain Canned Citrus Fruits	2007
255	Standard for Table Grapes	2007
256	Standard for Fat Spreads and Blended Spreads	2007
257 R	Regional Standard for Canned Humus with Tehena	2007
258 R	Regional Standard for Canned Foul Medames	2007
259 R	Regional Standard for Tehena	2007
260	Standard for Pickled Fruits and Vegetables	2007
262	Standard for Mozzarella	2006
263	Standard for Cheddar	1966
264	Standard for Danbo	1966
265	Standard for Edam	1966
266	Standard for Gouda	1966
267	Standard for Havarti	1966
268	Standard for Samsoe	1966
269	Standard for Emmental	1967
270	Standard for Tilsiter	1968
271	Standard for Saint-Paulin	1968
272	Standard for Provolone	1968
273	Standard for Cottage Cheese incl. Creamed Cottage Cheese	1968
274	Standard for Coulommiers	1969
275	Standard for Cream Cheese	1973
276	Standard for Camembert	1973
277	Standard for Brie	1973
278	Standard for Extra Hard Grating Cheese	1978
279	Standard for Butter	1971
280	Standard for Milkfat Products	1973
281	Standard for Evaporated Milks	1971
282	Standard for Sweetened Condensed Milks	1971

283	General Standard for Cheese	1978
284	Standard for Whey Cheeses	1971
288	Standard for Cream and Prepared Creams	1976
289	Standard for Whey Powders	1995
290	Standard for Edible Casein Products	1995
291	Standard for Sturgeon Caviar	2010
292	Standard for Live and Raw Bivalve Molluscs	2008
293	Standard for Tomatoes	2008
294 R	Regional Standard for Gochujang	2009
295 R	Regional Standard for Ginseng Products	2009
296	Standard for Jams, Jellies and Marmalades	2009
297	Standard for Certain Canned Vegetables	2009
298 R	Regional Standard for Fermented Soybean Paste	2009
299	Standard for Apples	2010
300	Standard for Bitter Cassava	2010
301 R	Regional Standard for Edible Sago Flour (Asia)	2011
302	Standard for Fish Sauce	2011
303	Standard for Tree Tomatoes	2011
304 R	Regional Standard for Culantro Coyote (LAC)	2011
305 R	Regional Standard for Lucuma (LAC)	2011
306 R	Regional Standard for Chili Sauce (Asia)	2011
307	Standard for Chilli Peppers	2011
308 R	Regional Standard for Harissa (Red Hot Pepper Paste)(Near East)	2011
309 R	Regional Standard for Halwa Tehenia (Near East)	2011

Table 2: ANNEX B: Food Category System

01.0	Dairy products, excluding products of food category 02.0
01.1	Milk and dairy-based drinks
01.1.1	Milk and butter milk (plain)
01.1.1.1	Milk (plain)
01.1.1.2	Butter milk (plain)
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yogurt, and whey-based drinks)
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)
01.2.1	Fermented milks (plain)
01.2.1.1	Fermented milks (plain), not heat-treated after fermentation
01.2.1.2	Fermented milks (plain), heat-treated after fermentation
01.2.2	Renneted milk (plain)
01.3	Condensed milk (plain) and analogues
01.3.1	Condensed milk (plain)
01.3.2	Beverage whiteners
01.4	Cream (plain) and the like
01.4.1	Pasteurized cream (plain)
01.4.2	Sterilized, UHT, whipping or whipped and reduced fat creams (plain)
01.4.3	Clotted cream (plain)
01.4.4	Cream analogues
01.5	Milk powder and cream powder (plain)
01.5.1	Milk and cream powder and powder analogues (plain)
01.5.2	Milk and cream powder analogues
01.6	Cheese and analogues
01.6.1	Unripened cheese
01.6.2	Ripened cheese
01.6.2.1	Ripened cheese, includes rind
01.6.2.2	Rind of ripened cheese
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)
01.6.3	Whey cheese
01.6.4	Processed cheese
01.6.4.1	Plain processed cheese
01.6.4.2	Flavoured processed cheese, including containing fruit, vegetables, meat, etc.
01.6.5	Cheese analogues
01.6.6	Whey protein cheese
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yogurt)
01.8	Whey and whey products, excluding whey cheese
01.8.1	Liquid whey and whey products, excluding whey cheeses
01.8.2	Dried whey and whey products, excluding whey cheeses
02.0	Fats and oils, and fat emulsions
02.1	Fats and oils essentially free from water
02.1.1	Butter oil, anhydrous milkfat, ghee
02.1.2	Vegetable oils and fats
02.1.3	Lard, tallow, fish oil, and other animal fats
02.2	Fat emulsions mainly of type water-in-oil
02.2.1	Butter
02.2.2	Fat spreads, dairy fat spreads and blended spreads
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7
03.0	Edible ices, including sherbet and sorbet
04.0	Fruits and vegetables (including mushrooms and fungi, root & tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
04.1	Fruit
04.1.1	Fresh fruit
04.1.1.1	Untreated fresh fruit
04.1.1.2	Surface-treated fresh fruit
04.1.1.3	Peeled or cut fresh fruit
04.1.2	Processed fruit
04.1.2.1	Frozen fruit
04.1.2.2	Dried fruit
04.1.2.3	Fruit in vinegar, oil, or brine

- 04.1.2.4 Canned or bottled (pasteurized) fruit
- 04.1.2.5 Jams, jellies, marmelades
- 04.1.2.6 Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5
- 04.1.2.7 Candied fruit
- 04.1.2.8 Fruit preparations, including pulp, purees, fruit toppings and coconut milk
- 04.1.2.9 Fruit-based desserts, including fruit-flavoured water-based desserts
- 04.1.2.10 Fermented fruit products
- 04.1.2.11 Fruit fillings for pastries
- 04.1.2.12 Cooked fruit
- 04.2 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and seaweeds, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.1 Fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.1.1 Untreated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera), seaweeds, and nuts and seeds
 - 04.2.1.2 Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.1.3 Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.2 Processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.2.1 Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.2.2 Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
 - 04.2.2.3 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soy sauce
 - 04.2.2.4 Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds
 - 04.2.2.5 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nut and seed purees and spreads (e.g., peanut butter)
 - 04.2.2.6 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5
 - 04.2.2.7 Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3
 - 04.2.2.8 Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds
- 05.0 Confectionery
 - 05.01 Cocoa products and chocolate products, including imitations and chocolate substitutes
 - 05.1.1 Cocoa mixes (powders) and cocoa mass/cake
 - 05.1.2 Cocoa mixes (syrops)
 - 05.1.3 Cocoa-based spreads, including fillings
 - 05.1.4 Cocoa and chocolate products
 - 05.1.5 Imitation chocolate, chocolate substitute products
 - 05.2 Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4
 - 05.2.1 Hard candy
 - 05.2.2 Soft candy
 - 05.2.3 Nougats and marzipans
 - 05.3 Chewing gum
 - 05.4 Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces
- 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0
 - 06.1 Whole, broken, or flaked grain, including rice
 - 06.2 Flours and starches (including soybean powder)
 - 06.2.1 Flours

- 06.2.2 Starches
- 06.3 Breakfast cereals, including rolled oats
- 06.4 Pastas and noodle and like products (e.g., rice paper, rice vermicelli, soybean pastas and noodles)
 - 06.4.1 Fresh pastas and noodles and like products
 - 06.4.2 Dried pastas and noodles and like products
 - 06.4.3 Pre-cooked pastas and noodles and like products
- 06.5 Cereals and starch based desserts (e.g., rice pudding, tapioca pudding)
- 06.6 Batters (e.g., for breading or batters for fish or poultry)
- 06.7 Pre-cooked or processed rice products, including rice cake (Oriental type only)
- 06.8 Soybean products (excluding soybean-based seasonings and condiments of food category 12.9)
 - 06.8.1 Soybean-based beverages
 - 06.8.2 Soybean-based beverage film
 - 06.8.3 Soybean curd (tofu)
 - 06.8.4 Semi-dehydrated soybean curd
 - 06.8.4.1 Thick gravy-stewed semi-dehydrated soybean curd
 - 06.8.4.2 Deep fried semi-dehydrated soybean curd
 - 06.8.4.3 Semi-dehydrated soybean curd, other than food categories 06.8.4.1 and 06.8.4.2
 - 06.8.5 Dehydrated soybean curd (kori tofu)
 - 06.8.6 Fermented soybean (e.g., natto, tempe)
 - 06.8.7 Fermented soybean curd
 - 06.8.8 Other soybean protein products
- 07.0 Bakery wares
 - 07.1 Bread and ordinary bakery wares and mixes
 - 07.1.1 Breads and rolls
 - 07.1.1.1 Yeast-leavened breads and specialty breads
 - 07.1.1.2 Soda breads
 - 07.1.2 Crackers, excluding sweet crackers
 - 07.1.3 Other ordinary bakery products (e.g., bagels, pita, English muffins)
 - 07.1.4 Breads-type products, including bread stuffing and bread crumbs
 - 07.1.5 Steamed breads and buns
 - 07.1.6 Mixes for breads and ordinary bakery wares
 - 07.2 Fine bakery wares (sweet, salty, savoury) and mixes
 - 07.2.1 Cakes, cookies, and pies (e.g., fruit-filled or custard types)
 - 07.2.2 Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)
 - 07.2.3 Mixes for fine bakery wares (e.g., cakes, pancakes)
- 08.0 Meat and meat products, including poultry and game
 - 08.1 Fresh meat, poultry and game
 - 08.1.1 Fresh meat, poultry and game, whole pieces or cuts
 - 08.1.2 Fresh meat, poultry and game, comminuted
 - 08.2 Processed meat, poultry and game products in whole pieces or cuts
 - 08.2.1 Non-heat treated processed meat, poultry and game products in whole pieces or cuts
 - 08.2.1.1 Cured (including salted) non-heat treated processed meat, poultry and game products in whole pieces or cuts
 - 08.2.1.2 Cured (including salted) and dried non-heat treated processed meat, poultry and game products in whole pieces or cuts
 - 08.2.1.3 Fermented non-heat treated processed meat, poultry and game products in whole pieces or cuts
 - 08.2.2 Heat-treated processed meat, poultry and game products in whole pieces or cuts
 - 08.2.3 Frozen processed meat, poultry and game products in whole pieces or cuts
 - 08.3 Processed comminuted meat, poultry, and game products
 - 08.3.1 Non-heat treated processed comminuted meat, poultry, and game products
 - 08.3.1.1 Cured (including salted) non-heat treated processed comminuted meat, poultry, and game products
 - 08.3.1.2 Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products
 - 08.3.1.3 Fermented non-heat treated processed comminuted meat, poultry, and game products
 - 08.3.2 Heat-treated processed comminuted meat, poultry, and game products
 - 08.3.3 Frozen processed comminuted meat, poultry, and game products
 - 08.4 Edible casings (e.g., sausage casings)
- 09.0 Fish and fish products, including mollusks, crustaceans, and echinoderms
 - 09.1 Fresh fish and fish products including mollusks, crustaceans, and echinoderms
 - 09.1.1 Fresh fish
 - 09.1.2 Fresh mollusks, crustaceans, and echinoderms

- 09.2 Processed fish and fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.1 Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.2 Frozen battered fish, fish fillets and fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.3 Frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.4 Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.4.1 Cooked fish and fish products
 - 09.2.4.2 Cooked mollusks, crustaceans, and echinoderms
 - 09.2.4.3 Fried fish and fish products, including mollusks, crustaceans, and echinoderms
 - 09.2.5 Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms
- 09.3 Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms
 - 09.3.1 Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly
 - 09.3.2 Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine
 - 09.3.3 Salmon substitutes, caviar, and other fish roe products
 - 09.3.4 Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste) excluding products of food categories 09.3.1-09.3.3
- 09.4 Fully preserved, incl. canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms
- 10.0 Eggs and egg products
 - 10.1 Fresh eggs
 - 10.2 Egg products
 - 10.2.1 Liquid egg products
 - 10.2.2 Frozen egg products
 - 10.2.3 Dried and/or heat coagulated egg products
 - 10.3 Preserved eggs, including alkaline, salted, and canned eggs
 - 10.4 Egg-based desserts (e.g., custard)
- 11.0 Sweeteners, including honey
 - 11.1 Refined and raw sugar
 - 11.1.1 White sugar, dextrose anhydrous, dextrose monohydrate, and fructose
 - 11.1.2 Powdered sugar, powdered dextrose
 - 11.1.3 Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar
 - 11.1.3.1 Dried glucose syrup used to manufacture sugar confectionery
 - 11.1.3.2 Glucose syrup used to manufacture sugar confectionery
 - 11.1.4 Lactose
 - 11.1.5 Plantation or mill white sugar
 - 11.2 Brown sugar excluding products of food category 11.1.3
 - 11.3 Sugar solutions syrup, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3
 - 11.4 Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)
 - 11.5 Honey
 - 11.6 Table-top sweeteners, including those containing high-intensity sweeteners
- 12.0 Salts, spices, soups, sauces, salads, protein products
 - 12.1 Salt and substitutes
 - 12.1.1 Salt
 - 12.1.2 Salt substitute
 - 12.2 Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)
 - 12.2.1 Herbs and spices
 - 12.2.2 Seasonings and condiments
 - 12.3 Vinegars
 - 12.4 Mustards
 - 12.5 Soups and broths
 - 12.5.1 Ready-to-eat soups and broths, including canned, bottled, and frozen
 - 12.5.2 Mixes for soups and broth
 - 12.6 Sauces and like products
 - 12.6.1 Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dips)
 - 12.6.2 Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)
 - 12.6.3 Mixes for sauces and gravies
 - 12.6.4 Clear sauces (e.g., fish sauce)
 - 12.7 Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories of 04.2.2.5 and 05.1.3

- 12.8 Yeast and like products
- 12.9 Soybean-based seasonings and condiments
 - 12.9.1 Fermented soybean paste (e.g., miso)
 - 12.9.2 Soybean sauce
 - 12.9.2.1 Fermented soybean sauce
 - 12.9.2.2 Non-fermented soybean sauce
 - 12.9.2.3 Other soybean sauces
- 12.1 Protein products other than from soybeans
- 13.0 Foodstuffs intended for particular nutritional uses
 - 13.1 Infant formulae, follow-on formulae, and formulae for special medical purposes for infants
 - 13.1.1 Infant formulae
 - 13.1.2 Follow-up formulae
 - 13.1.3 Formulae for special medical purposes for infants
 - 13.2 Complementary foods for infants and young children
 - 13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1)
 - 13.4 Dietetic formulae for slimming purposes and weight reduction
 - 13.5 Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6
 - 13.6 Food supplements
- 14.0 Beverages, excluding dairy products
 - 14.1 Non-alcoholic ("soft") beverages
 - 14.1.1 Waters
 - 14.1.1.1 Natural mineral waters and source waters
 - 14.1.1.2 Table waters and soda waters
 - 14.1.2 Fruit and vegetable juices
 - 14.1.2.1 Fruit juice
 - 14.1.2.2 Vegetable juice
 - 14.1.2.3 Concentrates for fruit juice
 - 14.1.2.4 Concentrates for vegetable juice
 - 14.1.3 Fruit and vegetable nectars
 - 14.1.3.1 Fruit nectar
 - 14.1.3.2 Vegetable nectar
 - 14.1.3.3 Concentrates for fruit juice
 - 14.1.3.4 Concentrates for vegetable juice
 - 14.1.4 Water-based flavoured drinks, including "sport", "energy", or "electrolyte" drinks and particulated drinks
 - 14.1.4.1 Carbonated water-based flavoured drinks
 - 14.1.4.2 Non-carbonated water-based flavoured drinks, including punches and ades
 - 14.1.4.3 Concentrates (liquid or solid) for water-based flavoured drinks
 - 14.1.5 Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding coccoa
 - 14.2 Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
 - 14.2.1 Beer and malt beverages
 - 14.2.2 Cider and perry
 - 14.2.3 Grape wines
 - 14.2.3.1 Still grape wine
 - 14.2.3.2 Sparkling and semi-sparkling grape wine
 - 14.2.3.3 Fortified grape wine, grape liquor wine, and sweet grape wine
 - 14.2.4 Wine (other than grape)
 - 14.2.5 Mead
 - 14.2.6 Distilled spirituous beverage containing more than 15% alcohol
 - 14.2.7 Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)
- 15.0 Ready-to-eat savouries
 - 15.1 Snacks-potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)
 - 15.2 Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)
 - 15.3 Snacks-fish based
- 16.0 Composite foods - foods that could not be placed in categories 01 - 15.

By CODEX GENERAL STANDARD FOR FOOD ADDITIVES *CODEX STAN 192-1995*

Table 3: ANNEX C: Cross-Reference List Sorted by GFSA Food Category Number

Food Cat. No.	Title	Stan. No.			
01.1.2	Fermented milks (drinks based on fermented milk, plain or flavoured, heat treated or not heat treated)	243-2003	01.6.2.1	Brie	277-1973
01.2.1	Fermented Milks (plain)	243-2003	01.6.2.1	Extra Hard Grating Cheese	278-1978
01.2.1.1	Fermented Milks (plain, non-heat treated)	243-2003	01.6.2.1	Cheese (ripened, including mould ripened)	283-1978
01.2.1.2	Fermented Milks (plain, heat treated)	243-2003	01.6.3	Whey Cheeses (whey cheese)	284-1971
01.3.1	Evaporated milks	281-1971	01.6.6	Whey Cheeses (whey protein cheese)	284-1971
01.3.1	Sweetened Condensed Milks	282-1971	01.7	Fermented Milks (flavoured, heat treated and non-heat treated)	243-2003
01.3.2	Blend of Evaporated Skimmed Milk and Vegetable Fat	250-2006	01.8.2	Whey powders	289-1995
01.3.2	Blend of Sweetened Condensed Milk and Vegetable Fat	252-2006	02.1	Edible Fats and Oils Not Covered by Individual Standards (General Standard)	019-1981
01.4.1	Cream and Prepared Creams (reconstituted cream, recombined cream, prepackaged liquid cream)	288-1976	02.1.1	Milkfat Products	280-1973
01.4.2	Cream and Prepared Creams (whipping cream, cream packaged under pressure, whipped cream)	288-1976	02.1.2	Named Vegetable Oils	210-1999
01.4.3	Cream and Prepared Creams (fermented cream, acidified cream)	288-1976	02.1.2	Olive Oil, Virgin and Refined, and Refined Olive Pomace Oil, Olive Oils and Olive Pomace Oils	033-1981
01.5.1	Milk Powders and Cream Powders	207-1999	02.1.3	Named Animal Fats	211-1999
01.5.1	Edible Casein Products	290-1995	02.2.1	Butter	279-1971
01.5.2	Blend of Skimmed Milk and Vegetable Fat in Powdered Form	251-2006	02.2.2	Dairy Fat Spreads	253-2006
01.6.1	Unripened Cheese, including Fresh Cheese	221-2001	02.2.2	Fat Spreads and Blended Spreads	256-2007
01.6.1	Mozzarella	262-2007	04.1.1.1	Dates (fresh)	143-1985
01.6.1	Cottage Cheese	273-1968	04.1.1.1	Pineapple	182-1993
01.6.1	Cream Cheese (Rahmfrischkäse)	275-1973	04.1.1.1	Papaya	183-1993
01.6.1	Cheese (unripened, including fresh cheese) - See also CODEX STAN 221-2001	283-1978	04.1.1.1	Mango	184-1993
01.6.2.1	Cheeses in Brine	208-1999	04.1.1.1	Carambola	187-1993
01.6.2.1	Cheddar	263-1966	04.1.1.1	Litchi	196-1995
01.6.2.1	Danbo	264-1966	04.1.1.1	Mangosteens	204-1997
01.6.2.1	Edam	265-1966	04.1.1.1	Bananas	205-1997
01.6.2.1	Gouda	266-1966	04.1.1.1	Limes	213-1999
01.6.2.1	Havarti	267-1966	04.1.1.1	Pumelos (<i>Citrus grand</i>)	214-1999
01.6.2.1	Samsøe	268-1966	04.1.1.1	Guavas	215-1999
01.6.2.1	Emmental	269-1967	04.1.1.1	Chayotes	216-1999
01.6.2.1	Tilsiter	270-1968	04.1.1.1	Mexican Limes	217-1999
01.6.2.1	Saint Paulin	271-1968	04.1.1.1	Grapefruits (<i>Citrus paradisi</i>)	219-1999
01.6.2.1	Provolone	272-1968	04.1.1.1	Longans	220-1999
01.6.2.1	Coulommiers	274-1969	04.1.1.1	Cape Gooseberry	226-2001
01.6.2.1	Camembert	276-1973	04.1.1.1	Pitahayas	237-2003
			04.1.1.1	Oranges	245-2004
			04.1.1.1	Rambutan	246-2005
			04.1.1.1	Table Grapes	255-2007
			04.1.1.1	Apples	299-2010
			04.1.1.1	Lucuma (Regional Standard)	305R-2011
			04.1.1.2	Dates (coated)	143-1985
			04.1.2.1	Quick Frozen Strawberries	052-1981
			04.1.2.1	Quick Frozen Raspberries	069-1981
			04.1.2.1	Quick Frozen Peaches	075-1981

04.1.2.1	Quick Frozen Bilberries	076-1981
04.1.2.1	Quick Frozen Blueberries	103-1981
04.1.2.2	Raisins	067-1981
04.1.2.2	Dried Apricots	130-1981
04.1.2.2	Grated Desiccated Coconut	177-1991
04.1.2.3	Pickled Fruits and Vegetables (pickled fruits)	260-2007
04.1.2.4	Canned Applesauce	017-1981
04.1.2.4	Canned Pineapple	042-1981
04.1.2.4	Canned Raspberries	060-1981
04.1.2.4	Canned Pears	061-1985
04.1.2.4	Canned Strawberries	062-1987
04.1.2.4	Canned Fruit Cocktail	078-1981
04.1.2.4	Canned Tropical Fruit Salad	099-1981
04.1.2.4	Canned Mangoes	159-1987
04.1.2.4	Canned Stone Fruits	242-2003
04.1.2.4	Certain Canned Citrus Fruits	254-2007
04.1.2.5	Jams, Jellies and Marmalades	296-2009
04.1.2.6	Mango Chutney	160-1987
04.1.2.8	Aqueous Coconut Products (coconut milk and coconut cream)	240-2003
04.1.2.10	Pickled Fruits and Vegetables (fermented fruits)	260-2007
04.2.1.1	Edible Fungi and Fungi Products (edible fungi)	038-1981
04.2.1.1	Fresh Fungus "Chanterelle" (Regional Standard)	040R-1981
04.2.1.1	Unshelled Pistachio Nuts	131-1981
04.2.1.1	Certain Pulses	171-1989
04.2.1.1	Nopal	185-1993
04.2.1.1	Prickly pear	186-1993
04.2.1.1	Baby Corn	188-1993
04.2.1.1	Avocado	197-1995
04.2.1.1	Peanuts	200-1995
04.2.1.1	Ginger	218-1999
04.2.1.1	Tannia	224-2001
04.2.1.1	Asparagus	225-2001
04.2.1.1	Sweet Cassava	238-2003
04.2.1.1	Tomatoes	293-2008
04.2.1.1	Bitter cassava	300-2010
04.2.1.1	Tree Tomatoes	303-2011
04.2.1.1	Culantro Coyote (Regional Standard)	304R-2011
04.2.1.1	Chilli Peppers	307-2011
04.2.2	Edible Fungi and Fungi Products (fungus products)	038-1981
04.2.2.1	Edible Fungi and Fungi Products (quick frozen)	038-1981
04.2.2.1	Quick Frozen Peas	041-1981

04.2.2.1	Quick Frozen Spinach	077-1981
04.2.2.1	Quick Frozen Leek	104-1981
04.2.2.1	Quick Frozen Broccoli	110-1981
04.2.2.1	Quick Frozen Cauliflower	111-1981
04.2.2.1	Quick Frozen Brussels Sprouts	112-1981
04.2.2.1	Quick Frozen Green Beans and Wax Beans	113-1981
04.2.2.1	Quick Frozen French-Fried Potatoes	114-1981
04.2.2.1	Quick Frozen Whole Kernel Corn	132-1981
04.2.2.1	Quick Frozen Corn-on-the-Cob	133-1981
04.2.2.1	Quick Frozen Carrots	140-1983
04.2.2.2	Edible Fungi and Fungi Products (incl. freeze dried, fungus grits and fungus powder)	038-1981
04.2.2.2	Dried Edible Fungi	039-1981
04.2.2.2	Ginseng Products (Regional Standard) (dried ginseng, dried raw ginseng, dried steamed ginseng)	295R-2009
04.2.2.3	Edible Fungi and Fungi Products (salted, pickled or in vegetable oil)	038-1981
04.2.2.3	Table Olives	066-1981
04.2.2.3	Pickled Cucumbers (Cucumber Pickles)	115-1981
04.2.2.3	Pickled Fruits and Vegetables (pickled vegetables)	260-2007
04.2.2.4	Preserved Tomatoes	013-1981
04.2.2.4	Edible Fungi and Fungi Products (sterilized)	038-1981
04.2.2.4	Canned Chestnuts and Canned Chestnut Puree	145-1985
04.2.2.4	Canned Bamboo Shoots	241-2003
04.2.2.4	Canned Humus with Tehena (Regional Standard)	257R-2007
04.2.2.4	Canned Foul Medames (Regional Standard)	258R-2007
04.2.2.4	Certain Canned Vegetables	297-2009
04.2.2.5	Processed Tomato Concentrates (tomato puree)	057-1981
04.2.2.6	Edible Fungi and Fungi Products (concentrate, dried concentrate or extract)	038-1981
04.2.2.6	Processed Tomato Concentrates (tomato paste)	057-1981
04.2.2.6	Tehena (Regional Standard)	259R-2007

04.2.2.6	Ginseng Products (Regional Standard) (ginseng extract, raw ginseng extract, steamed ginseng extract)	295R-2009
04.2.2.6	Harissa (Regional Standard)	308R-2011
04.2.2.7	Edible Fungi and Fungi Products (fermented)	038-1981
04.2.2.7	Gari	151-1985
04.2.2.7	Kimchi	223-2001
04.2.2.7	Pickled Fruits and Vegetables (fermented vegetables)	260-2007
04.2.2.7	Gochujang (Regional Standard)	294R-2009
05.1.1	Cocoa Powders (Cocoa) and Dry Mixtures of Cocoa and Sugar	105-1981
05.1.1	Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake	141-1983
05.1.3	Cocoa Butters	086-1981
05.1.4	Chocolate and Chocolate Products	087-1981
05.2.2.	Halwa Tehenia (Regional Standard)	309R-2011
06.1	Maize (Corn)	153-1985
06.1	Whole and Decorticated Pearl Millet Grains	169-1989
06.1	Sorghum Grains	172-1989
06.1	Rice	198-1995
06.1	Wheat and Durum Wheat	199-1995
06.1	Oats	201-1995
06.1	Couscous	202-1995
06.2.1	Wheat Flour	152-1985
06.2.1	Whole Maize (Corn) Meal	154-1985
06.2.1	Degermed Maize (Corn) Meal and Maize (Corn) Grits	155-1985
06.2.1	Pearl Millet Flour	170-1989
06.2.1	Sorghum Flour	173-1989
06.2.1	Edible Cassava Flour	176-1989
06.2.1	Durum Wheat Semolina and Durum Wheat Flour	178-1991
06.2.1	Edible Sago Flour (Regional Standard)	301R-2011
06.4.3	Instant Noodles	249-2006
06.8.8	Soy Protein Products	175-1989
08.2.2	Cooked Cured Ham	096-1981
08.2.2	Cooked Cured Pork Shoulder	097-1981
08.3.2	Canned Corned Beef	088-1981
08.3.2	Luncheon Meat	089-1981
08.3.2	Cooked Cured Chopped Meat	098-1981
09.1.2	Raw and Live Bivalve Molluscs (live)	292-2008
09.1.2	Raw and Live Bivalve	292-2008

	Molluscs (raw, chilled shucked)	
09.2.1	Quick-Frozen Finfish, Uneviscerated and Eviscerated	036-1981
09.2.1	Quick Frozen Shrimps or Prawns	092-1981
09.2.1	Quick Frozen Lobsters	095-1981
09.2.1	Quick Frozen Blocks of Fish Fillets, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh	165-1989
09.2.1	Quick Frozen Fish Fillets	190-1995
09.2.1	Quick Frozen Raw Squid	191-1995
09.2.1	Raw and Live Bivalve Molluscs (raw, frozen)	292-2008
09.2.2	Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets -Breaded and in Batter	166-1989
09.2.5	Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes	167-1989
09.2.5	Dried Shark Fins	189-1993
09.2.5	Crackers from Marine and Freshwater Fish, Crustaceans and Molluscan Shellfish	222-2001
09.2.5	Boiled Dried Salted Anchovies	236-2003
09.2.5	Salted Atlantic Herring and Salted Sprat	244-2004
09.3.3	Sturgeon caviar	291-2010
09.4	Canned Shrimps or Prawns	037-1981
09.4	Canned Salmon	003-1981
09.4	Canned Tuna and Bonito	070-1981
09.4	Canned Crab Meat	090-1981
09.4	Canned Sardines and Sardine-Type Products	094-1981
09.4	Canned Finfish	119-1981
11.1.1	Sugars (white sugar, dextrose anhydrous, dextrose monohydrate, fructose)	212-1999
11.1.2	Sugars (powdered sugar and powdered dextrose)	212-1999
11.1.3	Sugars (glucose syrup, dried glucose, soft white sugar, brown sugar, raw cane sugar)	212-1999
11.1.4	Sugars (lactose)	212-1999
11.1.5	Sugars (plantation or white mill sugar)	212-1999
11.5	Honey	012-1981
12.1.1	Food Grade Salt	150-1985
12.1.2	Special Dietary Foods with Low-Sodium Content, including salt substitutes (salt substitutes)	053-1981
12.5	Bouillon and Consommés	117-1981
12.6.2	Chilli Sauce (Regional Standard)	306R-2011

12.6.4	Fish Sauce	302-2011	13.2	Canned Baby Foods	073-1981
12.9.1	Fermented Soybean Paste (Regional Standard)	298R-2009	13.2	Processed Cereal-Based Foods for Infants and Children	074-1981
12.10	Wheat Protein Products, Including Wheat Gluten	163-1987	13.3	Foods for Special Dietary Use for Persons Intolerant to Gluten	118-1981
12.10	Vegetable Protein Products	174-1989	13.4	Formula Foods for Use in Weight Control Diets	181-1991
13.0	Special Dietary Foods with Low-Sodium Content, including salt substitutes (special dietary foods with low sodium content)	053-1981	13.4	Formula Foods for Use in Very Low Energy Diets for Weight Reduction	203-1995
13.1.1	Infant Formula and Formula for Special Dietary Purposes Intended for Infants (infant formula)	072-1981	14.1.1.1	Natural Mineral Waters	108-1981
13.1.2	Follow-Up Formula	156-1987	14.1.1.2	Bottled/Packaged Drinking Waters (other than natural mineral water)	227-2001
13.1.3	Infant formula and Formula for Special Dietary Purposes Intended for Infants (formula for special dietary purposes intended for infants)	072-1981	14.1.2.1	Fruit Juices and Nectars (fruit juices)	247-2005
			14.1.2.3	Fruit Juices and Nectars (concentrates for fruit juice)	247-2005
			14.1.3.1	Fruit Juices and Nectars (fruit nectars)	247-2005
			14.1.3.3	Fruit Juices and Nectars (concentrates for fruit nectars)	247-2005

3. CODEX GENERAL STANDARDS FOR FOOD ADDITIVES (GSFA)

General Standards for Food Additives (GSFA) have 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 have 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 Document 1 and, for reference, descriptions/definitions for food additives, flavor, processing aids and carry-over are summarized in Table 4.

CODEX GENERAL STANDARDS FOR FOOD ADDITIVES
CODEX STAN 192-1995, Rev. 7-2006

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.¹ Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe² by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)³ 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.

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

¹ 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.

² 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).

³ 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/>

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 qualities⁴.

- 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 risk⁵.
- c) **Acceptable Daily Intake "Not Specified" (NS)**⁶ is a term applicable to a food 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 intake⁷ from all food sources. Where the 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

⁴ Codex Alimentarius Procedural Manual.

⁵ 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.

⁶ 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, rather than on a toxicologically established ADI.

⁷ 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.

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)⁸

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 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 Commission⁹ 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 FOODS¹⁰

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

⁸ For additional information, see the Codex Alimentarius Commission Procedural Manual. Relations Between Commodity Committees and General Committees- Food Additives and Contaminants.

⁹ 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.org/standards/en/>). 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/>

¹⁰The Principle relating to the Carry-Over of Food Additives into Foods (the "Carry-over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. **The Carry-Over Principle applies to all foods covered by Codex Standards**, unless otherwise specified in such standards.

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.

An additive may be used in 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.

4.2 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 SYSTEM¹¹

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 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

¹¹ Annex B to this Standard.

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 non-numerical 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 aids¹².

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¹² 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.

4. CODEX METHODS OF ANALYSIS AND SAMPLING

There are Methods of Analysis and Sampling Committee in General Subject Committee in Codex Alimentarius Commission. The Committee's Terms of Reference in Codex are listed below:

- (1) To elaborate standards for methods of analysis and sampling suitable for food standards.
- (2) To function as an international coordinating organization for food standards.
- (3) To identify the generally applicable methods of analysis and sampling suitable for food standards.
- (4) To investigate, amend and approve the methods of analysis and sampling proposed by the Commodity Committee.
- (5) To organize the sampling methods and procedures as necessary.
- (6) To investigate problems with the specific methods of analysis and sampling presented to this Committee.
- (7) To elaborate evaluation procedures, protocol, guidelines or related documents for the Food Testing Organization System.

The Methods of Analysis and Sampling that have so far been elaborated were compiled in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999¹³), which can be found in the list of standards

(http://www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1) and downloaded.

¹³ http://www.codexalimentarius.org/download/standards/388/CXS_234e.pdf

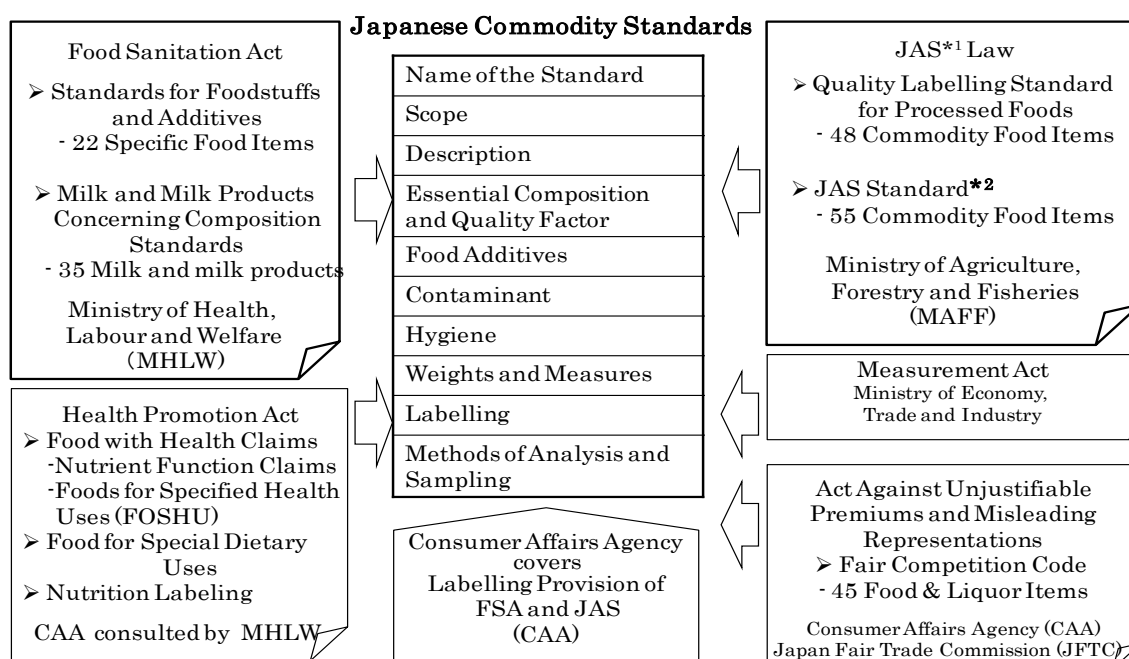
Table 4: Descriptions/Definitions in Codex Texts

	Description / Definition
Related Legislation	CODEX STAN 192-1995 CAC/GL 66-2008 CODEX STAN 107-1981
General Description/Definitions	
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.
Flavours	GUIDELINES FOR THE USE OF FLAVOURINGS CAC/GL 66-2008 1.1 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. 1.2 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: 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.

4.2 Japan

1. SUMMARY OF RELATIONSHIP BETWEEN FOOD REGULATORY SYSTEM AND COMMODITY STANDARDS

Summary chart of relationship between food regulatory system and commodity standards in Japan is shown in Figure 1.



*1 Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products
 *2 voluntary (other than organic foods) standard with the certification system to attach the JAS Mark
 *3 New governmental organization started in September 2009

Figure 1 Summary of Relationship between Japanese Food Regulatory System and Commodity Standards

2. FOOD SPECIFICATIONS AND QUALITY LABELING STANDARDS

2.1 Law concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law)

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

(1) The Quality Labeling Standards System

The Quality Labeling 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 (Table 1).

- Quality labeling standards for general application
 - fresh foods quality labeling standards
 - processed foods quality labeling standards
 - quality labeling standards regarding genetically modified foods

Table 1: Individual Quality Labeling Standards for Processed Foods

(MAFF) as of March 2010

	Canned and Bottled Products	25	Processed tomato
1	Canned and bottled agricultural products	26	Jams
2	Canned and bottled livestock products	27	Dried shiitake mushroom
3	Canned and bottled prepared foods		Marine Products
	Beverages	28	Processed <i>Uni</i> (sea urchin)
4	Fruits juice and fruit beverages	29	<i>Uni –Aemono</i> (mixture of sea urchin eggs and marine products)
5	Carbonated drinks Case Study (2)	30	Dried <i>Wakame</i> (<i>undaria pinnatifida</i>)
6	Soy milks	31	Salted <i>Wakame</i>
7	Carrot juice, Mixed carrot juice	32	<i>Kezuribushi</i> (shaved dried fish)
	Livestock and Fish Paste	33	Boiled and dried fishes
8	Bacon	34	Processed eel
9	Hams		Seasoning
10	Pressed ham	35	Dressing and dressing type seasonings
11	Mixed pressed ham	36	Edible vinegar
12	Sausage	37	Flavored seasonings
13	Mixed sausage	38	Dehydrated soup
14	Chilled hamburger stake	39	Worcester sauces
15	Chilled meat ball	40	Shoyu (Soy sauce)
16	Fish ham, Fish sausage	41	Miso (soy bean paste)
17	Specially packed steamed fish paste (abolished on Sep. 30, 2009)	42	Tuyu(Dipping soup) for noodles
18	Flavored steamed fish paste (abolished on Sep 30, 2009)		Oil and Fat
	Cereal Products	43	Edible vegetable oils and fats
19	Dried noodles	44	Margarine
20	Instant Noodles Case Study (1)		Others
21	Macaroni products	45	Retortable pouched food
22	Kori Dofu (dried frozen soy curd)	46	Frozen vegetable product
23	Breads	47	Chilled Gyoza
	Agricultural and Forestry Products	48	Prepared frozen food Case Study (3)
24	Pickled Agricultural products		

(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 (general JAS, specific JAS, organic JAS, JAS with product information, and JAS with controlled constant temperature distribution) (Table 2).

Table 2: List of JAS Standards for Food

(MAFF) as of Sep. 2009

■ GENERAL JAS		Seasoning	
Canned and Bottled Products		29	Dressings
1	Canned and bottled agricultural products	30	Fermented vinegar
2	Canned and bottled livestock products	31	Flavored seasonings
3	Canned and bottled marine products	32	Dehydrated soup
Beverage		33	Worcester sauces
4	Fruits juice and fruit beverages	34	<i>Shoyu</i> (soy sauce)
5	Apple straight pure juice	Oil and Fat and their Processed Product	
6	Carbonated drinks Case Study (2)	35	Edible vegetable oils and fats
7	Soy milks	36	Refined lard
8	Carrot juice, Mixed carrot juice	37	Margarines
Livestock Products		38	Shortening
9	Bacon	39	Edible refined and processed oils and fats
10	Hams	Others	
11	Pressed ham	40	Prepared frozen food Case Study (3)
12	Sausage	■ SPECIFIC JAS WITH PRODUCTION METHODS	
13	Mixed sausage	41	Matured Bacon
14	Hamburger patty	42	Matured Hams
15	Chilled ham burg stake	43	Matured sausage
16	Chilled meat ball	44	Handmade dried noodles
Cereal Products		45	Naturally Grown Chicken
17	Dried noodles	■ ORGANIC JAS	
18	Instant noodles Case Study (1)	46	Organic agricultural products
19	Macaroni products	47	Organic Processed foods
20	Vegetable protein	48	Organic feeds
21	Bread crumbs	49	Organic livestock products
Processed Agricultural Products		■ JAS WITH PRODUCTION INFORMATION	
22	Pickled agricultural products	50	Beef with the disclosed production information
23	Processed tomato products	51	Pork with the disclosed production information
24	Jams	52	Agricultural products with the disclosed production information
Processed Marine Products		53	Processed foods with the disclosed production information
25	<i>Kezuribushi</i> (shaved dried fish)	54	Farmed fishes with the disclosed production information
26	Boiled and dried fishes	■ JAS WITH CONTROLLED CONSTANT TEMPERATURE DISTRIBUTION	

	Sugars	55	Processed foods with controlled constant temperature distribution
27	Glucose		
28	High fructose corn syrup and sugar added high fructose corn syrup		

2.2 Food Sanitation Act and Related Laws and Regulations

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

(1) Standards for Foodstuffs and Food 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 (Table 3).

Table 3: Specific Food Items in the Standards for Foodstuffs and Food Additives

(MHLW) as of March 2010

1	Soft Drink Beverages Case Study (2)	12	Boiled Octopus
2	Powdered Soft Drink Beverages	13	Boiled Crab
3	Crushed Ice	14	Fresh Fish and Shellfish to be Eaten Raw
4	Frozen Confections	15	Oysters to be Eaten Raw
5	Meats and Whale Meat (with the exemption of frozen whale meat eaten raw)	16	Agar
6	Edible Birds' Eggs	17	Grains, Beans and Vegetables
7	Blood, Blood Corpuscles and Blood Plasma	18	Bean Jam or Further Processing
8	Meat Products	19	Soybean Curd ("tofu")
9	Whale Meat Products	20	Instant Noodles Case Study (1)
10	Fish-paste Products	21	Frozen Foods Case Study (3)
11	Salmon Roe and Cod Roe (defined as the ovaries of walleye or pollack preserved in salt; hereinafter the same in this section)	22	Food Packed in Containers and Sterilized by Pressurization and Heating

Note: 1. These standards are composed of 'Standard for Component', 'Standard for Production', 'Standard for Storage'

2. Details of Food Additives are available in English

<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html>

3.Details of Agricultural Chemical Residues are available in English
<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html>

(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 (Table 4).

Table 4: Specific Items in Ministerial Ordinance on Compositional Standards for Milk and Milk Products (MHLW) as of March 2010

Raw Milk		9	Concentrated milk
A	Raw Milk	10	Concentrated skimmed milk
B	Raw goat's milk	11	Evaporated milk
Drinking Liquid Milks and Milk Drinks		12	Evaporated skimmed milk
1	Cow's milk Case Study (4)	13	Sweetened condensed milk
2	Special cow's milk	14	Sweetened condensed skimmed milk
3	Pasteurized goat's milk	15	Whole milk powder
4	Composition-controlled cow's milk	16	Skimmed milk powder
5	Low fat cow's milk	17	Cream powder
6	Nonfat cow's milk	18	Whey powder
7	Processed milk	19	Whey powder protein concentrated
Milk Products		20	Butter milk powder
1	Cream	21	Sweetened milk powder
2	Butter	22	Formulated milk powder
3	Butter oil	23	Fermented milk
4	Processed cheese	24	Lactic acid bacteria drinks (nonfat milk solid not less than 3.0%)
5	Concentrated whey	25	Milk drinks
6	Ice cream	Foods Mainly Made from Milk	
7	Ice milk	1	Lactic acid bacteria drinks (nonfat milk solid less than 3.0%)
8	Lacto ice		

2.3 Fair Competition Code for Labeling of Food Items

Fair Competition Code based on Act against Unjustifiable Premiums and Misleading Representations stipulates voluntary standards for labeling of food items for individual firms and industry associations (Table 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.

Table 5: Fair Competition Code for Labeling of Food Items

(CAA/FTC) as of Feb. 2010.03

Milk and Milk Products		19	Instant noodles	Case Study (1)
1	Drinking milk	20	<i>Miso</i> (soy bean paste)	
2	Fermented milk, Lactic acid bacteria beverage	Confectionary		
3	Pasteurized lactic acid bacteria beverage	21	Biscuits	
4	Natural cheese, Processed cheese, Cheese food	22	Chocolates	
5	Ice creams	23	Food using chocolate	
Honeys		24	Chewing gum	
6	Honeys	25	Souvenir for tourist	
7	Royal jelly	Seasoning		
Processed marine Products		26	Edible vinegar	
8	<i>Uni</i> (sea urchin) foods	27	Synthetic lemon juice	
9	<i>Karashi Mentaiko</i> (spicy marinated roe of pollack)	28	Margarines	
10	<i>Kezuribushi</i> (shaved dried fish)	29	Dressings	
11	<i>Nori</i> (laver)	30	<i>Shoyu</i> (soy sauce)	
Processed Agricultural Products		31	Table salt	
12	Canned foods	Beverages		
13	Processed tomato	32	Fruit drinks	
14	Powdered <i>Wasabi</i> (Japanese horseradish)	33	Coffee drinks	
15	Raw noodles	34	Regular coffee, instant coffee	
16	<i>Kori-dofu</i> (dried frozen soy curd)	35	<i>Moromi-su</i> (vinegar drink from residue of rice brandy)	
17	Soy milks	Processed Livestock		
18	Packed bread	36	Ham, sausage	

3. ACTS AND REGULATIONS RELATED TO FOOD ADDITIVES

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:

- Ordinance of the Ministry of Health and Welfare No. 23 of July 13, 1948 “The Food Sanitation Act Enforcement Regulations”
- 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 labeling 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 55 JAS Mark standards under the Law concerning Standardization and Proper Labeling 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 Labeling Standard” system. Among several standards of the system, all processed foods except for alcohol beverage are regulated by the “Quality Labeling 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.

3.2 Food Additive Definitions & 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 labeling, i.e., the provisions of article 19, paragraph 1, item 1-e of the Cabinet Office Ordinance No.45, 2011, on the Criteria of Labeling 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 provision of item 2 of article 1 of the Cabinet Office Ordinance No.45, 2011, on the Criteria of Labeling 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.

3.3 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 labeling 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 (3.6 Application, Assessment, and Approval of Designation for New 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 9 years are;

2004	7 items	magnesium stearate, magnesium triphosphate, isobutanol, 2,3,5,6-tetramethylpyrazine, etc.
2005	8	propanol, isopropanol, amyl alcohol, hydroxypropylcellulose, natamycin, etc.
2006	7	acetaldehyde, 2-ethyl-3-methylpyridine, butanol, potassium alginate, etc.
2007	6	tocopherol acetate ester, isobutyraldehyde, 2-methylbutanol, butylaldehyde, 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.
2012	5	trans-2-methyl-2-butanol, trimethylamine, saccharin calcium, 2-ethyl-6-methylpyrazine, 3-amino-3-carboxypropyl, dimethyl sulfonium chloride, 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

See “3.2 Food Additive Definitions & Functional Classes” for the definition of 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 labeling 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.

3.4 Prohibited Substances for Use 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 55 JAS Mark Standards under the Law concerning Standardization and Proper Labeling 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.

3.5 Specifications and Standards 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.”

3.6 Application, Assessment, and Designation for New Food Additives

Designation of a new 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

3.7 Labeling of Food Additives Used in Foods

Labeling of food additives used in foods is regulated by both Food Sanitation Act and JAS law. The “Quality Labeling 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 labeling pursuant to item 1 of Article 19 of Food Sanitation Act.

3.8 Official Compilation of “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 labeling 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 website (http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec_stand_fa).

3.9 Summary of Food Additives

The definitions regarding food additives such as flavourings, processing aids, and carry over are summarized in Table 6, and other definitions such as designated/existing food additives and prohibited substances are summarized in Table 7.

4. SPECIFICATIONS & STANDARDS AND METHODS OF ANALYSIS FOR GENERAL FOODS

Specifications & Standards and Methods of Analysis for "General Foods" are shown in Table 8. Specifications & Standards and Methods of analysis for the food categories taken up in the Case Studies are described in these food categories, respectively.

5. CASE STUDIES

(1) Instant Noodles

Commodity Food Standards and Methods of Analysis:

Codex Commodity Standard for Instant Noodles was proposed by Japan and other Asian countries and adopted in 2006. Instant noodles are classified in 06.4.3 Pre-cooked pastas and noodles and like products in FCS (Food Category System) and this standard is a sole commodity standard in 06.4 category: Pastas, Noodles and like products.

In Table 9, summaries of "Instant Noodles" were compared with Codex Commodity Standards, Standards for Foodstuffs in Food Sanitation Act, Quality Labeling Standards in JAS Law and JAS Standards. In Table 10, the Methods of Analysis for "Instant Noodles" by Codex Standard are compared with those by Standards for Foodstuffs in Food Sanitation Act, Quality Labeling Standards in JAS Law, and JAS Standards.

Food Additives:

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 (Table 11).

(2) Carbonated Soft Drinks

Commodity Food Standards and Methods of Analysis:

In Codex Food Commodity Standards, beverages are classified in 14.0: Beverages excluding dairy products, 14.1: Non-alcoholic beverages and 14.2: Alcoholic beverages. Codex Commodity Food Standards defined in 14.1 are only for 3 items; Natural Mineral Waters (Stan 108-1981), Bottled/Packaged Waters other than natural mineral waters (Stan 227-2005) and Fruit juice and Nectars (Stan 247-2005).

Carbonated Drinks are fallen into 14.1.4.1: Carbonated water-based flavored drinks, in 14.1.4: Water-based flavored drinks including sport drinks, energy drinks and electrolyte beverages.

In Food Sanitation Act, Carbonated Drinks are included in wide-ranging "Soft Drinks"

defined in specified food items. Quality Labeling Standard and JAS Standard for "Carbonated Drinks" are set in JAS System. Summaries are compared in Tables 12 and 13.

Food Additives:

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 (Table 14).

(3) Prepared Frozen Foods

Commodity Food Standards and Methods of Analysis:

JAS Quality Labeling Standard defines that Prepared Frozen Foods are Frozen Fried Foods, Frozen Shaomai, Frozen Gyoza, Frozen Harumaki (spring rolls), Frozen Hamburger Steaks, Frozen Meatballs, Frozen Fish Hamburgers, Frozen Fishballs, Frozen Steamed Rice and Frozen Noodles. Prepared Frozen Foods are defined as food filled into containers or food packaged. Quality labeling standard are defined in details including name of materials, their contents, and percentage of coating and wrapping material. Prepared Frozen Foods was selected for a case study because large amounts of their materials and processed products are being imported to Japan and they are foods in high demand. In Food Sanitation Act, Prepared Frozen Foods are included in wide-ranging Frozen Foods defined in specified food items and should follow microbiological criteria and storage standards.

Twenty-three commodity standards for quick frozen foods (for example, vegetables, fruits, meat, fish and shellfish) are defined in Codex, while only one commodity standard for corresponding prepared frozen food in Japan (Quick frozen Fish Sticks (Fish fingers)), Fish portions and fish Fillets-Breaded in Batter (Stan 166-1989). Table 15 provides table for their comparison.

Food Additives:

"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 (Table 16).

(4) Cow's Milk

Commodity Food Standards and Methods of Analysis:

Commodity Food Standards and Methods of Analysis for Cow's Milk are defined by the

Ministerial Ordinance on Compositional Standards for Milk and Milk Products (Table 5), and are described in Table 17.

Food Additives:

Use of Food Additives in Cow's Milk is prohibited by Food Sanitation Act. There is no JAS Standards for Cow's Milk (Table 18).

Table 6: Summary/Definition of Food Additives (General)

	Summary/Definition	Reference
Related Legislation	Food Sanitation Act, 1947	http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=02
Summary (General)/Definition		
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. “Processing aids” are not found in the functional classification of food additives. “Manufacturing agents” exist in the functional classifications, and are assumed to be the closest to “Processing aids” in Codex.	Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948
Carry-over	“Carry-over” is defined, but only for labeling 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 7: Summary/Definition of Food Additives (Specific)

	Summary/Definition	Reference
Related legislation	Food Sanitation Act, 1947	http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=02
Summary (Specific)/Additional Laws		
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 labeling 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	There is no negative list of food additives under FSA.	
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.	http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa
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 labeling 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.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa

Table 8: Specifications and Methods of Analysis for General Foods

Related Legislation	Item	Specification	Method of Analysis	Reference
Food Sanitation Act	Antibiotics or Chemically synthesized antibacterial substances	Shall not be contained in foods		Food Sanitation Test Guideline "Animal Medicine·Feed Additive 2003"
	Foods shall not contain substances used as ingredients of agricultural chemicals and other chemical substances	Not detectable in foods	Each Test Methodology of 2,4,5-T, Azocyclotin and cyhexatin, Amitrol, Captafol, Carbadox, Coumaphos, Chloramphenicol, Chlorpromazine, Diethylstilbestrol, Dimetridazole, Daminozide, Nitrofurazone, Nitrofurantoin, Furazolidone, Furaltadone, Propham, Malachite Green, Metronidazole and Ronidazole.	Specifications and Standards for Foods, Food Additives, etc.
	Pesticide residues in foods	The residual standard is individually provided.	Systematic or individual analytical methods are generally as follows:	Test methodology of the substances being the elements of agricultural chemicals, feed additives or verterinary products remaining in foods. (Notice from the Ministry of Health, Labour and Welfare)
	Compositional standards which are not specified in 0-1 through 0-3 shall not contain substances used as agiricultural chemicals nor other chemical substances in excess of the amount.	Not exceed 0.01mg/L	(1)Sample preparation→(2)Extraction with solvent→(3)Purification by chromatography→(4)Preparation of test solution→(5)Instrumental analysis: GC or GC-MS for volatile substances, LC or LC-MS for non-volatile substances etc.	

Table 9: Case Study (1) Instant Noodles: Specifications & Standards (comparisons with Codex)

	Codex Commodity Standard	Food Sanitation Act	JAS Law	
		Standard for Foodstuffs	Quality Labeling Standard	JAS Standard
Name of the Standard	Instant Noodles CODEX STAN 249-2006	Instant Noodles	Instant Noodles	Instant Noodles
Scope	ready for consumption after dehydration process	<ul style="list-style-type: none"> ● Fried noodles 	<ul style="list-style-type: none"> ● include raw type 	
Description	Fried noodles, Non-fried noodles			
Essential Composition and Quality Factor	3.1 Composition 3.1.1 Essential Ingredients 3.1.2 Optional Ingredients 3.2 Quality Criteria 3.2.1 Organoleptic 3.2.2 Foreign Matter 3.2.3 Analytical Requirement for Noodle Block (a) Moisture Content maximum : fried 10% : non-fried 14% (b) Acid value maximum 2mg KOH/g oil	<ul style="list-style-type: none"> ● Acid value not more than 3 mg KOH/g oil ● Peroxide value not more than 30 meq/kg 	<ul style="list-style-type: none"> ● Wheat flower and/or buckwheat flower as the main ingredients ● Add salt or lye water 	<ul style="list-style-type: none"> ● Moisture not more than 14.5% (non-fried) ● Acid value not more than 1.5 mg KOH/g oil ● pH 3.8-4.8 (non-fried)
Food Additives	MRLs of GSFA			<ul style="list-style-type: none"> ● Positive List (limited use)
Contaminant	MRLs of GSCTFF			
Hygiene	6. Containers or Packing Condition 7.1 General Principle of Food Hygiene and other relevant Codex Text 7.2 Principle for the establishment and application of Microbiological Criteria for Foods	<ul style="list-style-type: none"> ● Storage Standard 		<ul style="list-style-type: none"> ● Container and Packing Condition
Weights and Measures				

Labeling	8.1 Name of the Food 8.2 Labeling for “HALAL”		● Specific Labeling Methods	● JAS Mark
Methods of Analysis and Sampling	9.1 Sampling 9.2 Determination of Moisture 9.3 Extraction of oil from Instant Noodle 9.4 Determination of Acid Value	● Acid value ● Peroxide value		● Moisture ● Acid value ● pH

* This Table does not contain details of standards regulated for all foodstuffs such as;

- Quality Labeling Standard for Processed Foods (JAS Law)
- General Compositional Standard for Food; General Food Production Processing and Preparation Standards; General Food Storage Standards (Food Sanitation Act)

Table 10: Case Study (1) Instand Noodles: Specifications and Methods of Analysis

Related Legislation	Item	Specification	Method of analysis	Reference
Food Sanitation Act	Acid value	Not more than 3 mg KOH/g oil	Acid value measurement method by titration	Specifications and Standards for Foods, Food Additives, etc.
	Peroxide value	Not more than 30 meq/kg	Peroxide value measurement method by titration	
JAS Standard	Moisture	Not more than 14.5% (non-fried)		
	Acid value	Not more than 1.5 mg KOH/g oil		
	pH	3.8-4.8 (non-fried)		

Table 11: Case Study (1) Instant Noodles: Food Additives

	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 Labeling of Agriculture and Forestry Products.

Table 12: Case Study (2) Carbonated Soft Drinks: Specifications & Standards

	Food Sanitation Act	JAS Law	
	Standard for Foodstuffs	Quality Labeling Standard	JAS Standard
Name of the Standard	Soft Drink Beverages	Carbonated Soft Drinks	Carbonated Soft Drinks
Scope	Non-alcoholic (less than 1% alcohol) beverages, excluding lactic acid bacterial drinks, milk and milk drinks	Water-based flavoured drinks with added carbon dioxide, sweetener, acidulant and others	Water-based flavoured drinks with added carbon dioxide, sweetener, acidulant and others
Description			
Essential Composition and Quality Factor	<ul style="list-style-type: none"> ● Must not be turbid (with some exception) ● Must not contain any sediment or any solid foreign matter (with some exception) ● Must not contain detectable levels of arsenic, lead or cadmium. The tin content must not exceed 150.0 ppm ● Tests for coliform bacilli must be negative ● Mineral water with a carbon dioxide pressure inside of the container of not more than 98 kPa at 20 degree in Celsius , and that has not been sterilized or disinfected, must test negative for enterococci or green pus bacilli ● For beverages made for solely apple juices and/or juiced fruit, the patulin content must not exceed 0.050 ppm 		<ul style="list-style-type: none"> ● Must have satisfactory tone of colour ● Must have refreshing flavour without off-taste and off-odour ● Must not be turbid (with some exception) ● Must carbon dioxide be dissolved well and have fine bubbles sustainably ● No foreign matters
Contaminant Hygiene			
Food Additives			<ul style="list-style-type: none"> ● Preservative: only sodium benzoate and p-hydroxybenzoic acid allowed to use ● Antioxidant: only L-ascorbic acid and sodium L-ascorbate allowed to use ● Emulsifier: only sucrose fatty acid ester and glycerin fatty acid ester allowed to use
Weights and Measures			Must meet designated volume appeared on the label
Labeling	<ul style="list-style-type: none"> ➢ Production Standards ➢ Packaging Standards ➢ Storage Standards 	Specific labeling methods	JAS mark
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ● Tests for arsenic, lead, cadmium, tin, patulin, coliform bacilli, enterococci or green pus bacilli ● Tests for water used as raw material ● Standards and testing methods for implements, containers and packaging 		<ul style="list-style-type: none"> ● Gas volume

Table 13: Case Study (2) Carbonated Soft Drinks: Specifications and Methods of Analysis

Sub-category	Related Legislation	Item	Specification	Method of analysis	Reference
Soft drink beverages	Food Sanitation Act	Turbidity	Negative		Specifications and Standards for Foods, Food Additives, etc.
		Foreign matter	Negative		
		Arsenic	Not detectable	Wet degradation method or Dry incineration method →Gutzeit method or Silver diethyldithiocarbamate method	
		Lead	Not detectable	Wet degradation method or Dry incineration method →Atomic absorption spectrophotometry or Polarographic analysis	
		Cadmium	Not detectable		
		Tin	Not exceed 150.00 ppm	Wet degradation method or Dry incineration method →Salicylidenamino-2-thiophenol method or Polarographic analysis	
		Coliform bacilli	Negative	Presumptive test (BTB lactose broth) →Confirmation test (Endo or EMB culture medium, or BGLB fermentation tube) →Conclusive test (Lactose broth fermentation tube and agar slant)	
Mineral water	Food Sanitation Act	Enterococci	Negative	Presumptive test (AC culture medium) →Confirmation test (new AC culture medium) →Conclusive test (Glucose agar medium)	
		Green pus bacilli	Negative	Presumptive test (Asparagine broth)→Confirmation test (Cetrimide agar medium)	

Table 14: Case Study (2) Carbonated Soft Drinks: Food Additives

	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			
Use Limitation and/or Maximum Level, if any	(14.1.4.1) Carbonated water-based flavoured drinks (14.2.2) 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”.		

Table 15: Case Study (3) Prepared Frozen Foods: Specifications and Methods of Analysis

Related Legislation	Sub-category	Item	Specification	Method of analysis	Reference
Food Sanitation Act	Without heating	Bacteria	<100,000/g	Standard agar medium 35±1.0°C, 24±2h	Specifications and Standards for Foods, Food Additives, etc.
		Coliform bacilli	Negative	Presumptive test (desoxycholate agar medium) →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →agar slant : microscopic test →Gram-negative nonspore-forming bacilli : coliform bacilli positive	
	After heating (heated before freezing)	Bacteria	<100,000/g	Standard agar medium 35±1.0°C 24±2h	
		Coliform bacilli	Negative	Presumptive test (desoxycholate agar medium) →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →agar slant : microscopic test →Gram-negative nonspore-forming bacilli : coliform bacilli positive	
	After heating (other than 2 above)	Bacteria	<3,000,000/g	Standard agar medium 35±1.0°C, 24±2h	
		Coliform bacilli	Negative	EC fermentation tube (EMB medium) →Gas generation : Presumptive test positive →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →The agar slant : microscopic test →Gram-negative nonspore-forming bacilli : <i>E.coli</i> positive	

Table 16: Case Study (3) Prepared Frozen Foods: Food Additives

	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. No positive/negative list on food additives in it. The restrictions in use of food additives are applied to the foods to be frozen, not to the frozen foods.	Positive List (limitation in use)
Positive and/or Negative List			
Use Limitation and/or Maximum Level, if any			

Table 17: Case Study (4) Cow's Milk: Specifications and Methods of Analysis

Related Legislation	Item	Specification	Method of analysis	Reference
Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards	Nonfat milk solids (%)	8.0%<	Calculated by subtraction of the amount of milk fat % from the amount of the material % dried until a constant weight % at 98-100°C	Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards
	Milk fat (%)	3.0%<	The frequency of fat layer is expressed as the amount of fat % by operating of the Gerber lactobutyrometer etc.	
	Specific gravity (at 15°C)	1.028-1.034 (Those using milk of cows other than Jersey cows only as raw materials)	The measurement of specific gravity by the floatage type lactometers in the range of 1.015 to 1.040.	
		1.028-1.036 (Those using milk of Jersey cows only as raw materials)		
Acidity (as lactic acid %)	< 0.18% (Those using milk of cows other than Jersey cows only as raw materials)	Titration with sodium hydroxide solution		

		< 0.20% (Those using milk of Jersey cows only as raw materials)		
	Bacteria (count /mL)	< 50,000/mL	Standard agar medium (32-35°C 48±3h)	
	Coliform bacilli	Negative	BGLB fermentation tube : gas formation →E.MB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →The agar slant : microscopic test →Gram-negative nonspore-forming bacilli : Coliform bacilli positive	

Table 18: Case Study (4) Cow's Milk: Food Additives

	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				

4.3 Republic of Korea

1. LEGAL FRAMEWORK RELATED TO FOOD STANDARDS

1.1 Administrative Authorities

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

Table 1: Food Safety Control System in Korea²³

Section	Production (Agriculture, Farming, Aquafarming)	Imported	Domestic
Agricultural Products	MFAFF	KFDA	
Marine Products	MFAFF	KFDA	
Livestock Products	MFAFF	MFAFF 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)		

MFAFF : Ministry for Food, Agriculture, Forestry and Fisheries

KFDA : Korea Food & Drug Administration

MEST : Ministry of Education, Science and Technology

KFDA²⁴ 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)^{25,26} is responsible for policymaking and legislation related to food safety. KFTC (Korea Fair Trade Commission) and KCA (Korea Consumer Agency) are responsible for proper labelling and protecting consumers.

Unlike in Japan, there is no independent body for risk assessment in Korea. As presented

²³ Cherl-Ho Lee; 2009 ILSI BeSeTo Meeting on Food Safety: Report of the First Meeting in Seoul, Korea, 16p, 2009.

²⁴ KFDA; Vision <http://www.kfda.go.kr/eng/index.do> Accessed: 2013/03/21)

²⁵ MIHWAF; Food Safety Management http://english.mw.go.kr/front_eng/jc/sjc0101mn.jsp?PAR_MENU_ID=1003&MENU_ID=10030101 (Accessed: 2013/03/21)

²⁶ Satoshi Fujita; Chapter 8, National Report, Comprehensive Survey of Food Related Systems in Major Foreign Countries for the Purpose of Safety and Security of Consumers: Commercial Law Center, Inc, 2009

in Table 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.

On March 25, 2013, KFDA (Korea Food & Drug Administration) was upgraded to MDFS (Ministry of Drug and Food Safety).

<http://www.mfds.go.kr/index.do> (Korean)

<http://www.mfds.go.kr/eng/index.do?nMenuCode=4> (English)

However, as of March 25, 2013, information is still accessible through the former Web site address. The purpose of this reorganization is that MDFS functions as the unified control tower for the safety management of foods and pharmaceuticals; for instance, the safety of agricultural, marine, and livestock products and their processed products which has been under the control of MIFAFF, are now under the control of MDFS.

1.2 Related Laws and Regulations

Laws and regulations related to food include the follows; Food Sanitation Act, Food Safety Basic 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; and 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 KFDA²⁷, but not so frequently updated.

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

²⁷ KFDA ; Relevant Rule <http://www.kfda.go.kr/eng/index.do?searchKeyCode=131&nMenuCode=16>
(Accessed: 2013/03/21)



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



2. SUMMARY OF FOOD STANDARDS

Figure 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 Code²⁸ laying down specifications and their standards for use (including analytical methods) is applied to all food additives used in foods.

²⁸ KFDA: Korea Food Additive Code (http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp) (Accessed: 2013/3/21)

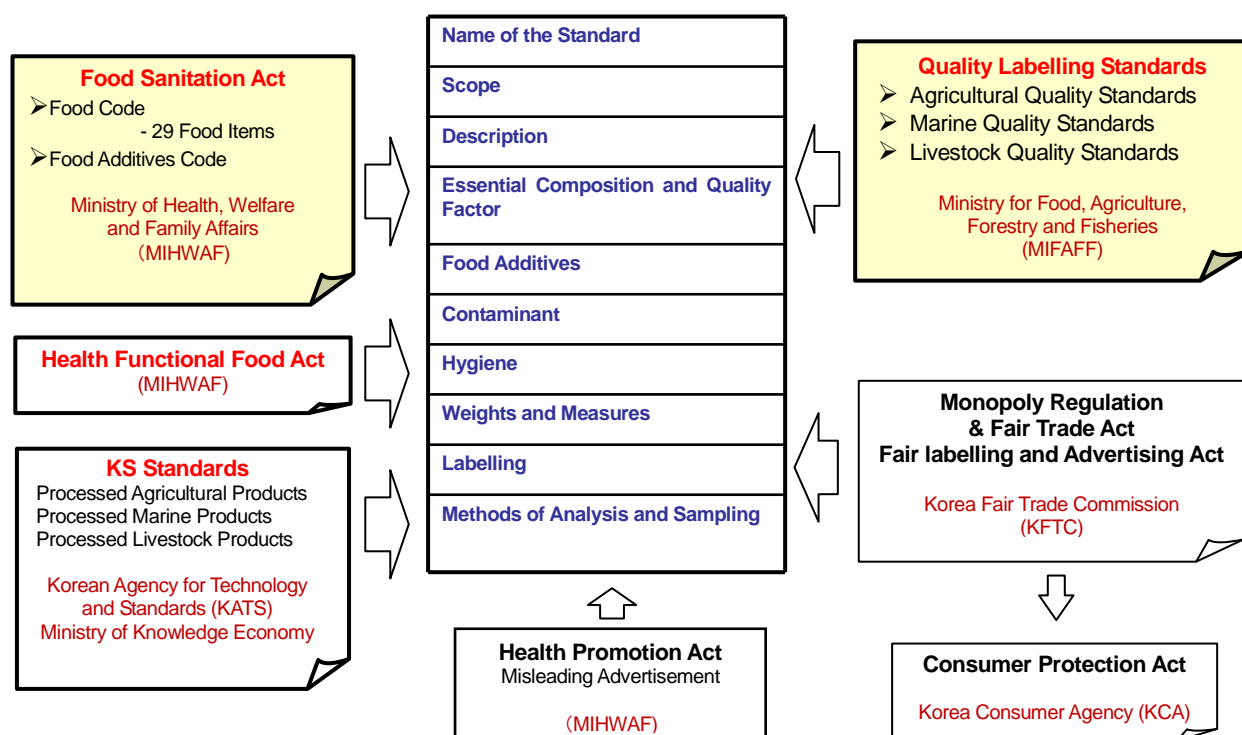


Figure 1: Summary of Food Standards in Korea

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.

- Article 1 General Provision
- Article 2 General Standards 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

Commodity standards defined in Article 3 (long shelf life foods) of Food Code are presented in Table 2, and commodity standards defined in Article 5 in Table 3.

Table 2: Commodity Standards Defined in Article 3 (long shelf life foods)

1	Canned & Bottled Food
2	Retort Food
3	Frozen food

Table 3: Commodity Standards Defined in Article 5

1	Confectionaries	16	Teas
2	Breads or Rice Cakes	17	Coffees
3	Cocoa Products or Chocolates	18	Beverages
4	Jams	19	Foods for Special Dietary Uses
5	Sugars	20	Soy Sauces or Pastes
6	Glucose	21	Seasonings
7	Fructose	22	Dressings
8	Glutinous Rice Jellies (Yeat)	23	Kimchies
9	Sugar Syrups	24	Salted and Fermented Seafoods (Jeotkal)
10	Oligosaccharides	25	Pickles
11	Processed Meat and Egg Products	26	Hard-boiled Foods
12	Fish Products	27	Alcoholic Beverages
13	Bean-Curds or Starch Jellies (Mook)	28	Dried Fish/Shellfish Fillets
14	Edible Oils and Fats	29	Other Foods
15	Noodles		

2.2 Korean Industrial Standards (KS Standards) Defined by KATS²⁹

KS standard is the set of national standards established under Industrial Standardization Act. The use of KS mark (Figure 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 28,000 and 596 standards of them are categorized as related to food including "product standard" and "procedure standard" such as analytical methods for nutrients³⁰. (Standards for Tobacco or essential oil, etc. are also included in this category) food "product standards" are listed in Tables 4 to 7.



Figure2: KS Mark

²⁹ KATS (<http://kats.go.kr/english/index.asp>) (Accessed: 2013/3/21)

³⁰ KATS: Search for Korean Industrial Standards
http://www.kats.go.kr/english/com/search_ks.asp?OlapCode=ATSU28Search (Accessed: 2013/3/21)

Table 4: KS Standards for Processed Agricultural Products

1	Margarine	34	Instant coffee	67	Seasoning mixture sauce
2	Sugar	35	Roasted coffee	68	Jujube beverage
3	Biscuits	36	Tomato juice	69	Ginseng extracts
4	Milk caramels	37	Ginseng tea	70	Dried ginseng
5	Glucose	38	Soy sauce	71	Olive oil
6	Starch	39	Doenjang (Soybean paste)	72	Perilla oil
7	Chocolates	40	Gochujang (Red pepper paste)	73	Safflower seed oil
8	Wheat flours	41	Corn, canned	74	Sunflower seed oil
9	Fat spreads	42	Mushroom, canned	75	Peanut oil
10	High fructose corn syrup	43	Peaches, canned	76	Red pepper seed oil
11	Oligosaccharide	44	Bamboo shoots, canned	77	Concentrated fruit and/or vegetable juice
12	Fruit and/or vegetable puree or paste	45	Green peas, canned	78	Powdered fruit and/or vegetable juice
13	Fruit and/or vegetable processed foods	46	Chestnut, canned	79	Fruit and/or vegetable juice
14	Spice products	47	Pears, canned	80	Fruit and/or vegetable beverage
15	Soybean curd products	48	Grapes, canned	81	Fruit flesh beverages
16	Muk (Starch gel products)	49	Jams	82	Curry powder
17	Saengshik (Uncooked foods)	50	Asparagus, canned	83	Dry curry mix products
18	Grape seed oils	51	Mandarin orange, canned	84	Instant curry mix products
19	Processed fats and oils	52	Tomato ketchup	85	Fresh peeled chestnuts
20	Blended edible oils	53	Red pepper ground (powder)	86	Pickled cucumber
21	Other edible oils	54	Composite seasoning	87	Spirits
22	Flavored oils	55	Black tea	88	Vinegar
23	Dressing	56	Green Tea	89	Cooked rice
24	Soybean oil	57	Corn Oil	90	Mejoo (fermented soybean lump)
25	Canola oil	58	Canned fruits	91	Soybean milk products
26	Rice bran oil	59	Danmooji (pickled radish)	92	Mixed soybean pastes
27	Shortening	60	Palm Oil	93	Dried noodles
28	Cottonseed oil	61	Palm Olein Oil	94	Fresh noodles
29	Sesame oil	62	Palm Stearin Oil	95	Precooked noodles
30	Chunjang	63	Palm Kernel Oil	96	Fried noodles
31	Mayonnaise	64	Kimchi	97	Seasoned and boiled agricultural products - Jorim
32	Pan bread	65	Coconut oil	98	Frozen croquette
33	Starch syrup	66	Dried Soup	99	Corn products for popcorn
				100	Bakery mixes

Table 5: KS Standards for Processed Livestock Products

1	Natural cheese
2	Infant formula
3	Follow-up formula
4	Milks
5	Reconstituted milk
6	Flavored milk
7	Milk beverage
8	Condensed milk
9	Goat's milk
10	Dried milk products
11	Butter
12	Ice cream
13	Cheddar cheese
14	Fermented milk
15	Liquid egg
16	Creams
17	Processed cheese
18	Mozzarella cheese
19	Hams
20	Processed hams
21	Sausage
22	Seasoned beef, canned
23	Bacon
24	Seasoned pork, canned
25	Beef, packaged
26	Pork, packaged
27	Meat patty
28	Dried sliced meat
29	Whole and cut-up chicken
30	Chicken stew with ginseng
31	Whole duck and boneless duck meat
32	Seasoned rib meat
33	Gomtang (beef-bone soup)
34	Seasoned and livestock products - Jorim
35	Frozen pork cutlet

Table 6: KS Standards for Processed Marine Products

1	Frozen raw breaded shrimp
2	Oyster, canned
3	Squid, canned
4	Mackerel, canned
5	Mackerel pike, canned
6	Boiled mackerel pike, canned
7	Boiled crab meat, canned
8	Fish sausage
9	Canned tuna in oil
10	Boiled sardine, canned
11	Fish paste
12	Canned fishes
13	Seasoned and roasted laver
14	Seasoned squid
15	Seasoned jeotgal (Fermented and seasoned fishery products)
16	Fermented anchovy sauce
17	Dried sea mustard
18	Bai-Top shell, canned
19	Dried laver
20	Dried anchovy
21	Sea tangle products
22	Seasoned and braised anchovy, canned
23	Salted mackerel
24	Dried seafood tea-bag
25	Seafood patty
26	Frozen fish cutlet
27	Edible sodium alginate
28	Chitosan products
29	Agar-agar
30	Canned tuna, seasoned
31	Slices of dried filefish
32	Flying fish roe, seasoned
33	Gwamegi
34	Dried Alaska pollack products
35	Frozen shrimps

Table 7: KS standards for Other Foods

1	Soluble saccharin
2	Carbonated soft drinks
3	Blended beverages
4	Extracted beverages
5	Beverage base
6	Chewing gum
7	Edible salts
8	Mono sodium glutamate
9	Baking soda
10	Edible sodium carbonate

3. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

3.1 Overview

In Korea, food additive management is controlled by 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),
- Korea Food Code (KFC), and
- Korea Food Labelling Standard (KFLS)

3.2 Food Additive Definitions & Functional Classes

1) Food additives

Food additive 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 but not remain in final foods or that are used for nutrition purpose.

2) Food Flavours

Flavours (“착향료” in Korean) is recognized as included in food additives. (Herein after, it is described as “food flavouring” or “flavouring” for convenience.) 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 chemical substances used for flavourings are classified in this group, but there are some substances that also appear in KFAC listed by their names, and 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, that can be used for natural flavourings in its definition:

“These materials are obtained from the following origins listed in Annex 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)²⁶ 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.”

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.”

5) Functional Classes of Food Additives

Food additives are not classified with their functions in KFAC, but KFDA consumer site²⁷ 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 nutrient s
- 3) to manufacture foods: coagulants, leaving agents, thickeners /stabilizers
- 4) to improve palatability: colorants, flavourings, flavour enhancers, sweeteners.

In KFLS the classifications are also appeared at the declaration rule of food additives (see 3.7 Labelling of food additives).

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 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

²⁶ <http://www.foodnara.go.kr>: Korean only (Accessed: 2013/3/21)

²⁷ <http://www.foodnara.go.kr>: Korean only (Accessed: 2013/3/21)

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 in the section of “food flavours”). When counting the number of items listed in KFAC, the number of additives are 599 total, as of Mar. 2012 (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 use levels of food additives are also listed in KFAC if regulated. For Additives which are distributed with temporal standard, usage and limitation are included in each temporal standard.

3.4 Prohibited Substances as Food Additives

In principle, the positive list system is taken as the management system of food additives under the KFSA, however, for some individual food items, negative list of food additives are described in their Commodity Standards in KFC or KS.

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 standard.

3.6 Application, Assessment and Designation of New 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. Article 7 (1) 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 such as materials used in sterilizing apparatus). There is a guideline on KFDA food additive WEB site²⁸ (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 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 the Article 7 (1), the provider may submit a dossier according to another notification to establish a “temporal standards and specifications”.

²⁸ <http://www.kfda.go.kr/fa/index.do?nMenuCode=7> (Korean only) (Accessed: 2013/3/21)

3.7 Labelling of Food Additives Used in Foods

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.

3.8 Korean Food Additive Code (KFAC)

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.

3.9 Summary of Food Additives

The definitions regarding food additives such as flavours, processing aids, and carry over are summarized in Table 8, and other definitions such as designated/existing food additives and prohibited substances are summarized in Table 9.

4. STANDARDS & SPECIFICATIONS AND MEHODS OF ANALYSIS FOR GENERAL FOODS

Standards & Specifications and Methods of Analysis applied for Foods generally are shown in Table 10. Those for specific food categories taken up in the Case Studies are described in those food categories, respectively.

5. CASE STUDIES

In order to compare the contents of food standards set in Food Code and those in KS Standard, (1) Instant Noodles, (2) Carbonated Soft Drinks, (3) Prepared Frozen Foods, and (4) Cow's Milk were chosen as examples.

For all of these 4 categories there exist commodity standards both in KFC (or Specification of Livestock Products) and KS standards, however, there are not significant differences among them regarding item of analysis and food additives. Because KS standards do not have more strict limitation in use of food additives that can be found in some JAS standards, there seems to be a realistic decision at the establishment of these standards that safety is well confirmed by Food Sanitation Act. On the other hand the analytical methods regulated in KS standards are stricter than those in FC, so it is assumed that the superiority in quality confirmed by KS standards is based on scientific evidence, i.e., standing on GMP point of view supported by strict analysis. It is important to clarify the character of KS standards by investigation of KS "procedure" standards which are set for analytical methods and comparison with Japanese method and

International standard method, as well as expanding such investigation to other food categories.

(1) Instant Noodles

Food Specifications & Standards and Methods of Analysis:

A comparison of specifications & standards between KFC and KS is summarized in Table 11, and a comparison of specifications and methods of analysis between KFC and KS is shown in Table 12.

Food Additives:

Specifications including use limitations of food additives based on KFC and KS are shown in Table 13.

(2) Carbonated Soft Drinks

Food Specifications & Standards and Methods of Analysis:

A comparison of specifications & standards between KFC and KS is summarized in Table 14, and standards and methods of analysis in KFC are shown in Table 15.

Food Additives:

Specifications including use limitations of food additives based on KFC and KS are shown in Table 16.

(3) Prepared Frozen Foods

Food Specifications & Standards and Methods of Analysis:

A comparison of specifications & standards between KFC and KS is summarized in Table 17, and a comparison of standards and methods of analysis between KFC and KS is shown in Table 18.

Food Additives:

Specifications including use limitations of food additives based on KFC and KS are shown in Table 19.

(4) Cow's Milk

Food Specifications & Standards and Methods of Analysis:

Specifications & standards based on Specification of Livestock Products are summarized in Table 20.

Food Additives:

Use limitations of food additives based on KFC and KS are shown in Table 21.

Table 8: Summary/Definition of Food Additives (General)

	Description/Definition	Reference
Related legislation	Korea Food Sanitation Act (KFSa), 2011 Korea Food Additive Code (KFAC), 2012 Korea Food Code (KFC), 2012	KFSa(http://www.kfda.go.kr/files/upload/eng/FOOD_SANITATION_ACT.pdf ; English) KFAC(http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp ; English) Korea Food Code (http://fse.foodnara.go.kr/residue/RS/jsp/menu_02_01_01.jsp ; Korean)
Summary (General)/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 Food Nara Glossary Site (Korean) http://www.foodnara.go.kr/foodnara/dic-list.do?seq=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	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.”	Glossary of Food Additives (Korean) http://www.kfda.go.kr/fa/index.do?nMenuCode=9&mode=view&boardSeq=8271

	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."	
Carry-over	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."	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 :Korean)

Table 9: Summary/Definition of Food Additives (Specific)

	Summary/Definition	Reference
Related legislation	Korea Food Sanitation Act (KFSA), 2010 Korea Food Code (KFC), 2010 Korea Food Additives Code (KFAC), 2010, 2011	
Summary (Specific)/Additional Lists		
1	List of Designated Food Additives As of March 2013(Notification #2012-34), 595 food additives in total are approved with the permission to use in respectively designated food groups. Standard and specification of the synthetic additives (404 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 16 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.	Article 3_ A, 3_ B, 3_ C of Korea Food Additive Code Appendix 2 (Excel file) http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English e-book) http://www.kfda.go.kr/fa/index.do?nMenuCode=12&page_gubun=1&gongjeoncategory=1 (Korean)
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=foodadditivename&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		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 10: Specifications & Standards and Methods of Analysis for General Foods

Related Legislation	Item	Specification	Methods of analysis	Reference
Food Sanitation Act	Foreign Material	<p>Food shall not contain unhygienic material to be mixed with foreign material.</p> <p>Iron filings as metallic foreign matter : < not more than 10.0 mg/kg</p> <p>Any metallic particles : <2.0 mm in length</p>	<p>Foreign materials: strainer method (fine powder), Filter method(Liquid), Wildeman Flask method (insect, animal fur/light materials), Precipitation method (mouse feces, etc. heavy matters)</p> <p>Metallic foreign matter : Prepare sample (500g powder, 1 kg liquid/paste in 5~6 L distilled water) →Use stick magnet (10,000 gauss) for 10 min to collect →Dry and measure weight →Screen using sieve (1.4x1.4 mm) and measure the size of metallic materials.</p>	Korea Food Code (Article 10.9.2.1)

Food poisoning bacteria	Not detectable in foods	<p>Systematic or individual methods of analysis are generally as follows: (1) Aseptic Sample preparation (homogenization and serial dilution if necessary) → (2) enrichment with respective media → (3) Plate on respective selective media and pick suspected colonies → (4) confirm by further identification test</p>	<p>Korea Food Code (Article 10-3) : Salmonella (10.3.11), <i>Staphylococcus aureus</i> (10.3.12), <i>Vibrio parahemolyticus</i> (10.3.13), <i>Clostridium perfringens</i> (10.3.14), <i>Listeria monocytogenes</i> (10.3.15), <i>E. coli</i> O157:H7 (10.3.16), <i>Yersinia enterocolitica</i> (10.3.17), <i>B. cereus</i> (10.3.18), <i>Camphylobacter jejuni</i> (10.3.19), <i>Clostridium botulinum</i> (10.3.20)</p>
Pesticide Maximum Residue Limits in foods	The residual standard is individually provided.	<p>Systematic or individual methods of analysis are generally as follows: (1) Sample preparation → (2) Extraction with solvent → (3) Purification by chromatography → (4) Preparation of test solution → (5) Instrumental analysis: GC or GC-MS for volatile substances, LC or LC-MS for non-volatile substances etc.</p>	<p>Korea Food Code (Article 10.4)</p>
Any veterinary drugs (including their metabolites) of which manufacture or import is not authorized due to safety or efficacy problems shall not be detected.	Not detectable in foods	<p>Nitrofurans and its derivatives (Furazolidone, Furaladone, Nitrofurazone, Nitrofurantoin, Nitrovin, etc.), Chloramphenicol, Malachite green and its derivatives, Diethylstilbestrol, Dimetridazole, Clenbuterol, Vancomycin, Chlorpromazine, Thiouracil, Colchicine, Pyrimethamine, Medroxyprogesterone acetate</p> <p>Simple, Preliminary Test : Charm II receptor assay, Fluorescence Immunoassay, or Enzyme Immuno Assay</p> <p>Confirmation Test : Liquid/Gas Chromatography-Mass Spectrometer</p>	<p>Korea Food Code (Article 10.5)</p>

Table 11: Case Study (1) Instant Noodles: Specifications & Standards

	Food Sanitation Act	KS standard
Name of the Standard	Noodles	Instant Noodles*
Scope	Noodle; Naengmyeon (cold noodle); Dangmyeon (chinese noodle, vermicelli); Oil-fried noodle; Pasta, and others	Fresh (uncooked) noodles (KS H 2506); Pre-cooked noodles (KS H 2507); Fried noodles (KS H 2508); Dried noodles (KS H 2505)
Description	Noodles refer to products made of cereals or starches by heat process, drying, etc. Each items have own their detailed descriptions.	Each items have own their descriptions.
Essential Composition and Quality Factor	Manufacturing and Processing Standards 1) For alcohol-treated products (not less than 1% of alcohol used), alcohol treatment should be performed in a manner that any residual alcohol does not adversely affect the quality. 2) Acid value and peroxide value of oil used for frying shall be not more than 2.5 and 50, respectively.	Dried noodle Max. Moisture content 11% (Dangmyeon 15%) Fried noodle Max. Moisture content 9% Acid value 1.5 Peroxide value 25
Food Additives	1) Tar colour: Should not be detected 2) Preservatives: Should not be detected Anything not specified follows "Korea Food Additives Code"	Tar colour should not be detected
Hygiene	* Containers/Packing condition * Storage Standard for cold noodle * Microbiological Criteria: 1) The number of Bacteria: Not more than 1,000,000 (applied to alcohol-treated products only) Not more than 100,000 (applied to pasteurized products only) 2) <i>E. coli</i> : Negative (applied to alcohol-treated products only) 3) Coliform group: Negative (applied to pasteurized products only)	* Containers/Packing condition * Microbiological Criteria: <i>E. coli</i> : Negative Coliform group: Negative The number of Bacteria: 1,000 (only for precooked noodle)
Labelling	Specific Labelling Methods required (Nutrition Facts, Pasteurized/ Non-pasteurized or Fried/ Alcohol-treated For fresh noodles)	Labelling Standards follow "General Standard of Labelling for Processed Foods" (KS H 1101) Labelling should meet the requirement of Food Sanitation Act.
Methods of Analysis and Sampling	Determination of Acid/Peroxide Value, Tar, Preservatives, Bacteria, <i>E.coli</i> , Coliform	Sensory test (KS H ISO 6658) Determination of Water Content (KS H 1201) Determination of Coliform group (KS H ISO 4832) Determination of Micro-organism (KS H ISO 7251, KSH ISO 4833/4832/4831) Determination of Water and Acid/Peroxide value Anything not specified is handled in accordance with the Food Sanitation Act.

* Standards for instant noodles under KS Standards were deleted as of December 28, 2009 and 4 Standards for fresh noodles, pre-cooked noodles, fried noodles and dried noodles were newly adopted.

* This table does not include basic details required for all foods.

Table 12: Case Study (1) Instant Noodles: Specifications and Methods of Analysis

Related Legislation	Item	Specification	Methods of analysis	Reference
Food Sanitation Act	Bacteria	Not more than 1,000,000 (Limited to alcohol-treated products)	Plate count agar (35±1°C 24-48h)	Korea Food Code (Article 10.3.5.1)
		Not more than 100,000 (Limited to pasteurized products)	Plate count agar (35±1°C 24-48h)	
	E. coli	Negative (Limited to alcohol-treated products)	EC fermentation tube (44.5°C 24±2h) →Gas generation: Presumptive test positive →EMB medium (35±1°C 24±2h) →Lactose broth fermentation tube and nutrient agar. The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 24±2h): microscopic test →Gram-negative nonspore-forming bacilli: <i>E.coli</i> positive	Korea Food Code (Article 10.3.8)
	Coliform	Negative (Limited to pasteurized products)	LB fermentation tube (35±1°C 48±3h) →Gas generation: Presumptive test positive →BGLB fermentation tube (35±1°C 48±3h) →Gas generation→EMB medium (35±1°C 24±2h) →Typical colony: Confirmative test positive →Lactose broth fermentation tube and nutrient agar . The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 48±3h): microscopic test →Gram-negative nonspore-forming bacilli: Coliform positive	Korea Food Code (Article 10.3.7)
	Acid value of oil	Not more than 2.5	Acid value measurement method by titration	Korean Food Code (Article 10, 1.1.5.3.1)
	Peroxide value of oil	Not more than 50	Peroxide value measurement method by titration	Korean Food Code (Article 10, 1.1.5.3.5)
KS Standard	E. coli	Negative	EC fermentation tube (44.5°C 24±2h) →Gas generation: Presumptive test positive →EMB medium (35±1°C 24±2h) →Lactose broth fermentation tube and nutrient agar. The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 24±2h): microscopic test →Gram-negative nonspore-forming bacilli: <i>E.coli</i> positive	KS Determination of Micro-organism (KS H ISO 7251, KS H ISO 4831~4833)

	Coliform group	Negative	LB fermentation tube (35±1°C 48±3h) →Gas generation : Presumptive test positive →BGLB fermentation tube (35±1°C 48±3h) →Gas generation →EMB medium (35±1°C 24±2h) →Typical colony: Confirmative test positive →Lactose broth fermentation tube and nutrient agar . The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 48±3h): microscopic test →Gram-negative nonspore-forming bacilli: Coliform positive	KS Determination of Micro-organism (KS H ISO 7251, KS H ISO 4831~4833)
	Bacteria	1,000 (only for precooked noodle)	Plate count agar (35±1°C 24-48h)	KS Determination of Micro-organism (KS H ISO 7251, KS H ISO 4831~4833)
	Max moisture	9%	Moisture measurement by air oven method	Determination of Water Content (KS H 1201)
	Acid value of oil	Not more than 1.5	Acid value measurement method by titration	Determination of Acid/Peroxide Value
	Peroxide value of oil	Not more than 25	Peroxide value measurement method by titration	

Table 13: Case Study (1) Instant Noodles: Food Additives

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	Specifications of noodles are described in Korea Food Code.		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.	http://fse.foodnara.go.kr/resize/RS/jsp/menu_02_01_03.jsp?idx=36 (Korean Definition)	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 Sodium Stearoyl Lactylate is permitted for use in noodles.		Tar colour should not be detected.	

Table 14: Case Study (2) Carbonate Soft Drinks: Specifications & Standards

	Food Sanitation Act	KS standard
Name of the Standard	Carbonated Beverages	Carbonated Soft Drinks (KS H 2016)
Scope	Carbonated Beverages; Carbonated Water	Carbonated Beverages; Carbonated Water
Essential Composition and Quality Factor	Pressure of carbonic acid gas (kg/cm ²) 1) Carbonated water: Not less than 1.0 2) Carbonated beverage: Not less than 0.5 Lead (mg/kg): Not more than 0.3 Cadmium (mg/kg): Not more than 0.1 Tin (mg/kg): Not more than 150 (Limited to canned products)	Must have satisfactory colour and flavour Must not have off-taste and off-odour Pressure of carbonic acid gas (kg/cm ²) 1) Carbonated water: Not less than 2.5 2) Carbonated beverage: Not less than 2.0 Lead (mg/kg): Not more than 0.3 Cadmium (mg/kg): Not more than 0.1 Tin (mg/kg): Not more than 150 (Limited to canned products) Packaging standards: The container shall not be swollen, deformed or rust, requiring complete sealing and appropriate degree of vacuume
Food Additives	Preservative: Any preservative except the followings should not be detected. (Sorbic acid, Sodium sorbate, Potassium sorbate, Calcium sorbate) Not more than 0.6g/kg as sorbic acid. (But it should not be detected in carbonated water)	
Hygiene	The number of Bacteria: Not more than 100 Coliform group: Negative	The number of Bacteria: Not more than 100 Coliform group: Negative
Labelling	Specific labelling methods 1) Products shall be labeled as either carbonated beverages or carbonated water. 2) If the calorie per 400ml is 2kcal or lower, the product can be labeled as "Diet". 3) Nutrition Facts required.	Labelling Standards follow "General Standard of Labelling for Processed Foods" (KS H 1101)
Methods of Analysis	Gas Pressure Lead and Cadmium, Tin The number of Bacteria Coliform group Preservatives	Gas Pressure, Lead and Cadmium Tin, The number of Bacteria, Coliform group General testing methods for canned food (KS H2146) Sensory test (KS H ISO 6658) Determination of Micro-organism (KS H ISO 7251, KSH ISO 4833/4832/4831) Anything not specified is handled in accordance with the Food Sanitation Act.

Table 15: Case Study (2) Carbonated Soft Drinks: Specifications and Methods of Analysis

Related Legislation	Item	Specification	Methods of analysis	Reference
Food Sanitation Act	Lead (mg/kg)	Not more than 0.3	Wet degradation method, Dry incineration methodour Solvent Extraction method →Inductively Coupled Plasma Spectrometry (ICP)	Korea Food Code (2010, 7.1.2.1)
	Cadmium (mg/kg)	Not more than 0.1	Wet degradation method, Dry incineration methodour Solvent Extraction method →Inductively Coupled Plasma Spectrometry (ICP)	Korea Food Code (2010, 7.1.2.2)
	Tin (mg/kg)	Not more than 150 (Limited to canned products)	Wet degradation methodour Dry incineration method →Salicylidenamino-2-thiophenol (SATP) methodour Polarographic analysis	Korea Food Code (2010, 7.1.2.6)
	Bacteria	Not more than 100/ml	Plate count agar (35±1°C 24-48h)	Korea Food Code (10.3.5.1)
	Coliform	Negative (Limited to pasteurized products)	LB fermentation tube (35±1°C 48±3h) →Gas generation : Presumptive test positive →BGLB fermentation tube (35±1°C 48±3h) →Gas generation →EMB medium (35±1°C 24±2h) →Typical colony: Confirmative test positive →Lactose broth fermentation tube and nutrient agar. The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 48±3h): microscopic test →Gram-negative nonspore-forming bacilli: Coliform positive	Korea Food Code (Article 10.3.7)

Table 16: Case Study (2) Carbonated Soft Drinks: Food Additives

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	Specifications of carbonated beverages are described in Korea Food Code- Carbonated beverages, Carbonated water.			
Positive and/or Negative List	Positive/negative list on food additives: Irestriction list for some additives in KFC, and defined at standards of use of individual food additives in KFAC (Korea Food Additives Code).	KFC http://fse.foodnara.go.kr/residue/RS/jsp/menu_02_01_03.jsp?idx=41 (Korean)	Carbonated soft drinks No positive/negative list included. It is recommended to follow the Korea Food Code.	KS H 2016
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 (as sum of benoic acid) are permitted to only carbonated beverages (excluding carbonated water). - Ester Gum less than 0.1/kg - Manganese gluconate (no maximum level specified) Some food additives are not allowed to use in carbonated beverages: -Food Red No.2 -Food Red No. 2 Aluminum Lake.	KFAC http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp (English)		

Table 17: Case Study (3) Prepared Frozen Foods: Specifications & Standards

	Food Sanitation Act	KS standard
Name of the Standard	Frozen Foods	Frozen Foods
Scope		Frozen croquette (KS H 4002) Frozen raw breaded shrimp (KS H 4003) Frozen pork cutlet (KS H 4004) Frozen fish cutlet (KS H 6032)
Description	<p>1. Product Definition "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 heating 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>2. Manufacturing and Processing Standards</p> <p>(1) Product before chilling shall be sterilized in a method, in which the temperature at the center of the product is not less than 63°C for 30 minutes, or the equivalent.</p> <p>(2) Thawing of refrigerated raw material shall be hygienically performed.</p> <p>3. Preservation and Distribution Standards</p> <p>(1) Preservation temperature of frozen chilled food means, except for separately specified in this code, that frozen temperature is not higher than -18°C and chilled temperature is 0~10°C.</p> <p>(2) After frozen food is thawed, it shall not be distributed as room temperature food or chilled food, and the room temperature food or chilled food shall not be distributed as frozen food.</p> <p>(3) Chilled food shall not be also distributed at room temperature (except fruit/vegetable).</p> <p>(4) Thawed food shall not be again frozen.</p> <p>(5) Transport of frozen or cold-storage products shall be performed with use of a vehicle able to maintain the specified temperature or in the equivalent or better manner.</p>	Each food items have their own Descriptions and Standards.
Food Additives	The products shall meet the requirements of Korea Food Additives Code	

	Food Sanitation Act				KS standard					
Hygiene		Frozen food not requiring heating before consumption	Frozen food requiring heating before consumption			Frozen croquette	Frozen raw bread shrimp	Frozen pork cutlet	Frozen fish cutlet	
			Heated food before freezing	Not-heated food before freezing						
	Bacterial Counts (cfu/g)	Not more than 100,000 (except fermented products or those added with lactic acid bacteria)	Not more than 100,000 (except fermented products or those added with lactic acid bacteria)	Not more than 3,000,000 (except fermented products or those added with lactic acid bacteria)	Bacterial Counts (cfu/g)	—	—	Not more than 3,000,000 (but heated /not-heated food before freezing <100,000)	Not more than 100,000	
	Coliform Group (cfu/g)	Not more than 10	Not more than 10	—	Coliform Group (cfu/g)	—	—	Not more than 10 (only for heated food before freezing)	Negative (only for heated food before freezing)	
	<i>E. coli</i>	—	—	Negative	<i>E. coli</i>	Negative	—	—	Negative (only for non-heated food before freezing)	
Lactic acid bacteria	Not less than labeled count (if only products added with lactic acid bacteria)									
	Food Sanitation Act				KS standard					
Labelling	<p>Frozen food shall be labeled according to the following criteria:</p> <p>(1) It shall be labeled as either frozen food good to eat unheated or frozen food to eat after heated.</p> <p>(2) Frozen food to eat after heating shall be additionally labeled as either "food heated before freezing" or "food unheated before freezing" depending on whether it was heat-treated, etc. Fermented products or products containing lactic acid bacteria shall indicate the number of yeasts or lactic acid bacteria.</p> <p>(3) Frozen food shall indicate the methods of storage in freezing conditions and the methods of thawing for cooking.</p> <p>(4) Products that require cooking or heating shall indicate the methods of cooking or heating.</p> <p>(5) The label shall not be done in a manner in which consumers can be</p>					<p>Labelling Standards follow "General Standard of Labelling for Processed Foods" (KS H 1101)</p>				

	<p>misled into thinking the whole of the raw materials is meat or produce. However, this may not apply if the quantity of meat or produce is labeled on the same position as that of the product name.</p> <p>(6) If two or more kinds of meats are used as raw materials, the name of a single kind of meat shall not be used as the product name. However, this may not apply if the quantity of the meat is labeled on the same position as that of the product name.</p>	
Methods of Analysis and Sampling	Determination of Bacteria counts, <i>E.coli</i> , Coliform group, Lactic acid bacteria.	<p>Sensory and Physical Examination (KS A 7002)</p> <p>Determination of Water Content (KS H 1201)</p> <p>Determination of Coliform group (KS H ISO 4832)</p> <p>Determination of Micro-organism (KS H ISO 4833)</p> <p>Anything not specified is handled in accordance with the Food Sanitation Act.</p>

Table 18: Case Study (3) Prepared Frozen Foods: Specifications and Methods of Analysis

Sub-category	Related Legislation	Item	Specification	Methods of analysis	Reference
Without heating	Food Sanitation Act	Bacteria	Not more than 100,000/g (Except for fermentative or lactic acid bacteria added products)	Plate count agar (35±1°C 24-48h)	Korea Food Code (10.3.5.1)
		Coliform	Not more than 10/g	Desoxycholate agar (35±1°C 20±2h) or Dehydrated coliform film (35±1°C 24±2h)	Korea Food Code (Article 10.3.7)
		Lactic acid bacteria	More than indicating quantity	BCP plate count agar (35-37°C 72±3h)	Korea Food Code (Article 10.3.9)
After heating (heated before freezing)	Food Sanitation Act	Bacteria	Not more than 100,000/g (Except for fermentative or lactic acid bacteria added products)	Plate count agar (35±1°C 24-48h)	Korea Food Code (10.3.5.1)

		Coliform	Not more than 10/g	LB fermentation tube (35±1°C 48±3h) →Gas generation: Presumptive test positive →BGLB fermentation tube (35±1°C 48±3h) →Gas generation→EMB medium (35±1°C 24±2h) →Typical colony: Confirmative test positive →Lactose broth fermentation tube and nutrient agar. The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 48±3h): microscopic test →Gram-negative nonspore-forming bacilli: Coliform positive	Korea Food Code (Article 10.3.7)
		Lactic acid bacteria	More than indicating quantity	BCP plate count agar (35-37°C 72±3h)	Korea Food Code (Article 10.3.9)
After heating (not heated before freezing)	Food Sanitation Act	Bacteria	Not more than 100,000/g (Except for fermentative or lactic acid bacteria added products)	Plate count agar (35±1°C 24-48h)	Korea Food Code (10.3.5.1)
		<i>E. coli</i>	Negative (Limited to alcohol-treated products)	EC fermentation tube (44.5°C 24±2h) →Gas generation: Presumptive test positive →EMB medium (35±1°C 24±2h) →Lactose broth fermentation tube and nutrient agar. The lactose broth fermentation tube (35±1°C 48±3h): gas generation →The nutrient agar (35±1°C 24±2h): microscopic test →Gram-negative nonspore-forming bacilli: <i>E.coli</i> positive	Korea Food Code (Article 10.3.8)
		Lactic acid bacteria	More than indicating quantity	BCP plate count agar (35-37°C 72±3h)	Korea Food Code (Article 10.3.9)

Table 19: Case Study (3) Prepared Frozen Foods: Food Additives

	Food Sanitation Act		KS (voluntary standards)	
Scope and/or Description	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.		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)	
Positive and/or Negative List	“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.	Definition: Korea Food Code 3-3 (korean; http://fse.foodnara.go.kr/residue/RS/jsp/menu_02_01_03.jsp?idx=17))	No positive/negative List is included. Generally, it should comply with the Korea Food Code and/or Food Additive Code.	KS H 4002 KS H 4003 KS H 4004 KS H 6032
Use Limitation and/or Maximum Level, if any	(1) Frozen food not requiring heat process before consumption: Frozen food that can be consumed without a separate heating process. (2) Frozen food requiring heating process before consumption: Frozen food that can be consumed only after a separate heating process.			

Table 20: Case Study (4) Cow's Milk: Specifications & Standards and Methods of Analysis

Related Legislation	Item	Specification	Methods of analysis	Reference
Livestock Processing Act	Nonfat milk solid (%)	8.0% <	Dry 5 g milk at 98~100°C to get dried material % and then subtract milk fat (%)	Notification on Standard and Specification of Livestock Products (No. 2010-2)
	Milk fat (%)	3.0% <	Gerber Method	
	Specific Gravity (at 15°C)	1.028~1.034	Measure specific gravity of sample after standing until there is no bubble using a hydrometer at 15°C	
	Acidity (as lactic acid %)	<0.18%	Titration of 20 ml sample (10 ml milk+10 ml distilled water) with 0.1 N sodium hydroxide solution	
	Bacteria (counts/ml)	Not more than 20,000/ml	Aerobic Plate Count agar (35±1°C 48h or 30±1°C 72h)	
	Coliform	Not more than 2/ml (negative for pasteurized product)	MPN (Most Probable Number) Method Desoxycholate agar (35±1°C 24±2h) or Dehydrated cliform film (35±1°C 24±2h)	

Table 21: Case Study (4) Cow's Milk: Food Additives

	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 PROOUCTS"	There is no positive/negative list in KS.	KS H 2195
Positive and/or Negative List	Use of food additives in milk is prohibited or restricted under the Korea FSA.	Notification on Standard and Specification of Livestock Products (No. 2010-2)		
Use Limitation and/or Maximum Level	(Sanitary control for livestock products has designated milks for milk, fortified milk, reconstituted milk, and lactic acid bacteria added milk.)	http://www.qia.go.kr/viewwebQiaCom.do?id=7660&type=1_41jgbz (Korean)		

4.4 People’s Republic of China

1. LEGAL FRAMEWORK RELATED TO FOOD STANDARDS

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 one national standard produced drastic improvements. “Food poisoning incidents caused by frozen dumpling contaminants” 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 establishment of a food recall system, unites sections responsible for monitoring, control and assessment of various food related risk. State Council decided to set up “Food Safety Committee” according to the law to establish the structure shown below in Figure 1 with the purpose of securing food safety and ensuring the public health and safety.

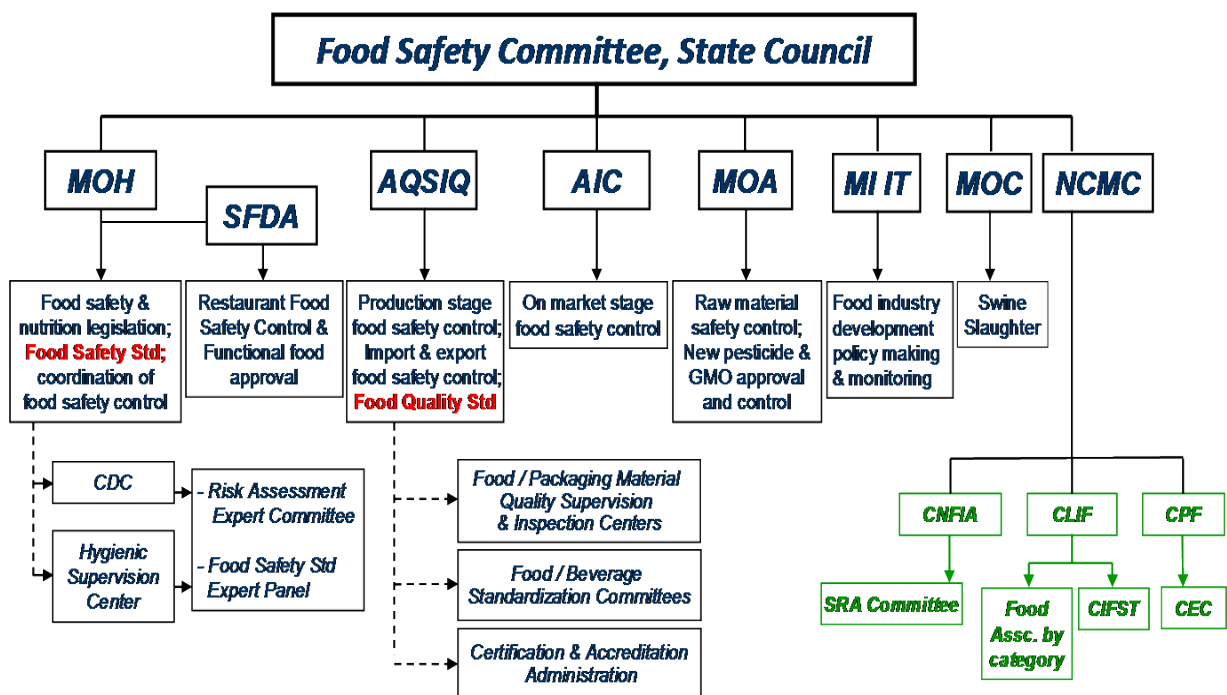


Figure 1: Food Administration Structure Established According to Food Safety Law

Food administration was so far conducted by plural governing structures where several concerned governments had been controlling many process of food manufacturing, distributions and sales and the structure 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.

2. 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, 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).

2.1 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. 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.

2.2 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: Supervises the local government in the food consumption process, and teaches first aid, inspections and information technology. 5th: Develops international interactions, and cooperation activities.

2.3 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.

2.4 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: Establishes 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 proceeds with the rural economic reform. 2nd: Investigates the fishing industry on behalf of the country, exercises 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. SUMMARY OF FOOD STANDARDS

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) or GB/T (Recommended standard). The following code numbers allow you to identify standard. SAC issues list of all National Standards (<http://www.sac.gov.cn/>). 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 2; National standard, Industry & Local Standard defined as regional standard and industry associations’ voluntary standard, and Enterprise Standard in each company. These all standards are expected to be unified as national standards, though, standardization requires more time.

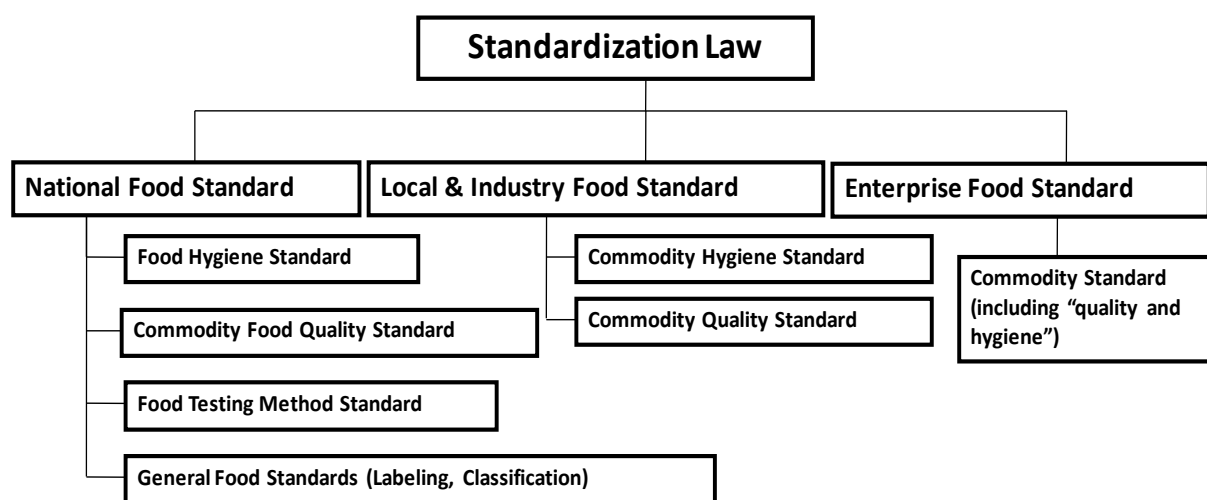


Figure 2: Three Levels of Standards in China

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 of the lower level 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 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 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.

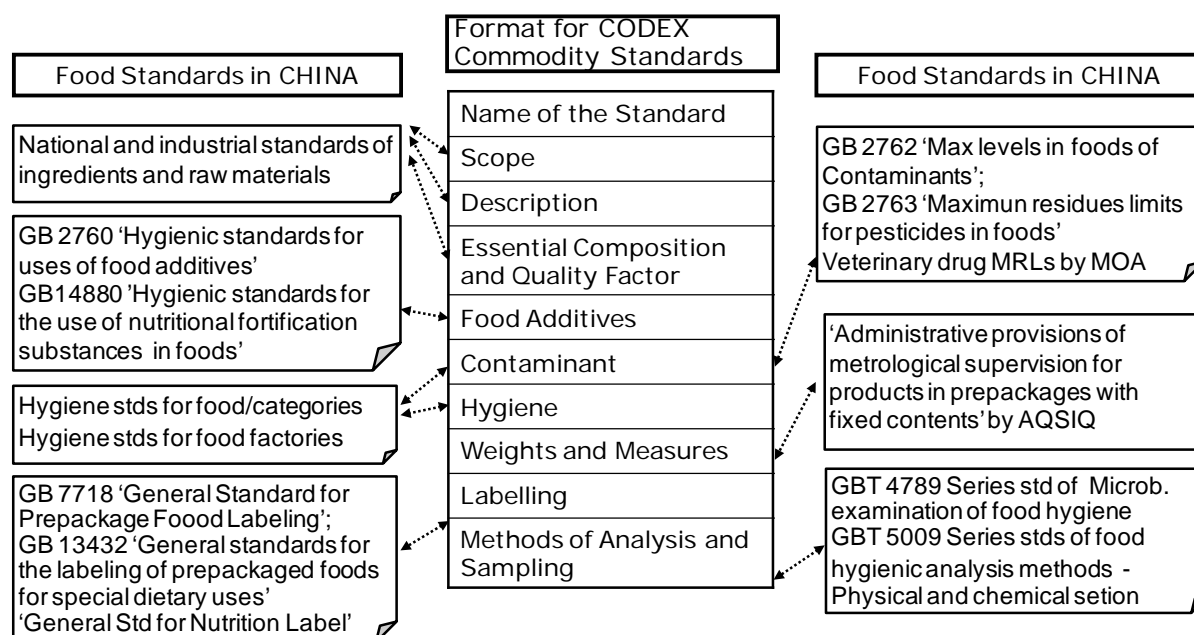


Figure 3: Summary of Food Standards in China

For specific examples, see summary of food standards described in “Case Studies” 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.

4. ACTS AND REGULATIONS RELATED TO FOOD ADDITIVES

4.1 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 140,000 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 for Food. Accordingly, where the National Standard for Food 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.

4.2 Food Additive Definitions & Functional Classes

1) Food Additives

It is defined that “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, or for the need of preservation and processing technical merits, including nutritional fortifying substances, flavours and processing aids.”

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

- a) Do not provide any harm to human by all means
- b) Do not hide rotting or deterioration of foods
- c) Do not use to fraud defects or poor quality foods
- d) Do not deteriorate nutritive values.
- e) Use minimum quantity necessary
- f) Do not remain in foods in case of processing aids and their residue level 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, consisting of function code of the food additive category (see Normative Annex E of this standard) and serial number.

2) Food Flavours

Food flavours refer to substances used in food manufacturing in order to modify or improve flavours of the food, and may include aids. But substances that provide only salty, sweet, or sour taste and flavour enhancers are excluded. Flavours are not usually used to be directly consumed.

The Application of flavours for food manufacturing shall be implemented according to the Normative Annex B.1 of this Standard.

3) Processing Aids

Food processing aids refer to substances used in food processing, without affecting the food itself. Filtration aids, clarifiers, absorbents, removers, decolouring agents, mold release agents, extraction solvents, and nutrients 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

Regarding the carry-over of food additives in food as a result of using an ingredient mixed with food additive, it is stipulated as follows;

- 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 maximum 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.

4.3 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.

4.4 Prohibited Substances for Use as Food Additives

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

4.5 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 like GB2760 is not published.

4.6 Application, Assessment and Approval of New 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 new 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 standard 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 article, submission of technical information can be excluded.

4.7 Labelling of Food Additives Used in Foods

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 its generic name and INS number according to its functional group.
- b) A prepackaged food 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.

4.8 Summary of Food Additives

The definitions regarding food additives such as flavours, processing aids, and carry-over are summarized in Table 1, and other definitions such as designated/existing food additives and prohibited substances are summarized in Table 2.

5. SPECIFICATIONS & STANDARDS AND METHODS OF ANALYSIS FOR GENERAL FOODS

Specifications & standards and methods of analysis for general foods are shown in Table 3. Those for the food categories taken up in the Case Study are described in the food categories, respectively.

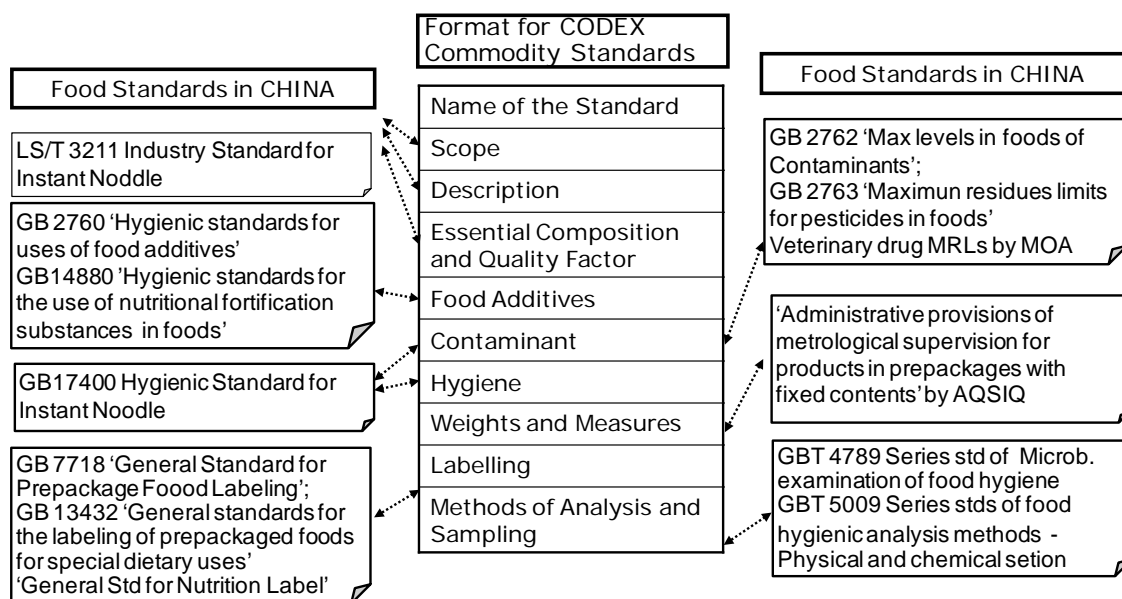
6. CSAE STUDIES

Food categories in GB2760 for (1) Instant Noodles, (2) Carbonated Soft Drinks, (3) Prepared Frozen Foods, and (4) Cow's Milk in Case Studies are summarized below. There are no food categories that fit "Instant Noodles" or "Prepared Frozen Foods" in China.

Food Categories	Food Categories in GB2760	References
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.
<ul style="list-style-type: none"> ▫ In GB2760-2011, the Table of Allowed Food Additives (A.1) is organized by the name of food additives instead of Food Categories. ▫ There is not any "Voluntary Standard" for use of Food Additives in China. 		

(1) Instant Noodles

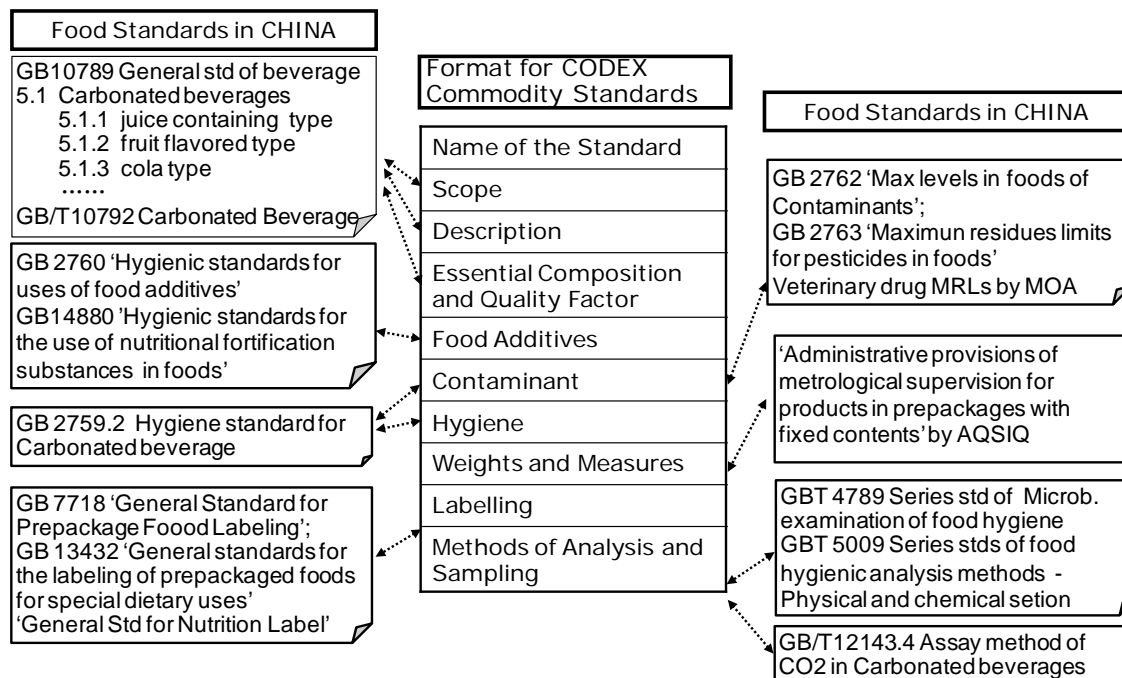
The legal system of food standards for instant noodles is shown below.



Food specifications & standards for instant noodles are summarized in Table 4, methods of analysis in Table 5, respectively.

(2) Carbonated Soft Drinks

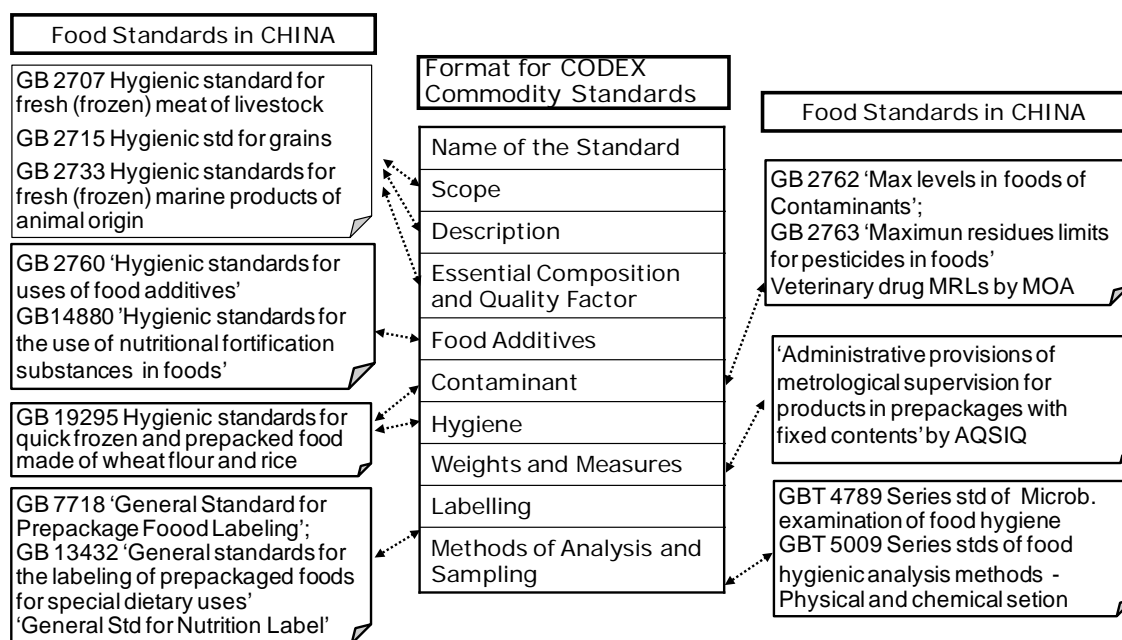
The legal system of food standards for carbonated soft drinks is shown below.



Food specifications & standards for carbonated soft drinks are summarized in Table 6, methods of analysis in Table 7, respectively.

(3) Prepared Frozen Foods

The legal system of food standards for prepared frozen foods is shown below.



Food specifications & standards for prepared frozen foods are summarized in Table 8, methods of analysis in Table 9, respectively.

(4) Cow's Milk

Food specifications & standards and methods of analysis for cow's milk is shown in Table 10, for raw milk, pasteurized milk, sterilized milk, modified milk, fermented milk, and evaporated milk, respectively.

Table 1: Summary/Definition of Food Additives (General)

	Summary/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
Summary/Definitions (General)		
Food additives	“Food additives” refer to the chemically synthetic or natural substances to be added to foods in order to improve food quality and colour, flavour and taste, or for the need of preservation and processing technology, including nutritional fortification components, flavours, gum base in chewing gum, and processing aids.	GB2760-2011 Article 2. Terms and definitions: 2.1 Food additive
Flavours	“Flavours” refer to substances used in food manufacturing in order to modify or improve the flavour of foods. They may contain aids. The substances which provide only salty, sweet, or sour taste, and flavour enhancers are excluded. Flavours are not usually used for direct consumption.	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 substances used in food processing, without affecting the food itself. Filtration aids, clarifiers, absorbents, removers, decolouring agents, mold release agents, extraction solvents, and nutrients for fermentation, etc. Processing aids are not allowed to remain in the product 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	Regarding the carry-over of food additives in food as a result of using an ingredient mixed with food additive, it is stipulated as follows; 1. The use of the food additive in the food ingredients can only be allowed according to this standard; 2. The level of this food additive in the food 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.	GB2760-2011 Article 3. Principles for use of food additives: 3.4 Carry-over principles

Table 2: Summary/Definition of Food Additives (Specific)

	Summary/Definition	Reference
Related Legislation	GB2760-2011 Standard for Use of Food Additives	http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaq/xxw/cmsmedia/document/doc321.pdf
Summary (Specific)/Additional Laws		
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 (nutritional fortification substances) is revised.
2	List of Existing Food Additives	There is no such category 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	There is no such category in China.
Negative list		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. All the published food safety standards are shown at the website in the right column. http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaq/xxw/s69/index.html
Official publication and/or gazette for food additives		

Table 3: Specifications & Standards and Methods of Analysis for General Foods

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 4789-2010 National Food Safety Standard Food Microbiological examination	Aerobic Plate Count	This standard is to state the analytical method for pathogens and hygiene indicator microbes. The specific limitation in certain food category will be stated in separate standards of category.	Difference with FDA/BAM, Chapter 3: Aerobic plate count, 2001 <ul style="list-style-type: none"> - Appropriate enumeration scope of plate counts computed change to 30 cfu~300 cfu from 25 cfu~250 cfu. - Incubate temperature change to 36±1°C from 35±1°C. - 10 times dilution, change to transferring 1ml of previous dilution to 9 ml of diluent from transferring 10ml of previous dilution to 90 ml - do not adopt the Spiral Plate Method 	GB 4789.2-2010 National Food Safety Standard Food Microbiological examination: Aerobic plate count
	Enumeration of coliforms		Difference with FDA/BAM, Chapter 4: Enumeration of Escherichia coli and the coliform bacteria, 2002 <ul style="list-style-type: none"> - Appropriate enumeration scope of plate counts computed change to 15 cfu~150 cfu from 25 cfu~250 cfu. - Incubate temperature change to 36±1°C from 35±1°C. - Sample size change to 25g (or 25ml) form 50g (or 50ml) 	GB 4789.3-2010 National Food Safety Standard Food Microbiological examination: Enumeration of coliforms
	Salmonella		Same as FDA/BAM, Chapter 5: Salmonella, 2003 and AOAC official Method 967.26, 967.27,967.28.	GB 4789.4-2010 National Food Safety Standard Food Microbiological examination: Salmonella

	<i>Staphylococcus aureus</i>		<p>total 3 Methods</p> <p>1. The First Method: Qualitative Analysis, it refers to AOAC office Method 987.09 <i>Staphylococcus aureus</i> in foods most probable number method for isolation and enumeration and ISO 6888-1: 1999 Microbiology of food and animal feeding stuffs- Horizontal method for the enumeration of coagulase-positive staphylococci, <i>Staphylococcus aureus</i> and other species - Part1 : Technique using Baird-Parker agar medium</p> <p>2. Second Method: Modified by AOAC 975.55 <i>Staphylococcus aureus</i> in foods surface plating method isolation and enumeration, 1976 and ISO 6888-1:1999, the difference are:</p> <ul style="list-style-type: none"> - Change the AOAC sampling size to 25g (or 25ml) from 50g (or 50ml) - Modified the ISO computational formula <p>3. The third Method: modified by AOAC 987.07, the difference is:</p> <ul style="list-style-type: none"> - Change the AOAC sampling size to 25g (or 25ml) from 50g (or 50ml) 	<p>GB 4789.10-2010 National Food Safety Standard Food Microbiological examination: <i>Staphylococcus aureus</i></p>
	Enumeration of moulds and yeasts		<p>Sampling Preparation, Dilution, plating and incubation of sampling (Potato dextrose agar, or Rose bengal medium) , counting of plate</p>	<p>GB 4789.15-2010 National Food Safety Standard Food Microbiological examination: Enumeration of moulds and yeasts</p>
	<i>Listeria monocytogenes</i>		<p>Difference with FDA/BAM, Chapter 10, <i>Listeria monocytogenes</i>, 2002</p> <ul style="list-style-type: none"> - Enrichment Medium, LB Broth replaced of BLEB Broth - Isolation Medium, PALCAM replaced of OXA, add CHROMAGAR <i>Listeria</i> colouration media - Add the preliminary screening step - Incubate temperature change to 36±1°C from 35±1°C. 	<p>GB 4789.30-2010 National Food Safety Standard Food Microbiological examination: <i>Listeria monocytogenes</i></p>

	Lactic acid bacteria		Presumptive test (Sampling Preparation, Dilution, plating and incubation of sampling (MRS agar, MC agar), counting of plate) → Identification test (MRS agar plate or MC agar plate) → Report	GB 4789.35-2010 National Food Safety Standard Food Microbiological examination: Lactic acid bacteria
	Enterobacter sakazakii		First method, Modified by ISO/TS 22964 : 2006 (Milk and milk products -Detection of <i>Enterobacter sakazakii</i>), the difference are: - Incubate temperature change to 36±1°C from 35±1°C - <i>Enterobacter sakazakii</i> isolated plate change to DFI from ESIA, incubate temperature change to 36±1°C from 44±1°C. - decide 100g (or 100ml) as the basic detection unit. Secod Method, it is refer to FDA, Isolation and enumeration of <i>Enterobacter sakazakii</i> form dehydrated powdered infant formula (July 2002)	GB 4789.40-2010 National Food Safety Standard Food Microbiological examination: <i>Enterobacter sakazakii</i>
Maximum levels of contaminants in food;	Lead (Pb)	cereals: 0.2 mg/kg; legume: 0.2 mg/kg; tubes: 0.2 mg/kg; meat and poultry: 0.2 mg/kg; edible meat and poultry offal: 0.5 mg/kg; fish: 0.5 mg/kg; fruit: 0.1 mg/kg; small fruit, berry and grape: 0.2 mg/kg; vegetable excluding bulb vegetable, leafy vegetable, fungi: 0.1 mg/kg; bulb vegetable: 0.3 mg/kg; leafy vegetable: 0.3 mg/kg; fresh milk: 0.05 mg/kg; infant formula: 0.02 mg/kg; fresh eggs: 0.2 mg/kg; wines: 0.2 mg/kg; fruit juice: 0.05 mg/kg; tea: 5 mg/kg	1. Graphite furnace atomic absorption spectrometry Sample preparation →ashing or digesting → standard solution preparation →determination by instrument. 2. Hydride Generation-atomic Fluorescence Spectrophotometry Sample preparation →digestion →standard solution preparation →determination 3. Flame Atomic Absorption Spectrometric analysis (FAAS) Sample preparation →extraction and separation → determination by instrument 4. Double sulphur hydrazone colourimetry Sample preparation →digestion →standard solution preparation →determination by spectrophotometer 5. single-sweep polarography Sample preparation →digestion →standard solution preparation →determination by polarographic analyze	GB 5009.12-2010 National food safety standard determination of lead in foods
Maximum levels of mycotoxins in foods				

	Cadmium (Cd)	<p>cereals - rice, soybean: 0.2 mg/kg, peanut: 0.5 mg/kg, flour: 0.1 mg/kg, coarse cereal (corn, millet, sorghum, tubers): 0.1 mg/kg; meat and poultry: 0.1 mg/kg; meat and poultry liver: 0.5 mg/kg; meat and poultry kidney: 1.0 mg/kg; fruit: 0.05 mg/kg; root and tuber vegetable excluding celery: 0.1 mg/kg; leafy vegetable, celery, fungi: 0.2 mg/kg; other vegetable: 0.05 mg/kg; fish: 0.1 mg/kg; fresh eggs: 0.05 mg/kg</p>	<ol style="list-style-type: none"> 1. Graphite furnace atomic absorption spectrometry Sample preparation →dry ashing or wet digestion →standard solution preparation →determination by instrument 2. Atomic Absorption Spectrometry (AAS) <ol style="list-style-type: none"> 2.1 Potassium iodide -4-methyl pentanone-2 Sample preparation →extraction and separation →determination by instrument 2.2 Double sulphur hydrazone-butyl acetate Sample preparation →extraction and separation →determination by instrument 3. Colourimetric method Sample preparation →digestion →determination by spectrophotometer 4. Atomic Fluorescence Spectrometric (AFS) Sample preparation →dry ashing or wet digestion →standard solution preparation →determination by AFS 	<p>GB/T 5009.15-2003 Determination of cadmium in foods</p>
	Mercury (Hg)	<p>cereals: 0.02mg /kg total Hg; tubers (potato, sweet potato), vegetable, fruit: 0.01 mg/kg total Hg; fresh milk: 0.01 mg/kg total Hg; meat, liquid eggs: 0.05 mg/kg total Hg; fish excluding carnivorous fish and other aquatic products: 0.5 mg/kg methyl Hg; carnivorous fish (shark, tuna, etc.): 1.0mg/kg methyl Hg</p>	<ol style="list-style-type: none"> 1. The determination of total mercury <ol style="list-style-type: none"> 1.1 Atomic fluorescence spectrophotometric Digestion →preparation of standard solution →determination by AFS 1.2 Cold atomic absorption spectrometry Sample preparation →digestion →instrumental analysis 1.3 Double sulphur hydrazone colourimetry Digestion →determination by visible spectrophotometer 2. Determination of methylmercury <ol style="list-style-type: none"> 2.1 Gas Chromatography (GC) or Cold Vapour Atomic Absorption Sample preparation →extraction →centrifugal or filtration →elution →extraction →determination by instrument 	<p>GB/T 5009.17-2003 Determination of total and organic-mercury in foods</p>
	Arsenic (As)	<p>cereals - rice: 0.15 mg/kg inorganic As; flour: 0.1 mg/kg inorganic As; coarse cereals: 0.2 mg/kg inorganic As; vegetable: 0.05 mg/kg inorganic As; fruit: 0.05 mg/kg inorganic As; meat and poultry: 0.05 mg/kg inorganic</p>	<ol style="list-style-type: none"> 1. The determination of total arsenic <ol style="list-style-type: none"> 1.1 Hydride Generation-atomic Fluorescence Spectrophotometry Wet digestion or dry ashing →standard solution preparation →determination by AFS 1.2 Silver salt method 	<p>GB/T 5009.11-2003 Determination of total and inorganic arsenic in foods</p>

		As; eggs: 0.05 mg/kg inorganic As; milk powder: 0.25 mg/kg inorganic As; fresh milk: 0.05 mg/kg inorganic As; legume: 0.1 mg/kg inorganic As; alcohol: 0.05 mg/kg inorganic As; fish: 0.1 mg/kg inorganic As; alga: 1.5 mg/kg inorganic As; shellfish, prawn, crab (calculated on fresh weight): 0.5 mg/kg inorganic As; shellfish, prawn, crab (calculated on dry weight): 1.0 mg/kg inorganic As; other aquatic products (calculated on fresh weight): 0.5 mg/kg inorganic As; edible oil: 0.1 mg/kg total As; fruit juice and fruit pulp: 0.2 mg/kg total As; cocoa butter and chocolate: 0.5 mg/kg total As; other cocoa products: 1.0 mg/kg total As; sugar: 0.5 mg/kg total As	Wet digestion or dry ashing →standard solution preparation →determination by spectrophotometer 1.3 Method of Spot of arsenic Wet digestion or dry ashing →standard solution preparation →determination by arsenic apparatus 1.4 Borohydride Reduction Colourimetric Method Wet digestion or dry ashing →standard solution preparation →determination by spectrophotometer 2. The determination of abio-arsenic 2.1 Hydride Generation-atomic Fluorescence Spectrophotometry The extraction of abio-arsenic →standard solution preparation →determination by AFS 2.2 Silver salt method The extraction of abio-arsenic →standard solution preparation →determination by spectrophotometer	
	Chrome (Cr)	cereals: 1.0 mg/kg; legume: 1.0 mg/kg; tubes: 0.5 mg/kg; vegetable: 0.5 mg/kg; fruit: 0.5 mg/kg; meat including liver and kidney: 1.0 mg/kg; fish and shellfish: 2.0 mg/kg; eggs: 1.0 mg/kg; fresh milk: 0.3 mg/kg; milk powder: 2.0 mg/kg	1. Graphite furnace atomic absorption spectrometry Sample preparation →wet digestion →constant volume →standard solution preparation →determination by atomic absorption spectrophotometer 2. The oscillographic method Sample preparation →standard solution preparation →determination by oscillographic polarograph	GB/T 5009.123-2003 Determination of chromium in foods
	Aluminum (Al)	flour-made products: 100 mg/kg	Sample preparation →digestion →standard solution preparation →determination by spectrophotometer	GB/T 5009.182-2003 Determination of aluminum in flour products

	Selenium (Se)	cereals: 0.3 mg/kg; legume and legume products: 0.3 mg/kg; vegetable: 0.1 mg/kg; fruit: 0.05 mg/kg; meat and poultry: 0.5 mg/kg; kidney: 3.0 mg/kg; fish: 1.0 mg/kg; eggs: 0.5 mg/kg; fresh milk: 0.03 mg/kg; milk powder: 0.15 mg/kg	1. Hydride Generation-atomic Fluorescence Spectrophotometry Sample preparation →digestion →standard solution preparation →determination by atomic fluorescence spectroscopy 2. Fluorescent method Sample preparation →digestion →extraction →standard solution preparation →determination by fluorescence spectrophotometer	GB/T 5009.93-2010 National food safety standard determination of selenium in foods
	Fluorin (Fi)	cereals - rice, flour: 1.0 mg/kg, other cereals: 1.5 mg/kg; legume: 1.0 mg/kg; vegetable: 1.0 mg/kg; fruit: 0.5 mg/kg; meat: 2.0 mg/kg; freshwater fish: 2.0 mg/kg; eggs: 1.0 mg/kg	1. Diffusion-Fluorine Reagent Colourimetric Analysis Sample preparation →diffusion →extraction and filtration →determination by visible spectrophotometer 2. Ashing and Distilling-Fluorine Reagent Colourimetric Analysis Sample preparation →fixation of fluorine →ashing →distilling →determination by visible spectrophotometer 3. Fluorine ion selective electrode Sample preparation →standard solution preparation →determination by calomel electrode	GB/T 5009.18-2003 Determination of fluorine in foods
	Benzo(a)pyrene	baked smoked meat: 5 µg/kg; vegetable oil: 10 µg/kg; cereals: 5 µg/kg	1. Fluorescence spectrophotometry Extraction →purification →separation →determination by Fluorescence spectrophotometry 2. Visual colourimetry Extraction →purification →separation →determination by ultraviolet light	GB/T 5009.27-2003 Determination of benzo(a)pyrene in foods
	N-nitrosamine	seafood: 4 µg/kg N-dimethyl nitrosamine, 7 µg/kg N-diethyl nitrosamine; meat products: 3 µg/kg N-dimethyl nitrosamine, 5 µg/kg N-diethyl nitrosamine	1. Gas Chromatography- Thermal Energy Analyzer (GC-TEA) Extraction →concentration →determination by GC-TEA 2. Gas chromatograph-Mass Spectrometer (GC-MS) Distill →extraction and purification →concentration →determination by GC-MS	GB/T 5009.26-2003 Determination of N-nitrosamines in foods

	Polychlorodiphenyls	marine fish, shellfish, prawn and alga products (edible parts): 2.0 mg/kg polychlorodiphenyls, 0.5 mg/kg PCB138, 0.5 mg/kg PCB153	1. Gas Chromatography/Mass Spectrometry with Isotopic Dilution Method Sample preparation →extraction →purification → separation →concentration →determination by GC-MS 2. Gas Chromatography (GC) Extraction →purification →concentration → determination by GC	GB/T 5009.190-2006 Determination of indicator polychlorinated biphenyls in foods
	Nitrite	Cereals (rice, flour, corn): 3 mg/kg; vegetable: 4 mg/kg; fish: 3 mg/kg; meat: 3 mg/kg; eggs: 5 mg/kg; picked vegetable: 20 mg/kg; milk powder: 2 mg/kg; salt (calculated on NaCl): 2 mg/kg	1. Ion Chromatography (IC) Sample preparation →extraction and purification →separation →determination by Conductivity Detector (CD) 2. Spectrophotometry Sample preparation →extraction →purification → determination by spectrophotometer 3. Determination of nitrite and nitrate in dairy products Sample preparation (remove fat and protein) →nitrate reduction →colouration →determination by spectrophotometer	GB/T 5009.33-2010 National food safety standard determination of nitrite and nitrate in foods
	Rare earth	cereals - rice, corn, wheat: 2.0 mg/kg; vegetable excluding spinach: 0.7 mg/kg; fruit: 0.7 mg/kg; peanut kernel: 0.5 mg/kg; potato: 0.5 mg/kg; mung bean: 1.0 mg/kg; tea: 2.0 mg/kg	Sample preparation →ashing →dissolution → centrifugal →standard solution preparation → determination by spectrophotometer	GB/T 5009.94-2003 Determination of rare earths in vegetable foods
	Aflatoxin B1	corn, peanut and its products: 20 µg/kg; rice, vegetable oil (excluding corn oil & peanut oil): 10 µg/kg; other cereals, legume, fermented food: 5 µg/kg; infant formula: 5 µg/kg	1. Thin-Layer Chromatography (TLC) Extraction →concentration →Thin-Layer separation →determination by ultraviolet lamp 2. Competition Enzyme-Linked Immunosorbent Assay (C-ELISA) Extraction →defat →concentration → determination by enzyme-labeled instrument	GB/T 5009.22-2003 Determination of aflatoxin B1 in foods
	Aflatoxin M1	fresh milk: 0.5 µg/kg; dairy products(calculated on fresh milk): 0.5 µg/kg	Purification →extraction →concentration → Thin-Layer separation →determination by ultraviolet lamp	GB/T 5009.24-2010 National food safety standard Determination of aflatoxin M1 and B1 in foods

	Deoxynivalenol (DON)	wheat: 1,000 µg/kg; corn: 1,000 µg/kg	1. Thin-Layer Chromatography (TLC) Extraction →purification →concentration →Thin-Layer separation →determination by ultraviolet lamp 2. Enzyme-Linked Immunosorbent Assay (ELISA) Extraction →purification →concentration →determination by enzyme-labeled instrument	GB/T 5009.111-2003 Determination of deoxynivalenol in cereal and cereal products
	Patulin	apple and hawthorn products: 50 µg/kg	Extraction →purification →concentration →Thin-Layer separation →determination by thin layer chromatogram scanner	GB/T 5009.185-2003 Determination of patulin in apple and hawthorn products

Table 4: Case Study (1) Instant Noodles: Specifications & Standards

	Hygienic Standard for Instant Noodle			Industry Standard for Instant Noodle		
Std Code	GB17400-2003			LS/T 3211-1995		
Scope	Fried and non-fried instant noodle.			Fried noodle, hot air dried noodle		
Ingredients	Should meet the requirement of relevant standards and regulation.			* Wheat flour should meet its national std * Fry oil should meet Hygiene std of edible oil frying process * Salt should meet its national standard		
Sensory requir'nt	* sould present its specific color; not burned or raw; could have shade of colour on both side. * Have normal smell; No moldy, rancid or other bad smell * Good in snape and pattern; Not foreign object or burned residue. * No broken, stuck after recovery with water; * No half-cooked and teeth-sticking texture.			* sould present its specific color; not burned or raw; could have shade of colour on both side. * No moldy, rancid or other strande smell and tast. * Good in shape and pattern; Not visible impurity. * No broken, stuck after recovery with water; * No half-cooked and teeth-sticking texture.		
Technical Criteria	\leq	Fried	Non-fried	\leq	Fried	Non-fried
	water (g/100g)	8	12	water, %	8	12
	Acid (Count as fat), KOH/mg/g	1.8		Acid (Count as fat) KOH/mg/g	1.8	
	Peroxide value (count as fat), g/100g	0.25		Peroxide value (count as fat), meq/100g	20	
	Carbonly value (count as fat) (meq/kg)	20		Fat, %	24	
	Pb, mg/kg	0.5		IoD Value	≥ 1.0	
	Total As, mg/kg	0.5		NaCl, %	2.5	
				Recovery time	4min	6min
			Weight variance	$\leq 3\%$ of declared weight		

	Hygienic Standard for Instant Noodle			Industry Standard for Instant Noodle		
	≤	Fried	Non-fried	≤	Fried	Non-fried
Microbe	Tbc, cfu/g	1 000	50 000	Tbc, count/g	1000	
	Coliform group, MPN/100g	30	150	Coliform group, count/100g	30	
	Pathogen	Absent		Pathogen	Absent	
Food additive	Meet relevant quality standards and regulation. Applying range and level meet GB2760 'Hygienic standard of food additive use'.			Food additives should meet national and industrial standards.		
Packaging	Packaging vessel and material should meet relevant hygiene standard and regulation			Should meet 'Hygiene standard of food packaging material'		
Labeling	Labeling should meet relevant regulation, and it is required to declare 'Fried' or 'Non-fried'			Should meet GB7718 'General labeling requirement for prepackaged food'		
Test method	Sensory requirement Technical criteria			Test method for each item		

Table 5: Case Study (1) Instant Noodles: Methods of Analysis

Related Legislation	Item	Specification	Method of Analysis	Reference
Hygienic Standard for Instant Noodle (GB 17400-2003)	moisture content	Not more than 8 g/100 g (Fried)	1) direct drying method 2) reduced pressure drying method 3) distillationmethod 4) karl-fischer method	GB 5009.3
		Not more than 12 g/100 g (Non-fried)		
	Acid value (Count as fat)	Not more than 1.8 KOH/mg/g (Fried)	1) extract fat by petroleum ether (GB/T5009.56) potassium hydroxide solution titration Peroxide value: a) potassium iodide solution titration b) ferric thiocyanate colorimetric method Carbonly value: dinitrophenylhydrazine colorimetric method	2) Acid value: GB/T5009.56 GB/T 5009.37
	Peroxide value (Count as fat)	Not more than 0.25 g/100g (Fried)		
	Carbonly value (count as fat)	Not more than 20 (meq/kg)		
Pb	Not more than 0.5 mg/kg	1. Graphite furnace atomic absorption spectrometry Sample preparation →ashing or digesting →standard solution preparation →determination by instrument. 2. Hydride Generation-atomic Fluorescence Spectrophotometry Sample preparation →digestion →standard solution preparation →determination 3. Flame Atomic Absorption Spectrometric analysis (FAAS) Sample preparation →extraction and separation →determination by instrument 4. Double sulphur hydrazone colorimetry Sample preparation →digestion →standard solution preparation →determination by spectrophotometer 5. Single-sweep polarography Sample preparation →digestion →standard solution preparation →determination by polarographic analyze"	GB 5009.12	

	Total As	Not more than 0.5 mg/kg	<p>1. The determination of total arsenic</p> <p>1.1 Hydride Generation-atomic Fluorescence Spectrophotometry Wet digestion or dry ashing →standardard solution preparation →determination by AFS</p> <p>1.2 Silver salt method Wet digestion or dry ashing →standardard solution preparation →determination by spectrophotometer</p> <p>1.3 Method of Spot of arsenic Wet digestion or dry ashing →standardard solution preparation →determination by arsenic apparatus</p> <p>1.4 Borohydride Reduction Colorimetric Method Wet digestion or dry ashing →standardard solution preparation →determination by spectrophotometer</p> <p>2. The determination of abio-arsenic</p> <p>2.1 Hydride Generation-atomic Fluorescence Spectrophotometry The extraction of abio-arsenic →standardard solution preparation →determination by AFS</p> <p>2.2 Silver salt method The extraction of abio-arsenic →standardard solution preparation →determination by spectrophotometer"</p>	GB/T 5009.11
	Tbc	Not more than 1,000 cfu/g (Fried)	<p>Difference with FDA/BAM, Chapter 3: Aerobic plate count, 2001</p> <ul style="list-style-type: none"> - Appropriate enumeration scope of plate counts computed change to 30 cfu~300 cfu from 25 cfu~250 cfu. - Incubate temperature change to 36±1°C from 35±1°C. - 10 times dilution, change to transferring 1ml of previous dilution to 9 ml of diluent from transferring 10ml of previous dilution to 90 ml - do not adopt the Spiral Plate Method" 	GB 4789.2
		Not more than 50,000 cfu/g (Non-fried)		
	Coliform group	Not more than 30 MPN/100g (Fried)	<p>Difference with FDA/BAM, Chapter 4: Enumeration of <i>Escherichia coli</i> and the coliform bacteria, 2002</p> <ul style="list-style-type: none"> - Appropriate enumeration scope of plate counts computed change to 15 cfu~150 cfu from 25 cfu~250 cfu. - Incubate temperature change to 36±1°C from 35±1°C. - Sample size change to 25 g (or 25 ml) form 50 g (or 50 ml)" 	GB 4789.3
		Not more than 150 MPN/100g (Non-fried)		

	Pathogen	Negative	a) Enrichment with BPW/TTB/SC medium, and confirm through biochemical and serological characteristics. b) Enrichment with GE, HE/SS and EMB agar, and confirm through biochemical and serological characteristics. c) 1) Enrichment and identify with coloration and coagulase test 2) Baird-Parker plate count 3) Staphylococcus MPN count	GB 4789.4 GB 4789.10 GB/T 4789.5 GB/T4789.12
	Peroxide value (count as fat)	Not more than 20 meq/100g (Fried)	1) extract fat by petroleum ether (GB/T5009.56) potassium hydroxide solution titration 2) Acid value: Peroxide value: a) potassium iodide solution titration b) ferric thiocyanate colorimetric method Carbonyl value: dinitrophenylhydrazine colorimetric method	GB/T5009.56 GB/T 5009.37
PRC Industry Standard for Instant Noodle (LS/T 3211-1995)	Fat	Not more than 24% (Fried)		GB/T 14772
	IoD Value	More than 1.0	Identified by indic colorific mensuration	GB 601 GB/T5009.56
	NaCl	Not more than 2.5%	Titration by standard solution of silver nitrate.	GB 601
	Recovery time	Not more than 4.0 min (Fried)	Place noodle in an insulation container with cover face; Add about five times weight boiling water as many as the noodle; Close the container and time-stamped. When using a piece of glass clamping softening noodles, observe gelatinization state without obvious hard heart, record the recovery time.	
		Not more than 6.0 min (Non-fried)		
	Weight variance	Not more than 3% of declared weight	Weight the packages Noddle three times by 0.5 g sensitivity scales; Compared with the declared weight; Claculated deviation	
	Tbc	Not more than 1,000 count/g		GB 4789.2
	Coliform group	Not more than 30 count/100g		GB 4789.3

Table 6: Case Study (2) Carbonated Soft Drinks: Specifications & Standards

Name of the Standard	Carbonated Beverage (Sparkling beverage)	Hygiene Standard of Carbonated Beverage
Scope	Classification; tech requirements; Assay method; Test rules; Labeling; packaging & transport	Limited level; Food additives; Process Hygiene requirement; Packaging; labeling; Storage & transport; test
Description	Beverage charged with external CO ₂ , excluding CO ₂ generated from fermentation .	Beverage charged with external CO ₂ , excluding CO ₂ generated from fermentation .
Essential Composition and Quality Factor	<ul style="list-style-type: none"> ● CO₂ content ≥ 1.5 ● Juice type: juice content ≥ 2.5% 	<ul style="list-style-type: none"> ● Should present the color and taste of main ingredients; without strange taste, bad smell and foreign object. ● Pb ≤ 0.3mg/L, As ≤ 0.3mg/L, Cu ≤ 5mg/L
Food Additives	<ul style="list-style-type: none"> ● GB2760 and GB14880 	<ul style="list-style-type: none"> ● GB2760 for Range and level requirement ● Also meet relative quality standard and regul'n
Contaminant		<ul style="list-style-type: none"> ● GB 2762
Hygiene		<ul style="list-style-type: none"> ● Microbe: Tbc ≤ 100 cfu/100ml, Coliform group ≤ 6 MPN/100ml, Mold count ≤ 10 cfu/100ml, Yeast ≤ 10 cfu/100ml, Pathogen (salmonella, Shigella, Staphylococcus aureus): Absent. ● GB12695 Beverage factory GMP Practice
Weight/Measure		
Labelling	<ul style="list-style-type: none"> ● GB7718 and GB13432. ● Juice type should declare juice content. 	
Methods of Analysis	<ul style="list-style-type: none"> ● CO₂ content test: <ol style="list-style-type: none"> 1) Reductor method; 2) Distilling titration 	<ul style="list-style-type: none"> ● Pb: To be tested as GB/T 5009.12 ● Total As: To be tested as GB/T 5009.11 ● Cu: To be tested as GB/T 5009.13 ● Micorbe: To be tested as GB/T 4789.21

Table 7: Case Study (2) Carbonated Soft Drinks: Methods of Analysis

Related Legislation	Item	Specification	Method of Analysis	Reference
Carbonated Beverages (GB10792)	CO₂ volume	≥ 1.5	1) Reductor method; 2) Treated with acid, caustic, and then distillation, absorb CO ₂ with NaOH. Add BaCl then titrate with HCl.	Assay method of CO ₂ in Carbonated beverages (GB/T 12143.4)
	Juice content	≥ 2.5%	NA	Only for Carbonated Beverages with Juice added
	Sensory evaluation	Should present the colour and taste of main ingredients; without strange taste, bad smell and foreign object.	Visually check	
	Lead	≤ 0.3 mg/L	1) Wet degradation method 2) Atomic absorption spectrophotometry 3) Polarographic analysis 4) Dithizone colourimetry method	National food safety standard -- Determine of lead in food (GB5009.12)
	Total Arsenic	≤ 0.2 mg/L (as of Arsenic)	1) Wet degradation method 2) Gutzeit method 3) Arsenic Stain Measurement method 4) Deoxidization and colourimetry method	Determination of total arsenic and abio-arsenic in foods (GB5009.11)
	Coper	≤ 5 mg/L	1) Atomic absorption spectrophotometry 2) Sodium diethyldithiocarbamate method	Determination of copper in foods (GB5009.13)
	Total plate count	≤ 100 cfu/ml	Cultured with PCA culture medium and count	National food safety standard -- Food microbiological examination: Aerobic plate count (GB4789.2)
	Coliform	≤ 6 MPN/100ml	1) Coliforms MPN count 2) Coliforms plate count	National food safety standard -- Food microbiological examination: Enumeration of coliforms (GB4789.3)
	Mold	≤ 10 cfu/ml	Cultured with Rose Bangal Medium and count	National food safety standard Food microbiological examination: Enumeration of moulds and yeasts (GB4789.15)

	Yeast	≤ 10 cfu/ml	Cultured with Rose Bangal Medium and count	National food safety standard Food microbiological examination: Enumeration of moulds and yeasts (GB4789.15)
	Pathogen (salmonella)	Negative	Enrichment with BPW/TTB/SC medium, and confirm through biochemical and serological characteristics.	National food safety standard Food microbiological examination: Salmonella (GB4789.4)
	Pathogen (Shigella)	Negative	Enrichment with GE, HE/SS and EMB agar, and confirm through biochemical and serological characteristics.	Microbiological examination of food hygiene--Examination of Shigella (GB4789.5)
	Pathogen (<i>Staphylococcus aureus</i>)	Negative	1) Enrichment and identify with colouration and coagulase test 2) Baird-Parker plate count 3) Staphylococcus MPN count	National food safety standard Food microbiological examination: <i>Staphylococcus aureus</i> (GB4789.10)

Table 8: Case Study (3) Prepared Frozen Foods: Specifications & Standards

Name of Standard	Contaminant and Physical/Chemical Index (≤)										
	Pb mg/kg	Cd mg/kg	Al mg/kg	Me Hg mg/kg	Tot. Hg mg/kg	Inor. As mg/kg	Tot. As mg/kg	Acid value KOH,mg/g	Perox. Val. g/100g	volatile basic N mg/100g	Aflatoxin µg/kg
GB19295 Hygienic std for quick-frozen and pre-packed food made of wheat & rice	0.5	--	--	--	--	--	0.5	3	0.15	15	5
GB 2715 Hygienic standards for grains	0.2	0.2 (rice/bean) 0.1 (wheat/corn /other)	--	--	0.02	0.15 (rice) 0.1(wheat) 0.2(other)	--	--	--	--	20(Corn) 10(Rice) 5(Other)
GB 2733 Hygienic std for fresh(frozen) marine products of animal origin	0.5 (Fish)	0.1 (Fish)	--	1.0 (Carnivore fish) 0.5(other)	--	0.1(fish) 0.5(other)	--	--	--	10--30	--
GB 2707 Hygienic standards for fresh(frozen) meat of livestock	0.2	0.1	--	--	0.05	0.05	--	--	--	15	--
GB16869 Fresh and frozen poultry product	0.2	0.5	--	--	0.05	--	--	--	--	15	--
DB11/615 Hygienic requirement of quick-frozen meat products	0.2	0.1	--	--	0.05	0.05	--	--	--	10	--
NYT1407 Green food-quick-frozen and pre-packed food made of wheat flour or rice	0.2	0.2	25	0.5 (含肉)	0.05 (含肉) 0.02 (无肉)	0.05	--	3(含馅)	0.15(含馅)	15(含肉)	5

Name of Standard	Microbiological Index(≤)							Storage temperature
	Tot. plate count (fresh) cfu/g	Tot. plate count (cooked) cfu/g	Colif.(fresh) MPN/100g	Colif. (cooked) MPN/100g	Mold count (fresh)	Mold count (cooked)	Microbe Pathogen	
GB19295 Hygienic std for quick-frozen and pre-packed food made of wheat & rice	3000000	100000	--	230	-	50	Not detected	-18°C±2°C
GB 2715 Hygienic standards for grains	--	--	--	--	--	--	--	--
GB 2733 Hygienic std for fresh(frozen) marine products of animal origin	--	--	--	--	--	--	--	-15°C to -18°C
GB 2707 Hygienic standards for fresh(frozen) meat of livestock	--	--	--	--	--	--	--	--
GB16869 Fresh and frozen poultry product	1000000	500000 (Frozen)	10000	5000 (Frozen)	--	--	0/25g (Salmonella) 0/25g (O157:H7)	-18°C±1°C
DB11/615 Hygienic requirement of quick-frozen meat products	500000(Total plate count)		5000(Coliform group)		--	--	Not detected	-18°C±2°C
NYT1407 Green food-quick-frozen and pre-packed food made of wheat flour or rice	3000000	100000	--	230	--	50	Not detected	-18°C±2°C

Table 9 Case Study (3) Prepared Frozen Foods: Methods of Analysis

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 19295 <Hygienic standard for quick-frozen and pre-packed food made of wheat flour and rice>	Lead	0.5 mg/kg	Dry incineration method →Atomic absorption spectrophotometry	GB 5009.12
	Total arsenic	0.5 mg/kg	Dry incineration method →Hydriding →Atomic fluophotometer	GBT 5009.11
	Acid value	3 mg/g	Acid value measurement method by titration	GBT 5530
	Peroxide value (for fat)	0.15 g/100 g	Peroxide value measurement method by titration	GBT 5538
	Total volatile basic nitrogen	15 mg/100 g	Titration with hydrochloric acid	SCT 3032
	Aflatoxin B1	5 µg/kg	Thin-layer chromatography	GBT 5009.22
	Aerobic plate count	3,000,000 cfu/g (raw) 100,000 cfu/g (heated before freezing)	Standard agar medium 36±1.0°C, 48±2h	GBT 4789.2
	Coliform	230MPN/100g (heated before freezing)	Coliform MPN count method: LST broth fermentation tube →gas generation →BGLB broth fermentation	GB 4789.3
	Salmonella	Negative	Agar plate count →serology test	GB 4789.4
	Shigella	Negative	Biochemical test →serology test	GBT 4789.5
	<i>Staphylococcus aureus</i>	Negative	Biochemical test →plasma-coagulase test	GB 4789.10
	Mold	≤50 cfu/g (heated before freezing)	Microscopic examination count method	GB 4789.15
GB 16869 <Fresh and frozen poultry product>	Mercury	0.05 mg/kg	Dry incineration method →Atomic fluophotometer	
GB 2733 <Hygienic standard for fresh and frozen marine products from animal origin>	Cadmium (for fish)	0.1 mg/kg	Dry incineration method →Atomic absorption spectrophotometry	GBT 5009.15

Table 10 Case Study (4) Cow's Milk: Food Specifications & Standards and Methods of Analysis

● **Raw Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk and milk products	Freezing point (°C) (test the sample after milking for 3h; only for Holstein cows)	-0.500~ -0.560	GB 5413.38 Determination of freezing point in raw milk	
	Relative density (20°C/4°C)	≥ 1.027	GB 5413.33 Determination of specific gravity in raw milk	
	Protein (g/100 g)	≥ 2.8	GB 5009.5 Determination of protein in foods	
	Fat (g/100 g)	≥ 3.1	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	Impurities (mg/kg)	≤ 4.0	GB 5413.30 Determination of impurities in milk and milk products	
	NFMS (g/100 g)	≥ 8.1	GB 5413.39 Determination of nonfat total milk solid in milk and milk products	
	Acidity (°T) (only for Holstein cows)	≥ 12~18	GB 5413.34 Determination of acidity in milk and milk products	
	Contaminants	see GB 2762 Maximum levels of contaminants in foods		
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		
	TPC [cfu/g(mL)]	≤ 2×10 ⁶	GB 4789.2 Food microbiological examination: Aerobic plate count	

● **Pasteurized Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk	Fat (g/100 g) (Only for full cream pasteurized milk)	≥ 3.1	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	Protein (g/100 g)	≥ 2.9	GB 5009.5 Determination of protein in foods	
	NFMS (g/100 g)	≥ 8.1	GB 5413.39 Determination of nonfat total milk solid in milk and milk products	
	Acidity (°T)	≥ 12~18	GB 5413.34 Determination of acidity in milk and milk products	
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		

and milk products	TPC (cfu/g or cfu/mL)	n=5; c=2 m=50,000; M=100,000	GB 4789.2 Food microbiological examination: Aerobic plate count	Samples preparation: GB 4789.1 Food microbiological examination: General guidelines and GB 4789.18 Food microbiological examination: Milk and milk products
	Coliform (cfu/g or cfu/mL)	n=5; c=2 m=1; M=5	GB 4789.3 Food microbiological examination: Enumeration of coliforms (plate count method)	
	<i>Staphylococcus aureus</i>	n=5; c=0 0/25 g (mL)	GB 4789.10 Food microbiological examination: <i>Staphylococcus aureus</i> (Qualitative test)	
	Salmonella	n=5; c=0 0/25 g (mL)	GB 4789.4 Food microbiological examination: Salmonella	

● **Sterilized Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk and milk products	Fat (g/100 g) (Only for full cream sterilized milk)	≥ 3.1	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	Protein (g/100 g)	≥ 2.9	GB 5009.5 Determination of protein in foods	
	NFMS (g/100 g)	≥ 8.1	GB 5413.39 Determination of nonfat total milk solid in milk and milk products	
	Acidity (°T)	≥ 12~18	GB 5413.34 Determination of acidity in milk and milk products	
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		
	Microbiological Index	commercial sterilization	GB/T 4789.26 Microbiological examination of food hygiene-Examination of commercial sterilization of canned food	

● **Modified Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk and milk products	Fat (g/100g) (Only for full cream products)	≥ 2.5	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	Protein (g/100g)	≥ 2.3	GB 5009.5 Determination of protein in foods	
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		
	Microbiological Index (For the modified milk which produced by sterilization process)	commercial sterilization	GB/T 4789.26 Microbiological examination of food hygiene-Examination of commercial sterilization of canned food	
	TPC (cfu/g or cfu/mL)	n=5; c=2 m=50,000; M=100,000	GB 4789.2 Food microbiological examination: Aerobic plate count	Samples preparation: GB 4789.1 Food microbiological examination: General guidelines and GB 4789.18 Food microbiological examination: Milk and milk products
	Coliform (cfu/g or cfu/mL)	n=5; c=2 m=1; M=5	GB 4789.3 Food microbiological examination: Enumeration of coliforms (plate count method)	
	<i>Staphylococcus aureus</i>	n=5; c=0 0/25g (mL)	GB 4789.10 Food microbiological examination: <i>Staphylococcus aureus</i> (Qualitative test)	
Salmonella	n=5; c=0 0/25g (mL)	GB 4789.4 Food microbiological examination: Salmonella		

● **Fermented Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk and milk products	Fat (g/100g) (Only for full cream products)	fermented milk: ≥ 3.1 flavored fermented milk: ≥ 2.5	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	NFMS (g/100g)	fermented milk: ≥ 8.1	GB 5413.39 Determination of nonfat total milk solid in milk and milk products	
	Protein (g/100g)	fermented milk: ≥ 2.9 flavored fermented milk: ≥ 2.3	GB 5009.5 Determination of protein in foods	
	Acidity (°T)	≥ 70.0	GB 5413.34 Determination of acidity in milk and milk products	
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		
	Coliform (cfu/g or cfu/mL)	n=5; c=2 m=1; M=5	GB 4789.3 Food microbiological examination: Enumeration of coliforms (plate count method)	Samples preparation: GB 4789.1 Food microbiological examination: General guidelines and GB 4789.18 Food microbiological examination: Milk and milk products
	<i>Staphylococcus aureus</i>	n=5; c=0 0/25g (mL)	GB 4789.10 Food microbiological examination: <i>Staphylococcus aureus</i> (Qualitative test)	
	Salmonella	n=5; c=0 0/25g (mL)	GB 4789.4 Food microbiological examination: Salmonella	
Yeasts	≤ 100	GB 4789.15 Food microbiological examination: Enumeration of moulds and yeasts		
Moulds	≤ 30			

● **Evaporated Milk, Sweetened Condensed Milk and Formulated Condensed Milk**

Related Legislation	Item	Specification	Method of Analysis	Reference
GB 5413.10-2010 National food safety standard Determination of vitamin K1 in foods for infants and young children, milk and milk products	Protein (g/100g)	Evaporated milk: $\geq 34\%$ of NFMS Sweetened condensed milk: $\geq 34\%$ of NFMS Formulated evaporated milk: ≥ 4.1 Formulated sweetened condensed milk: ≥ 4.6	GB 5009.5 Determination of protein in foods	NFMS (%) = 100% - fat (%) - water (%) - sucrose (%)
	Fat(X) (g/100g)	Evaporated milk: $7.5 \leq X < 15.0$ Sweetened condensed milk: $7.5 \leq X < 15.0$ Formulated evaporated milk: $X \geq 7.5$ Formulated sweetened condensed milk: $X \geq 8.0$	GB 5413.3 Determination of fat in foods for infants and young children, milk and milk products	
	Milk solid (g/100g)	Evaporated milk: ≥ 25.0 Sweetened condensed milk: ≥ 28.0	NA	Milk solid (%) = 100% - water (%) - sucrose (%)
	sucrose (g/100g)	Sweetened condensed milk: ≤ 45.0 Formulated sweetened condensed milk: ≤ 48.0	GB 5413.5 Determination of lactose and sucrose in foods for infants and young children, milk and milk products	
	Water (%)	Sweetened condensed milk: ≤ 27.0 Formulated sweetened condensed milk: ≤ 28.0	GB 5009.3 Determination of moisture in foods	
	Acidity (°T)	≤ 48.0	GB 5413.34 Determination of acidity in milk and milk products	
	Mycotoxins	see GB 2761 Maximum levels of mycotoxins in foods		

4.5 Republic of Indonesia

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.

2. REGULATORY SYSTEM AND RESPECTIVE STANDARDS FOR FOOD

The relationships are shown in Figure 1.

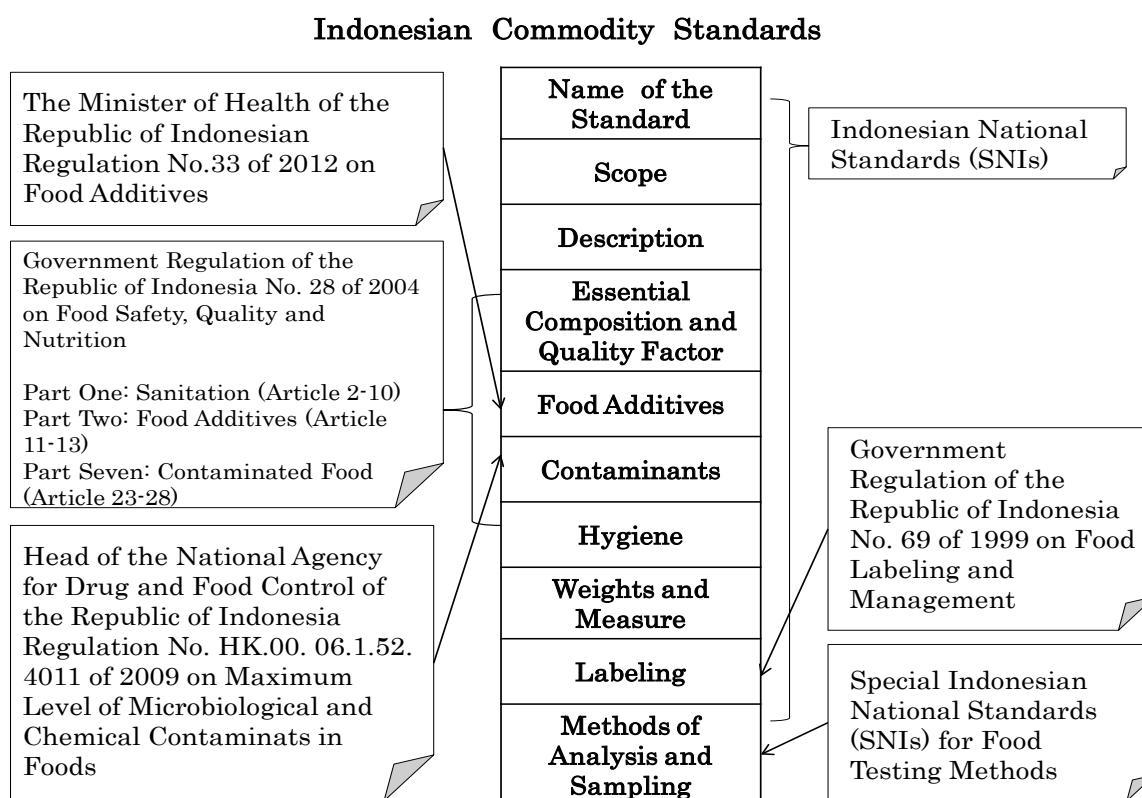


Figure 1: Indonesian Commodity Standards and Relevant Laws

3. RELEVANT FOOD 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 four 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 person 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 other areas:

- (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.

4. INDONESIAN NATIONAL STANDARDS (SNI)

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 (Format is listed in Table 1).

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.

Table 1: Format of Indonesian National Standard

Name of the Standard
Scope
Normative Reference
Definition
Composition and Quality Requirements
Sampling Method
Testing Methods
Hygienic and Sanitation Practices
Packaging Method
Labelling Requirements
Appendices

The selected Indonesian National Standards (SNIs) for foods are listed in Table 2, and the selected Indonesian National Standards (SNIs) for Food Testing Methods in Table 3.

Table 2: List of Selected Indonesian National Standards (SNIs) for Foods

Rice and Wheat Noodles			
1	Instant Rice Noodle SNI 01-3742-1995	4	Dried Noodles SNI 01-2974-1996
2	Rice Noodle SNI 01-2975-2006	5	Noodles SNI 01-6630-2002
3	Wet Wheat Noodles SNI 01-2987-1992	6	Instant Noodle SNI 01-3551-2000
Beverages			
1	Energizer Drink SNI 01-6684-2002	7	Flavoured Fermented Milk Drink SNI 7552:2009
2	Squash Drinks SNI 01-2984-1998	8	Coffee Drinks in Package SNI 01-4314-1996
3	Isotonik Drink SNI 01-4452-1998	9	Traditional Drink Powder SNI 01-4320-1996
4	Nutritious Beverages for Pregnant and or Suckled Mothers SNI 01-7148-2005	10	Fruit Juice SNI 01-3719-1995
5	Packaged Tea Drinks SNI 01-3143-1992	11	Mango Fruit Juice SNI 7382:2009
6	Orange Flavour Drink SNI 01-3722-1995	12	Orange Flavoured Drink Powder SNI 01-3722-1995
Frozen Seafood		Meat	
1	Frozen Scallop SNI 3230.1:2006	1	Quality of Beef Carcass and Meat SNI 3932:2008
2	Packed Frozen Steamed Crab SNI 3231.1:2010	2	Corned Beef SNI 1-3775-2006
3	Frozen Lobster SNI 3228.1:2010		

Miscellaneous Products			
1	Fish Cracker SNI 2713.1:2009	7	Canned Squid SNI 7317.1:2009
2	Prawn Crackers SNI 2714.1:2009	8	Coffee Powder SNI 01-3542-2004
3	Cooking Oil SNI 01-3741-2002	9	Maltodextrin SNI 7599:2010
4	Chilli Sauce SNI 01-2976-2006	10	Wheat Flour for Food SNI 3751:2009
5	Tomato Sauce SNI 01-3546-2004	11	Sago Starch Flour SNI 3729:2008
6	Fruit Jam SNI 3746:2008	12	White Sugar Crystal SNI 3140.3:2010

Table 3: List of Selected Indonesian National Standards (SNIs) for Food Testing Methods

SNI 2897: 2008 Testing methods for microbiological count in meat, egg, and milk, and their products		Reference: <ul style="list-style-type: none"> USFDA. 2001, 2006. Bacteriological Analytical Manual. Division of Microbiology, US Food and Drug Administration, Gaithersburg, USA. FAO. 1992. Manual of Food Quality Control. Microbiological Analysis, 4th ed., Food and Agriculture Organization, United Nations. 	
1	Total plate count (TPC)	5	<i>Salmonella spp.</i>
2	Coliform	6	<i>Campylobacter spp.</i>
3	<i>E.coli</i>	7	<i>Listeria monocytogenes</i>
4	<i>Staphylococcus aureus</i>		
SNI 01-2891-1992: Food testing methods		SNI 19-2896-1998: Metal contaminants testing method in foods Reference: AOAC, 1995	
SNI 01-2354.5-2006 Determination of Cadmium (Cd) in Fishery Products Reference: <ul style="list-style-type: none"> Determination of Metals in Foods by Atomic Absorption Spectrophotometry after Dry Ashing: NMKL, Collaborative Study. Journal of AOAC International, Vol. 83, No. 5: pp 1201-1211 AOAC. 2000. Official Methods of Analysis. 17th ed. Vol. 1, Chapter 9:pp 19-22 		SNI 01-2354.7-2006 Determination of Lead (Pb) in Fishery Products Reference: <ul style="list-style-type: none"> Determination of Metals in Foods by Atomic Absorption Spectrophotometry after Dry Ashing: NMKL, Collaborative Study. Journal of AOAC International, Vol. 83, No. 5: pp 1201-1211 AOAC. 2000. Official Methods of Analysis. 17th ed. Vol. 1, Chapter 9:pp 19-22 	
SNI 2354.10:2009 Determination of Histamine by Spectrofluorimetry and HPLC in Fishery Products Reference: <ul style="list-style-type: none"> John.M. Tennyson and R. Steve. Winlers. 2000. Histamin in Seafood: Fluorimetric Method, Fish and Other Marine Products. AOAC. 2000. Official Methods of Analysis. 17th ed. Vol 1, Chapter 35:pp 17-19 		SNI 01-2332.1-2006 Determination of Coliform and <i>E. coli</i> in Fishery Products Reference: <ul style="list-style-type: none"> AOAC. 2000. Official Methods of Analysis. 17th ed. USFDA. 1998. Bacteriological Analytical Manual. 8th ed. Note: SNI 01-2332.2-2006 (<i>Salmonella</i>), SNI 01-2332.3-2006 (TPC), SNI 01-2332.4-2006 (<i>Vibrio cholerae</i>), SNI 01-2332.5-2006 (<i>Vibrio parahaemolyticus</i>), SNI 01-2332.6-2006 (<i>Worm parasite</i>), SNI 01-2332.7-2006 (mould and yeast)	
SNI 01-4866-1998: Arsenic testing method in foods		SNI 01-2354.6-2006 Determination of Mercury (Hg) in Fishery Products	

Reference: AOAC. 1995. Official Methods of Analysis.

Reference:

▪ AOAC. 2000. Official Methods of Analysis. 17th ed. Vol. 1, Chapter 9:pp 36

5. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

5.1 Overview

In Indonesia, food additives are regulated by the Ministry of Health and National Agency for Drug and Food Control (NADFC or BPOM). The Ministry of Health is responsible for determining the list and types of food additives permitted to be used in foods in general, while NADFC/BPOM is responsible for setting the permissible use limits in specific foods as well as for monitoring of use and enforcement aspects. 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) Decision of the Director-General for Drug and Food Control No. 02592/B/SK/VIII/91 on Use of Food Additives; and
- 2) 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) Minister of Health Regulation No. 33 of 2012 on Food Additives:
This regulation has repealed earlier regulations on food additives, such as Minister of Health Regulation No. 722/MENKES/PER/IX/88 on Food Additives and Minister of Health Regulation No. 1168/MENKES/PER/X/1999 amending Minister of Health

Regulation No. 722/MENKES/PER/IX/88 on Food Additives. However, sections relating to the permissible use limits as found in the previous regulations are still applicable as long as they have not been revised by more updated regulations.

5.2 Food Additive Definitions & 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. 33 of 2012 on Food Additives as follows: “Food additive means substances that are added to food to affect the properties and form of food” Additionally, food additives that are to be used in food must satisfy the below conditions:

- 1) Food additives are not meant to be consumed directly and/or not to be treated as raw ingredients;
- 2) Food additives may or may not possess nutritional value, are intentionally added to food for a technological purpose in the production, processing, treatment, packing, packaging, storage and/or transportation of food to create or with the intention to create a component or affect the properties of the food, whether directly or indirectly;
- 3) Food additives do not include contaminants or substances that are added to food to fortify or increase the nutritional value.

Regulation No. 33 of 2012 also divides food additives into 27 functional classes in Indonesia, as follows:

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

13) Acidity regulator	27) Sequestrant
14) Preservative	

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 additives (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.”).

5.3 Permitted Food Additives and Maximum Limits

Although the regulations have been appealed, the positive list of permitted food additives together with the maximum permitted use levels found in the appendixes of Regulation No. 722/MENKES/PER/IX/88 and have been updated once by Regulation No. 1168/MENKES/PER/X/1999 are still applicable, subject to further revisions by future regulations.

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

5.4 Prohibited Substances for Use as Food Additives

A negative list of substances prohibited to be used as food additives are included in Regulation No. 33 of 2012. These include:

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

- 12) Cocaine,
- 13) Nitrobenzene,
- 14) Cinnamyl anthranilate,
- 15) Dihydrosafrole,
- 16) Tonka bean,
- 17) Calamus oil,
- 18) Tansy oil, and
- 19) Sasafras oil

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.

5.5 Specifications & Standards 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.

5.6 Application, Assessment, and Approval of New 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 additive is also approved for use in other countries

5.7 Labelling of Food Additives in Foods

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 be included. For colours used as food additive in particular, the special index numbers also needs to be attached.

Minister of Health Regulation No. 33 of 2012 also provides for specific labelling requirements for:

- 1) Food that contains artificial sweeteners must include on the label the words “Contains artificial sweeteners, recommended not to be consumed by children below the age of 5 (five), pregnant women, and breastfeeding mothers”;
- 2) Special dietary foods for diabetics and/or low calorie foods that contain artificial sweeteners must include on the label the words “For diabetics and/or persons who need low calorie food”;
- 3) Food that contains the sweetener poliol, must include the reminder “Excessive consumption has a laxative effect”;
- 4) Food that contains flavouring, must include the name of the flavour grouping (natural, nature identical, and artificial) in the ingredients list;
- 5) Food that contains carry over food additives must include on the label the carry over additive after the ingredient that contains the said food additive

Similarly, 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.

5.8 Summary of Food Additives

The definitions regarding food additives such as flavourings, processing aids, and carry over are summarized in Table 4, and other definitions such as designated/existing food additives and prohibited substances are summarized in Table 5.

6. SPECIFICATIONS & STANDARDS, AND METHODS OF ANALYSIS FOR GENERAL FOODS

Standards and methods of analysis for general foods are summarized in Table 6. Standards and methods of analysis for the food categories taken up in the Case Study are described in the food categories, respectively.

7. CASE STUDIES

(1) Instant Noodles

Food Specifications & Standards:

The specifications and standards for Instant Noodles (Mi Instan)” (SNI 01-3551-2000) are shown in Table 7.

Methods of Analysis:

General items concerning microbiological and chemical contaminants, as well as the specifications and methods of analysis concerning Instant Noodles (Mi Instan), Snack noodles (Mi makanan ringan)(SNI 01-6630-2002), and Instant rice noodles (Bihun instan) (SNI 01-3742-1995) are described in Table 8.

Food Additives:

Summary of food Additives for Instant Noodles (Mi Instan) and Instant Rice Noodles (Bihun instan) are shown in Table 9.

(2) Carbonated Soft Drinks

Food Specifications & Standards:

The specifications & standards for Energy drinks (SNI 01-6684-2002) are shown in Table 10, because there are no product specifications established for carbonated soft drinks.

Methods of Analysis:

General items concerning microbiological and chemical contaminants, as well as the specifications and methods of analysis concerning Soda water (Air soda: SNI 01-3708-1995), Soda (Limun: SNI 01-2972-1998), Diabetic diet soda (Limun diet diabetes: SNI 01-3699-1995), and Energy drinks (Minimum energy: SNI 01-6684-2002) are described in Table 11.

Food Additives:

Summary of food additives for “Lemonade” (SNI 01-2972-1998), “Diet lemonade” (SNI 01-3699-1995), “Soda water” (SNI 01-3708-1995) and “Energy drinks” (SNI 01-6684-2002) are shown in Table 12.

(3) Prepared Frozen Foods

Food Specifications & Standards:

The specifications & standards for Frozen scallops (SNI 3230.1:2010) are shown in Table 13 because there are no .product specifications established for prepared frozen foods.

Methods of Analysis:

General items concerning microbiological and chemical contaminants, as well as the specifications and methods of analysis for Frozen breaded shrimps (SNI 01-6163-1999)

and Chicken nuggets (SNI 01-6683-200) are described in Table 14.

Food Additives: Summary of food additives for “Chicken nugget” (SNI 01-6683-200) and “Frozen breaded shrimp” (SNI 01-6163-1999) is shown in Table 15.

(4) Cow’s Milk

The specifications & standards, methods of analysis, and summary of food additives for “Pasteurized milk” (SNI 01-3951-1995) are shown in Table 16 and Table 17.

Table 4: Summary/Definition (General) of Food Additives (General)

	Description/Definition	Reference
Related legislation	<p>Regulation No. 33 of 2012</p> <p>Minister of Health of the Republic of Indonesia Regulation No. 722/MENKES/PER/IX/88 on Food Additives</p> <p>SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products</p>	<p>http://www.pom.go.id/public/hukum_perundang/pdf/Regulation_%20722.pdf</p> <p>http://agri.sucofindo.co.id/Extra/PDF/SNI_01-0222-1995_Bahan_Tambahan_Makanan.pdf (in Indonesian)</p> <p>http://pustan.bpkimi.kemenperin.go.id/files/SNI_01-7152-2006.pdf</p>
Summary (General)/Definitions		
Definition of food additives	<p>The definition of food additives is further defined in subsidiary regulations in Minister of Health Regulation No. 33 of 2012 on Food Additives as follows:</p> <p>“Food additive means substances that are added to food to affect the properties and form of food”.</p> <p>1) Food additives are not meant to be consumed directly and/or not to be treated as raw ingredients.</p> <p>2) Food additives may or may not possess nutritional value, are intentionally added to food for a technological purpose in the production, processing, treatment, packing, packaging, storage and/or transportation of food to create or with the intention to create a component or affect the properties of the food, whether directly or indirectly.</p> <p>3) Food additives do not include contaminants or substances that are added to food to fortify or increase the nutritional value.</p>	<p>Regulation No. 33 of 2012 Article 1.1, 2</p>
Flavours	<p>“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.</p> <p>“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.</p>	<p>Regulation No. 722/MENKES/PER/IX/88 Article 1, 14</p> <p>SNI 01-7152-2006 Food additives – Flavours - Conditions for use in food products</p>

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	“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.”	General Guidelines on Food Labelling

Table 5: Summary/Definition of Food Additives (Specific)

	Description/Definition	Reference
Related legislation	<p>Minister of Health of the Republic of Indonesia Regulation No. 33 of 2012 on Food Additives</p> <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>
Summary (Specific)/Additional Laws		
1	List of Designated Food Additives	Includes antifoaming agent, anticaking agent, antioxidant, carbonating agent, emulsifying salt, packaging gas, humectant, glazing agent, sweetener, carrier, gelling agent, foaming agent, acidity regulator, preservative, raising agent, emulsifier, thickener, firming agent, flavour enhancer, bluing agent, stabilizer, colour retention agent, flavouring, flour treatment agent, colour, propellant, sequestrant.
		Regulation No. 33 of 2012, 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	1) Boric acid and its compounds, 2) Salicylic acid and its salts, 3) Diethylpirocarbonate DEPC, 4) Formaldehye, 5) Dulcin, 6) Potassium bromated, 7) Potassium chlorate, 8) Chloramphenicol, 9) Brominated vegetable oils, 10) Nitrofurazone, 11) Dulcamara, 12) Cocaine, 13) Nitrobenzene, 14) Cinnamyl anthranilate, 15) Dihydrosafrole, 16) Tonka bean, 17) Calamus oil, 18) Tansy oil, 19) Sasafras oil SNI 01-7152-206 Food additives set conditions for use of flavouring materials in food.	Regulation No. 33 of 2012 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 6: Specifications & Standards, and Methods of Analysis for General Foods

Related legislation	Item	Specification	Analytical Methods	Reference
Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52.4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Food	Microbiological contaminants	As specified in Regulation No. HK.00.06.1.52.4011 of 2009	SNI 01-2891-1992 Analytical Methods for Food and Beverages; SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Metal contaminants	As specified in Regulation No. HK.00.06.1.52.4011 of 2009	SNI 01-2896-1998 Analytical Methods for Metal Contaminants; SNI 01-4866-1998 Analytical Methods for Arsenic	
	Other chemical contaminants	As specified in Regulation No. HK.00.06.1.52.4011 of 2009	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
Joint Decision of Ministry of Health and Ministry of Agriculture No. 881/MENKES/SKB/VIII/1996 on Maximum Residue Limits for Agricultural Products	MRLs for pesticide residues	As specified in Joint Decision No. 881/MENKES/SKB/VIII/1996	Analytical Methods as determined by the Pesticide Commission of the Department of Agriculture, AOAC Methods, and international methods.	
SNI 7313:2008 Maximum Residue Limits for Agricultural Products	MRLs for pesticide residues	As specified in SNI 7313:2008	Analytical Methods as determined by the Pesticide Commission of the Department of Agriculture, AOAC Methods, and international methods.	

Table 7: Case Study (1) Instant Noodles: Specifications & Standards

	SNI 01-3551- 2000
Name of the Standard	Instant Noodle
Scope	This standard covers definition, composition and quality requirements, sampling, testing method, hygiene, packaging method and labelling of instant noodle.
Description	Instant noodle is made from dough of wheat or rice or other flour as main ingredient with or without addition of other materials. It can be treated with alkaline. Pregelatinization process is done before the noodle is dried by frying process or other dehydration process. Note 1 The above definition consists of “mi” (noodle from wheat flour), “bihun” (from rice and sago), “sohun” (from mango bean and or sago) and “kwetiau” (from rice and or wheat flour).

	<p>Note 2 Instant is indicated by the presence of added spices and it needs a rehydration process to become ready for consumption.</p>
<p>Essential Composition and Quality Factor</p>	<p>Composition Main Raw Materials 1. Wheat flour, rice flour or other flour. 2. Water</p> <p>SNI 01-3751-2000: Wheat flour for foods Other ingredients which can be added 1. Starch and other flour 2. Salt 3. Hydrocolloids 4. Sugar and its derivatives 5. Fats and oils 6. Permitted food additives 7. Permitted flavouring agents 8. Spices and spices products 9. Egg and egg products 10. Livestock, poultry, fish and their products 11. Milk and milk products 12. Vegetable and vegetable products 13. Fruit and fruit products 14. Vitamin and mineral</p> <p>SNI 01-3556-1999: Kitchen salt Quality Requirements</p>

	No.	Testing Criteria	Unit	Requirements
	1	Conditions		
	1.1	Texture		normal/acceptable
	1.2	Aroma		normal/acceptable
	1.3	Taste		normal/acceptable
	1.4	Colour		normal/acceptable
	2	Foreign materials		None
	3	Integrity	% w/w	Min 90
	4	Moisture content		
	4.1	Frying process	% w/w	Max. 10.0
	4.2	Drying process	% w/w	Max. 14.5
	5	Protein content		
	5.1	Noodle from wheat flour	% w/w	Min. 8.0
	5.2	Noodle from flour other than wheat flour	% w/w	Min. 4.0
	6	Acid value	mg KOH/g of oil	Max. 2.0
	7	Metal contaminants		
	7.1	Lead (Pb)	mg/kg	Max. 2.0
	7.2	Mercury (Hg)	mg/kg	Max. 0.05
	8	Arsen (As)	mg/kg	Max. 0.5
	9	Microbiological contaminants		
	9.1	Total Plate Counts	colony/g	Max 1.0 x 10 ⁶
	9.2	<i>E. coli</i>	MPN/g	<3
	9.3	Salmonella	-	Negative in 25 g
	9.4	Moulds	colony/g	Max 1.0 x 10 ³
Food Additives	The Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives The Minister of Health of the Republic of Indonesia Regulation No. 1168/MenKes/PER/X/1999 of 1999 on Food Additives			
Contaminant	Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52. 4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Foods			
Hygiene	Government Regulation of the Republic of Indonesia No. 28 of 2004 on Food Safety, Quality and Nutrition, Part One Sanitation (Article 2-10)			
Weights and Measures	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement			

Labelling	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement
	The Head of the National Agency for Drug and Food Control of the Republic of Indonesia Decree No. HK.00.05.52.6291 of 2007 on Nutrition Labelling Reference for Food Products
	The Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.51. 0475 of 2005 on Guideline for Putting Information of Nutrient Value on the Label
Methods of Analysis and Sampling	Sampling Method Sampling in accordance with CAC/RM 42-1969, the FAOMWHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL-6.5)
	Methods of Analysis AOCS official method Cd.3d.63-1993 : Determination of acid value.
	SNI 01-2891-1992: Food testing methods (conditions, moisture, protein, foreign matters)
	SNI 19-2896-1998: Metal contaminants testing method in foods
	SNI 19-2897-1992: Microbiological contaminants testing methods
	SNI 01-4866-1998: Arsenic testing method in foods

Table 8: Case Study (1) Instant Noodles: Specifications and Methods of Analysis

Related legislation	Item	Specification	Analytical Methods	Reference
Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52.4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Food	Total Plate Count	< 1 x 10 ⁶ cfu/g, 30°C for 72h	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Coliforms	< 100 cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Staphylococcus aureus</i>	< 1 x 10 ³ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Bacillus cereus</i>	< 1 x 10 ³ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Yeast & Moulds	< 1 x 10 ⁴ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Escherichia coli</i>	< 1 x 10 ⁴ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Deoksinivalenol	750 ppb or mcg/kg	SNI 01-2891-1992 Analytical Methods for Food and Beverages	

SNI 01-3551-2000 Instant Noodles (Mi Instan)	Quality characteristics for texture, aroma, taste and colour	Normal/acceptable	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Foreign matter	Not present	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Integrity	Min. 90% W/W	SNI 01-3551-2000 Item 6.1.2	
	Moisture content	Using frying process: 10.0% w/w; Using drying process: 14.5% w/w	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Protein content	Wheat noodles: Min 8.0% w/w; Other noodles: Min 4.0% w/w	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Acid value	Max 2.0 mg KOH/g oil	AOCS Official Method Cd 3d-63, 1993. Determination of acid value.	
	Metal contaminants	Lead: < 2.0 mg/kg; Mercury: <0.05 mg/kg	SNI 01-2896-1998 Analytical Methods for Metal Contaminants	
	Arsenic	< 0.5 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 1.0 x 10 ⁶ cfu/g; <i>E. coli</i> : < 3 MPN/g; Salmonella: absent per 25 g; Moulds: < 1.0 x 10 ³ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
Sampling	In accordance with FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (CAC/RM-1969)			
SNI 01-6630-2002 Snack noodles (Mi makanan ringan)	Quality characteristics for texture, aroma, taste and colour	Normal/acceptable	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Foreign matter	Not present	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Moisture content	Max 7.0% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Protein content	Min 5.0% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Acid value	Max 2.0 mg KOH/g oil	SNI 01-6630-2002 Item 6.6	
	Borax	Negative	SNI 01-2358-1991 Determination of borax content in food	

	Prohibited food additives	Negative as described in Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives and Regulation No. 1168/Menkes/PER/X/1999 on Food Additives	SNI 01-2895-1992 Analytical Methods for Colour Additives; SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives	
	Metal contaminants	Lead: < 1.0 mg/kg; Copper: <10.0 mg/kg; Zinc: < 40.0 mg/kg; Mercury: <0.05 mg/kg	SNI 01-2896-1998 Analytical Methods for Metal Contaminants	
	Arsenic	< 0.5 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 1.0 x 10 ⁴ cfu/g; <i>E. coli</i> : <3 MPN/g; Salmonella: absent per 25g; Moulds: < 1.0 x 10 ³ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
SNI 01-3742-1995 Instant rice noodles (Bihun instan)	Quality characteristics for texture, aroma, taste and colour	Normal/acceptable	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Foreign matter	Not present	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Integrity	Min. 90% W/W	SNI 01-3742-1995 Item 5.4	
	Cooking time	Max 3 minutes (bihun : water is 1:5)	SNI 01-3742-1995 Item 5.5	
	Moisture content	Max 11.0% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Ash content (without salt)	Max 2% W/W	SNI 01-3742-1995 Item 5.7	
	Protein content	Min 6% W/W (N x 6.25)	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Acid value	Max 3 mg KOH/100g sample	SNI 01 - 3555 - 1994 Analytical Methods for Fats & Oils	
	Metal contaminants	Lead: < 1.0 mg/kg; Copper: <10.0 mg/kg; Zinc: < 40.0 mg/kg; Mercury: <0.05 mg/kg	SNI 01-2896-1998 Analytical Methods for Metal Contaminants	
	Arsenic	< 0.5 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	

	Microbiological contaminants	Total Plate Count: < 1.0 x 10 ⁶ cfu/g; <i>E. coli</i> : < 3 MPN/g; Moulds: < 1.0 x 10 ³ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Sampling	In accordance with FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (CAC/RM-1969)		
	Prohibited food additives	Negative as described in Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives and Regulation No. 1168/Menkes/PER/X/1999 on Food Additives	SNI 01-2895-1992 Analytical Methods for Colour Additives; SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives	

Table 9: Case Study (1) Instant Noodles: Food Additives

	Summary/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 10: Case Study (2) Carbonated Soft Drinks (Energy Drinks): Specifications & Standards

	SNI 01-6684-2002
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Name of the Standard	Energy Drinks			
Scope	This standard covers reference, definition, requirements, sampling, testing methods, labelling and packaging for energy drinks			
Description	Energy drink is a drink which contains one or more substances easily absorbed by the human body to produce energy with or without permitted food additives Note: Energy drink is not a food supplement			
Essential Composition and Quality Factor	Quality Requirements			
	No.	Testing Criteria	Unit	Requirements
	1	Conditions		
	1.1	Appearance		transparent
	1.2	Aroma		normal/specific
	1.3	Taste		normal/ specific
	2	pH		2.5 – 4.0
	3	Total energy	Kcal/portion	Min. 100
	4	Total sugar (as saccharose)	% w/w	Min. 12.5
	5	Reducing sugar	% w/w	Min. 7
	6	Taurine	mg/portion	Max. 1000
	7	Caffeine	mg/portion	Max. 50
	8	Food Additives		
	8.1	Artificial sweeteners		as SNI 01-0222-1995
	8.2	Preservatives		as SNI 01-0222-1995
	8.3	Colouring		as SNI 01-0222-1995
	9	Metal contaminants		
	9.1	Lead (Pb)	mg/kg	Max. 0.2
	9.2	Copper (Cu)	mg/kg	Max. 2.0
	9.3	Zinc (Zn)	mg/kg	Max. 5.0
	9.4	Tin (Sn)		Max. 40/250.0*
	10	Arsen contaminant (As)	Mg/kg	Max. 0.1
	11	Microbiological contaminants		
	11.1	Total Plate Counts	colony/ml	Max 2.0 x 10 ²
	11.2	Coliform	MPN/ml	Max. 20
	11.3	<i>E. coli</i>	MPN/ml	<3
	11.4	Salmonella	/25 ml	negative
11.5	Staphylococcus aureus	colony/ml	0	
11.6	Vibrio sp.	/ml	negative	
11.7	Moulds	colony/ml	Max 50	
11.8	Yeast	colony/ml	Max 50	
	*packaged in can			

Food Additives	The Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives The Minister of Health of the Republic of Indonesia Regulation No. 1168/MenKes/PER/X/1999 of 1999 on Food Additives
Contaminant	Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52. 4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Foods
Hygiene	Government Regulation of the Republic of Indonesia No. 28 of 2004 on Food Safety, Quality and Nutrition, Part One Sanitation (Article 2-10)
Weights and Measures	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement
Labelling	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement The Head of the National Agency for Drug and Food Control of the Republic of Indonesia Decree No. HK.00.05.52.6291 of 2007 on Nutrition Labelling Reference for Food Products The Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.51. 0475 of 2005 on Guideline for Putting Information of Nutrient Value on the Label
Methods of Analysis and Sampling	<p>Sampling Method Sampling in accordance with SNI 19-0428-1993: Guideline for sampling of solid material</p> <p>Methods of Analysis Sample preparation as in SNI 01-2891-1992: Food testing methods, point 4.4 Testing of conditions as in SNI 01-2891-1992: Food testing methods, point 1.2 Testing of pH as in SNI 01-2891-1992: Food testing methods, point 16 Testing of moisture, ash, protein, carbohydrate as in SNI 01-2891-1992: Food testing methods Testing of total sugar as in SNI 01-2891-1992: Food testing methods, point 3.1 Testing of reducing sugar as in SNI 01-2891-1992: Food testing methods, point 2.1 Testing of taurine as in AOAC Official Method 997.05. – 1999 (Annex A) Tasting of caffeine as in AOAC Official Method 962.13.- 1999. (Annex B)) Testing of artificial sweeteners as in SNI 01-2831-1992: Artificial sweetener testing methods. If saccharin positive, continued with AOAC Official Method 934.04 - 1999. (Annex C.1) Testing of sorbitol as in AOAC Official Method 973.28 - 1999. (Annex C.3) Testing of preservative as in SNI 01-2894-1992: Preservative testing method Testing of colouring as in SNI 01-2895-1992: Colouring testing method Testing of metal contaminants as in SNI 01-2896-1998: Testing method of metal contaminants in foods Testing of arsenic as in SNI 01-4866-1998: Testing method of arsenic in foods Testing of microbe as in SNI 01-2897-1992: Testing method of microbiological contaminants</p>

Table 11: Case Study (2) Carbonated Soft Drinks: Specifications and Methods of Analysis

Related legislation	Item	Specification	Analytical Methods	Reference
Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52.4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Food	Microbiological contaminants	Total Plate Count: < 1.0 x 10 ² cfu/ml; Coliforms: < 1 cfu/100 ml; <i>Salmonella</i> sp.: absent per 100 ml; <i>Staphylococcus aureus</i> : absent per ml; Yeast & moulds: < 1.0 x 10 ² cfu/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Metal contaminants	Arsenic: < 0.1 ppm; Tin: < 150.0 ppm; Lead: < 0.2 ppm	SNI 01-2896-1998 Analytical Methods for Metal Contaminants; SNI 01-4866-1998 Analytical Methods for Arsenic	
SNI 01-3708-1995 Soda water (Air soda)	Quality characteristics for appearance, aroma and taste	Appearance: clear/colourless; Aroma: odourless; Taste: normal	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Carbon dioxide	3-5 atm (CO ₂ , 27°C)	SNI 01-3708-1995 Item 5.3	
	Dissolved solids	Max 500 mg/kg	SNI 01-3708-1995 Item 5.4	
	Food additives	Prohibited, except for mineral salts, as per SNI 01-0222-1987 Food Additives	SNI 01-2895-1992 Analytical Methods for Colour Additives; SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives; SNI 01-3708-1995 Item 5.8 Determining mineral salts as sodium (Na)	
	Metal contaminants	Lead: < 0.2 mg/kg; Copper: < 2.0 mg/kg; Zinc: < 5.0 mg/kg; Mercury: < 0.03 mg/kg; Tin: 40.0, 250.0 (if packaged in can)	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 0.1 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 2.0 x 10 ² cfu/ml; coliforms: < 20 MPN/ml; <i>E. coli</i> : < 3 MPN/ml; <i>Salmonella</i> sp.: absent per 100ml; <i>Staphylococcus aureus</i> : 0 cfu/ml; <i>Vibrio</i> sp.: Absent per 100ml; <i>Clostridium perfringens</i> : Absent per 100ml; Yeast & moulds: < 50 cfu/ml;	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	

	Sampling	As specified in SNI 19-0429-89 Sampling Guidelines for Liquid and Semi-solid Food Products		
SNI 01-2972-1998 Soda (Limun)	Quality characteristics for aroma, taste and colour	Normal	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Sugar content	6-15% W/W (as sucrose)	SNI 01-2892-1992 Analytical Method for Sugars	
	Saccharine & cyclamate	Prohibited	SNI 01-2895-1992 Analytical Methods for Artificial Sweeteners	
	Colour additives	As per SNI 01-0222-1995	SNI 01-2895-1992 Analytical Methods for Colour Additives	
	Preservatives	As per SNI 01-0222-1995	SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives	
	Carbon dioxide pressure	20-70 psi (at temp. range: 27-30°C)	SNI 01-2972-1998 Item 6.2	
	Metal contaminants	Lead: < 0.2 mg/kg; Copper: < 2.0 mg/kg; Zinc: < 5.0 mg/kg; Tin: 40.0, 250.0 (if packaged in can)	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 0.1 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 2.0 x 10 ² cfu/ml; Coliforms: < 20 MPN/ml; <i>E. coli</i> : < 3 MPN/ml; <i>Salmonella sp.</i> : absent per 25ml; <i>Staphylococcus aureus</i> : 0 cfu/ml; <i>Vibrio sp.</i> : Absent per 25ml; <i>Clostridium perfringens</i> : Absent per 100ml; Yeast & moulds: < 50 cfu/ml;	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Sampling	As specified in SNI 19-0429-89 Sampling Guidelines for Liquid and Semi-solid Food Products		
SNI 01-3699-1995 Diabetic diet soda (Limun diet diabetes)	Quality characteristics for aroma, taste and texture	Normal	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Glucose content	Max 0.10% W/W	SNI 01-2892-1992 Analytical Method for Sugars	

	Total energy	As specified on the label	SNI 01-3699-1995 Item 5.3	
	Carbon dioxide pressure	Max 70 psi (27-30°C)	SNI 01-3699-1995 Item 5.4	
	Food additives (Artificial sweeteners, colour additives & preservatives)	As per SNI 01-0222-1987 and its revisions	SNI 01-2895-1992 Analytical Methods for Artificial Sweeteners; SNI 01-2895-1992 Analytical Methods for Colour Additives; SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives	
	Metal contaminants	Lead: < 0.2 mg/kg; Copper: < 2.0 mg/kg; Zinc: < 5.0 mg/kg; Tin: 40.0, 250.0 (if packaged in can)	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 0.1 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 2.0 x 10 ² cfu/ml; Coliforms: < 20 MPN/ml; E. coli: < 3 /ml; Salmonella: negative; <i>Staphylococcus aureus</i> : 0 cfu/ml; Vibrio sp.: negative; Yeast & Moulds: < 50 cfu/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Sampling	As specified in SNI 19-0429-89 Sampling Guidelines for Liquids and Semi-solid Food Products		
SNI 01-6684-2002 Energy drinks (Minimum energy)	Quality characteristics for appearance, aroma and taste	Appearance: clear/colourless; Aroma: normal/typical; Taste: normal/typical	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	pH	2.5 - 4.0	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Total energy	Min 100 Kkal/serving	SNI 01-6684-2002 Item 6.4	
	Total sugars	Min 12.5 % W/W (as sucrose)	SNI 01-2892-1992 Analytical Method for Sugars	
	Reducing sugars	Min 7.0% W/W	SNI 01-2892-1992 Analytical Method for Sugars	
	Taurine	Max 1,000 mg/serving	AOAC Official Method 997.05 - 1999	
	Caffeine	Max 50 mg/serving	AOAC Official Method 962.13 - 1999	

	Food additives (Artificial sweeteners, colour additives & preservatives)	As specified in SNI 01-0222-1995	SNI 01-2895-1992 Analytical Methods for Artificial Sweeteners (if saccharine positive, then apply AOAC Official Method 934.04 - 1999; If cyclamate positive, then apply AOAC Official Method 957.10 - 1999; If Sorbitol positive, then apply AOAC Official Method 973.28 - 1999); SNI 01-2895-1992 Analytical Methods for Colour Additives; SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives	
	Metal contaminants	Lead: < 0.2 mg/kg; Copper: < 2.0 mg/kg; Zinc: < 5.0 mg/kg; Tin: 40.0, 250.0 (if packaged in can)	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 0.1 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total Plate Count: < 2.0 x 10 ² cfu/ml; Coliforms: < 20 MPN/ml; E. coli: < 3 MPN/ml; Salmonella: negative; <i>Staphylococcus aureus</i> : 0 cfu/ml; <i>Vibrio sp.</i> : negative; Yeast & Moulds: < 50 cfu/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Sampling	As specified in SNI 19-0429-89 Sampling Guidelines for Liquid and Semi-solid Food Products		

Table 12: Case Study (2) Carbonated Soft Drinks: Food Additives

	Summary/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 13: Case Study (3) Prepared Frozen Food (Frozen Scallop): Specifications & Standards

	SNI 3230.1:2010			
Name of the Standard	Frozen Scallop			
Scope	This standard determines specifications which cover hygienic and sanitation technique, food quality and safety requirements of frozen fresh Scallop (<i>Amusium pleuronectes</i>)			
Description	Frozen Scallop is a fishery product obtained from live Scallop as raw material which is handled, processed and frozen.			
Essential Composition and Quality Factor	Raw Materials and Processing Aids In accordance with SNI 3230.2:2010 (fresh Scallop) and SNI 3230.3:2010 (processing aids) Quality Requirements			
		Testing Criteria	Unit	Requirements
	a.	Organoleptic	Value (1-9)	Min. 7
	b.	Microbiological Contaminants		
		• Total Plate Count	colony/g	Max. 5.0×10^5
		• <i>Escherichia coli</i>	MPN/g	<3
		• Salmonella	per 25 g	Negative
		• <i>Vibrio cholerae</i>	per 25 g	Negative
		• <i>Staphylococcus aureus</i>	colony/g	Max. 1.0×10^3
	c.	Chemical Contaminants*		
		• Cadmium (Cd)	mg/kg	Max. 1.0
		• Mercury (Hg)	mg/kg	Max. 0.5
		• Lead (Pb)	mg/kg	Max. 1.0
	d.	Biotoxine*		
		• PSP	□g/kg	Max. 800
	• DSP	□g/kg	Max. 160	
	• ASP	mg/kg	Max. 20	
	*Note: If required by market			
Food Additives	Processing aids used comply with SNI 3230.3: 2010 The Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives			

Standard for Crackers of Marine and Freshwater Fish, Crustaceae, and Molluscan Shellfish (CODEX STAN 222-2001)

Contaminants	Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52. 4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Foods			
	No.	Testing Criteria	Unit	Requirements
	1	Microbiological Contaminants		
		• Total Plate Count	colony/g	Max. 5.0×10^5
		• <i>Escherichia coli</i>	MPN/g	<3
		• Salmonella	per 25 g	Negative
		• <i>Vibrio cholerae</i>	per 25 g	Negative
		• <i>Staphylococcus aureus</i>	colony/g	Max. 1.0×10^3
	2	Chemical Contaminants*		
		• Cadmium (Cd)	mg/kg	Max. 1.0
	• Mercury (Hg)	mg/kg	Max. 0.5	
	• Lead (Pb)	mg/kg	Max. 1.0	
Hygiene	Government Regulation of the Republic of Indonesia No. 28 of 2004 on Food Safety, Quality and Nutrition, Part One Sanitation (Article 2-10)			
	Handling and processing of frozen Scallop comply with SNI 3230.3: 2010			
	Raw materials comply with the freshness, cleanliness, and safety according to SNI 3230.2: 2010			
	Handling, processing, packaging, storage, distribution, and marketing of frozen Scallop are conducted with containers, methods and equipment according to hygiene and sanitation requirements of fishery products processing unit.			
Weights and Measures	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement			
Labelling	Government Regulation of the Republic of Indonesia No. 69 of 1999 on Food Labelling and Advertisement			
	Each pack of frozen Scallop for market is labeled correctly and easy to read with required language and comply with label and advertisement requirements. Labelling is in accordance with SNI 3230.3: 2010.			
Methods of Analysis and Sampling	Sampling Method Sampling in accordance with SNI 2326:2010: Sampling methods of fishery products.			
	Methods of Analysis			
	Sensory SNI 2346: Guideline of organoleptic and or sensory testing of fishery products.			
	Microbiology SNI 01-2332.1-2006: Microbiological testing, Chapter 1: Determination of Coliform and <i>Escherichia coli</i> in fishery products.			

SNI 01-2332.2-2006: Microbiological testing, Chapter 2: Determination of Salmonella in fishery products.
SNI 01-2332.3-2006: Microbiological testing, Chapter 3: Determination of Total Plate Count in fishery products.
SNI 01-2332.4-2006: Microbiological testing, Chapter 4: Determination of *Vibrio cholerae* in fishery products.
SNI 01-2332.9-2006: Microbiological testing, Chapter 9: Determination of *Staphylococcus aureus* in fishery products.

Chemistry

SNI 01-2354.5-2006: Determination of cadmium (Cd) and lead (Pb) in fishery products.
SNI 01-2354.6-2006: Determination of mercury (Hg) in fishery products.

Biotoxine

Association of Official Analytical Chemistry (Paralytic Shellfish Poison), Official Methods of Analysis, 18th Edition, 2005. Chapter 49.10.01

Intergovernmental Oceanographic Commission (Diarrhetic Shellfish Poison). Manual of Harmful Microalgae, UNESCO, 2004. Chapter 13.4.1.2.2

Intergovernmental Oceanographic Commission (Amnestic Shellfish Poison). Manual of Harmful Microalgae, UNESCO, 1995

Table 14: Case Study (3) Prepared Frozen Foods: Specifications and Methods of Analysis

Related legislation	Item	Specification	Analytical Methods	Reference
Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52.4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Food	Total Plate Count	< 1 x 10 ⁴ cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Coliforms	< 3/g (MPN)	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Salmonella sp.	negative per 25 g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Staphylococcus aureus	negative per g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
SNI 01-6163-1999 Frozen breaded shrimp	Organoleptic	Min 7 on the hedonic scale (1-9)	SNI 01-2345-1991 Analytical method for organoleptic testing	
	Microbiological contaminants	Total plate count: < 2 x 10 ⁵ cfu/g; <i>Escherichia coli</i> < 3 MPN/g; Salmonella: absent per 25 g; <i>Vibrio cholerae</i> : absent per 25 g; <i>Vibrio parahaemolyticus</i> : < 3 /g (MPN); <i>Staphylococcus aureus</i> : < 10 ³ cfu/g	SNI 01-2339-1991 Determination of total aerobic plate count in fishery products; SNI 01-2332-1991 Determination of <i>Escherichia coli</i> in fishery products; SNI 01-2335-1991 Determination of Salmonella in fishery products; SNI 01-2337-1991 Determination of <i>Staphylococcus aureus</i> in fishery products; SNI 01-2341-1991 Determination of <i>Vibrio cholera</i> in fishery products; SNI 01-2340-1991 Determination of <i>Vibrio parahaemolyticus</i> in fishery products;	
	Filth	0	SNI 01-2372.7-1998 Analytical method for physical testing of fishery products	
	Batter/dough and flour content	50% (weight)	AOAC Official Method No. 971.13 1986	
	Internal temperature	Max -18°C	SNI 101-2378.1-1998 Determination of internal temperature of fish	
SNI 01-6683-2002 Chicken nugget	Quality characteristics for aroma, taste and texture	Aroma: normal/appropriate as per label; taste: normal/appropriate as per label; texture: normal	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Foreign matter	Not present	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Moisture content	Max 60% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	

	Protein content	Min 12% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Fat content	Max 20% W/W	SNI 01-2891-1992 Analytical Methods for Food and Beverages	
	Carbohydrate content	Max 25% W/W	SNI 01-6683-2002 Item 6.6	
	Calcium (Ca)	Max 30 mg/kg	AOAC Official Method 975.03, 1990 Metal in Plants. AAS Method, SNI 01-6683-2002 Item 6.7	
	Preservatives & colourings	As specified in SNI 01-0222-1995	SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives; SNI 01-2895-1992 Analytical Methods for Artificial Sweeteners	
	Metal contaminants	Lead: < 2.0 mg/kg; Copper: < 20.0 mg/kg; Zinc: < 40.0 mg/kg; Tin: < 40.0 mg/kg; Mercury: < 0.03 mg/kg	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 1.0 mg/kg	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Microbiological contaminants	Total plate count: < 5 x 10 ⁴ cfu/g; Coliforms: < 10 MPN/g; E. coli: <3 MPN/g; Salmonella: absent per 25g; <i>Staphylococcus aureus</i> : < 1 x 10 ² cfu/g	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Sampling	As specified in SNI 19-0428-1993 Sampling Guidelines for Solid Food Products		

Table 15: Case Study (3) Prepared Frozen Foods: Food Additives

	Summary/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 16: Case Study (4) Cow's Milk: Specifications & Standards, and Methods of Analysis

Related legislation	Item	Specification	Analytical Methods	Reference
Head of the National Agency for Drug and Food Control of the Republic of Indonesia Regulation No. HK.00.06.1.52.4011 of 2009 on Maximum Level of Microbiological and Chemical Contaminants in Food***	Total Plate Count	< 5 x 10 ⁴ cfu/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Coliforms****	< 10 MPN/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Escherichia coli</i>	< 3 MPN/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Salmonella sp.</i>	negative per 25 ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Staphylococcus aureus</i>	< 1x 10 ² cfu/ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	<i>Listeria monocytogenes</i>	negative per 25ml	SNI 19-2897-1992 Analytical Methods for Microbiological Contaminants	
	Metal contaminants	Arsenic: < 0.1 ppm; Mercury: < 0.03 ppm; Lead: < 0.02 ppm;	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Aflaxatoxin	Aflaxatoxin M ₁ : < 0.5 ppb	Not specified	

SNI 01-3951-1995	Quality characteristics for aroma, taste and color	aroma: typical; taste: typical; color: typical	Organoleptic	
	Fat content	Unflavoured milk: min 2.80% W/W; Flavoured milk: min 1.50% W/W	SNI 01-2782-1998 Analytical Methods for Fresh Milk	
	Density level without fat	Unflavoured milk: min 7.7% W/W; Flavoured milk: min 7.5% W/W	SNI 01-2782-1998 Analytical Methods for Fresh Milk	
	Reductaste test with methylene blue	0	SNI 01-2782-1998 Analytical Methods for Fresh Milk	
	Protein content	Unflavoured milk: min 2.5% W/W; Flavoured milk: min 2.5 W/W	SNI 01-2782-1998 Analytical Methods for Fresh Milk	
	Phosphate test	0	SNI 01-2782-1998 Analytical Methods for Fresh Milk	
	Total Plate Count	< 3 x 10 ⁴	SNI 2897:2008 Analytical Methods for Microbiological Contaminants in Meat, Eggs and Milk, and its Products*****	
	Presumptive Coliform	< 10 MPN/ml	SNI 2897:2008 Analytical Methods for Microbiological Contaminants in Meat, Eggs and Milk, and its Products*****	
	Metal contaminants	Lead: < 1.0 ppm; Cooper: < 2.0 ppm; Zinc: < 5 ppm	SNI 01-2896-1998 Analytical Methods for Metal Contaminants;	
	Arsenic	< 1.0 ppm	SNI 01-4866-1998 Analytical Methods for Arsenic	
	Preservatives	As specified in Minister of Health of the Republic of Indonesia Regulation No. 722/Menkes/Per/IX/88 on Food Additives and Regulation No. 1168/Menkes/PER/X/1999 on Food Additives	SNI 01-2894-1992 Analytical Methods for Food Additives/Preservatives;	
	Sampling	As specified in SNI 01-3951-1995 Item 5		

Table 17: Case Study (4) Cow's Milk: Food Additives

	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

4.6 Republic of Singapore

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.

2. FOOD LAW SYSTEM AND RESPECTIVE FOOD STANDARDS

Figure 1 shows the Commodity Standards and relevant Food Law System.

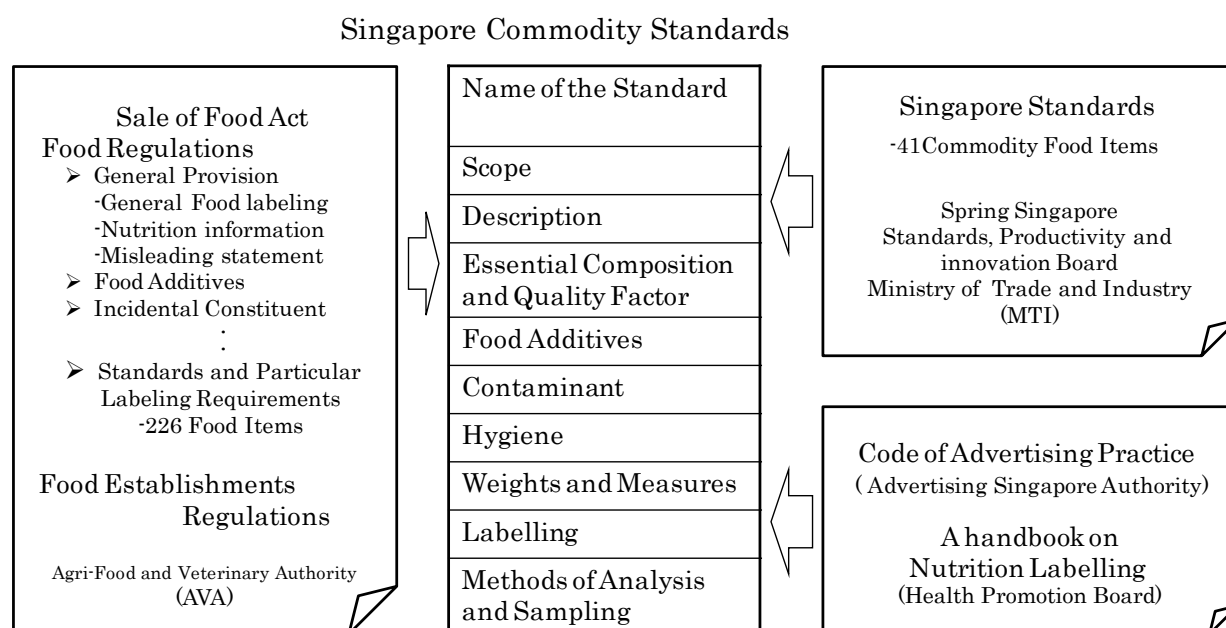


Figure 1 Commodity Standards and Relevant Food Law System

3. SALE OF 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-2002⁴⁷

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.

(2) Food Regulation-2006⁴⁸

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 (Table 1) are listed. It stipulated minimum definition, component standards and special labelling requirements.

⁴⁷ Singapore - Sale of Food Act
http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/8725/Attach59_legislative_on_SaleofFoodAct.pdf

⁴⁸ Singapore – Food Regulations
<http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/11405/FoodRegulations1.pdf>

Table 1: Commodity Standards in Food Regulations

No.	Title
FLOUR, BAKERY AND CEREAL PRODUCTS	
39	Flour or wheat flour
40	Wholemeal, whole wheat or entire wheat flour
41	Vital gluten flour
42	Self-raising flour
43	Protein-increased flour
44	Corn flour
45	Rice flour
46	Tapioca flour
47	Bakery products
48	Bread
49	Wholemeal bread
50	Fruit bread
51	Rye bread
52	Milk bread
53	Labelling of bakery products
54	Flour confectionery
55	Pasta
55-1	Noodles
55-2	Rice noodles
56	Labelling of pasta
AERATING INGREDIENTS	
57	Cream of Tartar
58	Baking powder
MEAT AND MEAT PRODUCTS	
59	Meat
60	Fresh, raw or chilled meat
60A	Dressed Bird
61	Frozen meat
62	Corned, cured, pickled or salted meat
63	Smoked meat
64	Minced or chopped meat
65	Hamburgers or beefburgers and similar products
66	Sausage meat
67	Sausages
68	Meat extracts, meat essences and meat juices
69	Chicken essence and double strength chicken essence
70	Meat paste or pate
FISH AND FISH PRODUCTS	
71	Fish
72	Fresh or chilled fish
73	Frozen fish
74	Smoked fish
75	Salted fish
76	Fish paste

77	Fish cakes and fish balls
EDIBLE FATS AND OILS	
78	Edible fats and oils
79	Labelling of edible fats or oils
80	Coconut oil
81	Corn oil
82	Cottonseed oil
83	Groundnut oil
84	Olive oil
85	Safflower oil
86	Sesame oil
87	Soya bean oil
88	Sunflower seed oil
89	Dripping
90	Lard
91	Margarine
91A	Fat spread
92	Vanaspati
MILK AND MILK PRODUCTS	
93	Milk
94	Pasteurised milk
95	Ultra heat treated milk
96	Sterilised milk
97	Homogenised milk
98	Reconstituted or recombined milk
99	Evaporated milk
100	Sweetened condensed milk
101	Dried milk or milk powder or dried whole milk or dried full cream milk or full cream milk powder
102	Dried half cream milk
103	Skimmed or separated milk or defatted milk
104	Filled milk
105	Flavoured milk
106	Lactobacillus milk drink or cultured milk drink
107	Malted milk powder
108	Whey
109	Labelling of milk
110	Cream
111	Homogenised cream
112	Reconstituted or recombined cream
113	Thickened cream
114	Reduced cream
115	Sour cream
116	Butter
117	Cheese
118	Cheddar cheese
119	Unnamed cheese
120	Cream cheese
121	Processed or emulsified cheese
122	Cheese spread or cheese paste
123	Yoghurt

124	Fruit yoghurt
125	Ghee or ghi
ICE-CREAM, FROZEN CONFECTIONS AND RELATED PRODUCTS	
126	Ice-cream
127	Dairy ice-cream
128	Milk-ice
129	Frozen confections
SAUCE, VINEGAR AND RELISHES	
130	Sauce
131	Soya bean sauce
132	Oyster sauce
133	Tomato sauce
134	Chilli sauce
135	Vinegar
136	Distilled vinegar
137	Blended vinegar
138	Artificial or imitation vinegar
139	Labelling of vinegar
140	Salad dressing
141	Pickles
142	Chutney
SUGAR AND SUGAR PRODUCTS	
143	Sugar
144	Refined soft brown sugar
145	Icing sugar or icing mixture
146	Molasses
147	Table molasses
148	Dextrose anhydrous
149	Dextrose monohydrate
150	Glucose syrup
151	Honey
151A	A Royal jelly
152	Sugar confectionery
TEA, COFFEE AND COCOA	
153	Tea
154	Tea dust, tea siftings and tea fannings
155	Instant tea
156	Brewed tea
157	Coffee
158	Coffee and chicory
159	Coffee mixture
160	Instant coffee or soluble coffee
161	Instant coffee and chicory or soluble coffee and chicory
162	Decaffeinated coffee
163	Cocoa beans
164	Cocoa nibs
165	Cocoa paste, cocoa mass or cocoa slab
166	Cocoa, cocoa powder or powdered cocoa
167	Cocoa essence or soluble cocoa
168	Chocolate

169	Milk chocolate
170	Chocolate confectionery
FRUIT JUICES AND FRUIT CORDIALS	
171	Fruit juices
172	Concentrated fruit juice
173	Nectar
174	Fruit juice cordials, squashes or syrups
175	Fruit drinks or fruit crushes
JAMS	
176	Jams
177	Fruit jelly
178	Marmalade
179	Kaya or egg jam
NON-ALCOHOLIC DRINKS	
180	Flavoured cordials or syrups
181	Soya bean milk
182	Flavoured soya bean milk
183	Soft drinks
183A	A Natural mineral water
184	Labelling of non-alcoholic drinks
ALCOHOLIC DRINKS	
185	Intoxicating liquors
186	Ale, beer, lager, porter or stout
187	Wine
188	Malt wine
189	Quinine wine
190	Aromatic wine, wine cocktail and vermouth
191	Port and sherry
192	Meat wine or beef wine
193	Sparkling wine
194	Carbonated wine
195	Fruit wine
196	Cider or perry
197	Sparkling cider or sparkling perry
198	Aerated cider or aerated perry
199	Honey wine
200	Cereal grain wine and Chinese wine
201	Brandy
202	Marc brandy
203	Fruit brandy
204	Whisky
205	Rum
206	Gin
207	Vodka
208	Liqueurs and alcoholic cordials
209	Blended liquor
210	Compounded liquor
SALTS	
211	Salt
212	Iodised salt

SPICES AND CONDIMENTS	
213	Spices and condiments
214	Aniseed (Jintan manis)
215	Caraway seed (Jintan)
216	Greater Cardamon (Kepulaga Besar) or Lesser Cardamon (Kepulaga Kecil)
217	Celery seed (Biji Seladeri)
218	Chilli
219	Cinnamon (Kayu Manis)
220	Cloves (Bunga Cengkih)
221	Coriander (Ketumbar)
222	Cumin seed (Jintan Putih)
223	Black Cumin (Jintan Hitam)
224	Dill seed (Adas Manis)
225	Fennel fruit or seeds (Adas Pedas)
226	Fenugreek (Halba)
227	Ginger
228	Mace (Jaitree) (Bunga Pala)
229	Mustard seed (Biji Sawi)
230	Prepared mustard
231	Nutmeg (Buah Pala)
232	Black pepper or pepper corn
233	White pepper
234	Star anise (Bunga Pekak)
235	Tumeric (Kunyit)
236	Curry powder
FLAVOURING ESSENCES OR EXTRACTS	
237	Almond essence
238	Ginger essence
239	Lemon essence

240	Lemon oil
241	Orange essence
242	Peppermint essence
243	Rose essence
244	Vanilla extract
245	Flavouring essences
FLAVOUR ENHANCERS	
246	Monosodium glutamate
SPECIAL PURPOSE FOODS	
247	Special purpose foods
248	Labelling requirements for special purpose foods
249	Low-calorie food
250	Diabetic food
251	Infants' food
252	Infant formula
253	Infant milk formula or infant milk preparation
254	Labelling of infant formula
MISCELLANEOUS FOODS	
255	Agar
256	Custard powder
257	Edible gelatin
258	Fish crackers
259	Prawn crackers
RICE	
260	Rice

To note : Missing sequential regulation numbers are due to intentional deletion of the regulation from the Food Regulations.

(3) Food Establishments Regulations-2009³¹

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

4. SINGAPORE STANDARDS (SS)

Singapore Standards (SS) exist as commodity standards 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, they are basically voluntary standards (it may become mandatory standards when issues related to safety, environment and health are referred by administrative authority).

³¹ Singapore – Sale of Food (Food Establishment) Regulations, http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/8729/Attach64_legislation_Sale_FdEstb_rules.pdf

Singapore Standards shown in Table 2 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 (Table 3) out of them. These are basically voluntary standards, but, certified mark can be labeled by obtaining official certification.

Table 2: Format of Singapore Standard

SINGAPORE STANDARD SS 219:1979 (ICS 67.06) Specification for dried noodles and pasta products	
Contents	Appendices
1 Scope	Annex A Determination of Protein Content – Improved Kjeldahl Method
2 Classification	Annex B Determination of Moisture Content – Air-Oven Method
3 Requirements	Annex C Determination of Total Solids in Gruel
4 Sampling and preparation of Test Sample	Annex D Determination of free Fatty Acids and Peroxide Value of Extracted Oil
5 Tests	
6 Packaging	
7 Marking	

Table 3: Commodity Standards in Singapore Standard

S/N	Product Title	Stan. No.		
			14	Refined and deodorized soya bean oil Status: Current
1	Full-cream sweetened condensed milk Status: Archived	SS 10:1970	15	Vanaspati Status: Current
2	Groundnut (peanut) oil Status: Current	SS 12:1995	16	Reconstituted or recombined milk Status: Archived
3	Coconut oil Status: Current	SS 13:1995	17	Vegetable cooking oil Status: Current
4	Wheat flour (white) Status: Archived	SS 46:1971	18	Peanut butter Status: Current
5	Margarine Status: Current	SS 47:1997	19	Refined and deodorized palm olein Status: Current
6	Monosodium glutamate for seasoning Status: Archived	SS 61:1972	20	Dried noodles and pasta products Status: Archived
7	Carbonated and non-carbonated beverages Status: Current	SS 62:1997	21	Sesame oil Status: Current
8	White refined sugar Status: Archived	SS 94:1972	22	Rice vermicelli Status: Current
9	Butter Status: Current	SS 95:1997	23	Tomato ketchup Status: Current
10	Glucose syrup Status: Current	SS 113:1995	24	Palm kernel oil Status: Current
11	Evaporated milk Status: Archived	SS 114:1974	25	White pan bread Status: Current
12	Cordials Status: Current	SS 115:1995	26	Skimmed and whole milk powder Status: Archived
13	Refined, deodorized and winterized corn (or maize) oil Status: Current	SS 134:1995	27	Cream crackers Status: Current

28	Soy sauce Status: Current	SS 288:1998	35	Refined, deodorized and winterized sunflower seed oil Status: Current	SS 349:1997
29	Soya bean milk and soya bean drink Status: Current	SS 302:1985	36	Semolina Status: Current	SS 350:1990
30	Black pepper and white pepper (whole and ground) Status: Current	SS 315:1997	37	Self-raising flour Status: Current	SS 351:1990
31	Cocoa butter Status: Current	SS 319:1997	38	Wholemeal flour Status: Current	SS 352:1990
32	Plain semi-sweet biscuits (non-creamed) Status: Current	SS 329:1988	39	Sugar confectionery Status: Current	SS 464:1999
33	Filled milk sweetener Status: Current	SS 330:1988	40	Kaya Status: Current	SS 466:1999
34	Chilli sauce Status: Current	SS 340:1999	41	Chillies and capsicums, whole or ground (powered) Status: Current	SS 487:2001

5. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

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 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.

5.2 Food Additive Definitions & Functional Classes

Food additives are defined in the Food Regulations as follows:

“Food additive includes –

- 1) 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
- 2) 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.

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, and Thirteenth 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.

5.4 Prohibited Substances for Use as Food Additives

There is a list of prohibited substances regarding flavoring agents. According to Regulation 22(7), prohibited flavouring agents include coumarin, tonka bean, safrole, saffrafras 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.

5.5 Specifications and Standards 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 FAO/WHO Expert Committee on Food Additives (JECFA).

5.6 Application, Assessment and Approval of New Food Additives

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

5.7 Labelling of Food Additives in Food

Food additives are required to be declared on the ingredients list of food labels using the

“appropriate designation³²”. 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”;
- 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 (FD Red #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:

5.8 Summary of Food Additives

The definitions regarding food additives such as flavorings, processing aids and carry-overs are summarized in Table 4; the descriptions of other items such as designated/existing food additives and prohibited substances are summarized in Table 5.

6. SPECIFICATIONS & STANDARDS, AND METHODS OF ANALYSIS FOR GENERAL FOODS

Standards and methods of analysis for General Foods are summarized in Table 6. Standards and methods of analysis for the specific food categories taken up in the Case Study are described in the sections of those food categories, respectively.

³²<http://www.ava.gov.sg/NR/rdonlyres/B96B0EC2-1D1E-4448-9C25-ABD8470D2BF4/20119/AGuidetoFoodLabellingandAdvertisementsVersionOctob.pdf>

7. CASE STUDIES

(1) Instant Noodles

Commodity Food Standards and Methods of Analysis:

Instant noodles are defined as "Pasta" including noodles, beehoon, macaroni, spaghetti and "mee" in Food Regulations-2006. The standard is not specific for instant noodles. Singapore Standards (SS) is the same; therefore, dried noodles and pasta products (SS 219:1979) is also presented as reference (Tables 7 and 8).

Food Additives:

Singapore Standards for "Dried noodles and pasta products" (SS 219:1979) and Food Regulations for "Pasta" are described. Neither specifies "instant" products (Table 9).

(2) Carbonated Soft Drinks

Commodity Food Standards and Methods of Analysis:

In Food Regulations-2006, any standards only for carbonated soft drinks are not set. It covers variety of items like common soft drinks, and is different from Japanese standard in more food items excluded from soft drink. Singapore Standards for "Carbonated and non-carbonated beverages" (SS 62:1997) set standards for wide variety of beverages including carbonated soft drinks (Table 10, 11).

Food Additives:

There is no standard set in Food Regulations exclusively for carbonated drinks, but are standards including maximum limit for use of food additives for general soft drinks. However, Singapore Standards for "Carbonated and on-carbonated beverages"(SS 62:1997) designate permitted food additives (Table 12).

(3) Prepared Frozen Foods

Commodity Food Standards, Methods of Analysis and Food Additives:

In Food Regulations-2006, any standards only for prepared frozen foods are not set. Also, in Singapore Standard, there is sole standard for disposition and handling of quick frozen foods (CP 46:1989).

(4) Cow's Milk

Commodity Food Standards and Methods of Analysis are shown in Table 13. **Food Additives** are prohibited to be used according to Food Regulations-1985 (Table 14).

Table 4: Description/Definition of Food Additives (General)

	Description/Definition	Reference
Related Legislation	Food Regulations	http://www.ava.gov.sg/NR/ronlyres/0CA18578-7610-4917-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	<p>“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.</p>	Food Regulations, Part III, Regulation No. 28 (1)
Carry-over	<p>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.</p>	Food Regulations, Part III, Regulation No. 15 (4)

Table 5: Summary/Definition of Food Additives (Specific)

	Description/Definition	Reference
Related Legislation	Food Regulations	http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/19280/2web_SO_F_FoodRegulations15April2011.pdf
Summary (Specific)/Additional Laws		
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
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	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 6: Specifications & Standards and Methods of Analysis for General Foods

Related Legislation	Item	Specification	Analytical Methods	Reference
Food Regulations	Incidental Constituents	No person shall import, sell, advertise, manufacture, consign or deliver any food containing an incidental constituent except as otherwise permitted by these Regulations	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Pesticide residues	<ol style="list-style-type: none"> 1. No person shall import, sell, advertise, manufacture, consign or deliver any article of food containing any pesticide residue other than those specified in column 1, in relation to those articles specified in column 3 and in the proportion specified in column 2 of the Ninth Schedule. 2. Where it is not so provided in these Regulations, the pesticide residue contained in any food shall not exceed the limits as recommended by the Codex Alimentarius Commission. 3. A manufactured or mixed food containing one or more of the foods in which pesticide residues are permitted shall not contain such residues in greater amount than is permitted for the quantity of the food or foods containing residues used in the preparation of the manufactured or mixed food. 4. No person shall import, sell, advertise, manufacture, consign or deliver any article of food containing the residue of 2 or more of the pest 	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Heavy metals, arsenic, lead and copper	No person shall import, sell, advertise, manufacture, consign or deliver any article of food containing arsenic, lead and copper in amounts in excess of those specified in the Tenth Schedule; Tin: <250 ppm; Cadmium: <0.2 ppm; Antimony: <1.0 ppm; Selenium: <1.0 ppm	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Antibiotic residues	No person shall import, sell, advertise, manufacture, consign or deliver any article of food intended for human consumption which contains detectable antibiotic residues or their degradation products (except nisin in the preservation of cheese and canned foods which have been sufficiently heat processed to destroy spores of <i>Clostridium botulinum</i>)	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore

Table 7: Case Study (1) Instant Noodles: Specifications & Standards

Standard Item	Food Regulations (as at 1 st September 2006)	SS 219:1979
Name of the Standard	Pasta	Dried noodles and pasta products
Scope	<ul style="list-style-type: none"> ▪ Noodles of various types, including products which are commonly known as “mee” (“mian”) or other “mee” products. ▪ Noodles including “spaghetti”, “macaroni” and the product commonly known as “mee sua” (“mian xian”). ▪ Rice noodles of various types, including products which are commonly known as “kuay teow” (“guo tiao”), “bee tai mak” (“mi shai mu”) and “hor fun” (“he fen”), “bee hoon” (“mi fen”). 	<ul style="list-style-type: none"> ▪ Dried noodle products covering noodles, instant noodles and “mian xian”.
Description	<ul style="list-style-type: none"> ▪ Any product which is prepared by drying of extruded or moulded units of dough or by steaming of slitted dough with or without drying. 	<ul style="list-style-type: none"> ▪ Prepared from wheat flour, with or without the addition of sodium chloride, sodium bicarbonate, permitted colouring, flavouring matters and other food additives. The instant noodles could be flavoured separately by means of the soup base sachets. This group of products shall be subjected to a sheeting process. The products shall be in the form of rods or ribbons except for “mian xian” which shall be in the form of long thin threads.
Essential Composition and Quality Factor	<ul style="list-style-type: none"> ▪ Principally of a cereal meal. ▪ May contain common salt, eggs, various kinds of starch, edible fats and oils, and any other foodstuffs. ▪ Noodles except those with <20% moisture (includes “mee” and “mee products”): >50% flour ▪ Noodles with <20% moisture (includes “spaghetti”, “macaroni” and “mee sua”): >70% wheat flour ▪ Rice noodles except those with <20% moisture (including “kuay teow”, “bee tai mek” and “hor fun”): >50% rice flour ▪ Rice noodles with <20% moisture: >80% rice flour 	<ul style="list-style-type: none"> ▪ Made from raw materials which are clean, wholesome and free from evidence of insect and rodent infestation and other objectionable matter. ▪ The finished product shall be of good colour and reasonably free from broken units and dark specks. ▪ When cooked, the products shall be tender and firm and possess a good characteristic flavour and odour. ▪ Instant noodles shall be cooked within 3 minutes. ▪ Protein content: min. 9.0% on dry weight basis ▪ Moisture content: max. 13% ▪ Total solids in gruel: max. 8% ▪ Free fatty acids, as oleic acid of extracted oil (applies only to noodles products which have been deep fried in edible oils during processing): max. 0.8% ▪ Peroxide value of extracted oil (applies only to noodles products which have been deep fried in edible oils during processing): 10.0 per kg oil
Food Additives	<ul style="list-style-type: none"> ▪ Permitted flavouring agents ▪ Permitted colouring matters ▪ Subject to general requirements for food additives. 	<ul style="list-style-type: none"> ▪ Not specified

Contaminant	<ul style="list-style-type: none"> ▪ Arsenic (As): <1 ppm ▪ Lead (Pb): <2 ppm ▪ Copper (Cu): <20 ppm ▪ Tin (Sn): <250 ppm ▪ Cadmium (Cd): <0.2 ppm ▪ Antimony (Sb): <1 ppm ▪ Selenium (Se): <1 ppm 	<ul style="list-style-type: none"> ▪ Not specified
Hygiene	<ul style="list-style-type: none"> ▪ Package or container made with compounds known to be carcinogenic, mutagenic, teratogenic or any other poisonous or injurious substance. ▪ Mycotoxins: negative ▪ Total Count at 37°C for 48 hours: Not more than 1000,000 per mg ▪ Sale of Food (Food Establishments) Regulations 	<ul style="list-style-type: none"> ▪ The product shall be suitably packaged to protect the contents from contamination and deterioration under normal conditions of storage and transport.
Weight and Measures	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified
Labelling	<ul style="list-style-type: none"> ▪ If labelled with the word “egg” or any word of similar meaning: >4% egg solids calculated on dry basis ▪ Subject to general requirements for labelling. ▪ Nutrition labelling is required only if a nutritional claim is made (regulation 8A of the Food Regulations) 	<ul style="list-style-type: none"> ▪ The packet shall be legibly marked as follows: <ul style="list-style-type: none"> a) Name and type of the product b) Name and address of the manufacturer and/or his registered trade mark c) Batch or code number d) Net weight
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Food additives, contaminants, microorganisms, mycotoxins 	<ul style="list-style-type: none"> ▪ Protein content: Improved Kjeldahl method ▪ Moisture content: Air-oven method ▪ Total solids in gruel ▪ Free fatty acids and peroxide value of extracted oil

Table 8: Case Study (1) Instant Noodles: Methods of Analysis

Related Legislation	Item	Specification	Analytical Methods	Reference
Food Regulations	Food additives	Permitted flavouring agents & colouring matters	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Metal contaminants	Arsenic: <1.0 ppm; Lead: <2.0 ppm; Copper: <20 ppm; Tin: <250 ppm; Cadmium: <0.2 ppm; Antimony: <1.0 ppm; Selenium: <1.0 ppm	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Mycotoxins	Absence	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Total colony count	< 10 ⁵ cfu/g, 37 °C for 48h	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
SS 219: 1979 - Specifications for Dried Noodles and Pasta Products	Protein content	> 9% on dry weight basis	SS 219:1979 Appendix A	
	Moisture content	< 13%	SS 219:1979 Appendix B	
	Total solids in gruel	< 8%	SS 219:1979 Appendix C	
	Free fatty acids	< 0.8%	SS 219:1979 Appendix D	
	Peroxide value of extracted oil	10.0 miliequivalents of peroxide oxygen per kg oil	SS 219:1979 Appendix D	

Table 9: Case Study (1) Instant Noodles: Food Additives

	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 Dried noodles and pasta products
Positive and/or Negative List	Not specified.	
Use Limitation and/or Maximum Level, if any		

Table 10: Case Study (2) Carbonated Soft Drinks: Specifications & Standards

Standard Item	Food Regulations (as at 1 st September 2006)	SS 62:1997
Name of the Standard	Soft drinks	Carbonated and non-carbonated beverages
Scope	<ul style="list-style-type: none"> ▪ Any flavoured drink ready for consumption without dilution ▪ Soda water, Indian or quinine tonic water, and any carbonated water whether flavoured or unflavoured; Ginger beer and any beverage made from any harmless herbal or botanical substance; Fruit drink or fruit crush. 	<ul style="list-style-type: none"> ▪ Fruit-flavoured carbonated beverages ▪ Flavoured carbonated beverages ▪ Beverages containing natural extracts ▪ Non-flavoured and unsweetened carbonated beverages
Description	<ul style="list-style-type: none"> ▪ Soft drink shall be any substance in liquid or solid form intended for sale as drink for human consumption, either with or without dilution 	<ul style="list-style-type: none"> ▪ Non-alcoholic carbonated beverages are beverages prepared from refined sugar, or syrup base, flavours and/or acidulants with or without fruit juices and are artificially charged with carbon dioxide in sealed packages.
Essential Composition and Quality Factor	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Potable water – colourless, clear, odourless, pleasant to taste and safe for human consumption. ▪ Carbon dioxide – minimum purity of 99.5 (v/v) carbon dioxide. It shall be colourless and odourless and shall not contain any extraneous mineral or organic substances. ▪ Sugar – pure, white, crystalline solids giving a polarization reading of at least 99.8°S and should be free from moulds and yeasts. Sugar may be substituted with syrup base. ▪ Fruit concentrates – of a quality that gives a satisfactory flavour and colour ▪ Flavourings – natural flavourings are those obtained from fruits or plants by extraction, distillation, expression or any other suitable process. Artificial flavours are those obtained from chemical synthesis. ▪ Finish product – free from dust, dirt, extraneous fibres, hairs, rags, insect and rodent contamination, fragments of cork or glass or other foreign matter. ▪ Flavour – have a well-balanced and pleasant flavour. They shall be free from off-flavours and off-odours. ▪ Sugar content – min. 5 °Brix ▪ Fruit juice content – min. 5% ▪ Carbonation – 1.5 volume

Food Additives	<ul style="list-style-type: none"> ▪ May contain: ester gum: <100 ppm sucrose acetate isobutyrate: <300 ppm dimethyl polysiloxane: <10 ppm dimethyl dicarbonate: <250 ppm sulphur dioxide: <70 ppm benzoic acid: <160 ppm methyl or propyl para-hydroxy benzoate: < 160 ppm sorbic acid: <300 ppm quillaia: <200 ppm ▪ Subject to general requirements for food additives. 	<ul style="list-style-type: none"> ▪ Acidulants – Include citric acid, tartaric acid, malic acid, lactic acid, phosphoric acid, ascorbic acid, acetic acid, adipic acid, fumaric acid, hydrochloric acid, <u>dl</u>-lactic acid, <u>dl</u>-malic acid, <u>ortho</u>-phosphoric acid and L (+) tartaric acid. ▪ Permitted food colours, clouding agents, foaming agents, emulsifying and stabilising agents, and preservatives.
Contaminant	<ul style="list-style-type: none"> ▪ Arsenic (As): <0.1 ppm ▪ Lead (Pb): <0.2 ppm ▪ Copper (Cu): <2 ppm ▪ Tin (Sn): <250 ppm ▪ Cadmium (Cd): <0.2 ppm ▪ Antimony (Sb): <1 ppm ▪ Selenium (Se): <1 ppm 	<ul style="list-style-type: none"> ▪ Arsenic – <0.1 mg/kg ▪ Lead – <0.2 mg/kg ▪ Copper – <2 mg/kg
Hygiene	<ul style="list-style-type: none"> ▪ Package or container made with compounds known to be carcinogenic, mutagenic, teratogenic or any other poisonous or injurious substance. ▪ Mycotoxins: negative ▪ Escherichia coli: 20 per ml ▪ Total Count at 37°C for 48 hours: Not more than 100,000 per ml ▪ Sale of Food (Food Establishments) Regulations 	<ul style="list-style-type: none"> ▪ Processing site for carbonated and non-carbonated beverages shall be kept hygienically clean and shall be free from flies, bees, other insects and rodents. ▪ Total bacteria count: 200 per 20ml; 10 per ml ▪ Coliform count: Negative per 20ml; Negative per 10ml ▪ Yeast and mould count: Negative per 20ml; Negative per ml
Weight and Measures	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified
Labelling	<ul style="list-style-type: none"> ▪ The term “non-alcoholic” shall be reserved only for those products which contain not more than 0.5% (v/v) alcohol at 20°C. Any drink for human consumption without dilution which incorporates the name of a fruit, vegetable or flower in its name but does not use the juice of that fruit, vegetable or flower shall be labelled in the following manner: ▪ a) (Name of fruit, vegetable or flower)–ade ▪ b) (Name of fruit, vegetable or flower) flavoured drink; and ▪ c) Imitation (name of fruit, vegetable or flower) drink. ▪ Subject to general requirements for labelling 	<ul style="list-style-type: none"> ▪ Each package shall be legibly and indelibly marked as follows: <ul style="list-style-type: none"> a) Name of product; b) Name and address of manufacturer, packer or vendor and/or his registered trademark; c) Net volume; d) Batch or code number; e) Date marking.

	<ul style="list-style-type: none"> Nutrition labelling is required only if a nutritional claim is made (regulation 8A of the Food Regulations) 	
Methods of Analysis and Sampling	<ul style="list-style-type: none"> Food additives, contaminants, microorganisms, mycotoxins 	<ul style="list-style-type: none"> Sugar content: hydrometer or refractometer method Gas volume Total colony count: Membrane filter enumeration method Coliforms: Membrane filter enumeration method Coliforms (for pulpy sample): MPN method Yeast & moulds: Membrane filter enumeration method Yeast & moulds (for pulpy sample): Spread plate method Arsenic, lead, copper: Atomic absorption spectrophotometric method

Table 11: Case Study (2) Carbonated Soft Drinks: Method of Analysis

Related Legislation	Item	Specification	Analytical Methods	Reference
Food Regulations	Food additives	ester gum: <100 ppm; sucrose acetate isobutyrate: <300 ppm; dimethyl polysiloxane: <10 ppm; dimethyl dicarbonate: <250 ppm; sulphur dioxide: <70 ppm; benzoic acid: <160 ppm; methyl or propyl para-hydroxy benzoate: <160 ppm; sorbic acid: <300 ppm; quillaia: <200 ppm	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Metal contaminants	Arsenic: <0.1 ppm; Lead: <0.2 ppm; Copper: <2.0 ppm; Tin: <250 ppm; Cadmium: <0.2 ppm; Antimony: <1.0 ppm; Selenium: <1.0 ppm	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Mycotoxins	Absence	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Total colony count	< 10 ⁵ cfu/ml, 37°C for 48h	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	<i>E. coli</i>	< 20 cfu/ml	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
SS 62: 1997 - Specifications for Carbonated and non-carbonated beverages	Sugar content	> 5 Degrees Brix, 20 °C	SS 62:1997 Appendix A	
	Gas volume	1.5 volume	SS 62:1997 Appendix B	
	Total colony count	< 200 cfu/20ml or <10 cfu/ml	SS 62:1997 Appendix C & D	
	Coliforms	absent per 20 ml or absent per 10 ml	SS 62:1997 Appendix E & F	
	Viable yeasts & moulds	absent per 20 ml or absent per ml	SS 62:1997 Appendix G & H	
	Metal contaminants	Arsenic: <0.1mg/kg; Lead: <0.2 mg/kg; Copper: <2 mg/kg	SS 62:1997 Appendix I, J & K	

Table 12: Case Study (2) Carbonated Soft Drinks: Food Additives

	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 Carbonated and non-carbonated beverages
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	
Use Limitation and/or Maximum Level, if any	Permitted food colours, clouding agents, foaming agents, emulsifying and stabilizing agents, and preservatives	

Table 13: Case Study (4) Cow's Milk: Food Specifications & Standards and Methods of Analysis

Related Legislation	Item	Specification	Analytical Methods	Reference
Food Regulations	Milk fat	> 3.25%	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Milk solids other than milk fat	> 8.5%	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Added water, permitted food additive, other added substances or trace of antibiotic substance	Prohibited	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Metal contaminants	Arsenic: < 0.1 ppm; Lead: < 0.3 ppm; Copper: < 20 ppm (only for milk & milk products in tins)	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Antibiotic residues	No person shall import, sell, advertise, manufacture, consign or deliver any milk which contains detectable antibiotic residues or their degradation products	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Total count	< 10 ⁵ cfu/g, 37°C for 48h (pasteurized milk only)	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore
	Coliforms	< 50 cfu/g (pasteurized milk only)	International standards (AOAC, ISO, APHA, etc)	Email communication with AVA Singapore

Table 14: Case Study (4) Cow's Milk: Food Additives

	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		

4.7 Kingdom of Thailand

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.

2. FOOD LAW SYSTEM AND RESPECTIVE FOOD STANDARDS

A brief summary of food laws in Thailand that relate to the elaboration and regulation of food commodity standards within the country is presented in Figure 1.

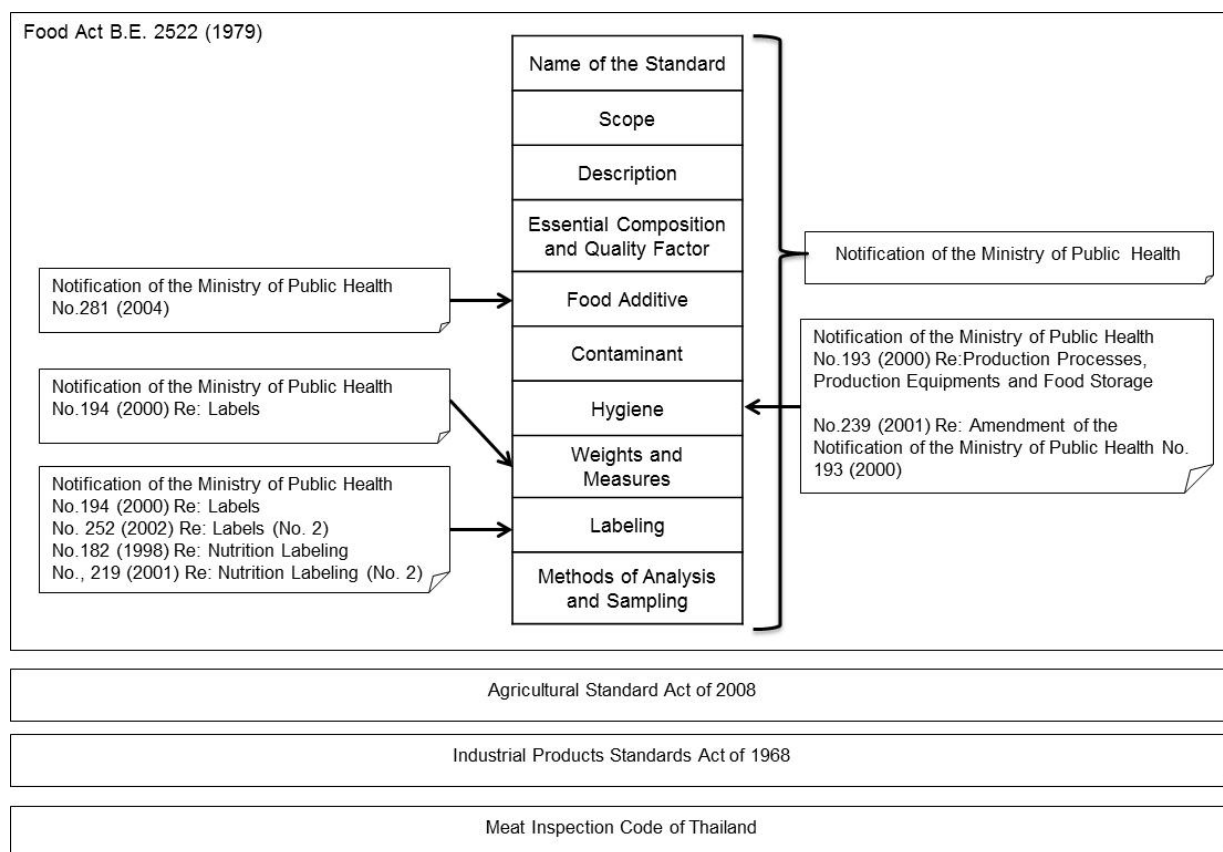


Figure 1 Food Laws in Thailand in Relation to Food Commodity Standards

3. RELEVANT FOOD LAWS

(1) Food Act of B.E.2522 (1979)⁵¹

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

⁵¹ Food Act of B.E.2522 <http://www.thailawforum.com/database1/food-act.html>

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 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). Respective food specifications according to food laws⁵² are shown in Table 1.

⁵² The Notifications of the Ministry of Public Health
http://www.qmaker.com/fda/new/web_cms/subcol.php?SubCol_ID=77&Col_ID=14
<http://newsser.fda.moph.go.th/food/Law%20Notification%20of%20Ministry%20of%20PublicHealth%2007.php> (Thai version)

Table 1: Respective Food Specifications according to Food Laws

Notification Number	Title
23 / 2522(1979)	Prescribed Peanut Oil to be Specific Controlled Food and Prescribed Qualities or Standards, Production Processes and Labelling
44 / 2523(1980)	Flour of Husked Rice
56 / 2524(1981)	Palm Oil
57 / 2524(1981)	Coconut Oil
61 / 2524(1981)	Drinking Water in Sealed Container
78 / 2527(1984)	Ice
83 / 2527(1984)	Chocolates
92 / 2528(1985)	Prescribed Quality or Standard for Food Containers, Use of Food Containers and Prohibition of Use of Certain Materials as Food Containers
98 / 2529(1986)	Standard for Foods with Contaminants, which are Sufficiently Supported
100 / 2529(1986)	Label of Finished Gelatin and Jelly
102 / 2529(1986)	Standards of Food Contaminated with Radioactivity
113 / 2531(1988)	Sodium Cyclamate and Foods Containing Sodium Cyclamate
116 / 2531(1988)	Standards of Food Contaminated with Radioactivity (No.2)
117 / 2532(1989)	Feeding Bottle
121 / 2532(1989)	Weight-Control Foods
135 / 2534(1991)	Drinking Water in Sealed Container (No.2)
137 / 2534(1991)	Ice (No.2)
144 / 2535(1992)	Food Packed in Sealed Container
150 / 2536(1993)	Vitaminized Rice
151 / 2537(1994)	Prescribed Prohibited Substances to be Used in Foods
156 / 2537(1994)	Modified Milk for Infant and Modified Milk of follow-up Formula for Infant and Children
157 / 2537(1994)	Food for Infant and Food of Follow-up Formula for Infant and Small Children
158 / 2537(1994)	Supplementary Food for Infants and Young Children
171 / 2539(1996)	Supplementary Food for Infants and Young Children (No.2)
174 / 2539(1996)	Prescribed Prohibited Food to be Imported or Sold
179 / 2540(1997)	Food in Sealed Containers (No.2)
182 / 2541(1998)	Nutrition Labelling
184 / 2543(2000)	Palm oil (No.2)
193 / 2543(2000)	Production Processes, Production Equipments, and Foods Storages
194 / 2543(2000)	Labels
195 / 2543(2000)	Electrolyte Dinks
196 / 2543(2000)	Tea
197 / 2543(2000)	Coffee
198 / 2543(2000)	Soybean Milk in Sealed Containers
199 / 2543(2000)	Mineral Water
200 / 2543(2000)	Sauces in Sealed Containers
201 / 2543(2000)	Some Particular Kinds of Sauces
202 / 2543(2000)	Food Seasonings Derived from Hydrolysis or Fermentation of Soybean Protein
203 / 2543(2000)	Fish Sauce
204 / 2543(2000)	Vinegar
205 / 2543(2000)	Oil and Fat
206 / 2543(2000)	Butter Oil
207 / 2543(2000)	Margarine
208 / 2543(2000)	Cream
209 / 2543(2000)	Cheese
210 / 2543(2000)	Semi-processed Food
211 / 2543(2000)	Honey
213 / 2543(2000)	Jam, Jelly and Marmalade in Sealed Containers
214 / 2543(2000)	Beverage in Sealed Containers
215 / 2544(2001)	Prescribed Prohibited Foods to be Produced, Imported or Sold

217 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.215) B.E. 2544 (2001)
219 / 2544(2001)	Nutrition Labelling (No.2)
220 / 2544(2001)	Drinking Water in Sealed Containers (No.3)
221 / 2544(2001)	Prescribed Foods to Show Food Serial Number on Food Labels
222 / 2544(2001)	Ice Cream
223 / 2544(2001)	Flavouring Agents
224 / 2544(2001)	Bread
226 / 2544(2001)	Ghee
227 / 2544(2001)	Butter
228 / 2544(2001)	Chewing Gum and Candy
229 / 2544(2001)	Repeal of the Notification of the Ministry of Public Health (No.162) B.E. 2538 (1995)
230 / 2544(2001)	Beverage in Sealed Containers (No.2)
232 / 2544(2001)	Repeal of the Notification of the Ministry of Public Health (No.14) B.E. 2522 (1979)
233 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.23), B.E. 2522 (1979), Prescribed Peanut Oil to be Specific Controlled Food and Prescribed Qualities or Standards, Production Processes, and Labellings
234 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.56) B.E. 2524 (1981), Palm Oil
235 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.57) B.E. 2524 (1981), Coconut Oil
236 / 2544(2001)	Alkaline-preserved Eggs
237 / 2544(2001)	Labelling of Ready-to-Cook Foods and Ready-to-Eat Foods
238 / 2544(2001)	Special Purposed Foods
239 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.193) B.E. 2543 (2000)
243 / 2544(2001)	Meat Products
244 / 2544(2001)	Labelling of Foods Packed Together with Material Intended for Qualities Control Purpose
245 / 2544(2001)	Labelling of Foods Containing Aloe Vera
246 / 2544(2001)	Amendment of the Notification of the Ministry of Public Health (No.217) B.E. 2544 (2001)
247 / 2544(2001)	Prescribed Prohibited Substances to be Used in Foods (No. 2)
248 / 2544 (2001)	Food Seasonings Derived from Hydrolysis or Fermentation of Soybean Protein (No.2)
251 / 2543(2000)	Labelling of Food Obtained through Certain Techniques of Genetic Modification/Genetic Engineering
252 / 2545(2002)	Labels (No.2)
253 / 2545(2002)	Foods in Sealed Containers (No.3)
254 / 2545(2002)	Ice (No.3)
255 / 2545(2002)	Labelling of Foods with Ginkgo biloba Leaves or Extraction from Ginkgo biloba Leaves
256 / 2545(2002)	Drinking Water in Sealed Containers (No.4)
257 / 2545(2002)	Ice Cream (No.2)
259 / 2545(2002)	Application of Methyl Alcohol as Processing Aid in Some Foods
262 / 2545(2002)	Stevioside and Foods Containing Stevioside
263 / 2545(2002)	Prescribed Prohibited Foods to be Produced, Imported or Sold
264 / 2545(2002)	Prescribed Prohibited Foods to be Produced, Imported or Sold
265 / 2545(2002)	Cow's Milk
266 / 2545(2002)	Flavoured Milk
267 / 2545(2002)	Other Milk Products
268 / 2546(2003)	Prescribed Standards for Certain Chemical Contamination in Foods
269 / 2546(2003)	Prescribed Standards for B-Agonist Chemicals Group Contamination in Foods
271 / 2546(2003)	Amendment of the Notification of the Ministry of Public Health (No.260) B.E. 2545 (2002)
272 / 2546(2003)	Distilled Spirits

273 / 2546(2003)	Standard for Foods with Contaminants (No.2)
275 / 2546(2003)	Distilled Spirits (No. 2)
276 / 2546(2003)	Coffee (No.2)
277 / 2546(2003)	Tea (No.2)
279 / 2546(2003)	Amendment of the Notification of the Ministry of Public Health (No.271) B.E. 2546 (2003)
280 /2547(2004)	Herbal tea
281 /2547(2004)	Food Additives
282 /2547(2004)	Cow's Milk (No.2)
283 /2547(2004)	Prescribed Total Polar Compounds in Used Frying Oil or Cooking Oil
284/2547(2004)	Drinking Water in Sealed Containers (No.5)
285 /2547(2004)	Ice (No.4)
286 /2547(2004)	Modified Milk for Infants and Modified Milk for follow-up Formula for Infants and Children (No.2)
287 /2548(2005)	Infant food and Food of Follow-up Formula for Infants and Young Children (No. 3)
288 / 2548(2005)	Foods with Toxic Residues
289 / 2548(2005)	Fermented Milk
290 / 2548(2005)	Beverage in Sealed Containers (No.3)
292 / 2548(2005)	Prohibited Foods to be Produced, Imported or Sold
293 / 2548(2005)	Dietary Supplement
294 / 2548(2005)	Royal Jelly and Royal Jelly Products
295 / 2548(2005)	Prescribed Qualities or Standards for Containers Made from Plastic
296 / 2549(2006)	Foods with Risk from Bovine Spongiform Encephalopathy
298 / 2549(2006)	Production Processes, Production Equipments, and Storage of Ready-to-Consume Milk Products in Liquid Form which Passed Through Pasteurization Heat Treatment
299 / 2549(2006)	Prescribed Standards for Certain Chemical Contamination in foods (No.2)
300 / 2549(2006)	Appointment of Competent Officers for the Execution of the Food Act B.E. 2522 (1979)
301 / 2549(2006)	Food Packed in Sealed Container (No.4)
303 / 2550(2007)	Veterinary Drug Residues in Foods
305 / 2550(2007)	Labelling of Certain Kinds of Ready-to-Eat Foods
307 / 2550(2007)	Modified Milk for Infant and Modified Milk of Follow up Formula for Infant and Young Children (No.3)
308 / 2550(2007)	Infant Food and Food of Follow-up Formula for Infants and Young Children (No.4)
309 / 2550(2007)	Dietary Supplements (No.2)
310 / 2551(2008)	Prohibition of Production, Importation or Sales of Foods Containing Other Non-Food Items or Objects in the Container and Packaging
311 / 2551(2008)	Prescribed Prohibited Food to be Produced, Imported of Sold
- / 2552 (2009)	Food Standard on Pathogens
- / 2552 (2009)	Distilled Spirits
- / 2553 (2010)	Drinking Water in Sealed Containers (No.6)
- / 2553 (2010)	Food Seasonings Derived from Hydrolysis or Fermentation of Soybean Protein
- / 2553 (2010)	Amendment of the Notification of the Ministry of Public Health (No.193) B.E. 2543 (2000)
- / 2553 (2010)	Amendment of the Notification of the Ministry of Public Health (No.220) B.E. 2544 (2001)
- / 2553 (2010)	Amendment of the Notification of the Ministry of Public Health (No.298) B.E. 2549 (2006)
- / 2553 (2010)	Iodized Salt
- / 2553 (2010)	Food Seasonings Derived from Hydrolysis or Fermentation of Soybean Protein (No.2)
- / 2553 (2010)	Fish Sauce (No.2)
- / 2553 (2010)	Brine for Cooking
- / 2553 (2010)	Irradiated Foods

(2) The Agricultural Standard Act B.E. 2551 (2008)⁵³

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) Packing, packaging, 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.

● 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.

⁵³ http://www.acfs.go.th/km/download/AGRICULTURAL_STANDARDS_ACT.pdf

- **Standard Certification Mark (Q-mark)**

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 the producer, exporter or importer who receives certificate for either Mandatory or Voluntary Standards.

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

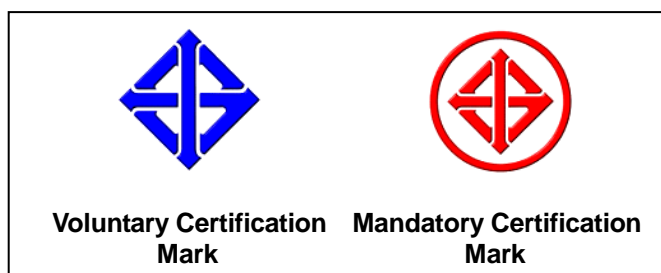
The public Act known as “Industrial Product Standard Act B.E. 2511 (1968)”³⁶, mandates the Thai Industrial Standards Institute (TISI) to “undertake standardization with commitment to the promotion and development of the industry, maximizing the benefits for entrepreneurs, consumers and the nation as 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
- 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.



³⁶ http://www.tisi.go.th/eng/index.php?option=com_content&view=article&id=20&Itemid=6

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)³⁷” 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.

³⁷ <http://faolex.fao.org/docs/pdf/tha4931.pdf>

4. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

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.

4.2 Food Additive Definitions & Functional Classes

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

“Food additives mean 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.”

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

4.3 Permitted Food Additives and Maximum Limits

According to Notification No. 281³⁸, 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 (GSFA) (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.

4.4 Prohibited Substances for Use in Food as Food Additives

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) Furfylframide;
- 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

4.5 Specifications & Standards 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 FAO/WHO Expert Committee on Food Additives (JECFA);

³⁸<http://www.fda.moph.go.th/fda-net/html/product/food/ntf/DirtyFood3Attach.html>

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.

4.6 Application, Assessment and Approval of New 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.

4.7 Labelling of Food Additives in Food

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

4.8 Summary of Food Additives

The definitions regarding food additives such as flavourings, processing aids, and carry-overs are summarized in Table 2; the descriptions of other items such as designated/existing food additives and prohibited substances are summarized in Table 3.

5. SPECIFICATIONS & STANDARDS, AND METHODS OF ANALYSIS FOR GENERAL FOODS

In Thailand, standards and methods of analysis for general foods covering all foods are required to comply with Food Act B.E. 2522 (1979). Standards and methods of analysis for the food categories taken up in the Case Study are described in the food categories, respectively.

6. CASE STUDIES

(1) Instant Noodles

Food Specifications & Standards and Methods of Analysis:

The standards for “Semi-processed food” (Notification of the Ministry of Public Health No. 210 B.E. 2543 (2000)) are shown; as for the methods of analysis, items specified in the Notification of the Ministry of Public Health No. 210 B.E. 2543 (2000) are described (Tables 4 and 5).

Food Additives:

The Specifications is set in the MOPH Notification No. 210 B.E. 2543 for “Semi-processed food”; standards for use of food additives in “Semi-processed food” is regulated by MOPH Notification No. 281 B.E. 2547 for “Food additives” (Table 6).

(2) Carbonated Soft Drinks

Food Specifications & Standards and Methods of Analysis:

The standards for “Beverages in sealed container” (Notification of Ministry of Public Health No. 214 B.E. 2543 (2000)) are shown; as for the methods of analysis, items specified in the Notification of Ministry of Public Health No. 214 B.E. 2543 (2000) are described (Tables 7 and 8).

Food Additives:

The standards are set in “Beverages in sealed container” (Notification of Ministry of Public Health No. 214 B.E. 2543 (2000)) for artificial sweeteners, sulfur dioxide, benzoic acid, etc; conditions for use of other additives are in accordance with MOPH Notification No. 281 B.E. 2547 (Table 9)

(3) Prepared Frozen Foods

Food Specifications & Standards, Methods of Analysis and Food Additives:

No specific specification or standard related to frozen prepared food products were found within any food related laws and regulations in Thailand. The standards for prepared frozen foods are controlled under the standards corresponding to specific issues e.g. microbiological quality, use of food additives, etc.

(4) Cow’s Milk

Food Specifications & Standards, Methods of Analysis and Food Additives:

The specifications are set in Notification of Ministry of Public Health No. 265 B.E. 2543 (2000) for cow’s milk. Preservatives and artificial sweeteners are not permitted. Conditions for use of other additives are in accordance with MOPH Notification No. 281 B.E. 2547 for “Food additives”(Tables 10 and 11).

Table 2: Description/Definition for Food Additives (General)

	Description/Definition	Reference
Related Legislation	Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives	
Summary of Definitions		
Definition of Food Additives	Food additives are defined in the Notification No. 281 as follows: “Food additives mean 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: Description/Definition for Food Additives (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)
Summary of Specific List of Food Additives		
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://www.fda.moph.go.th/fda-net/html/product/food/ntf/DirttyFood3Attach.html (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.
Negative List	As per listed in the attachment to the Notification of the Ministry of Public Health No. 281 B.E. 2547 Re: Food Additives 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-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,	http://iodinethailand.fda.moph.go.th/fda/new/images/cms/tp_upload/1148400006_261-45%281%29.pdf 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/tp_upload/1169705816_no.292.pdf 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/tp_upload/1224050701_Notification_No.311_B.E.2551.pdf Notification of the Ministry of Public Health No. 247 B.E.

	2,2'-oxybis-ethanol or 2,2'-oxydiethanol; 19) daminozide or succinic acid 2,2-dimethylhydrazide	<p>2544 (2001) Re: Prescribed Prohibited Substances to be Used in Foods (No. 2) http://iodinethailand.fda.moph.go.th/fda/new/images/cms/tp_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/tp_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/tp_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/tp_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/tp_upload/1169710676_single%20food%20additive.pdf</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/t_op_upload/1148400098_262-45%281%29.pdf
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/sub_col.php?SubCol_ID=77&Col_ID=14

Table 4: Case Study (1) Instant Noodles: Specifications & Standards

Standard	Notification of the Ministry of Public Health No. 210 B.E. 2543 (2000)
Item	
Name of the Standard	Semi-processed food
Scope	Semi-processed food is classified into 4 types as follows: 1. Noodle, a sheet of rice noodle (Guay-Jub), wheat noodle, rice vermicelli and mung bean vermicelli 2. Kao Tom (Boiled rice) and Joke (Porridge rice). 3. Broth and concentrated soup in cube, powdered or dried form. 4. Curries and curry pastes.
Description	<ul style="list-style-type: none"> ▪ Semi-processed Foods means food which has been passed through partially cooked processes, and can be consumed after passing simple cooked processes in short time, such as filling hot water, boiling or adding other food.
Essential Composition and Quality Factor	Noodles shall be of the qualities or standards as follows: 1. Free of rancid odour. 2. Moisture content not more than 10% by weight, in case being fried with oil and not more than 13% by weight, in case made from other process. 3. Protein not less than 8.5% by weight for wheat noodle. 4. Free of pathogenic microorganisms. Bacillus cereus not more than 100 per 1 g of food. 5. Free of toxic substances released by microorganisms in quantity which may be hazardous to health. 6. Escherichia coli shall be found less than 3 per 1 g. of food by Most Probable Number Method. 7. Bacteria not more than 10,000 per 1 g. of wheat noodle and not more than 30,000 per 1 g. of noodle, a sheet of rice noodle (Guay-Jub), rice vermicelli and mung bean vermicelli. 8. Mold not more than 100 per 1 g of food.
Food Additives	<ul style="list-style-type: none"> ▪ In accordance to the notification of the Ministry of Public Health No. 281 (2004) Re: Food additives
Contaminant	<ul style="list-style-type: none"> ▪ Not specified
Hygiene	<ul style="list-style-type: none"> ▪ Semi-processed Foods producers or importers for sales shall follow to the notification of the Ministry of Public Health No.193 (2000) Re: Production processes, production equipments and foods storages.

Weight and Measures	<ul style="list-style-type: none"> ▪ The net content by weight in metric system
Labelling	<ul style="list-style-type: none"> ▪ Labelling of semi-processed foods shall be labeled and marked with the information according to the notification of the Ministry of Public Health No. 194 (2000) Re: Labels ▪ Labels of foods to be sold to consumers must be expressed in Thai language alphabets, but may contain some foreign language alphabets which are acceptable and must be expressed of the following declarations, except for the exception from the Food and Drug Administration: <ol style="list-style-type: none"> 1. Name of food. 2. Food serial number. 3. Names and addresses of producers or re-packers of food which is produced within the country, names and addresses of importers and country of producers as the case may be. For foods which are produced within the country, names and addresses of head office of producers or re-packers may be expressed instead. 4. The net content by weight in metric system 5. Main ingredients shall be expressed by percentage of approximate weight. 6. Declaration of “Utilizing preservatives” for any usage. 7. Declarations of “Natural colour” or “Artificial colour” for any usage cases. 8. Declaration of “Utilize offor flavour enhancer” (the blank is for the name of flavour enhancer used.) 9. Declaration of “Utilize ofas food artificial sweetener” (the blank is for the name of artificial sweetener.) by alphabets of not smaller than 2 millimeter height and colour of the text shall be highly contrast with the background of the label. 10. Declarations of “Natural flavour”, “Identical artificial flavour”, or “Artificial flavour” as the applicable case. 11. Declarations of date, month and year of manufacture; month and year of manufacture; date, month and year of expiry; or date, month and year within which food remains in good quality or conforms to the standard 12. Instruction for food storage. (If any) 13. Food preparation method for consumption. (If any)
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Methods of sampling – shall be in accordance with those of the FAO/WHO Codex Alimentarius

Table 5: Case Study (1) Instant Noodles: Methods of Analysis

Related Legislation	Item	Specification	Analytical Methods	Reference
Notification of the Ministry of Public Health No. 210 B.E. 2543 (2000)	Moisture content	Not more than 10% by weight, in case being fried with oil, and not more than 13% by weight, in case made from other process	Drying: oven or vacuum	AOAC standard method
	Protein	Not less than 8.5% by weight for wheat noodle	Kjeldahl	AOAC standard method
	Bacteria	Not more than 10,000 per 1 g of wheat noodle		Bacteriological Analytical Manual,
	Pathogenic microorganisms	Free from pathogenic microorganisms		Bacteriological Analytical Manual,
	<i>Bacillus cereus</i>	Not more than 100 per 1 g of food		Bacteriological Analytical Manual,
	<i>Escherichia coli</i>	Less than 3 per 1 g of food	Most Probable Number Method	Bacteriological Analytical Manual,
	Mold	Not more than 100 per 1 g of food		Bacteriological Analytical Manual,
	Toxic substances released by microorganisms	Free of toxic substances released by microorganisms in quantity which may be hazardous to health		
	Food Additives	Notification of the Ministry of Public Health No. 281 (2004) Re: Food additives	Depending on specific additives used	
	Contaminant	Not specified		

Table 6: Case Study (1) Instant Noodles: Food Additives

	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 7: Case Study (2) Carbonated Soft Drinks: Specifications & Standards

Standard Item	Notification of Ministry of Public Health No. 214 B.E. 2543 (2000)
Name of the Standard	Beverages in sealed container
Scope	Beverages in Sealed Containers is prescribed to be specific controlled food, can be classified into 5 categories as follows: 1. Water with dissolved carbon dioxide or oxygen gas. 2. Beverage, which is containing or made from fruits, plants or vegetables, and may also contain dissolved carbon dioxide or oxygen gas. 3. Beverage, which is containing or made from other constituents, except fruits, plants or vegetables, and may also contain dissolved carbon dioxide or oxygen gas. 4. Beverage as stipulated in (2) or (3), which is concentrated and needs to be diluted before consumption. 5. Beverage as stipulated in (2) or (3) in dried form.
Description	<ul style="list-style-type: none"> ▪ Carbonated drink (soda) – A ready-to-drink beverage prepared by mixing carbonated water and sweetening agent or agents with citrus sugar-concentrate or extract.
Essential Composition and Quality Factor	1. Odour and flavour inherent to specific characteristics of that beverage. 2. Free of sediment, except sedimentation naturally occurring from ingredients. 3. Water to be used in production shall follow to qualities or standards in the notification of the Ministry of Public Health, Re: Drinking water in Sealed Containers. 4. Coliform bacteria shall be found less than 2.2 per 100 ml. of beverage by Most Probable Number Method. 5. Free of Escherichia coli. 6. Free of pathogenic microorganisms. 7. Free of toxic substances released by microorganisms or other toxic substances in quantity which may be hazardous to health. 8. Free of yeast and mold 9. Natural alcoholic content from ingredients or alcohol used in production process, the total quantity of alcohol shall be not more than 0.5% by weight. In necessary case where total quantity of alcohol is higher than prescription, such matters must be approved by the Food and Drug Administration.

	Methyl alcohol shall not be used in production process.
Food Additives	<p>Artificial sweetener shall follow the Food Standard of Joint FAO/WHO Codex Re: Food additives, and the amended version, and may be used in single or combination with sugar.</p> <p>In case where no standards is prescribed in the first phrase, the Food and Drug Administration shall prescribe according to an approval of the Food Committee.</p>
Contaminant	<p>Free of contaminants, except the followings:</p> <ul style="list-style-type: none"> ▪ Arsenic not more than 0.2 mg per 1 kg of beverage. ▪ Lead not more than 0.5 mg per 1 kg of beverage. ▪ Copper not more than 5 mg per 1 kg of beverage. ▪ Zinc not more than 5 mg per 1 kg of beverage. ▪ Iron not more than 15 mg per 1 kg of beverage. ▪ Tin not more than 250 mg per 1 kg of beverage. ▪ Sulfur dioxide not more than 10 mg per 1 kg of beverage.
Hygiene	<ul style="list-style-type: none"> ▪ Prepared and handled in accordance to the notification of the Ministry of Public Health No.193 (2000) Re: Production processes, production equipments and foods storages.
Weight and Measures	<ul style="list-style-type: none"> ▪ The net volume in metric system
Labelling	<ul style="list-style-type: none"> ▪ Labels for beverage shall follow to the notification of the Ministry of Public Health No. 194 (2000), Re: Labels <ol style="list-style-type: none"> 1. Name of food. 2. Food serial number. 3. Names and addresses of producers or re-packers of food which is produced within the country, names and addresses of importers and country of producers as the case may be. For foods which are produced within the country, names and addresses of head office of producers or re-packers may be expressed instead. 4. The net volume in metric system 5. Main ingredients shall be expressed by percentage of approximate weight 6. Declaration of "Utilizing preservatives" for any usage. 7. Declarations of "Natural colour" or "Artificial colour" for any usage cases. 8. Declaration of "Utilize offor flavour enhancer" (the blank is for the name of flavour enhancer used.) 9. Declaration of "Utilize ofas food artificial sweetener" (the blank is for the name of artificial sweetener.) by alphabets of not smaller than 2 millimeter height and colour of the text shall be highly contrast with the background of the label. 10. Declarations of "Natural flavour", "Identical artificial flavour", or "Artificial flavour" as the applicable case. 11. Declarations of date, month and year of manufacture; month and year of manufacture; date, month and year of expiry; or date, month and year within which food remains in good quality or conforms to the standard 12. Instruction for food storage. (If any)
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Methods of sampling – shall be in accordance with those of the FAO/WHO Codex Alimentarius

Table 8: Case Study (2) Carbonated Soft Drinks: Methods of Analysis

Related Legislation	Item	Specification	Analytical Methods	Reference
Notification of Ministry of Public Health No. 214 B.E. 2543 (2000)	Coliform bacteria	Less than 2.2 per 100 ml of beverage	Most Probable Number Method	Bacteriological Analytical Manual,
	<i>Escherichia coli</i>	Free of <i>Escherichia coli</i>		Bacteriological Analytical Manual,
	Pathogenic microorganisms	Free from pathogenic microorganisms		Bacteriological Analytical Manual,
	Yeast and mold	Free of yeast and mold		Bacteriological Analytical Manual,
	Toxic substances released by microorganisms	Free of toxic substances released by microorganisms in quantity which may be hazardous to health		
	Alcohol	Not more than 0.5% by weight		
	Free of contaminants, except the followings:			
	* Arsenic	Not more than 0.2 mg per 1 kg of beverage	Atomic absorption	
	* Lead	Not more than 0.5 mg per 1 kg of beverage	Atomic absorption	
	* Copper	Not more than 5 mg per 1 kg of beverage	Atomic absorption	
	* Zinc	Not more than 5 mg per 1 kg of beverage	Atomic absorption	
	* Iron	Not more than 15 mg per 1 kg of beverage	Atomic absorption	
	* Tin	Not more than 250 mg per 1 kg of beverage		
	* Sulfur dioxide	not more than 10 mg per 1 kg of beverage	Optimized Monier-Williams	

Table 9: Case Study (2) Carbonated Soft Drinks: Food Additives

	Description/Definition	Reference
Scope and/or Description	Beverage in sealed container	<p>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</p>
Positive and/or Negative List	<p>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>	
Use Limitation and/or Maximum Level, if any	<p>1. Sulfur dioxide: <70mg/kg 2. Benzoic acid (and salts): <200mg/kg 3. Sorbic acid (and salts): <200mg/kg</p> <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>	

Table 10: Case Study (4) Cow's Milk: Specifications, Standards, and Methods of Analysis

Related legislation	Item	Specification	Analytical Methods	Reference
Notification of the Ministry of Public Health No. 265 B.E. 2545 (2002)	Milk protein content	Not less than 2.8% by weight	Kjeldahl	AOAC standard method
	Milk solid non-fat and milk fat		Acid hydrolysis, solvent extraction	
	* Whole milk	Milk solid non-fat content not less than 8.25% by weight, milk fat content not less than 3.2% by weight		
	* Partly skimmed milk	Milk solid non-fat content not less than 8.5% by weight, milk fat content more than 0.1% by weight but less than 3.2% by weight		
	* Skimmed milk	Milk solid non-fat content not less than 8.8% by weight, milk fat content not more than 0.1% by weight		
	Pathogenic microorganisms	Free from pathogenic microorganisms		Bacteriological Analytical Manual,
	Bacterial count in pasteurized milk	Not more than 10,000 in 1 ml. at manufacturing factory and not more than 50,000 at all time after that to the expiry date		Bacteriological Analytical Manual,
	Bacterial count in sterilized and UHT milk	Not be detected in 1 ml		Bacteriological Analytical Manual,
	<i>Escherichia coli</i>	Not detected in 0.1 ml of heat treated milk		Bacteriological Analytical Manual,
	Coliform bacteria	Not more than 100 in 1 ml of pasteurized milk at manufacturing factory		Bacteriological Analytical Manual,
	<i>Bacillus cereus</i>	Not more than 100 in 1 ml of pasteurized milk		Bacteriological Analytical Manual,
	Contaminant	Free of toxic substances and contaminants in quantity which may be hazardous to health		
Food Additives	<ul style="list-style-type: none"> • Permitted food additives to be used in milk powder and filled milk powder (Maximum level): • Stabilizers Sodium citrates , Potassium citrates - 5,000 mg/kg for single used or combination used, calculated on dry basis. • Firming agents Potassium chloride, Calcium chloride - appropriate quantities necessary for production. 			

		<ul style="list-style-type: none"> •Acidity regulators Sodium phosphates, Potassium phosphates, Diphosphates, Triphosphates, Polyphosphates, Sodium carbonates, Potassium carbonates <ul style="list-style-type: none"> - 5,000 for single used or combination used, calculated on dry basis. •Emulsifiers Lecithins or phospholipids from natural sources. appropriate quantities necessary for production. •Mono- and diglycerides of fatty acids. <ul style="list-style-type: none"> - 2,500 mg/kg •Anti-caking agents Calcium carbonates, Tricalcium orthophosphate, Trimagnesium orthophosphate, Magnesium carbonate, Magnesium oxide, Silicon dioxide, amorphous, Calcium silicate, Magnesium silicate, Sodium aluminosilicate, Calcium aluminium silicate, Aluminium silicate <ul style="list-style-type: none"> - 10,000 for single use or combination use - • Polydimethylsiloxane - 10 mg/kg •Antioxidants L-Ascorbic acid, Sodium ascorbate, Ascorbyl palmitate <ul style="list-style-type: none"> - 500 mg/kg calculated as ascorbic acid Butylated hydroxyanisole BHA 100 mg/kg 		
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		<ul style="list-style-type: none"> • Permitted food additives to be used in condensed milk, recombined condensed milk, filled condensed milk. • Stabilizers Sodium citrates, Potassium citrates, Calcium citrates <ul style="list-style-type: none"> - 2,000 mg/kg for single use or 3,000 mg/kg for combination use, calculated on dry basis. • Firming agents Potassium chloride, Calcium chloride <ul style="list-style-type: none"> - 2,000 mg/kg for single use or 3,000 mg/kg for combination use, calculated on dry basis. • Acidity regulators Calcium carbonates, Sodium phosphates, Potassium phosphates, Calcium phosphates, Diphosphates, Triphosphates, Polyphosphates, Sodium carbonates, Potassium carbonates <ul style="list-style-type: none"> - 2,000 mg/kg for single use or 3,000 mg/kg for combination use, calculated on dry basis • Emulsifier Lecithins <ul style="list-style-type: none"> - appropriate quantities necessary for production. • Thickener Carrageenan 150 mg/kg 		
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Table 11: Case Study (4) Cow's Milk: Food Additives

	Description/Definition	Reference
Scope and/or Description	Cow's milk	
Positive and/or Negative List	Preservatives and artificial sweeteners are not permitted.	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
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.	

4.8 Republic of the Philippines

1. FOOD ADMINISTRATION

The 1987 Constitution of the Philippines³⁹ 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 Philippines⁴⁰ 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.

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 1.

Table 1: Food Safety Control System

	Safety and Hygiene of Agricultural Products and Primary Processed Foods	Safety and Hygiene of Processed Foods
	Department of Agriculture (DA)	Department of Health (MOH)
Agricultural products	Bureau of Plant Industry (BPI)	Food and Drug Administration (FDA) * *Formerly called BFAD (Bureau of Food and Drugs Administration), but as the law was amended in August 2009 to strengthen capability and augment human resources, it was renamed.
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)	

2. FOOD LAW SYSTEM AND SPECIFIC FOOD STANDARDS

The relationship between the Food Law system and Commodity Standards is shown in Figure 1.

³⁹ http://www.gov.ph/index.php?option=com_content&task=view&id=200034&Itemid=26

⁴⁰ http://www.gov.ph/index.php?option=com_content&task=view&id=200034&Itemid=26

Philippine Commodity Standards

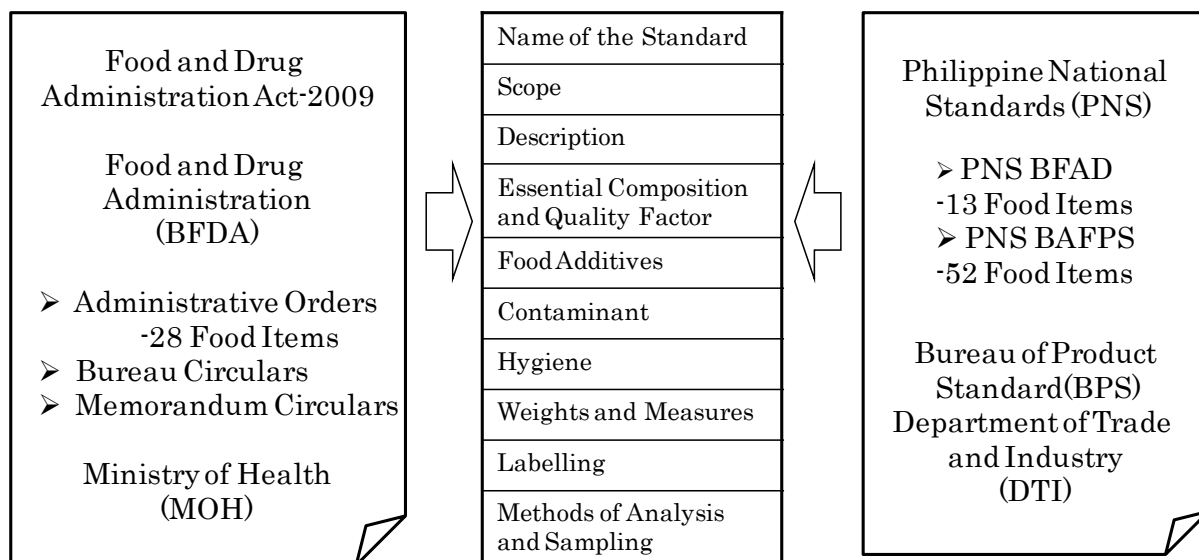


Figure 1: Philippine Commodity Standards and Relevant Laws

(1) Food and Drug Administration Law⁴¹

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 Orders and Circulars⁴²

Administrative orders (AO) related to commodity standards are presented in Table 2.

Table 2: Commodity Standards in Publication of Administrative Orders

Administrative Orders	Titles
AO 125 s. 1970	Regulation prescribing the Standard of Identity and Fill of Container for Canned Pineapple Juice (B-4.7-01)

⁴¹ <http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1232>

⁴² <http://www.bfad.gov.ph/default.cfm?CFID=89868&CFTOKEN=85282931#>

AO 129 s. 1970	Regulation prescribing the Standard of Identity and Quality of Bagoong (Fish or Shrimp) (B-4.7-01)
AO 132 s. 1970	Regulation prescribing the Standard of Identity and Quality of Milk and Milk Products
AO 134 s. 1970	Regulation prescribing the Standard of Identity and Quality of Vinegar
AO 154 s. 1971	Regulation B-4 Definition and Standards of Identity of Foods: 4.14 Meat and Meat Products 4.14.01 Sausages
AO 200-A s. 1973	Regulation B-4 Definition and Standards of Identity of Foods: 4.5 Cheese and Cheese Products
AO 228 s. 1974	Regulation B-4 Definition and Standards of Identity of Foods: 4.17 Nut Products 4.17.01 Peanut Butter
AO 230 s. 1974	Regulation B-4 Definition and Standards of Identity of Foods: 4.15 Fats and Oils 1.15.01 Shortening
AO 231 s. 1974	Regulation B-4 Definition and Standards of Identity of Foods: 4.15 Fats and Oils 4.15.02 Lard
AO 232 s. 1974	Regulation B-4 Definition and Standards of Identity of Foods: 4.18 Margarine
AO 233 s. 1974	Regulation B-4 Definition and Standards of Identity of Foods: 4.9 Condiments, Sauces, Seasoning 4.9.01 Tomato Catsup (Catsup)
AO 235 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.6 Dressings for Food 4.6.01 Mayonnaise (Mayonnaise Dressing and Mayonnaise Salad Dressing)
AO 236 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.6 Dressings for Food 4.6.03 Salad Dressing
AO 237 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.6 Dressings for Food 4.6.02 French Dressing
AO 238 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.13 Jams (Fruit Preserves) and Jellies 4.13.01 Jams (naming the fruit)
AO 239 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.13 Jams (Fruit Preserves) and Jellies 4.13.02 Jellies (naming the fruit)
AO 243 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.18 Margarine
SAO 257 s. 1976	Standardization of Rum
SAO 258 s. 1976	Standardization of Vodka
SAO 259 s. 1976	Standardization of Whiskies
AO 325 s. 1977	Regulation B-4 Definition and Standards of Identity of Foods: 4.9 Condiments, Sauces and Seasonings 4.9.01 Standard of Identity and Quality for Patis
SAO 356 s. 1978	Standardization of Beer
SAO 358 s. 1978	Standardization of Brandies
AO 123-A s. 1985	Standard for Banana Sauce
AO 136-A s. 1985	Standard of Instant Coffee
AO 136-B s. 1985	Standard for Soluble Coffee with Added Carbohydrates
AO 18-A s. 1993	Standard of Quality and Requirement for the Processing, Packaging and Labeling of Bottled Drinking Water
AO 2005-0018	Philippine National Standards on Ethnic Food Products

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 as follows.

Food Additives	<ul style="list-style-type: none"> • BC 2006-16: Updated List of Food Additives
Hygiene	<ul style="list-style-type: none"> • AO 153s. 2004: Guidelines, Current Good Manufacturing Practices in Manufacturing, Packing, Repacking or Storage of foods. • BC 01-as. 2004: Guidelines for the Assessment of Microbiological Quality of Processed Foods
Labeling	<ul style="list-style-type: none"> • AO 16s. 1979: Date Marking of Prepackaged Foods. • AO 88-Bs, 1984: Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines • BC No. 9s 1999: Labeling of prepackaged Processed Meat Products • BC 2007-002: Guidelines in the use of Nutrition and Health Claims in food
Weight and Measures	<ul style="list-style-type: none"> • BC 6As. 1988: Permissible Net Content Variation in Prepackaged Food

(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. Format is shown in Table 3.

Table 3: Format of Philippine National Standards

PHILIPPINE NATIONAL STANDARDS PNS/BFAD 11:2007 ICS 67.160.20 Citrus beverage products – Specification	
Contents	
1 Scope 2 Definition of terms 3 Description of products 4 Essential composition and quality factors 5 Food additives 6 Contaminants 7 Hygiene 8 Weight and measures 9 Labelling 10 Methods of sampling and analysis	Table1 Food additives for fruit juices Annexes 1 Varieties of Philippine citrus fruits utilized in the production of Philippine citrus beverage products 2 Measurement of pH 3 Determination of titrable acidity 4 Determination of total soluble solids 5 Determination of alcohol in fruits products

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 name of FDA) are mandatory standards (Table 4). There are 13 commodity standards excluding code of practices for processing.

Table 4: Specific Standards and Code of Practice for Processed Food (Mandatory Standards)

Standard Number	Title
PNS-BFAD 01:2005	Ethnic food products – Dry base mixes for soups and sauces
PNS-BFAD 02:2005	Ethnic food products – Sweet preserves
PNS-BFAD 03:2006	Recommended code of practice for the processing and handling of sweet

	preserves
PNS-BFAD 04:2006	Ethnic food products – Dried, salted fish – Specification
PNS-BFAD 05:2006	Recommended code of practice for the processing and handling of dried fish
PNS-BFAD 06:2006	Thermally processed fish products – Specification
PNS-BFAD 07:2006	Recommended code of practice for the processing and handling of thermally processed fish products
PNS-BFAD 08:2007	Fermented milks – Specification
PNS-BFAD 09:2007	Mango beverage products – Specification
PNS-BFAD 10:2007	Recommended code of practice for the processing and handling of mango beverage products
PNS-BFAD 11:2007	Citrus beverage products – Specification
PNS-BFAD 12:2007	Recommended code of practice for the processing and handling of citrus beverage products
PNS-BFAD 13:2007	Banana chips – Specification
PNS-BFAD 14:2007	Recommended code of practice for the processing and handling of banana chips
PNS-BFAD 15:2007	Dried mango products – Specification
PNS-BFAD 16:2007	Dried tropical fruits – Specification
PNS-BFAD 17:2007	Recommended code of practice for the processing and handling of dried tropical fruits
PNS-BFAD 18:2008	Flour sticks (pancit canton) – Specification
PNS-BFAD 19:2008	Recommended code of practice for the processing and handling of flour sticks (pancit canton)
PNS-BFAD 20:2009	Sugar cane wine (basi) – Specification
PNS-BFAD 21:2009	Recommended code of practice for the processing and handling of sugar cane wine (basi)

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 5 shows standards for specifications, grade and classification of specific food, and these are mandatory standards as well.

Table 5: Standards for Fresh Foods (Mandatory Standards)

Standard Number	Item
PNS/BAFPS 01:2003	Coffee beans (green)
PNS/BAFPS 07:2003	Organic agriculture
PNS/BAFPS 08:2004	Banana Saba and Cardaba
PNS/BAFPS 09:2004	Pineapple
PNS/BAFPS 10:2004	Corn grains
PNS/BAFPS 11:2004	Pummelo
PNS/BAFPS 12:2004	Durian
PNS/BAFPS 13:2004	Mango
PNS/BAFPS 14:2003	Bulb Onions
PNS/BAFPS 15:2004	Corn grits
PNS/BAFPS 16:2005	Broccoli
PNS/BAFPS 17:2005	Cabbage
PNS/BAFPS 18:2005	Cauliflower
PNS/BAFPS 19:2005	Lettuce
PNS/BAFPS 26:2006	Tomato
PNS/BAFPS 29:2008	Dried cassava chips and granules
PNS/BAFPS 30:2005	Calamansi
PNS/BAFPS 31:2006	Mangosteen
PNS/BAFPS 33:2005	Papaya

PNS/BAFPS 34:2005	Pili nuts (shelled)
PNS/BAFPS 35:2005	Table eggs
PNS/BAFPS 38:2006	Carrots
PNS/BAFPS 52:2007	Eggplant
PNS/BAFPS 56:2007	Watermelon
PNS/BAFPS 57:2007	Fresh mandarin

3. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

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

3.2 Food Additive Definitions & 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 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

3.3 Permitted Food Additives and Maximum Limits

The Philippines has adopted the Codex General Standard for Food Additives (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.

3.4 Prohibited Substances for Use 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 Specifications for Food Additives

Specifications for food additives are in accordance with the specifications of identity and purity recommended by the Codex Alimentarius Commission, Joint FAO/WHO Expert Committee on Food Additive (JECFA) or, in the absence of such specifications, by responsible international regulating bodies.

3.6 Application, Assessment, and Approval of New 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

3.7 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.

3.8 Summary of Food Additives

The definitions regarding food additives such as flavours, processing aids, and carry-overs are summarized in Table 6; the descriptions of other items such as designated/existing food additives and prohibited substances are summarized in Table 7.

4. SPECIFICATIONS & STANDARDS AND METHODS OF ANALYSIS FOR GENERAL FOODS

Standards and methods of analysis for General Foods are summarized in Table 8; standards and methods of analysis for the food categories taken up in the Case Study are described in the sections of these food categories respectively.

5. CASE STUDIES

(1) Instant Noodles

Commodity Food Standards, Methods of Analysis and Food Additives:

Pancit Canton (PNS BFAD 18:2008) which are like instant pan-fried noodles are taken (Tables 9, 10, and 11) as the similar food.

(2) Carbonated Soft Drinks

Commodity Food Standards, Methods of Analysis and Food Additives:

No standard covers only carbonated soft drinks like in Japan. There are National Standards for Citrus Beverage Products (PNS BFAD 11: 2007) which can be applied for wide range of products like Japanese standards for carbonated soft drinks (Tables 12 13, and 14).

(3) Prepared Frozen Foods

While there are standards for frozen squid, frozen shrimp and frozen fish, no standard more like Japanese standard for prepared frozen food.

(4) Cow's Milk

Commodity Food Standards, Methods of Analysis and Food Additives:

The use of food additives in "Fresh milk" (PNS BFAD 36: 2007) is prohibited (Tables 15 and 16).

Table 6: Summary/Definitions of Food Additives (General)

	Summary/Definitions	References
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
Summary of General Definitions for Food Additives		
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-overs	Defined in general principles according to BC 2006-16	FDA Circular No. 2006-016, Part III, C

Table 7: Summary/Definitions of Food Additives (Specific)

	Description/Definitions	References	
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	
Summary of Specific Food Additives Lists			
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. However, flavours, either natural or synthetic, shall comply with FEMA GRAS or IOFO.	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	

Table 8: Specifications & Standards and Methods of Analysis for General Foods

Food Categories	Related Legislations	Items	Specifications	Methods of Analysis	References
Food in General (Applied to All Foods)	FDA Circular 2006-016: Updated List of Food Additives	Food additives	As specified in the FDA Circular 2006-016	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines
	FDA Circular 01-As. 2004: Guidelines for the Assessment of Microbiological quality of processed foods	Microbiological quality of processed foods	As specified in the FDA Circular 01-As. 2004	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines
	FDA Circular 2010-008: Adoption of the Codex Standards on Food Contaminants in Processed Food	Food contaminants	As specified in the FDA Circular 2010-008, following Codex Alimentarius Standards on Food Contaminants	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines

Table 9: Case Study (1) Instant Noodles: Specifications & Standards

Standards	PNS/BFAD 18:2008	
Items		
Name of the Standards	Flour sticks (pancit canton)	
Scope	<ul style="list-style-type: none"> ■ Processed flour sticks (pancit canton) for human consumption 	
Descriptions	<ul style="list-style-type: none"> ■ Flour sticks or 'pancit canton' are molded and fried noodle strands, which can be consumed with or without prior cooking preparation, made from wheat flour, singly or in combination with other flours and/or starches, water and salt with or without added optional ingredients. 	
Essential Composition and Quality Factors	<ul style="list-style-type: none"> ■ Basic Ingredients: wheat flour; potable water; salt; cooking oil ■ Optional Ingredients: other flours and starches; fresh eggs or egg powder; fresh or powdered fruit and vegetables; seasoning and condiments. ■ General requirements – Moisture content: <8%; Free fatty acids: 0.5% (as oleic acid); Sensory properties: uniform size of noodle strands with acceptable colour, no rancid odour and taste and crispy texture. ■ Types of defects – Foreign matter: any matter which has not been derived from the components or constituents of ingredients used in the product; does not pose a threat to human health and can be recognized without magnification or is present at a level determined by a method including magnification that indicates non-compliance with good manufacturing and sanitation practices. ■ Appearance: 	

	<ul style="list-style-type: none"> (a) Brownish or blackish specks or discolouration that affects > 5% of the weight of the sample unit after manufacture; (b) Loose or broken noodle strands present in weights >5 % of the weight of the sample unit after manufacture. ■ Odour and flavour: <ul style="list-style-type: none"> (a) Objectionable odour and flavour indicative of deterioration or contamination (like rancidity, fermentation or taints) on uncooked and cooked noodles; (b) Pronounced burnt odour on uncooked and cooked noodles.
Food Additives	<ul style="list-style-type: none"> ■ In accordance to BFAD Bureau Circular No. 2006-016, the Codex Alimentarius Commission and/or authority for these products. ■ Permitted food additives to be used: <ul style="list-style-type: none"> <u>Acid regulator</u> NaOH – GMP <u>Antioxidant</u> BHA – Max: 100 mg/kg; BHT – Max: 200 mg/kg; Tocopherol – GMP <u>Colour</u> FD&C Yellow #5 (Tartrazine) – Max: 300 mg/kg; FD&C Yellow #6 (Sunset Yellow) - Max: 300 mg/kg <u>Flour treatment agent</u> Phosphates (as Na or K Phosphates) – Max: 2,200 mg/kg <u>Raising agent/stabilizer</u> Na₂CO₃ – Max: 2,600 mg/kg; K₂CO₃ – Max: 2,600 mg/kg ■ Carry-over of other food additives not listed shall be allowed provided they are approved by BFAD regulation and in accordance to Section 5.2 of the “Codex Principles Relating to the Carry-Over of Food Additives into Foods (CAC/Volume 1 1991)”.
Contaminants	<ul style="list-style-type: none"> ■ Not specified
Hygiene	<ul style="list-style-type: none"> ■ Prepared and handled in accordance to “ Codex Recommended International Code of Practice – General Principles of Food Hygiene” and/or “BFAD A.O. No. 153 s. 200 – Guidelines on the Current Good Manufacturing Practices in Manufacturing , Packing, Repacking or Holding Food” and processed according to the “Recommended Code of Practice for the Processing of Flour Sticks (Pancit Canton) (PNS 19:2008)”. ■ When tested by appropriate methods of sampling and examination: <ul style="list-style-type: none"> a) free from filth that may pose a hazard to health; b) free from parasites which may represent a hazard to health; c) not contain any substance originating from microorganisms in amounts which may represent a hazard to health; and d) free from spoilage or pathogenic microorganisms capable of survival and multiplication under normal storage conditions ■ The product shall be packed in suitable hygienic primary and secondary packages that will maintain its quality during storage and transport.
Weight and Measures	<ul style="list-style-type: none"> ■ The average net weight of sample unit may exceed declared net weight; however, no individual package shall be <95% of the declared net weight.
Labelling	<ul style="list-style-type: none"> ■ Labelling of retail packages/container – each retail container shall be labelled and marked with the information according to BFAD Labelling Regulations and shall contain the following information: <ul style="list-style-type: none"> a) The name of the product. The name of the product shall be “Flour Sticks” or “Pancit Canton”. The product may be called by other common names like: “Wheat Flour Sticks”, “Wheat Noodles”, “Wheat Flour Noodles”, “C(K)anton Noodles” or

	<p>“Panc(s)it C(K)anton Noodles”, provided such name is accepted in the country of distribution.</p> <p>b) The Name and address of either the manufacturer, packer, distributor, importer, exporter or vendor of the food.</p> <p>c) The complete list of ingredients and food additives used in the preparation of the product in descending order of proportion.</p> <p>d) The net content by weight in metric system. Other systems of measurement required by importing countries shall appear in parenthesis after metric system unit.</p> <p>e) The words “Best/Consume Before”/“Use by date”, indicating end of period at which the product shall retain its optimum quality attributes at define storage conditions.</p> <p>f) Lot identification marked in code identifying product lot.</p> <p>g) The words “Product of the Philippines” or similar expressions, or the country of origin if imported.</p> <p>h) Additional requirements – a pictorial representation of the product(s) on the label should not mislead the consumer with respect to the product so illustrated.</p> <ul style="list-style-type: none"> ■ Labelling of non-retail, bulk containers – The name of the product, lot identification code and the name and address of the manufacturer or packer shall appear in the container. However, the name and address of the manufacturer may be replaced by identification marks provided that such mark is clearly identified with accompanying documents. ■ Nutrition labelling – Nutrition labelling shall conform to established regulations by the BFAD.
<p>Methods of Analysis and Sampling</p>	<ul style="list-style-type: none"> ■ Method sampling – shall be in accordance with the FAO/WHO Codex Alimentarius Sampling Plans for Pre-packaged Foods (CAC/RM 42-1969) ■ Determination of moisture – according to method of AOAC (2005, 18th edition) using the Oven Method ■ Determination of free fatty acids (FFA) – according to the method of AOAC (2005, 18th edition) using the Titrimetric Method ■ Determination of net weight

Table 10: Case Study (1) Instant Noodles: Methods of Analysis

Related Legislations	Items	Specifications	Methods of Analysis	References
PNS/BFAD 18:2008 - Flour Sticks (Pancit Canton)	Sampling	In accordance with FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (CAC/RM-1969)		
	Moisture content	<8%	Oven Method	AOAC (2005, 18 th Edition)
	Free fatty acids	< 0.5% (as oleic acid)	Titrimetric Method	AOAC (2005, 18 th Edition)
	Net weight	The average net weight of the sample unit may exceed the declared net weight, however, no individual package shall be less than 95% of the declared net weight.	PNS/BFAD 18:2008 Annex C	

Table 11: Case Study (1) Instant Noodles: Food Additives

	Description/Definitions	References
Scope and/or Description	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.	PNS/BFAD 18:2008 Flour sticks (pancit canton)
Use Limitation and/or Maximum Level	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 12: Case Study 2 Carbonated Soft Drinks: Specifications & Standards

Standard Item	PNS/BFAD 11:2007
Name of the Standard	Citrus beverage products
Scope	<ul style="list-style-type: none"> ■ Philippine calamansi (<i>Microcarpa Bunge</i>) and dalandan (<i>Citrus aurantium</i>) beverages including ready-to-drink (RTD) beverages made from sound and mature calamansi or dalandan preserved exclusively by physical means. Preservation by physical means does not include ionizing radiation. Other citrus cultivars may also be used provided they conform to the standard stated herein.
Description	<ul style="list-style-type: none"> ■ Carbonated drink (soda) – A ready-to-drink beverage prepared by mixing carbonated water and sweetening agent or agents with citrus sugar-concentrate or extract.
Essential Composition and Quality Factors	<ul style="list-style-type: none"> ■ Basic Ingredients – Citrus: Calamansi or dalandan – fruit to be used shall be fresh, sound, clean and mature from any cultivated variety suitable to the characteristics of the fruits of <i>Microcarpa Bunge</i> or <i>Citrus aurantium</i> variety. Other cultivars of citrus may also be used. ■ Potable water: Water fit for human consumption. Sweetening agent: One or more of the sugars, honey, high intensity sweeteners or artificial sweeteners. Other ingredients: Other food-grade ingredients may be added. ■ General requirements – the citrus beverage product shall have the characteristic colour, aroma and flavour of the variety of citrus fruit from which it is made and shall be free from objectionable sensory characteristics. ■ pH and titrable acidity – the pH of the extract for calamansi: >2.0, dalandan: >2.50; titrable acidity (as % citric acid) for calamansi: >4.5%, dalandan: >0.7% ■ Soluble solids – the soluble solids content of the extract (exclusive of added sweetening agent/s) for calamansi: >6.0% m/m, for dalandan: >7.0% m/m, as determined by refractometer at 20°C, uncorrected for acidity and read as °Brix on the International Sucrose Scales. ■ Sweetening agent – one or more of the sugars, honey, high intensity sweeteners and artificial sweeteners may be added in amounts according to regulations set by BFAD, the Codex Alimentarius Commission and/or authority for these products. ■ Ethanol content – the ethanol content shall not exceed 3 g/kg. ■ Volatile acids – traces of volatile acids may be present. ■ Sensory properties – the product shall have the characteristic colour, aroma and flavour of the citrus fruit (calamansi or dalandan) used. ■ Types of defects – Foreign matters: any matter, which has not been derived from the citrus fruit (calamansi or dalandan), does not pose a threat to human health and is readily recognized without magnification or is present at a level determined by magnification method or any equivalent methods that indicates non-compliance with good manufacturing practices and sanitation practices. ■ Odour/flavour/colour: a sample unit affected by objectionable odours or flavours indicative of decomposition and unacceptable discolouration due to product deterioration.
Food Additives	<ul style="list-style-type: none"> ■ In accordance to BFAD Bureau Circular No. 2006-016, the Codex Alimentarius Commission and/or authority for these products. ■ Permitted food additives to be used: <u>Acid regulator</u> Citric acid; malic acid; calcium carbonate; adipates

	<p><u>Anticaking agent</u> Calcium aluminium silicate (synthetic); microcrystalline cellulose; aluminium silicate; carnauba wax</p> <ul style="list-style-type: none"> ■ <u>Antioxidant</u> Ascorbic acid; calcium ascorbate; erythorbic acid; potassium ascorbate; sodium ascorbate; sodium erythroate <p><u>Colour</u> Carotenoids; chlorophylls, copper complexes; curcumin; riboflavin; sunset yellow; tartrazine</p> <p><u>Preservatives</u> Benzoates; hydrobenzoates; sorbates; sulphites; carbon dioxide; phosphates; EDTA</p> <p><u>Processing aids</u></p> <ol style="list-style-type: none"> a. Antifoaming agents – polydimethylsiloxane b. Clarifying agents/filtration aids/flocculating agents – adsorbent clays; adsorbent resins; activated carbon (only from plants); bentonite; cellulose; chitosan; colloidal silica; diatomaceous earth; gelatine (from skin collagen); ion exchange resins (cation and anion); kaolin; perlite; polyvinylpyrrolidone; rice hulls; silicasol; tannin c. 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) d. Packing gas – nitrogen, carbon dioxide <p><u>Stabilizer/thickener</u> 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</p> <p><u>Sweetener</u> Acesulfame potassium; aspartame; saccharin; sucralose</p>
Contaminants	<ul style="list-style-type: none"> ■ Pesticide residues – amount of residue shall comply with those maximum residue limits for pesticides established by the Codex Alimentarius Commission and/or authority for these products. ■ Heavy metal contamination – the citrus beverage products covered by the provisions of this standard shall comply with those maximum residue levels for heavy metal contamination established by the Codex Alimentarius Commission and/or authority for these products.
Hygiene	<ul style="list-style-type: none"> ■ Prepared and handled in accordance with the appropriate sections of the “Codex Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1 -1969, Rev. 4-2003)” and/or “BFAD A.O. No. 153 s.2004 – Guidelines, Current Good Manufacturing Practices in Manufacturing, Packing, Repacking or Holding Food” and processed according to the “Recommended Code of Practice for the Processing and Handling of Citrus Beverage Products (PNS/BFAD 12:2007)”. ■ When tested by appropriate methods of sampling and examination: <ol style="list-style-type: none"> a) free from filth that may pose a hazard to health; b) free from parasites which may represent a hazard to health; c) not contain any substance originating from microorganisms in amounts which may represent a hazard to health; d) free from spoilage or pathogenic microorganisms capable of survival and multiplication under normal storage conditions; and e) free from container integrity defects which may compromise the hermetic seal
Weight and Measures	<ul style="list-style-type: none"> ■ Minimum fill – the citrus beverage product shall occupy not less than 90% of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C, which the sealed container will hold when completely filled. A container that fails to meet the requirement for minimum fill (90% container capacity) shall be considered “slack filled”.

<p>Labelling</p>	<ul style="list-style-type: none"> ■ Each container shall be labelled and marked with the following information in accordance with current BFAD's Labelling Regulation: <ul style="list-style-type: none"> a) The name of the product shall be "[Name of citrus fruit + Type of beverages product]" (ex. Calamansi Juice; Dalandan Juice Powder); b) Products using artificial sweetener/s shall have statement/s referring to its low and/or reduced caloric value and the possibility of hypersensitivity to some of its components; c) The complete list of ingredients and food additives used in the preparation of the products in descending order of proportion; d) The net quantity of content by weight in the metric system. Other systems of measurement required by importing countries shall appear in parenthesis after the metric system unit; e) The name and address of the manufacturer, packer and/or distributor of the food; f) Open date marking: The word "Best/Consume before"/"Use by date", indicating end of period at which the product shall retain its optimum quality attributes at defined storage conditions; g) Lot or code number identifying product lot; h) The words "Product of the Philippines", or the country of origin if imported; i) Additional requirements – A pictorial representation of fruit(s) on the label should not mislead the consumer with respect to the fruit so illustrated; j) Direction for use should be indicated in the label; k) Storage instructions – where the citrus beverage product requires to be kept under conditions of refrigeration, there shall be information for storage and, if necessary, thawing of the product. Where practicable, storage instructions should be in close proximity to the open date marking; ■ Nutrition labelling – nutrition labelling shall conform to established regulations of BFAD.
<p>Methods of Analysis and Sampling</p>	<ul style="list-style-type: none"> ■ Measurement of pH – according to AOAC Official Methods of Analysis, Method No. 981.12, 16th ed., 1995. ■ Determination of titrable acidity – According to AOAC Official methods of Analysis No. 942.15, 16th ed., 1995. ■ Determination of total soluble solids – According to AOAC Official methods of Analysis No. 932.14C, 16th ed., 1995. ■ Determination of alcohol in fruit products – According to AOAC Official methods of Analysis No. 920.150, 16th ed., 1995 ■ Method of sampling – Sampling shall be in accordance with the FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods – CAC/RM 42-1969, Codex Alimentarius Volume 13, 1994. ■ Determination of lead using atomic absorption spectrophotometer – According to AOAC Official methods of Analysis No. 972.25, 16th ed., 1995. ■ Determination of tin using atomic absorption spectrophotometer – According to AOAC Official methods of Analysis No. 985.16, 16th ed., 1995.

Table 13: Case Study (2) Carbonated Soft Drinks: Methods of Analysis

Related Legislation	Items	Specifications	Methods of Analysis	References
PNS/BFAD 11:2007 - Citrus Beverage Products	pH	pH of extract for calamansi: >2.0, dalandan: >2.50	AOAC Method No. 981.12	AOAC Official Methods of Analysis, 16 th Edition, 1995
	Titration acidity	Titration acidity (as % citric acid) for calamansi: >4.5%, dalandan: >0.7%	AOAC Method No. 942.15	AOAC Official Methods of Analysis, 16 th Edition, 1995
	Total soluble solids	Soluble solids of the extract (exclusive of added sweetening agents) for calamansi: >6.0% m/m, for dalandan: >7.0% m/m, as determined by refractometer at 20C, uncorrected for acidity and read as Degrees Brix on the International Sucrose Scales	AOAC Method No. 932.14C	AOAC Official Methods of Analysis, 16 th Edition, 1995
	Alcohol in fruit products	< 3g/kg	AOAC Method No. 920.150	AOAC Official Methods of Analysis, 16 th Edition, 1995
	Sampling	In accordance with FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (CAC/RM-1969)		
	Lead	According to maximum limits established by Codex Alimentarius Commission and/or authority for these products	AOAC Method No. 972.25	AOAC Official Methods of Analysis, 16 th Edition, 1995
	Tin	According to maximum limits established by Codex Alimentarius Commission and/or authority for these products	AOAC Method No. 985.16	AOAC Official Methods of Analysis, 16 th Edition, 1995

Table 14: Case Study (2) Carbonated Soft Drinks: Food Additives

	Summary/Definitions	References
Scope and/or Description	Citrus beverage products	
Positive and/or Negative List	Usage of food additives in accordance with FDA Circular No. 2006-016 and Codex GSFA.	
Use Limitations and/or Maximum Levels	<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) 	<p>PNS/BFAD 11:2007 Citrus beverage products</p>

Table 15: Case Study (4) Cow's Milk: Food Specifications, Standards, and Methods of Analysis

Related Legislations	Items	Specifications	Methods of Analysis	References
Administrative Order No. 132 s.1970: Regulation Prescribing the Standard of Identity and Quality of Milk and Milk Products (B-4. 12-01)	Milk fat	> 3.0%	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines
	Non-fat milk solids	> 8.25%	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines
FDA Circular 01-As. 2004: Guidelines for the Assessment of Microbiological Quality of Processed Foods	Pasteurized milk	Coliforms, cfu/ml: n=5, c=1, m=10 ² , M=10 ³ (must be negative for <i>E. coli</i>); Salmonella/25ml: n=5, c=0, m=0; <i>Listeria monocytogenes</i> /25ml: n=5, c=0, m=0; Psychrotrophic bacteria, cfu/ml: n=5, c=1, m=10, M=10 ² ; SPC/APC, cfu/ml: n=5, c=1, m=5x10 ⁴ , M=10 ⁵	International standards (AOAC, ISO, APHA, etc.)	Email communication with FDA Philippines

Table 16: Case Study (4) Cow's Milk

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

4.9 Socialist Republic of Vietnam

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.

2. FOOD LAW SYSTEM AND SPECIFIC FOOD STANDARDS

A brief summary of the food laws in Vietnam that relate to regulation and standards for food products/commodities are presented in Figure 1.

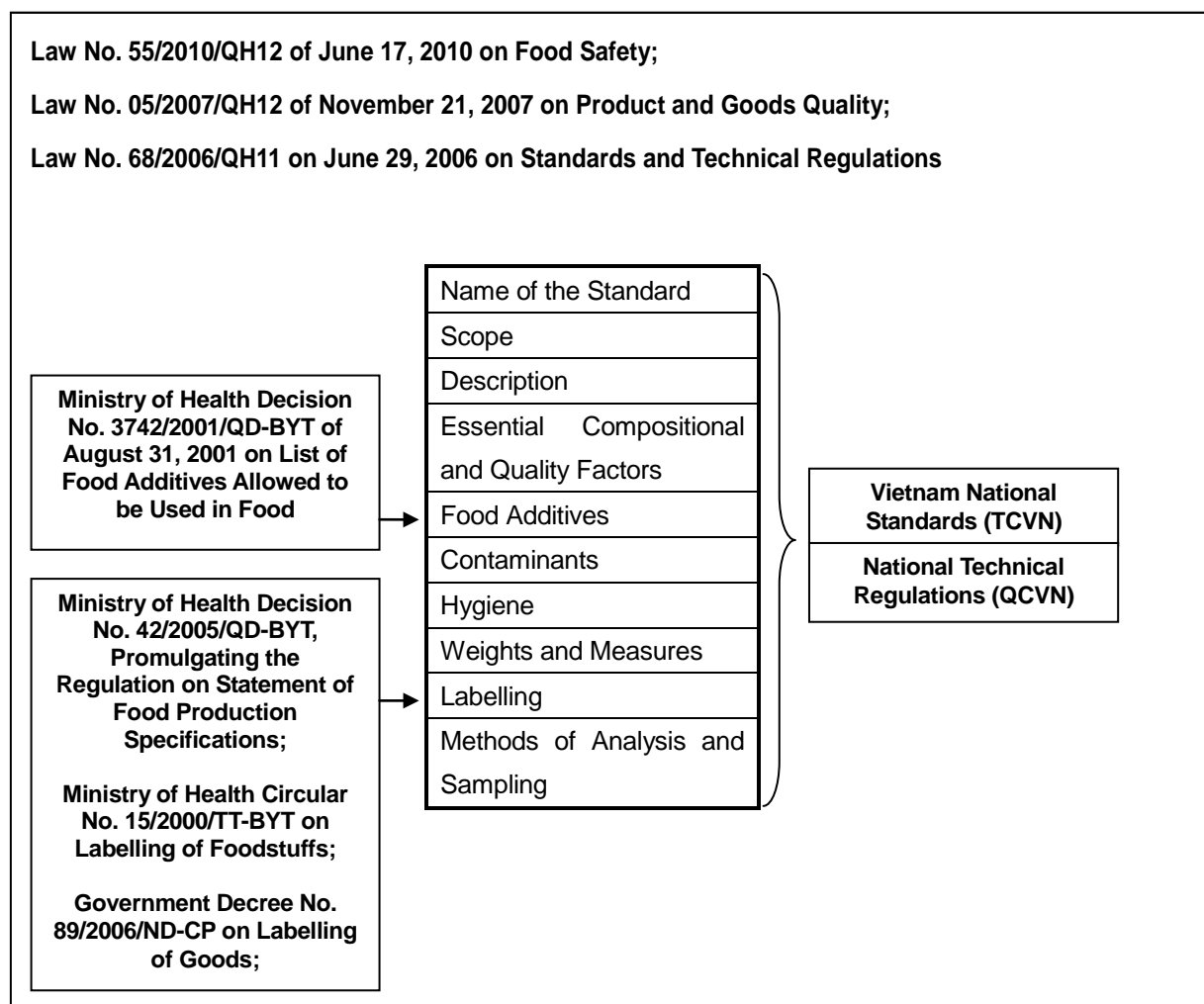


Figure 1: Food Laws in Relation to Food Commodity Regulations and Standards

3. RELEVANT FOOD 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 (MOH) 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”.

● **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 the 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;

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.

Only the standards that are considered as TCVN for food specifications judging from the titles are listed (Table 1).

Table 1: Food Commodity Standards

ICS No.	TCVN No.	Title (Vietnum)	Title (English)
67.080.20	4845-89	Ca` chua tu+o+i	Fresh tomatoes
67.180.20	5909:1995	Ba`nh bi`ch quy. Ye`u ca` u ky~ thua`.t	Biscuits. Specifications
67.140.30	7518:2005	Ha.t cacao. Thua`.t ngu+~ va` ?i.nh nghi~a	Cocoa beans. Terms and definitions
67.080.10	1873-86	Cam qu?a tu+o+i xua`t kha`u	Fresh oranges for export
67.120.30	7525:2006	Va`y ca' ma`.p kho`	Dried shark fins
67.140.20	6929:2001	Ca` phe` nha`.n. Hu+o+ng da`~n phu+o+ng pha`p mo` ta? ca`c quy ?i.nh	Green coffee. Guidance on methods of specification
67.160.10	1647-75	Ru+o+.u cam. Ye`u ca` u ky~ thua`.t	Orange liquor. Specification
67.120.30	2066-77	Ca' la`m sa(~n ?o`ng la.nh (u+o+p ?o`ng). Ye`u ca` u ky~ thua`.t	Frozen dressed fishes. Specifications
67.140.10	2843-79	Che` ?o.t tu+o+i. Ye`u ca` u ky~ thua`.t	Tea leaves. Specifications
67.120.10	4377:1993	Thi.t lo+.n la.nh ?o`ng	Frozen pork for export
67.220.10	7037:2002	Ha.t tie`u tra(`ng (Piper nigrum L.). Quy ?i.nh ky~ thua`.t	White pepper (<i>Piper nigrum L.</i>). Specification
67.200.10	6044:2007	Mo+~ ?o`.ng va`.t	Animal fats
67.200.10	6031:1995	Da` u chanh nha`.n ?u+o+.c ba(`ng chu+ng ca`.t	Oil of lime, obtained by distillation
67.120.30	2646-78	Ca' bie`n u+o+p nu+o+c ?a'. Ye`u ca` u ky~ thua`.t	Iced salt-water fishes. Specifications
67.220.20	5647:1992	Muo`i io`.t	Iodinated salt
67.120.30	4544-88	To`m tu+o+i. Pha`n loa.i theo gia' tri. su+? du.ng	Fresh shrimps. Classification for use
01.040.67	5643:1992	Ga.o. Thua`.t ngu+~ va` ?i.nh nghi~a	Rice. Terms and definitions
67.080.10	1872:2007	Chuo`i qua? tu+o+i	Bananas
67.080.10	1577:1994	?o` ho`.p qu?a. Va?i ho`.p	Canned fruits. Canned litchi
67.080.10	1870:2007	Mu+t cam, quy't	Citrus marmalade
67.080.10	5259-1990	Chuo`i xanh. ?ie` u kie`.n la`m chi`n	Green bananas. Ripening conditions

67.060	4359-86	Bo [^] .t mi [~] . Ye [^] u ca [^] u ky~ thua [^] .t	Wheat flour. Specifications
67.080.20	4844-89	Du+a chuo [^] .t tu+o+i	Fresh cucumbers
67.080.20	5606:1991	?o [^] ho [^] .p rau. Na [^] m ho [^] .p	Canned vegetables. Canned mushrooms
67.160.20	1682:1994	?o [^] ho [^] .p nu+o+'c qu?a. Nu+o+'c cam	Canned fruit juices. Orange juice
001.040.6 7	3294-1980	Sa?n xua [^] t tinh bo [^] .t. Thua [^] .t ngu+~ va [^] ?i.nh nghi~a	Starch production. Terms and definitions
67.200.10	6309:1997	Da [^] u ?a [^] .u tu+o+ng thu+.c pha [^] ?m	Edible soya bean oil
67.180.10	5908:1995	Ke.o. Ye [^] u ca [^] u ky~ thua [^] .t	Sweets. Specifications
67.080.10	1440-1986	?o [^] ho [^] .p qu?a. Ma [^] .n nu+o+'c ?u+o+`ng	Canned fruits. Plum in syrup
67.160.20	1549:1994	?o [^] ho [^] .p qu?a. Nu+o+'c du+'a	Canned fruits. Pineapple juice
67.140.10	5087-90	Che [^] ?en. Thua [^] .t ngu+~ va [^] ?i.nh nghi~a	Black tea. Terms and definitions
67.040	7087:2002	Ghi nha~n thu+.c pha [^] ?m bao go'i sa(~n	Labeling of prepackaged foods
67.120.30	3692-81	Ca' nu+o+'c ngo.t. Ca' bo [^] .t. Ye [^] u ca [^] u ky~ thua [^] .t	Fresh water fishes. Fries. Specification
67.120.10	7047:2002	Thi.t la.nh ?o [^] ng. Quy ?i.nh ky~ thua [^] .t	Frozen meat. Specification
67.140.10	3242-79	Hom che [^] gio [^] ng	Tea cuttings
67.020	7247:2003	Thu+.c pha [^] ?m chie [^] u xa.. Ye [^] u ca [^] u chung	Irradiated foods. General requirements
67.120.30	3590-1988	Rong ca [^] u	Gracilaria
67.140.20	4193:2005	Ca [^] phe [^] nha [^] n	Green coffee
67.080.10	1577:2007	Va?i ho [^] .p	Canned lychee
67.200.20	4850-89	Nha [^] n ha.t ?ie [^] u. Ye [^] u ca [^] u ky~ thua [^] .t	Caskew kernels. Specifications
67.060	1683-86	Ba [^] nh mi [~] . Ye [^] u ca [^] u ky~ thua [^] .t	Bread. Specification
67.080.20	4845:2007	Ca [^] chua tu+o+i	Fresh tomatoes
67.060	6095:1995	Ha.t lu'a mi [~] . Ye [^] u ca [^] u ky~ thua [^] .t	Wheat. Specifications
67.120.30	7106:2002	Ca' phile ?o [^] ng la.nh nhanh	Quick frozen fish fillets
67.140.20	5250:2007	Ca [^] phe [^] rang	Roasted coffee
67.080.10	7856:2007	Du+'a ?o [^] ng la.nh. Pha [^] n ha.ng	Grades of frozen pineapple
67.120.30	3695-81	Ca' nu+o+'c ngo.t. Ca' bo [^] me.. Ye [^] u ca [^] u ky~ thua [^] .t	Fresh water fishes. Fish breeders. Specification
67.120.30	3726-89	To [^] m nguye [^] n lie [^] .u tu+o+i	Fresh shrimps for food processing
67.220.10	2080-86	o+'t bo [^] .t xua [^] t kha [^] ?u	Powdered chillies for export
67.100.10	7979:2009	Su+~a bo [^] .t va [^] cream bo [^] .t	Milk powders and cream powder
67.100.10	6403:2007	Su+~a ?a(.c co' ?u+o+`ng	Sweetened condensed milk
67.040	7399:2004	Tie [^] u chua [^] ?n chung cho ca'c sa?n pha [^] ?m protein thu+.c va [^] .t	General standard for vegetable protein products (VPP)
67.120.30	6392:1998	Ca' xay che [^] bie [^] n hi`nh que, ca' ca('t mie [^] ng, ca' phile [^] . Ta [^] ?m bo [^] .t xu [^] va [^] bo [^] .t nha~o ?o [^] ng la.nh nhanh	Quick frozen fish sticks (fish finger) fish portion and fish fillets. Breaded or in batter
67.180.10	5267-90	Ma [^] .t ong tu+. nhie [^] n. Ye [^] u ca [^] u ky~ thua [^] .t	Honey. Specifications
67.060	5932:1995	Ba [^] nh pho [^] ng to [^] m. Ye [^] u ca [^] u ky~ thua [^] .t	Dried prawn crackers. Specifications
67.080.10	7398:2004	Tu+o+ng ca [^] chua. Ye [^] u ca [^] u ky~ thua [^] .t	Tomato sauce. Technical requirements

67.120.10	7048:2002	Thi.t ho^p. Quy ?i.nh ky~ thua^t	Canned meat. Specification
67.080.10	1872-86	Chuo^i tie^u tu+o+i xua^t kha^?u	Fresh bananas for export
67.100.10	7108:2008	Thu+c a(n theo co^ng thu+c da`nh cho tre? so+ sinh va` thu+c a(n theo co^ng thu+c vo+i ca'c mu.c ?i'ch y te^ ?a(.c bie^t da`nh cho tre? so+ sinh	Standard for infant formula and formulas for special medical purposes intended for infants
67.220.10	5837:1994	Ha.t tie^u. Ye^u ca^ u ky~ thua^t	Pepper. Specifications
67.100.10	5539:2002	Su+~a ?a(.c co' ?u+o+`ng. Quy ?i.nh ky~ thua^t	Sweetened condensed milk. Specification
67.080.10	1578:1994	?o^ ho^p qu?a. Cam qui't ho^p	Canned fruits. Canned mandarin oranges
67.120.30	4379-86	Thu?y sa?n ?o^ng la.nh xua^t kha^?u. Ca'. Ye^u ca^ u ky~ thua^t	Frozen aquatic products for export. Fishes. Specifications
67.080.10	187:1994	?o^ ho^p qu?a. Du+`a ho^p	Canned fruits. Canned pineapple
67.100.10	6403:1998	Su+~a ?a(.c co' ?u+o+`ng va` su+~a ?a(.c co' ?u+o+`ng ?a~ ta'ch cha^t be'o	Sweetened condensed milk and skimmed sweetened condensed milk
67.160.20	6096:1995	Nu+o+c uo^ng ?o^ng chai	Bottled drinking water
67.080	1873:2007	Cam tu+o+i	Oranges
67.180.10	6961:2001	?u+o+`ng tho^	Raw sugar
67.120.30	6391:2008	Ca' ?o^ng ho^p	Canned finfish
67.120.30	6392:2008	Ca' xay che^ bie^`n hi`nh que, ca' mie^ng va` ca' phile^ ta^?m bo^t xu` hoa(.c bo^t nha~o ?o^ng la.nh nhanh	Quick frozen fish sticks (fish finger), fish portions and fish fillets-breaded or in batter
67.080.10	5605:2008	Ca` chua ba?o qua?n	Preserved tomatoes
67.200.20	2383:2008	La.c	Peanuts
67.06	5643:1999	Ga.o. Thua^t ngu+~ va` ?i.nh nghi~a	Rice. Terms and definitions
67.080.10	5608:1991	?o^ ho^p qua?. Xa la't qua? nhie^t ?o+i	Canned fruits. Tropical fruit salads
235	4545:1994	To^m hu`m ?o^ng la.nh	Frozen spiny lobster
243	7050:2002	Thi.t che^ bie^`n kho^ng qua xu+? ly' nhie^t. Quy ?i.nh ky~ thua^t	Non-heat treated processed meat. Specification
245	4359:2008	Bo^t mi`	Wheat flour
247	7036:2008	Ha.t tie^u ?en (Piper Nigrum L.). Quy ?i.nh ky~ thua^t	Black pepper (<i>Piper nigrum L.</i>). Specification
248	4334:2007	Ca` phe^ va` sa?n pha^?m ca` phe^ Thua^t ngu+~ va` ?i.nh nghi~a	Coffee and coffee products. Vocabulary
249	6346:1998	Pho+? a(n lie^`n	Instant pho
256	5538:1991	Su+~a bo^t. Ye^u ca^ u ky~ thua^t	Powdered milk. Specifications
258	3140-86	Ha`nh ta^y xua^t kha^?u	Onion for export
262	7401:2004	Tie^u chua^?n chung ?o^i vo+i phomat	General standard for cheese
263	5777:2004	Mi` a(n lie^`n	Instant noodles
268	7809:2007	To?i ta^y kho^c. Ca'c ye^u ca^ u	Dehydrated garlic (<i>Allium sativum L.</i>). Specification
271	5644:1992	Ga.o. Ye^u ca^ u ky~ thua^t	Rice. Specification
285	7524:2006	Ca' ?o^ng la.nh nhanh	Quick frozen finfish uneviscerated and eviscerated
293	6929:2007	Ca` phe^ nha^`n. Hu+o+ng da^~n phu+o+ng pha'p mo^ ta? ye^u ca^ u ky~ thua^t	Green coffee. Guidelines on methods of specification
294	7402:2004	Kem thu+c pha^?m. Ye^u ca^ u ky~ thua^t	Edible ices cream. Technical requirements
295	6348:1998	Mie^`n a(n lie^`n	Instant mien

304	5267-1:2008	Ma [^] .t ong. Pha [^] n 1: Sa [?] n pha [^] ?m ?a~che [^] bie [^] n va [^] su+? du.ng tru+.c tie [^] p	Honey. Part one: Processed and intended for direct consumption products
308	7042:2002	Bia ho+i. Quy ?i.nh ky~ thua [^] .t	Draught beer. Specification
311	6430:1998	Ma [^] .n ho [^] .p	Canned plums
315	7968:2008	?u+o+`ng	Sugars
322	5251-90	Ca [^] phe [^] bo [^] .t. Ye [^] u ca [^] u ky~ thua [^] .t	Ground coffee. Specifications
324	4800-1989	Bo [^] .t ca [^] . Thua [^] .t ngu+~ va [^] ?i.nh nghi~a	Fish powder. Terms and definitions
333	7030:2009	Su+~a le [^] n men	Fermented milks
334	7046:2002	Thi.t tu+o+i. Quy ?i.nh ky~ thua [^] .t	Fresh meat. Specification
335	6027:1995	Bo [^] .t mi [^] . ?a(.c ti [^] nh va [^] .t ly' cu?a kho [^] i bo [^] .t nha [^] .o. Xa [^] c ?i.nh ?a(.c ti [^] nh lu+u bie [^] n ba([^] ng bie [^] ?u ?o [^] alveograph	Wheat flour. Physical characteristics of doughs. Determination of rheological properties using an alveograph
342	3591-1988	Rong ca [^] u	Agar
349	3974-84	Muo [^] i a(n. Ye [^] u ca [^] u ky~ thua [^] .t	Kitchen salt. Specification
352	188-66	?o [^] ho [^] .p thi.t. Thi.t lo+.n ha [^] p	Canned meat. Stewed pork
363	3693-81	Ca [^] nu+o+ [^] c ngo.t. Ca [^] hu+o+ng. Ye [^] u ca [^] u ky~ thua [^] .t	Fresh water fish. Larvules. Specification
366	1763:2008	Nu+o+ [^] c tu+o+ng	Soy sauce
371	1871-88	Du+ [^] a qu?a tu+o+i	Fresh pineapple
372	1871:2007	Du+ [^] a qua? tu+o+i	Pineapples
373	3694-81	Ca [^] nu+o+ [^] c ngo.t. Ca [^] gio [^] ng. Ye [^] u ca [^] u ky~ thua [^] .t	Fresh water fish. Breed fishes. Specification
377	7044:2009	Ru+o+.u mu [^] i. Quy ?i.nh ky~ thua [^] .t	Liqueur. Specification
382	168-1991	?o [^] ho [^] .p rau. Du+ [^] a chuo [^] .t da [^] m da [^] m	Canned vegetables. Cucumber pickles
384	7105:2002	Mu+.c o [^] ng ?o [^] ng la.nh nhanh	Quick frozen raw squid
385	7714:2007	Thu+.c pha [^] ?m che [^] bie [^] n tu+` ngu~ co [^] c da [^] nh cho tre? so+ sinh va [^] tre? nho?	Codes standard for processed cereal-based foods for infants and young children
386	7265:2003	Quy pha.m thu+.c ha [^] nh ?o [^] i vo+ [^] i ?o [^] .ng va [^] .t cha [^] n ?a [^] u	Code of practice for cephalopods
388	5305-91	Ca [^] chua co [^] ?a(.c	Tomato concentrates
393	5860:2007	Su+~a tu+o+i thanh tru`ng	Pasteurized fresh milk
395	4043-85	?o [^] ho [^] .p nu+o+ [^] c qu?a. Nu+o+ [^] c ?u ?u? pha ?u+o+`ng	Canned fruit juices. Papaya juice with sugar
396	5613:1991	Che [^] . Phu+o+ng pha [^] p xa [^] c ?i.nh ?o [^] . a [^] ?m	Tea. Determination of moisture content
402	6298:1997	Hu+o+ng da [^] ~n cho nu+o+ [^] c qua? ho [^] ~n ho+.p	Guidelines for mixed fruit juices
403	5540:1991	Sa [?] n pha [^] ?m su+~a bo [^] .t ?a(.c bie [^] .t du`ng cho tre? so+ sinh va [^] co [^] n nho? tuo [^] ?i. Ye [^] u ca [^] u ky~ thua [^] .t	Special powdered milk for babies and infants. Specifications
406	7266:2003	Quy pha.m thu+.c ha [^] nh ?o [^] i vo+ [^] i thuy? sa [?] n ?o [^] ng ho [^] .p	Code of practice for canned fish
408	7523:2005	Qua? thanh long	Dragon fruit
410	6299:1997	Hu+o+ng da [^] ~n cho necta qua? ho [^] ~n ho+.p	Guidelines for mixed fruit nectars
412	2644:1993	Mu+.c ?o [^] ng la.nh. Ye [^] u ca [^] u ky~ thua [^] .t	Frozen cuttles and squids. Technical requirements
413	5000:2007	Xu [^] p lo+. Hu+o+ng da [^] ~n ba?o qua?n va [^] va [^] .n chuye [^] ?n la.nh	Cauliflowers. Guide to cold storage and refrigerated

			transport
415	7406:2004	Ba'nh ngo.t kho'ng kem. Ye'u ca^u ky~ thua^t	Non-cream sweet cake. Technical requirements
421	1459-74	Mi' chi'nh-Natri glutamat 80%. Ye'u ca^u ky~ thua^t	80%monosodium glutamate. Specification
424	1648-75	Ha.t gio'ng la.c. Pha'n ca^p cha^t lu+o+.ng va` ye'u ca^u ky~ thua^t	Peanut seeds. Quality gradarion and specification
430	1275-72	Ru+o+.u ca' phe^l. Ye'u ca^u ky~ thua^t	Coffee liquor. Specification
431	7043:2002	Ru+o+.u tra('ng. Quy ?i.nh ky~ thua^t	Distilled alcoholic beverages. Specification
432	7045:2009	Ru+o+.u vang. Quy ?i.nh ky~ thua^t	Wine. Specification
436	7028:2009	Su+~a tu+o+i tie^t tru'ng	Sterilized fresh milk
439	6958:2001	?u+o+`ng tinh luye^l.n	Refined sugar
440	7804:2007	Sa?n pha^?m rau, qua?. Xa'c ?i.nh cha^t ra('n kho'ng tan trong nu+o+'c	Fruit and vegetable products. Determination of water-insoluble solids
441	6047:1995	Da^u la.c thu+.c pha^?m (da^u ?a^u pho^ng)	Edible arachis oil
442	7247:2008	Thu+.c pha^?m chie^u xa.. Ye'u ca^u chung	General requirements for irradiated foods
446	6389:1998	Thi.t cua ?o'ng ho^p	Codex standard for canned crab meat
448	7405:2004	Su+~a tu+o+i nguye^n lie^u. Ye'u ca^u ky~ thua^t	Raw fresh milk. Technical requirements
453	6390:1998	Ca' tri'ch va` ca'c sa?n pha^?m da.ng ca' tri'ch ?o'ng ho^p	Canned sardines and sardine-type products
454	3243-79	Hom che` gio'ng PH1	PH1 tea cuttings
457	2815-78	?o^ ho^p nu+o+'c qu?a. Nu+o+'c chanh tu+. nhie^n	Canned fruit juices. Natural lemon juice
460	4042-85	?o^ ho^p nu+o+'c qu?a. Nu+o+'c ma~ng ca^u pha ?u+o+`ng	Canned fruit juices. Custard apple juice with sugar
469	1763-86	Nu+o+'c cha^m. Ye'u ca^u ky~ thua^t	'Nuoc cham' sauce. Specifications
470	7044:2002	Ru+o+.u mu'i. Quy ?i.nh ky~ thua^t	Liqueur. Specification
471	7028:2002	Su+~a tu+o+i tie^t tru'ng. Quy ?i.nh ky~ thua^t	Sterilized fresh milk. Specification
473	5107:1993	Nu+o+'c ma('m	Fermented fish sauce
474	4041-85	?o^ ho^p nu+o+'c qu?a. Nu+o+'c xoa`i pha ?u+o+`ng	Canned fruit juices. Mango juice with sugar
482	3251-79	Ca' bie^?n u+o+p muo^i la`m chu+o+p	Salted salt-water fishes for manufacturing of half-salted products
483	7108:2002	Su+~a bo^t da`nh cho tre? ?e^n 12 tha'ng tuo^?i. Quy ?i.nh ky~ thua^t	Dried milk for infants up-to 12 months age. Specification
486	3219-79	Co'ng nghe^l. che^l bie^l.n che`. Thua^t ngu+~ va` ?i.nh nghi~a	Tea processing technology. Terms and definitions
489	6386:1998	Ca' ho^i ?o'ng ho^p	Canned salmon
492	5009:2007	To?i. Ba?o qua?n la.nh	Garlic. Cold storage
496	6388:1998	Ca' ngu+` ?o'ng ho^p	Canned tuna and bonito
497	7029:2002	Su+~a hoa`n nguye^n tie^t tru'ng. Quy ?i.nh ky~ thua^t	Sterilized reconstituted milk. Specification
501	5526:1991	Nu+o+'c ma('m. Chi? tie^u vi sinh	Fermented fish sauce (Nuoc mam). Microbiological

			characteristics
502	5651:1992	Mu+.c kho^ xua^t kha^?u. Ye^u ca^ u ky~ thua^t	Dried squids for export. Specification
503	7049:2002	Thi.t che^ bie^'n co' xu+? ly' nhie^t. Quy ?i.nh ky~ thua^t	Heat treated processed meat. Specification
505	5503-91	Thi.t bo` la.nh ?o^ng	Frozen beef
517	5644:2008	Ga.o tra('ng. Ye^u ca^ u ky~ thua^t	White rice. Specifications
518	4067:1985	Ke.o. Phu+o+ng pha'p la'y ma~u	Confectionery. Sampling methods
519	1695-87	?u+o+`ng tinh luye^'n va` ?u+o+`ng ca't tra('ng. Ye^u ca^ u ky~ thua^t	Refined and white sugars. Specifications
523	6297:1997	Tie^u chua^?n chung cho nu+o+c qua? ?u+o+c ba?o qua?n chi? ba('ng ca'c bie^'n pha'p va^t ly' ne^u kho^ng co' ca'c tie^u chua^?n rie^ng	General standard for fruit juices preserved exclusively by physical means not covered by individual standards
525	5538:2002	Su+~a bo^t. Quy ?i.nh ky~ thua^t	Milk powder. Specification
528	7036:2002	Ha.t tie^u ?en (piper nigrum L.).Quy ?i.nh ky~ thua^t	Black pepper (<i>Piper nigrum L.</i>). Specification
530	5607:1991	?o^ ho^p qua?. Qua? ho^~n ho+p	Canned fruits. Fruits cocktails
531	7879:2008	Sa?n pha^?m ngu~ co^c da.ng so+.i a(n lie^'n	Instant noodles
534	6347:1998	Bu'n kho^ a(n lie^'n	Instant rice vermicelli
538	5644:1999	Ga.o tra('ng. Ye^u ca^ u ky~ thua^t	White rice. Specifications
541	7041:2009	?o^ uo^ng kho^ng co^'n. Quy ?i.nh ky~ thua^t	Soft drinks. Specification
551	3974:2007	Muo^'i thu+.c pha^?m	Food grade salt
555	1454:1993	Che` ?en ro+`i. ?ie^'u kie^'n ky~ thua^t	Black tea. Specifications
556	3696-81	Ca' nu+o+c ngo.t. Ca' thi.t	Fresh water fishes. Food fishes
560	7975:2008	Che` tha?o mo^c tu'i lo.c	Herbal tea in bag
561	4809-89	Xie^'n la'y ma~u ca` phe^ nha^'n	Coffee triers
565	4849:1989	?o^~ tu+o+ng. Ye^u ca^ u ky~ thua^t	Soya-bean. Specifications
576	6057:1995	Bia ho^p. Ye^u ca^ u ky~ thua^t	Canned beer. Specifications
577	5835:1994	To^m thi.t ?o^ng la.nh IQF xua^t kha^?u	Individual quick frozen peeled shrimps for export
580	6057:2009	Bia. Quy ?i.nh ky~ thua^t	Beer. Specification
583	1274-72	Ru+o+.u chanh. Ye^u ca^ u ky~ thua^t	Lemon liquor. Specification
590	5288-90	To^m gio^ng. Ye^u ca^ u ky~ thua^t	Breed shrimps (postlosval). Specification
596	4187-86	Ke.o chuo^'i xua^t kha^?u	Banana bonbon for export
598	7808:2007	Ha`nh ta'y kho^'. Ca'c ye^u ca^ u	Dehydrated onion (<i>Allium cepa Linnaeus</i>). Specification
601	6389:2003	Thi.t cua ?o^ng ho^p	Canned crab meat
602	7240:2003	Ba'nh ?a^u xanh	Green bean cake
603	6392:2002	Ca' xay che^' bie^'n hi`nh que, ca' ca'(t mie^'ng va` ca' phile ta^?m bo^t xu` hoa(.c bo^t nha~o ?o^ng la.nh nhanh	Quick frozen fish sticks (fish finger), fish portions and fish fillets - breaded or in batter
604	7404:2004	Su+~a bo^t ga^y. Ye^u ca^ u ky~ thua^t	Skimmed milk powder. Technical requirements
613	2383:1993	La.c qua? va` la.c ha.t. Pha^'n ha.ng cha^t lu+o+ng	Peanuts in shell and peanut kernels. Quality classification
621	4782-89	Rau qu?a tu+o+i. Danh mu.c chi? tie^u cha^t lu+o+ng	Fresh vegetables and fruits. List of quality characteristics

623	5777:1994	Mi` a(n lie^`n	Instant noodle
626	2830-79	Thi.t lo+.n. Pha lo.c va` pha^`n ha.ng trong thu+o+ng nghie^`p ba'n le?	Pork. Cutting and sorting for retail trade
634	5652:1992	Mu+.c tu+o+i	Fresh squids and cuttles
638	5107:2003	Nu+o+'c ma('m	Fish sauce
639	6387:2006	To^`m ?o'ng ho^`p	Canned shrimps or prawns
640	5147-1990	Thi.t va` sa?n pha^`m cu?a thi.t. Phu+o+ng pha'p xa'c ?i.nh du+ lu+o+.ng penixilin	Meat and meat products. Determination of penicillin residues
641	4191-86	Ru+o+.u Thanh mai xua^`t kha^`u. Ye^`u ca^`u ky~ thua^`t	Apricot liquor for export. Specifications
643	5089-90	Ba?o qua?n ngu~ co^`c va` ?a^`u ?o^`~. Ye^`u ca^`u co+ ba?n	Storage of cereals and pulses. Basic requirements
644	7043:2009	Ru+o+.u tra('ng. Quy ?i.nh ky~ thua^`t	White spirit. Specification
645	7110:2008	To^`m hu`m ?o'ng la.nh nhanh	Quick frozen lobsters
650	6046:1995	Da^`u ha.t hoa hu+o+'ng du+o+ng thu+.c pha^`m	Edible sunflowerseed oil
658	7041:2002	?o^` uo^`ng pha che^` sa(~n kho^`ng co^`n. Quy ?i.nh ky~ thua^`t	Soft drinks. Specification
659	4813-89	Mu+.c tu+o+i. Xe^`p loa.i theo gia' tri. su+? du.ng	Fresh squids and cuttles. Classification for use
660	7400:2004	Bo+. Ye^`u ca^`u ky~ thua^`t	Butter. Technical requirements
661	5322:1991	Na^`m a(n va` sa?n pha^`m na^`m a(n	Edible fungi and fungus products
667	4334:2001	Ca` phe^` va` ca'c sa?n pha^`m cu?a ca` phe^`. Thua^`t ngu+~ va` ?i.nh nghi~a	Coffee and its products. Vocabulary
669	7946:2008	Nu+o+'c qua? va` nectar	Fruit juices and nectars
671	1442-1986	Tru+'ng vi.t tu+o+i. Thu+o+ng pha^`m	Fresh duck eggs
677	5108-90	Che^` bie^`n to^`m. ?ie^`u kie^`n ky~ thua^`t va` ve^`. sinh	Shrimps processing. Specification and hygienic requirements
678	7974:2008	Che` (<i>Camellia sinensis</i>) (L.) O. Kuntze) tu'i lo.c	Tea (<i>Camellia sinensis</i>) (L.) O. Kuntze) in bag
683	6048:1995	Da^`u co. thu+.c pha^`m	Edible palm oil
684	4850:1998	Nha^`n ha.t ?ie^`u	Cashew kernal
685	7397:2004	Tu+o+ng o+t. Ye^`u ca^`u ky~ thua^`t	Chilli sauce. Technical requirements
688	6096:2004	Nu+o+'c uo^`ng ?o'ng chai	Bottled/packageged drinking waters
696	4995:2008	Ngu~ co^`c. Thua^`t ngu+~ va` ?i.nh nghi~a	Cereals. Vocabulary
706	6959:2001	?u+o+`ng tra('ng	White sugar
709	6049:2007	Bo+ thu+.c va^`t	Margarin
710	5109-90	To^`m ?o'ng la.nh nhanh	Quick frozen shrimps or prawns
715	7045:2002	Ru+o+.u vang. Quy ?i.nh ky~ thua^`t	Wine. Specification
716	5250-90	Ca` phe^` rang. Ye^`u ca^`u ky~ thua^`t	Roasted coffee. Specifications
717	6310:1997	Da^`u ha.t bo^`ng thu+.c pha^`m	Edible cottonseed oil
718	6388:2006	Ca' ngu+` ?o'ng ho^`p	Canned tuna and bonito
719	7597:2007	Da^`u thu+.c va^`t	Vegetable oils
727	5289:1992	To^`m mu+.c ?o'ng la.nh. Ye^`u ca^`u vi sinh	Frozen shrimps and cuttles (or squids). Microbiological requirements
728	5371-91	Mo+~ lo+.n ra'n	Rendered pork fat

734	1858-1986	Tru+ng ga` tu+o+i thu+o+ng pha^?m	Fresh chicken eggs
747	187:2007	Du+a ho^p	Canned pineapple
748	6459:1998	Phu. gia thu+.c pha^?m. Pha^?m ma`u Riboflavin	Food additive. Riboflavin
751	7396:2004	Bo^t canh gia vi.. Ye^u ca^ u ky~ thua^t	Spicing salt powder. Technical requirements
754	4843:2007	Qua? kho^ va` qua? sa^y kho^ .?i.nh nghi~a va` te^n go.i	Dry fruits and Dried fruits. Definitions and nomenclature
762	3806-83	?o^ ho^p qu?a. Cho^m cho^m nu+o+'c ?u+o+`ng	Canned fruits. Rambutan in syrup
765	5370-91	Nu+o+'c khoa'ng ?o'ng chai	Bottled mineral waters
769	5258:2008	Ngo^ (ha.t)	Maize (Corn)
770	7519:2005	Ha.t cacao	Cocoa beans
771	2637:1993	Da^ u thu+.c va^t. Phu+o+ng pha'p xa'c ?i.nh ta.p cha^t kho^ng tan	Vegetable oils. Determination of insoluble impurities content
772	5650:1992	To^m no~n kho^ xua^t kha^?u. Ye^u ca^ u ky~ thua^t	Dried peeled shrimps for export. Specification
773	6044:1995	Mo+~ lo+.n ra'n	Rendered pork fat
774	4193:1993	Ca` phe^ nha^n. Ye^u ca^ u ky~ thua^t	Green coffee. Specifications
780	2623-78	Ru+o+.u gu+`ng 40o. Ye^u ca^ u ky~ thua^t	40°ginger liquor. Specification
783	7268:2003	?u+o+`ng. Thua^t ngu+~ va` ?i.nh nghi~a	Sugar. Terms and definitions
786	4193:2001	Ca` phe^ nha^n. Ye^u ca^ u ky~ thua^t	Green coffee. Specification
787	3250-88	Ca' bie^?n tu+o+i. Pha^n loa.i theo gia' tri. su+? du.ng	Fresh salt-water fishes. Classification for use
788	2080:2007	o+t chilli va` o+t capsicum, nguye^n qua? hoa(.c xay (da.ng bo^t). Ca'c ye^u ca^ u	Chillies and capsicums, whole or ground (powdered). Specification
791	1455:1993	Che` xanh. ?ie^ u kie^ .n ky~ thua^t	Green tea. Specifications
796	6045:1995	Da^ u vu+`ng thu+.c pha^?m (Da^ u me`)	Edible sesame seed oil
798	4334-86	Ca` phe^ va` ca'c sa?n pha^?m cu?a ca` phe^ . Thua^t ngu+~ va` ?i.nh nghi~a	Coffee and coffee products. Terms and definitions
812	5258-90	Ngo^ (Ha.t)	Maize (Corn)
813	6312:1997	Da^ u o^liu chu+a tinh che^ , tinh che^ va` da^ u o^liu, tinh che^ ba(`ng phu+o+ng pha'p tri'ch ly	Olive oil, virgin and refined, and refined olive-pomace oil
816	6462:1998	Phu. gia thu+.c pha^?m. Pha^?m ma`u Erythrosin	Food additive. Erythrosine
817	7267:2003	Kho^i ca' phile^ , thi.t ca' xay va` ho^~n ho+.p ca' phile^ vo+`i thi.t ca' xay ?o^ng la.nh nhanh	Quick frozen blocks of fish fillet, minced fish flesh and mixtures of fillets and minced fish flesh
818	4546:1994	To^m mu~ ni ?o^ng la.nh	Frozen slipper lobster
819	3295-1980	Sa?n xua^t ?u+o+`ng glucoza-ma^t tinh bo^t. Thua^t ngu+~ va` ?i.nh nghi~a	Syrup-dextrose production. Terms and definitions
826	2064-77	To^m ?o^ng la.nh (u+`o+p ?o^ng). Ye^u ca^ u ky~ thua^t	Frozen shrimps. Specification
830	5836:1994	To^m thi.t luo^c chi'n ?o^ng la.nh xua^t kha^?u	Frozen peeled and cooked shrimps for export

831	7403:2004	Thu+'c a(n da`nh cho tre? em tu+` 6 tha'ng ?e^`n 36 tha'ng tuo^?i. Ye^u ca^`u ky~ thua^t	Foods intended for use for children from 6 months up to 36 months of age. Technical requirements
834	5860:1994	Su+~a thanh tru'ng	Pasteurized milk
835	6463:1998	Phu. gia thu+.c pha^?m. Cha^t ta.o ngo.t. Kali sacarin	Food additive. Potassium saccharin
836	6390:2006	Ca' tri'ch va` ca'c sa?n pha^?m ca' tri'ch ?o'ng ho^p	Canned sardines and sardine-type products
842	7110:2002	To^m hu`m ?o'ng la.nh nhanh	Quick frozen lobsters
843	1575-74	?o^` ho^p thi.t. Thi.t ga` ha^`m nguye^`n xu+o+ng	Canned meat. Stewed chicken
846	6345:1998	Hu? tie^`u a(n lie^`n	Oriental style instant noodle
848	6312:2007	Da^`u o^liu va` da^`u ba~ o^liu	Olive oils and olive pomace oils
849	4359:1996	Bo^t mi`	Wheat flour
851	5251:2007	Ca` phe^ bo^t	Ground coffee
853	7042:2009	Bia ho+i. Quy ?i.nh ky~ thua^t	Draught beer. Specification
856	6387:1998	To^m ?o'ng ho^p	Canned shrimps or prawns
858	1521-86	?o^` ho^p qu?a. Chuo^i tie^u nu+o+'c ?u+o+`ng. Ye^u ca^`u ky~ thua^t	Canned fruits. Bananas in syrup. Specifications
860	377-70	Ru+o+.u Lu'a mo+'i. Ye^u ca^`u ky~ thua^t	'Lua moi' alcohol (rice vodka). Specification
869	4784-89	Thi.t la.nh ?o'ng. Danh mu.c chi? tie^u cha^t lu+o+ng	Frozen meat. List of quality characteristics
872	7030:2002	Su+~a chua. Quy ?i.nh ky~ thua^t	Yoghurt. Specification
874	3141-86	To?i cu? xua^t kha^?u	Garlic bulbs for export
875	6095:2008	Ha.t lu'a mi` (<i>Triticum aestivum</i> L.). Ca'c ye^u ca^`u	Wheat (<i>Triticum aestivum</i> L.). Specification
880	4381:1992	To^m vo? ?o'ng la.nh. Ye^u ca^`u ky~ thua^t	Unpeeled frozen shrimps. Specifications
882	1578:2007	Cam quy't ho^p	Canned mandarin oranges
886	6311:1997	Da^`u du+`a thu+.c pha^?m	Edible coconut oil
891	5305:2008	Ca` chua co^`a(.c	Processed tomato concentrates
893	5450-91	?o^` ho^p thi.t. Thi.t trong nu+o+'c xo^t thi.t. Ye^u ca^`u ky~ thua^t	Canned meat. Meat in sauce. Specifications
894	1870-76	?o^` ho^p qu?a. Mu+t cam. Ye^u ca^`u ky~ thua^t	Canned fruits. Orange marmalade. Specifications
895	4192-86	Ru+o+.u Hu+o+ng chanh 40o xua^t kha^?u. Ye^u ca^`u ky~ thua^t	40° lemon liquor for export. Specification
897	2065-77	Ca' phi le^` ?o'ng la.nh (u+o+'p ?o'ng). Ye^u ca^`u ky~ thua^t	Frozen fish fillets. Specifications
898	3220-79	?o^` ho^p su+~a. Danh mu.c ca'c chi? tie^u cha^t lu+o+ng	Canned milk. List of quality characteristics
899	4186-86	To^m va` mu+.c ?o'ng la.nh. Chi? tie^u vi sinh va^t	Frozen shrimps and cuttles. Microbiological characteristics
903	4039-85	Du+a la.nh ?o'ng	Frozen pineapple
909	6175:1996	Thuy? sa?n kho^`. Mu+.c, ca' kho^` ta^?m gia vi. a(n lie^`n	Dried fishery products. Seasoned squid and fish ready to eat
913	3578:1994	Sa('n kho^`	Dried manioc
915	4844:2007	Du+a chuo^t tu+o+i	Cucumbers

919	3244-79	Ca^y che` ca`nh. Ye^u ca^u ky~ thua^t va` phu+o+ng pha`p thu+?	Tea plants. Specification and test methods
921	4380:1992	To^m thi.t ?o`ng la.nh. Ye^u ca^u ky~ thua^t	Peeled frozen shrimps. Specifications
923	6386:2003	Ca' ho^i ?o`ng ho^p	Canned salmon
927	2624-78	Ru+o+.u quy^t. Ye^u ca^u ky~ thua^t	Mandarin liquor. Specification
929	5539:1991	Su+~a ?a(.c co' ?u+o+`ng. Ye^u ca^u ky~ thua^t	Sweetened condensed milk. Specifications
930	5605:1991	?o^ ho^p rau. Ca` chua ?o`ng ho^p	Canned vegetables. Canned tomatoes
939	1576-74	?o^ ho^p thi.t. Thi.t vi.t ha^m nguye^n xu+o+ng	Canned meat. Stewed duck
940	6049:1995	Bo+ thu+.c va^t	Margarine
945	7029:2009	Su+~a hoa`n nguye^n tie^t tru`ng va` su+~a pha la.i tie^t tru`ng	Sterilized reconstituted milk and sterilized recombined milk
954	5109:2002	To^m bie^?n hoa(.c to^m nu+o+'c ngo.t ?o`ng la.nh nhanh	Quick frozen shrimps or prawns
955	6391:1998	Ca' ?o`ng ho^p	Canned finfish

5. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

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.

5.2 Food Additive Definitions & 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;

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/QD-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

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.

5.5 Standards and Criteria 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.

5.6 Assessment and Approval of New Food Additives

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

5.7 Labelling of Food Additives used in Food

Labelling of food additives in food should be in accordance with Minister of Health Decision No. 15/2000/TT-BYT on Food Labelling. According to Decision No. 3742/2001/QD-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 flavour enhancers, 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”.

5.8 Summary of Food Additives

The definitions regarding food additives such as flavourings, processing aids, and carry-overs are summarized in Table 2. The descriptions of other items such as designated/existing food additives and prohibited substances are summarized in Table 3

6. STANDARDS, CRITERIA AND METHODS OF ANALYSIS FOR GENERAL FOODS

Regarding the criteria and methods of analysis for general foods, there are Microbiological Standards (QCVN 2010/BYT National technical regulation on the safety limits of Microbiological contaminants in food) and Criteria for Chemical Substance (TCVN 4832-89 List of contaminants and their maximum levels in food), but the details are unclear. Criteria and Methods of analysis for the food categories taken up in the Case Study are described in the food categories, respectively.

7. CASE STUDIES

(1) Instant Noodles

Commodity Food Standards and Methods of Analysis:

Regarding Food Standards, those for cereal products in which instant noodles are specified in TCVN 7879: 2008 are shown. As for Methods of Analysis, only microbiological contaminants are described in Tables 4 and 5.

Food Additives:

As National Standards, TCVN 7879:2008 is for “Cereal products instant noodles”. Standard for use of food additives is in accordance with CODEX STN/249:2006 (Table 6).

(2) Carbonated Soft Drinks

Commodity Food Standards and Methods of Analysis:

Regarding Food Standards, those for soft drinks including fruits beverages and nectar beverages ready to drink without alcohol are shown (QCVN 6-2:2010/BYT National technical regulation for soft drinks). Those standards cannot be applicable for functional foods. As for Methods of Analysis, only microbiological contaminants are described in Tables 7 and 8.

Food Additives:

The use of food additives is in accordance with the Decision of the MOH No.3742:2001

QD-BYT (Table 9).

(3) Prepared Frozen Foods

Commodity Food Standards and Methods of Analysis:

Food Standards for frozen aquatic products (TCVN 5289: 2006) and for frozen meats (TCVN 7047: 2002) are shown in Table 10.

Food Additives:

There are no food additive standards for general frozen foods.

(4) Cow's Milk

Commodity Food Standards and Methods of Analysis:

There is QCVN 5-1-2010/BYT National technical regulation for fluid milk products, but the details are unclear.

Food Additives:

Use of food additives for Fluid Milk Products is in accordance with the Decision of the MOH No.3742:2001 QD-BYT (Table 11).

Table 2: Summary/Definitions of Food Additives (General)

	Descriptions/Definitions	References
Related Legislation	Law No. 55/2010/QH 12 on Food Safety	http://www.vcalaw.com/legal-documents/law-a-ordinance/29-2010lawonfoodsafedownload.html
Summary of General 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: Summary/Definitions of Food Additives (Specific)

	Descriptions/Definitions	References
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)
Summary of Specific Additional Lists		
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
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		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	National Technical Regulations on 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	<p>QCVN 4-1:2010/BYT – national technical regulations on food additives – flavour enhancer</p> <p>QCVN 4-2:2010/BYT – national technical regulations on food additives – humectant</p> <p>QCVN 4-3:2010/BYT – national technical regulations on food additives – raising agent</p> <p>QCVN 4-4:2010/BYT – national technical 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</p>	

		agent QCVN 4-16:2010/BYT – national technical regulations on food additives – bulking agent QCVN 4-17:2010/BYT – national technical regulations on food additives – propellant QCVN 4-18:2010/BYT – national technical regulations on food additives – modified starch QCVN 4-19:2010/BYT – national technical regulations on food additives – enzyme QCVN 4-20:2010/BYT – national technical regulations on food additives – glazing agent QCVN 4-21:2010/BYT – national technical regulations on food additives – thickener QCVN 4-22:2010/BYT – national technical regulations on food additives – emulsifier QCVN 4-23:2010/BYT – national technical regulations on food additives – foaming agent
Official publication and/or gazette for food additives	There is no official publication or gazette for food additives in Vietnam.	

Table 4: Case Study (1) Instant Noodles: Standards and Specifications

Standard	TCVN 7879: 2008
Items	Instant noodles
Name of the Standard	Instant noodles
Scope	Cereal products instant noodles
Description	Wheat flour, cereal powder, others are used, added with or without added optional ingredients
Essential Composition and Quality Factors	Basic ingredients: wheat flour, cereal powder, others; portable water
	General requirements:
	Moisture content: <= 10% for fried products; <=14% for non-fried products
	Acidity index: <= 2 mg KOH/g oil (applied for fired products)
Food additives	In accordance to the Codex Alimentarius Commission (Codex Stan 249 : 2006)
	Permitted food additives to be used
	Acid regulator
	Antioxidant

	Colours
	Flour treatment agent
	Stabilizer
	Chat lam day
	Chat tao nhu
	Preservatives
	Chat giu am
Contaminants	In accordance to the Codex Alimentarius Commission (Codex Stan 193 : 1995)
Package and wrapping	Packaged in hygiene wrapping, nutrition, characteristics of perceptibles and technologies of products
	Package and materials of packages must be made from safe materials and suitables to used goal. Package must be not transmissible toxic substances or odour or undesired odour in products
Hygiene	in accordance to TCVN 5603:2008 (Cac/RCP 1-1969; Rev. 4-2003) Guideline for practical general principles for food hygiene and the other related as Codex
	Bacteria in products must be complied with microbiology standard established to CAC/GL 21-1997 - Principles to establishing and application microbiology standard in food
Labeling	The products of this standard must be labeled according to TCVN 7087: 2008 (Codex Stan 1-2005) Food labelling for packaged products
	Name of products
	Name of products must be labeled "Instant noodles" or "Instant noodles with fry" or "Instant noodles without fry"
	Labeling for "HALAL" products
	When claiming "HALAL" food in instant noodles product's label, it must be complied with Codex CAC/GL 24-1997; General Guidelines for Using Hala's terminology
Methods of analysis and sampling	Method sampling - shall be in accordance with the CAC/GL 50-2004 General Guidelines for sampling
	Determination of moisture - according to TCVN 7879:2008
	Determination of free oil - according to TCVN 7879:2008
	Determination of acidity index - according to TCVN 7879:2008

Table 5: Case Study (1) Instant Noodles: Methods of Analysis

Items	Specifications	Methods of Analysis	References
Bacteria	10,000/q	ISO 4833: 1991	EU, Australia
Coliforms	10/q	ISO 4832: 1991	
<i>E. coli</i>	3	ISO 7251: 1993	
<i>S. aureus</i>	10/q	ISO 6883: 1983	
<i>Cl. perfringens</i>	10/q	ISO 7937: 1985	
<i>Bacillus cereus</i>	10/q	ISO 7932: 1987	
Salmonella	Negative	ISO 6579:1983	
Yeasts and moulds	100/q	ISO 7954: 1987	

Table 6: Case Study (1) Instant Noodles: Food Additives

	Descriptions/Definitions	References
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 7: Case Study (2) Carbonated Soft Drinks: Standards and Specifications

Standard	QCVN 6-2:2010/BYT		
Item			
Name of the Standard	National technical regulation for soft drinks		
Scope	This national technical regulate the food safety standard items ans management demands for soft drinks products including: fruits beverages, necta beverages, ready to drink without alcohol. This national technical is non-applicable for functional food		
Description			
Essential Composition and Quality Factors	Demand of water's quality of soft drink, it is suitable to QCVN 01:2009/BYT of quality of water, issued in accordance to regulation No 04/2009/TT-BYT dated on 17/6/2009 by Minister of Health Demand of food safety of soft drink products		
Contaminants	MRLs	Methods of Analysis	
Heavy metals	Plomb (Pb) (mg/l)	0.05	TCVN 8126: 2009

	Tin (Sn) (applied to canned products used Tin (mg/l)	150	TCVN 7769: 2007 (ISO 17240:2004); TCVN 7788:2007
Toxicology of micro-fungus	Patulin in apple beverages and nectar apple (mcg/l)	50	TCVN 8161:2009 (EN 14177:2003)
Pesticides residues	Frutis beverages (citrus)		
	Piperonyl butoxid (mg/l)	0.05	US FDA PAM, Vol.1, Section 302, E1/E4+C4
	Orange beverages and nectar		
	2-phenylphenol (mg/l)	0.5	US FDA PAM, Vol.1, Section 302, E1/E2
	Propargit (mg/l)	0.3	US FDA PAM, Vol.1, Section 302, E1/E2
	Apple beverages and nectar apple		
	Diphenylamin (mg/l)	0.5	US FDA PAM, Vol.1, Section 302, E1/E2
	Propargit (mg/l)	0.2	US FDA PAM, Vol.1, Section 302, E1/E2
	Grapes beverages and nectar grapes		
	Propargit (mg/l)	1	US FDA PAM, Vol.1, Section 302, E1/E2
	Tomoto beverages and nectar tomato		
	Carbaryl (mg/l)	3	TCVN 8171-1:2009 (EN 14185-1:2003)
	Malathion (mg/l)	0.01	AOAC 970.53
	Piperonyl butoxid (mg/l)	0.3	US FDA PAM, Vol.1, Section 302, E1/E4+C4
Microbiology	Total of plate counte (cfu/ml)	100	TCVN 4884 : 2005 (ISO 4833:2003)
	Coliforms (cfu/ml)	10	TCVN 6848 : 2007 (ISO 4832 : 2006); TCVN 4882 : 2007 (ISO 4831:2006)
	<i>E.coli</i> (cfu/ml)	Absent	TCVN 7924-1:2008 (ISO 16649-1:2001)
			TCVN 7924-2:2008 (ISO 16649-2:2001); TCVN 7924-3:2008 (ISO/TS 16649-3:2005)
	<i>Str.faecal</i> (cfu/ml)	Absent	TCVN 6189-2:1996 (ISO 7899-2:1984)
	<i>Ps.aeruginosa</i> (cfu/ml)	Absent	ISO 16266:2006
	<i>S.aureus</i> (cfu/ml)	Absent	TCVN 4830-1:2005 (ISO 6888-1:1999 with Amd.1:2003); TCVN 4830-2:2005 (ISO 6888-2:1999, with Amd.1:2003); TCVN 4830-3:2005 (ISO 6888-2:2003)
	<i>Cl.perfringens</i> (cfu/ml)	Absent	TCVN 4991:2005 (ISO 7937:2004)
Total of Yeats and Mould (cfu/ml)	10	TCVN 8275-1:2009 (ISO 21527-1:2008)	
Food additives	in according to regulation No 3742/2001 by Ministry of Health		
Labelling	Labelling of soft drink products must be followed regulation No 89/2006/ND-CP issued on 30/8/2006 by Government		
Sampling	Not specified		

Table 8: Case Study (2) Carbonated Soft Drinks: Methods of Analysis

Related Legislation	Items	Specifications	Methods of Analysis	References
QCVN 6-2:2010/BYT - National technical regulation for soft drink	Coliforms	10 cfu/ml	ISO 4832: 2006; ISO 4831: 2006	
	<i>E. coli</i>	No detective	ISO 16649-1:2001; ISO 16649-2:2001; ISO 16649-3:2005	
	<i>S. aureus</i>	No detective	ISO 6888-1:1999, with Amd. 1:2003); ISO 6888-2:1999, with Amd. 1:2003); ISO 6888-2:2003)	
	<i>Cl. perfringens</i>	No detective	ISO 7937: 2004	
	<i>S. faecal</i>	No detective	ISO 7899-2:1984	
	<i>Yeasts and moulds</i>	10 cfu/ml	ISO 21527-1:2008	
	<i>P.aeruginosa</i>	No detective	ISO 16266:2006	
	Total aerobic bacterial	100 cfu/ml	ISO 4833:2003	

Table 9 Case Study (2) Carbonated Soft Drinks: Food Additives

	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		

Table 10: Case Study (3) Prepared Frozen Foods: Standards & Specifications and Methods of Analysis

Standard		TCVN 5289 : 2006	
Item	Frozen aquatic products - Hygienic requirements		
Name of the Standard	Frozen aquatic products - Hygienic requirements		
Scope	applied to MRLs of histamine, heavy metal residues and microbiology in frozen aquatic products, used to food processing		
Contaminants		MRLs	Methods of Analysis
		Histamine (mg/kg)	100
Heavy metal	Arsenic (mg/kg)	0.5	Not specified
	Plomb (mg/kg)		
	soft animals	1	Not specified
	other aquatic products	0.5	Not specified
	Mercury (mg/kg)		
	fish-eating (shark, tuna)	1	Not specified
	other aquatic products	0.5	Not specified
	Cadmium		
	Fish	0.1	Not specified
	Crustacean	0.5	Not specified
	soft animals	1	Not specified
Microbiology	Total of plate count (cfu/g)	1,000,000	Not specified
	<i>E.coli</i> (cfu/g)	100	Not specified
	<i>S.aureus</i> (cfu/g)	100	Not specified
	<i>Cl.perfringens</i> (cfu/g)	100	Not specified
	Salmonella (/25g)	0	Not specified
	<i>V.parahaemolyticus</i> (cfu/g)	100	Not specified
Sampling	Not specified		

Standard		TCVN 7047:2002 - Technical regulations	
Item	Frozen meat - Specification		
Name of the Standard	Frozen meat - Specification		
Scope	applied to cattle, poultry, bird meat, animals which are frozen and frozen preservation used as food		
Description	fresh meat is frozen and frozen preservation used as food at the temperature under -12 degree		
		MRLs	Methods of analysis
Technical requirements	Materials		
	Fresh meat		TCVN 7046 : 2002

	not permitted to use frozen meat		
Hygiene	pH	5.5 - 6.2	TCVN 4835 : 2002 (ISO 2917 : 1999)
	Hydro sunfure (Qualification)	negative	TCVN 3699 : 1990
	Ammoniac (mg/100g)	35	TCVN 3699 : 1990
Contaminants			
Heavy metal	Plomb (mg/kg)	0.5	TCVN 5151 : 19901
	Cadmium (mg/kg)	0.05	AOAC 945.58
	Mercury (mg/kg)	0.03	TCVN 5152 : 1990
Microbiology	Total of plate count (cfu/g)	1,000,000	TCVN 5667 : 1992
	<i>E.coli</i> (cfu/g)	100	TCVN 5155 : 1990
	Coliforms (cfu/g)	100	TCVN 4882 : 2001 (ISO 4831 : 1993)
	<i>Cl.perfringens</i> (cfu/g)	10	TCVN 4991 : 1989 (ISO 7937 : 1985)
	Salmonella (/25g)	0	TCVN 5153 : 1990 (ISO 6888 : 1993)
	<i>S.aureus</i> (cfu/g)	100	TCVN 5156 : 1990
	<i>B.cereus</i> (cfu/g)	100	TCVN 4992 : 1989
	<i>Cl.botulinum</i> (cfu/g)	0	AOAC 977.26
Pesticides residues	Cabaryl (mg/kg)	0	Not specified
	DDT (mg/kg)	0.1	Not specified
	2,4 D (mg/kg)	0	Not specified
	Lindan (mg/kg)	0.1	Not specified
	Triclophon (mg/kg)	0	Not specified
	Diclovos (mg/kg)	0	Not specified
	Diazinon (mg/kg)	0.7	Not specified
	Fenclophos (mg/kg)	0.3	Not specified
	Clopyrifos (mg/kg)	0.1	Not specified
	Cuomaphos (mg/kg)	0.2	Not specified
Hormone residues	Diethylstilbestrol (mg/kg)	0	Not specified
	Testosterol (mg/kg)	0.015	Not specified
	Estadiol (mg/kg)	0.0005	Not specified
Labelling	in accordance to Regulation of labelling circulated in nationwide and imported & exported food No 178/1999/QD-TTg		
Sampling	In accordance to Standard TCVN 4833-1:2002 (ISO 3100-1:1991) - Meat and meat products - Sampling and prepared testing samples - Part 1: Sampling and TCVN 4833-2:2002 (ISO 3100-2:1988) - Meat and meat products - Sampling and prepared testing sample - Part 2: Preparing of testing samples for micribiological tesing		

Table 11: Case Study (4) Cow's Milk: Food Additives

	Summary/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. 3742/2001QD-BYT on List of Additives Permitted for Use in Food	
Use Limitation and/or Maximum Level		

4.10 Malaysia

1. FOOD ADMINISTRATION

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

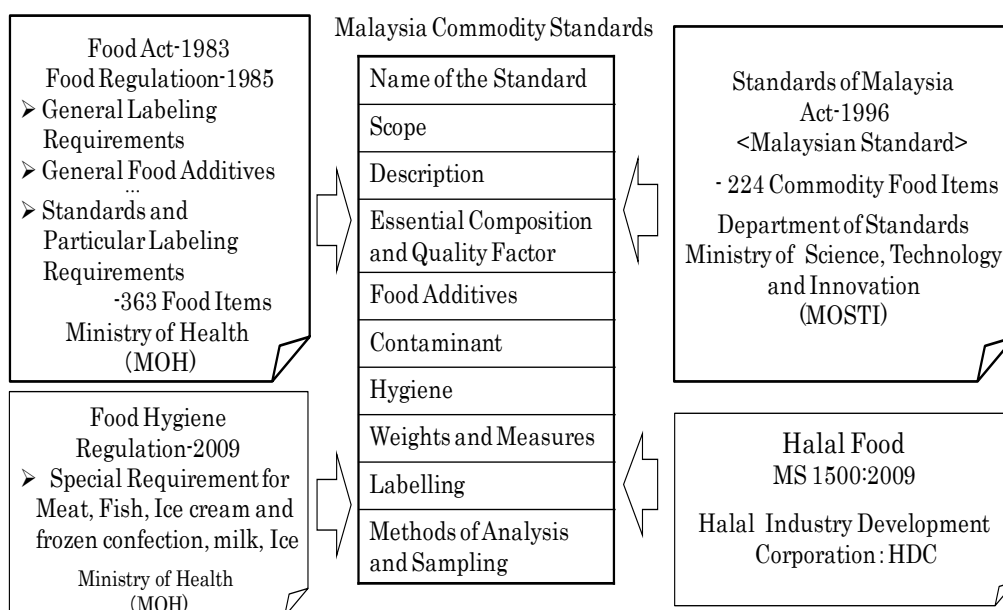
Table 1: Food Safety Control System in Malaysia

	Safety and Hygienic Control for Production and Primary Processing	Safety and Hygienic Control for Imported Foods and Processed Foods
	Ministry of Agriculture and Agro-Based Industry (MOA)	Ministry of Health (MOH)
Agricultural Products	Department of Agriculture (DOA), MOA	Food Safety and Quality Division (FSQD), MOH
Marine Products	Fisheries Department (DOF), MOA	
Livestock Products	Department of Veterinary Services (DVS), MOA	

2. SUMMARY OF ACTS AND REGULATIONS RELATED TO RESPECTIVE FOOD STANDARDS

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

Figure 1: Malaysian Commodity Standards and Relevant Laws



3. FOOD ACT (MINISTRY OF HEALTH)

(1) Food Act-1983⁶¹

The Food Act is a key law in food administration. It was enforced to protect the public against health hazards and fraud in the production, 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-1985⁶²

Supplementary provisions are compiled in Food Regulations-1985. Food Regulations-1985 is continuously updated on amendment and newly setting of regulations. Food Regulations-1985 provides general requirements for labelling, food additives and supplements, packaging, contaminants, and bacterial toxin etc.; in addition, Commodity Standards and Particular Labelling Requirements for 363 food items in Chapter 8 (Table 2). It stipulates minimum definitions, component standards and special labelling requirements.

(3) Food Hygiene Regulations-2009⁶³

Food Hygiene Regulations-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 Regulations 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 Regulations 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.

4. MALAYSIAN FOOD STANDARDS

As commodity standards, Malaysian Standards (MS) stipulated by the 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 Table 3 are in the same format for the Codex Commodity Standards.

Approximately 6,000 Malaysian Standards are issued. As of March, 2010, there are 454

⁶¹ <http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=22>

⁶² <http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21>

⁶³ http://fsq.moh.gov.my/uploads/Food_Hygiene_Regulations_2009.pdf

Malaysian Standards issued in International Classification of Standards (ICS) code 67 (Food technology). Of them, 224 Malaysian Standards are related to Specifications (Table 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 (Table 4) are registered as mandatory standards referred by administrative authority.

Table 2: Commodity Standards in Food Regulations-1985

Cereal, Cereal Product, Starch and Bread		Food Aerating Substance	
42	Flour	79	Cream of Tartar
43	Wheat Flour	80	Acid Phosphate
44	Chlorinated Wheat Flour	81	Baking Powder
45	Gluten Wheat Flour	Milk and Milk Product	
46	Protein-Increased Wheat Flour	82	Milk, Raw Milk or Fresh Milk
47	Self-Raising Wheat Flour	83	Milk Product
48	Whole meal Wheat Flour	84	Skimmed Milk, Skim Milk, Non-Fat Milk or Separated Milk
49	Rice	85	Pasteurized Milk
50	Milled Rice	86	Sterilized Milk
51	Rice Flour or Ground Rice	87	Ultra High Temperature Milk or U.H.T Milk
52	Glutinous Rice	88	Reference to Milk as Food
53	Glutinous Rice Flour	89	Flavoured Milk
54	Tapioca or Cassava	90	Full Cream Milk Powder or Dried Full Cream Milk
55	Tapioca Flour or Tapioca Starch	91	Skimmed Milk Powder, Skim Milk Powder, Dried Non-Fat Milk Solids or Separated Milk Powder
56	Sago	91A	Malted Milk Powder.
57	Sago Flour	92	Recombined Milk
58	Corn Flour or Corn Starch	93	Reconstituted Milk
59	Custard Powder	94	Evaporated Milk or Unsweetened Condensed Milk
60	Meal	95	Condensed Milk or Sweetened Condensed Milk
61	Wheat Germ Meal or Wheat Germ	96	Lactose Hydrolysed Milk
62	Oatmeal	97	Filled Milk
63	Pasta	97A	Filled Milk Powder.
64	Prepared Cereal Food	98	Evaporated Filled Milk or Unsweetened Condensed Filled Milk
65	Bread	99	Condensed Filled Milk or Sweetened Condensed Filled Milk
66	White Bread	100	Cream or Raw Cream
67	[Deleted by P.U.(A) 162/88]	101	Pasteurized Cream
68	Fruit Bread	102	Reduced Cream or Pouring Cream
69	Milk Bread	103	Butter
70	Meal Bread	104	Recombined Butter
71	[Deleted by P. U. (A) 162/88]	105	Ghee
72	Rye Bread	106	Cheese
73	Wheat-Germ Bread	107	Cottage Cheese
74	Wholemeal Bread		
75	Enriched Bread		
Malt and Malt Extract			
76	Malt		
77	Malt Extract		
78	Bakers' Malt Extract, Commercial Malt Extract, or Bakers' Maltose		

108	Cream Cheese
109	Processed Cheese
110	Cheese Paste, Cheese Spread or Cheese Mixture
111	Club Cheese or Luncheon Cheese
112	Dried Cheese or Powdered Cheese
113	Cultured Milk or Fermented Milk
114	[Deleted by P.U.(A) 162/88]
115	[Deleted by P.U.(A) 162/88]
116	Ice Cream
117	Particular Labelling Requirements of Milk and Milk Product
Sweetening Substance	
118	Sugar
118A	Stevia Extract
118B	Enzymatically Modified Stevia
119	Soft Brown Sugar
120	Coloured Sugar or Rainbow Sugar
121	Dextrose Anhydrous
122	Dextrose Monohydrates
123	Refiner's Syrup
124	Glucose
125	Glucose
126	Gula Melaka
127	Gula Kabong
128	Fructose
129	High Fructose Glucose Syrup
130	Honey
131	Icing Sugar
132	Molasses
132A	Artificial Sweetener
133	Non-nutritive Sweetening Substance
134	Aspartame, Glycerol and Sorbitol
134A	Beverage Whitener
134B	Sweetened Creamer
134C	Non Dairy Creamer
Confection	
135	Flour Confection
136	Sugar Confection
137	Frozen Confection
138	Ice Confection
139	Table Confection
140	Particular Labelling Requirement of Confection
Meat and Meat Product	
141	Meat or Fresh Meat
142	Chilled Meat
143	Frozen Meat
144	Minced Meat
145	Meat Product
146	Meat Paste
147	Manufactured Meat
148	Smoked Meat
149	Canned Meat
150	[Repealed by P.U. (A) 162/88]

151	Canned Meat With Other Food
152	Meat Extract or Meat Essence
153	Edible Gelatin
154	Meat or Meat Product Shall Not Contain Oestrogen Residue
155	Particular Labelling Requirement of Meat and Meat Product
Fish and Fish Product	
156	Fish
157	Fish Product
158	Cured, Pickled or Salted Fish
159	Smoked Fish
160	Prepared Fish
161	Canned Fish
162	Fish Paste
163	Belacan
164	Fish Sauce
165	[Repealed by P.U. (A) 162/88]
166	Cincaok
166A	Oyster Sauce
166B	Oyster Flavoured Sauce
167	Fish Ball or Fish Cake
168	Fish Keropok
169	Otak Udang, Petis or Heko
170	Pekasam
Egg and Egg Product	
171	Egg
172	Liquid Egg
173	Liquid Egg Yolk
174	Liquid Egg White
175	Dried Egg, Dried Egg Yolk or Dried Egg White
176	Reference to Egg as Food or as Ingredient in Food
177	Preserved Egg
178	Particular Labelling Requirement of Egg
Edible Fat and Edible Oil	
179	General Standard for Edible Fat and Edible Oil
180	Dripping
181	Suet
182	Lard
183	Refined, Bleached, Deodorized Palm Stearin
184	Neutralized, Bleached, Deodorized Palm Stearin
185	Margarine
186	Fat Spread
187	Vanaspati
188	General Standard for Edible Oil
189	Cooking Oil
190	Refined Coconut Oil
191	Unrefined Coconut Oil
192	Corn Oil
193	Cottonseed Oil
194	Groundnut Oil, Peanut Oil or Arachis Oil

195	Mustardseed Oil
196	Refined, Bleached, Deodorized, Palm Oil
197	Neutralized, Bleached, Deodorized Palm Oil
198	Refined, Bleached, Deodorized Palm Olein
199	Neutralised, Bleached, Deodorized Palm Olein
200	Refined, Bleached, Deodorized Palm Kernel Oil
201	Olive Oil
202	Rice Bran Oil
203	Rapeseed Oil of Toria Oil
204	Safflowerseed Oil
205	Sesameseed Oil or Gingelly Oil
206	Soya Bean Oil
207	Sunflower Seed Oil
208	Particular Labelling Requirement of Edible Fat and Edible Oil
Vegetable and Vegetable Product	
209	Vegetable
210	Fresh Vegetable
211	Dried or Dehydrated Vegetable
212	Frozen Vegetable
213	Vegetable Product
214	Salted Vegetable
215	Dried Salted Vegetable
216	Tomato Paste
217	Tomato Pulp
218	Tomato Puree
219	Vegetable Juice
220	Canned Vegetable
221	Fermented Soya Bean Product
222	Hydrolysed Vegetable Protein or Hydrolysed Plant Protein
Soup and Soup Stock	
223	Soup
224	Soup Stock
Fruit and Fruit Product	
225	Raw Fruit or Fresh Fruit
226	Dried Fruit
227	Mixed Dried Fruit
228	Fruit Product
229	Candied Fruit or Glaced Fruit or Crystallized Fruit
230	Salted Fruit
231	Dried Salted Fruit
232	Candied Peel
233	Canned Fruit
234	Canned Fruit Cocktail
235	Fruit Juice
236	Apple Juice
237	Grapefruit Juice
238	Lemon Juice
239	Lime Juice
240	Orange Juice
241	Passion Fruit Juice

242	Pineapple Juice
243	Particular Labelling Requirement of Fruit Juice
243A	Fruit Nectar
244	Fruit Pulp
245	Fruit Puree or Fruit Paste
Jam, Fruit Jelly, Marmalade and Seri Kaya	
246	Jam
247	Fruit Jelly
248	Marmalade
249	Seri Kaya
250	Pectin
251	Jam Setting Compound
Nut and Nut Product	
252	Nut
253	Coconut Milk
254	Coconut Cream
255	Coconut Cream Powder
256	Desiccated Coconut
257	[Repealed by P.U. (A) 162/88]
258	Coconut Paste
259	Peanut Butter
Tea, Coffee, Chicory and Related Product	
260	Tea
261	Tea Dust, Tea Fanning or Tea Sifting
262	Tea Extract, Instant Tea or Soluble Tea
263	Scented Tea
263A	Tea Mix
264	Particular Labelling Requirement of Tea
265	Coffee Bean
266	Coffee or Ground Coffee or Coffee Powder
267	Instant Coffee or Soluble Coffee
267A	Decaffeinated Coffee
268	Coffee Essence or Liquid Coffee Extract
269	Coffee Mixture
269A	Premix Coffee
270	Chicory
271	Coffee and Chicory
272	Instant Coffee and Chicory or Soluble Coffee and Chicory Extract
273	Coffee and Chicory Essence or Liquid Coffee and Chicory Extract
Cocoa and Cocoa Product	
274	Cocoa Bean
275	Cocoa Nib or Cracked Cocoa
276	Cocoa Paste, Cocoa Mass, Cocoa Slab or Cocoa Liquor
277	Cocoa Butter
278	Cocoa and Cocoa Powder or Soluble Cocoa
279	Chocolate
280	White Chocolate
281	Milk Chocolate
Milk Shake	

282	Milk Shake
Salt and Spice	
283	Salt
284	Table Salt
285	Iodised Table Salt or Iodised Salt
286	Spice
287	Aniseed
287A	Aniseed Powder
288	Caraway Seed
289	Caraway Powder
290	Cardomom
291	Cardamom Seed
292	Cardamom Powder
293	Cardamom Amomum
294	Cardamom Amomum Seed
295	Cardamom Amomum Powder
296	Celery Seed
297	Chilli
298	Chilli Powder
299	Chilli Slurry
300	Cinnamon
301	Cinnamon Powder
302	Cloves
303	Cloves Powder
304	Coriander
305	Coriander Powder
306	Cumin
307	Cumin Powder
308	Cumin Black
309	Cumin Black Powder
310	Dill Seed
311	Fennel
312	Fennel Powder
313	Fenugreek
314	Fenugreek Powder
315	Ginger
316	Ginger Powder
317	Mace
318	Mace Powder
319	Mustard
320	Mustard Powder
321	Nutmeg
322	Nutmeg Powder
323	Black Pepper
324	Black Pepper Powder
325	White Pepper
326	White Pepper Powder
327	Mixed Pepper Powder
328	Pimento
329	Saffron
330	Star Anise
331	Tumeric
332	Tumeric Powder
332A	Blended Tumeric Powder

333	Mixed Spice
333A	Curry Powder
Vinegar, Sauce, Chutney and Pickle	
334	Vinegar
335	Distilled Vinegar
336	Blended Vinegar
337	Artificial Vinegar or Synthetic Vinegar
338	Particular Labelling Requirement of Vinegar
339	Sauce
340	Soya Sauce or Soya Bean Sauce or Kicap
341	Hydrolysed Vegetable Protein Sauce or Hydrolysed Plant Protein Sauce
341A	Blended Hydrolysed Vegetable Protein Sauce or Blended Hydrolysed Plant Protein Sauce
342	Chilli Sauce
343	Tomato Sauce or Tomato Ketchup or Tomato Catsup
344	Salad Dressing
345	Mayonnaise
346	Chutney
347	Pickle
Soft Drink	
348	General Standard for Soft Drink
349	Syrup
350	Fruit Syrup, Fruit Cordial or Fruit Squash
351	Flavoured Syrup or Flavoured Cordial
352	Fruit Juice Drink
353	Fruit Drink
354	Flavoured Drink
355	Soft Drink Base or Soft Drink Premix
356	Botanical Beverage Mix
357	Soya Bean Milk
358	Soya Bean Drink
359	[Repealed by P.U. (A) 162/88]
360	Particular Labelling Requirement of Soft Drink
Natural Mineral water	
360A	Natural Mineral Water
Packaged Drinking water	
360B	Packaged Drinking Water
Alcoholic Beverage	
361	General Standard for Alcoholic Beverage
362	Wine
363	Wine Cocktail, Vermouth or Wine Aperitif
364	Aerated Wine
365	Dry Wine
366	Sweet Wine
367	Fruit Wine
368	Apple Wine
369	Cider

370	Pear Wine
371	Perry
372	Vegetable Wine
373	Honey Wine or Mead
374	Beer, Lager, Ale or Stout
375	Rice Wine
376	Toddy
377	Spirit
378	Brandy
379	Fruit Brandy
380	Rum
381	Whisky
382	Vodka
383	Gin
384	Samsu

385	Particular Labelling Requirement of Spirit
386	Liqueur
Shandy	
387	Shandy
Special Purpose Food	
388	Special Purpose Food
389	Infant Formula
389A	Follow-up Formula
390	Canned Food for Infants and Children
391	Cereal-Based Food for Infants and Children
392	Low Energy Food
393	Formula Dietary Food
393A	Special Dietary Foods With Low Sodium Content Including Salt Substitute

Note : Missing sequential regulation numbers are due to intentional deletion of the regulation from the Food Regulations

Table 3: Format of Malaysian Standards (MS)

MALAYSIAN STANDARDS MS 526:2009 ICS: 67.060, 180.20 Instant Wheat Noodles – Specification (Second Revision)	
Contents	
1 Scope	Table 1 Requirements for instant wheat noodles (fried and non-fried, excluding seasonings) .
2 Normative references	
3 Definitions	
4 Minimum requirements	Annex A Determination of moisture content
5 Packaging and labelling	Annex B Determination of cooking or soaking time
6 Hygiene	Annex C Determination of protein content
7 Sampling	Annex D Determination of acid value
8 Testing	
9 Compliance	
10 Legal requirements	

Table 4: Specifications in Malaysian Standards

MS No.	Title		
85:2010	Edible Wheat Flour - Specification (Third Revision)	1252:2009*	Fresh French Beans - Specification (First Revision)
513:2009	Caramel in The Manufacture of Soy Sauce - Specification (Second Revision)	2249:2009	Fresh Baby Corn - Specification
742:2009	Prawns/Shrimps Canned in Brine - Specification (First Revision)	997:2009	Canned Baked Beans in Tomato Sauce - Specification (First Revision)
2255:2009	Dried Wheat Noodles - Specification	ISO 6574:2008	Celery Seed (Apium Graveolens Linnaeus) - Specification (Iso 6574:1986, ldt)
2254:2009	Wet and Raw Wheat Noodles - Specification	ISO 10621:2008	Dehydrated Green Pepper (Piper Nigrum L.) - Specification (Iso 10621:1997, ldt)
526:2009	Instant Wheat Noodles - Specification (Second Revision)	1118:2008	Malaysian Cocoa Butter - Specification (First Revision)

ISO 11162:2008	Peppercorns (Piper Nigrum L.) in Brine - Specification and Test Methods (Iso 11162:2001, ldt)
ISO 11163:2008	Dried Sweet Basil (Ocimum Basilicum L.) - Specification (Iso 11163:1995, ldt)
1323:2008*	Fresh Mustards - Specification (First Revision)
1376:2008	Malaysian Cocoa Mass - Specification (First Revision)
1229:2008	Fresh Sweet Corn - Specification (First Revision)
2202:2008	Fresh Pummelo – Specification
2201:2008	Fresh Pitahaya – Specification
1798:2008	Milk and Milk Products - Specification of Mojonnier-Type Fat Extraction Flasks (Iso 3889:2006, Mod)
1284:2008	Soft, Light and Dark Brown Sugar - Specification (First Revision)
1994:2007	Fresh 'Cavendish' Banana — Specification
1995:2007	Fresh Rambutan – Specification
ISO 882-1:2007	Cardamom [Elettaria Cardamomum (Linnaeus) Maton Var. Minuscula Burkill] - Specification - Part 1: Whole Capsules (Iso 882-1:1993, ldt)
ISO 882-2:2007	Cardamom [Elettaria Cardamomum (Linnaeus) Maton Var. Minuscula Burkill] - Specification - Part 2: Seeds (Iso 882-2:1993, ldt)
597:2007	Beer – Specification (First Revision)
2054:2007	Coriander (Coriandrum Sativum L.), Whole or Ground (Powdered) - Specification (Iso 2255:1996, Mod)
2055:2007	Fennel Seed, Whole or Ground (Powdered) – Part 1: Bitter Fennel Seed (Foeniculum Vulgare P. Miller Var. Vulgare) – Specification (Iso 7927-1:1987, Mod)

2056:2007	Fenugreek, Whole or Ground (Powdered) – Specification (Iso 6575:1982, Mod)
2062:2007	Aniseed (Pimpinella Anisum Linnaeus) - Specification (Iso 7386:1984, Mod)
815:2007 *	Palm Stearin - Specification (Second Revision)
2042:2007	Salty Soy Sauce – Specification
2043:2007	Virgin Coconut Oil – Specification
545:2007	Fresh, Chilled and Frozen Beef – Specification (First Revision)
ISO 11178:2007	Star Anise (Illicium Verum Hook. F.) - Specification (Iso 11178:1995, ldt)
814:2007 *	Palm Oil - Specification (Second Revision)
816:2007 *	Palm Olein - Specification (Second Revision)
1148:2007	Fine Granulated Sugar and Castorsugar – Specification (First Revision)
1980:2007	Flavoured Milk – Specification
236:2007	Palm Kernels - Specification (Second Revision)
894:2005 *	Fresh Chillies - Specification (First Revision)
1875:2006	Groundnuts (Peanuts) - Specification
1783:2005	Edible Ice in Food Processing and Food Services – Specification
1028:2005 *	Fresh Watermelon - Specification (First Revision)
234:2005	Black and White Pepper, Whole - Specification (Second Revision)
293:2005	Cocoa Beans – Specification for Grading (Fourth Revision)
1819:2005	Chocolate Flavoured Confections – Specification
1306:2005 *	Fresh Ginger – Specification
779:2005	Margarine - Specification (Second Revision)

883:2005	Vanaspati/Compound Vegetable Fat - Specification(First Revision)	1001:2002	Specification for Dried Chillies in Ground (Powdered) Form
4:2005	White Refined Sugar for General Use – Specification (Third Revision)	361:2002	Specification for Fresh, Chilled and Frozen Poultry (First Revision)
1283:2005	Oyster Flavoured Sauce -Specification (First Revision)	1127:2002 *	Specification for Fresh Carambola (Second Revision)(Codex Stan 187-1993, Neq)
1310:2005	Oyster Sauce – Specification	871 : 2001	Specification for Malaysian Cocoa Powder
807:2005	Light Soy Sauce – Specification	1041:2001	Specification for Fresh Pineapple (First Revision)
1264:2005	Dark (Thick) Soy Sauce - Specification (First Revision)	1507:2001	Specification for Refined Palm Glycerine
1234:2005	Vegetable Shortening – Specification	714:2001	Specification for Packaged Pineapple Juice (First Revision)
1820:2005	Fresh Sekaki Papaya – Specification	531:2001	Specification for Tomato Sauce (Ketchup) (Second Revision)
1859:2005	Fresh Chokanan Mango – Specification	889 : 2001	Specification for Turmeric, Whole and Ground(First Revision)
82:2005	White Refined Sugar for Industrial Use – Specification (Third Revision)	543 : 2001	Specification for The Production of Vegetable Seeds
892:2004 *	Spesifikasi Bagi Kobis Bulat	1516:2001	Specification for Vinegar
713:2004	Seri Kaya – Specification	295:1999	Specification for Tea
1762:2004	Palm Superolein – Specification	476:1998	Specification for Cream-Crackers (First Revision)
1102:2003	Specification for Black and White Pepper, Ground	1434:1998	Specification for Semi-Sweet Biscuits and Cookies
682:2004	Cooking Oils – Specification	6:1998	Specification for Dried Crackers (Keropok Kering) from Freshwater and Marine Fish, Crustacea and Molluscan Shellfish (First Revision)
1000:2003	Specification for Soya Bean Milk and Drink (First Revision)	898 : 1998	Specification for Dry-Salted Anchovies (Ikan Bilis) (Second Revision)
85 : 2003	Specification for Edible Wheat Flour(Second Revision)	1437:1998	Specification for Palm Kernel Stearin
1715 : 2003	Specification for Chocolate and Chocolate Products	241:1998	Specification for Bread
1126:2003	Meat Burgers - Specification (First Revision)	84 : 1998	Specification and Grades for Paddy (First Revision)
1145:2003 *	Specification for Fresh Eksotika Papaya	6:1998	Specification for Quick-Frozen, Raw and Cooked Shrimps or Prawns (Second Revision)
956 : 2003 *	Spesifikasi Bagi Timun	1436:1998	Specification for Palm Kernel Olein
893:2003 *	Spesifikasi Bagi Tomato	600:1998	Specification for Cordials, Squashes and Syrups
951:2003 *	Spesifikasi Bagi Kacang Panjang		
1125:2003	Meat Frankfurters – Specification		
302:2003	Specification for Canned Pineapple (First Revision)		

225 : 1997	Specification for Grading of Milled Rice	156 : 1994	Specification for Tapioca Pearl
83:1997	Specification and Methods of Test for Sugarcane Final Molasses(Second Revision)	155:1994	Specification for Industrial Tapioca Starch (First Revision)
1393:1996 *	Specification for Fresh Chinese Cabbage (Head Type)	1351:1994	Specification for Coconut Cream Powder
1124:1996 *	Specification for Fresh Sweet Pepper (Bell Pepper)	1282: PART 5:1994	Specification for Food Additives Part 5 : Stabilizers, Thickeners and Gelling Agents
532:1995	Specification for Red Chilli Sauce (Second Revision)	154:1994	Specification for Edible Tapioca Starch (First Revision)
890 : 1995	Specification for Curry Powder (First Revision)	468:1994	Specification for Industrial Sago Starch (First Revision)
1374:1995	Specification for Fresh, Chilled and Frozen Rabbit Meat	601:1994	Specification for Ready-to-Drink Beverages(Carbonated and Non Carbonated)(First Revision)
1381:1995	Specification for Desiccated Coconut	1325:1993 *	Specification for Fresh Muskmelon (Tembikai Wangi)
410:1995	Specification for Pasteurized and Pasteurized, Homogenized Full-Cream and Low-Fat Milk (Second Revision)	1282: PART 3:1993	Specification for Food Additives Part 3 : Antioxidants
1376:1995	Specification for Cocoa Mass	1309:1993	Specification for Nutmeg (Whole or Broken)
1373:1995	Specification for Serunding Daging (Spicy Shredded Meat)	1324:1993 *	Specification for Fresh Kale (Kailan)
1372:1995	Specification for Satay Sauce	469 : 1993	Specification for Rice (Oryza Sativa) Seed for Planting
1282: PART 8:1995	Specification for Food Additives Part 8 : Colouring Substance	467 : 1993	Specification for Cocoa (Theobroma Cacao) Seeds for Planting
680 : 1995	Specification for Fresh Chicken Eggs	598:1993	Specification for Ice-Cream
1057 : 1995	Specification for Adjustable Louvre Windows	1308:1993	Specification for Mace (Whole, in Pieces or Ground)
779:1994	Specification for Margarine (First Revision)	513:1993	Specification for Caramel in The Manufacture of Soya Sauce (First Revision)
1362:1994 *	Specification for Fresh Spinach	599:1993	Specification for Full Cream Milk Powder (First Revision)
1361:1994 *	Specification for Fresh Head Lettuce	1282: PART 4:1993	Specification for Food Additives Part 4 : Flavour Enhancers
1282: PART 7:1994	Specification for Food Additives Part 7 : Anticaking Agents	1250:1992	Specification for Duck Eggs
1282: PART 6:1994	Specification for Food Additives Part 6: Solvents	1282: PART 2:1992	Specification for Food Additives Part 2 : Preservatives
1356:1994	Specification for Rice Flour(Non-Glutinous) and Blended Rice Flour	1282: PART 1:1992	Specification for Food Additives : Part 1 : Acid Regulators
1357:1994	Specification for Sago Pearl		

1284:1992	Specification for Soft Brown Sugar and Brown Sugar	1121:1988	Specification for Canned Fish in Oil
1249:1992	Specification for Canned Mutton / Goat Meat in Curry	1122:1988	Specification for Canned Fish in Brine
1251:1992	Specification for Canned Cuttlefish or Squid	813:1988	Specification for Gelatin
1261:1992	Specification for Potato Chips	675:1988	Specification Forcanned Fish in Tomato Sauce (First Revision)
1253:1992	Specification for Cultured Milk(Fermented Milk)	1112:1988	Specification for Instant Beehoon (Instant Rice Vermicelli)
1262:1992	Specification for High Fructose Glucose Syrup 42	1111:1988	Specification for Raw Unprocessed in-Shell Groundnuts to Be Processed Into Menglembu Groundnuts
1259:1992, Including AMD. 1:1993	Specification for Icing Sugar (Powdered Sugar)	673:1988	Specification for Canned Sweet Corn (First Revision)
1260:1992	Specification for Canned Ikan Bilis (Anchovies)	243:1988	Specification for Monosodium Glutamate
470:1992	Specification for Edible Sago Starch (First Revision)	242:1988	Specification for Butter/Recombined Butter (First Revision)
1236 : 1991	Specification for Tamarind Pulp	80 : 1987	Specification for Palm Kernel Oil
1232:1991	Specification for Green Coffee	1083:1987	Specification for Ultra High Temperature (Uht) Flavoured Milk
1235:1991	Specification for Roasted Ground Coffee	239:1987	Specification for Coconut Oil (First Revision)
1230:1991 *	Specification for Fresh Okra (Lady'S Finger)	1040:1986 *	Specification for Fresh Papaya
1200:1991	Specification for Corn Starch	1024:1986	Specification for Wheel Nuts for Passenger Vehicles
1191:1991	Specification for Cereal-Based Snack Foods	1053:1986, Including AMD.1:1991 & AMD. 2	Specification for Evaporated Filled Milk
526:1988 (CONFIRME D:2003)	Specification for Instant Noodles (First Revision)	1055 : 1986 *	Specification for Fresh Jackfruit
1433:1998	Specification for Wafers	1054:1986, Including AMD. 1:1991 & AMD. 2:1993	Specification for Condensed Filled Milk
872 : 1990	Specification for Canned Beef Curry	997 : 1986	Specification for Canned Beans in Tomato Sauce
1126:1989	Specification for Chilled and Frozen Meatburgers	998 : 1986	Specification for Canned Long Beans
1149:1989 *	Specification for Fresh Guava	412:1986	Specification for Recombined Ultra High Temperature Milk and Recombined Ultra High Temperature Homogenized Milk (First Revision)
1128:1989 *	Specification for Quick Frozen Mangosteen		
1146:1989 *	Specification for Fresh Bitter Gourd		
999 : 1989	Specification for Canned Chicken Curry		
1075:1987, Including AMD.1:1989 *	Export Specification for Fresh 'Mas' Bananas		
1118:1988	Specification for Malaysian Cocoa Butter		
1115:1988	Specification for Table Salt		

411:1986	Specification for Ultra High Temperature Milk and Ultra High Temperature Homogenized Milk (First Revision)
235 : 1986	Specification for Copra
1027:1986	Specification for Canned Passion Fruit Nectar
952 : 1985	Specification for Canned Processed Peas
955 : 1985	Specification for Beehoon (Rice Vermicelli)
958 : 1985	Specification for Citric Acid (Food Grade)
915 : 1985	Specification for Sodium Benzoate, Food Grade
950 : 1985	Specification for Canned Guava
885 : 1984 *	Specification for The Grading of Mangoes for Fresh-Fruit Consumption
884 : 1984	Specification for Canned Jackfruit
895 : 1984	Specification for Hard Boiled Sweets
899 : 1984	Specification for Dried Prawns
891 : 1984	Specification for Peanut Butter
901 : 1984	Specification for Canned Mango Nectar
902 : 1984	Specification for Canned Guava Nectar
25:1983, Including AMD. 1:1993	Specification for Condensed Milk (First Revision)
818:1983	Specification for Ice Used in The Fish and Prawn Industry
819:1983	Specification for Sodium Metabisulphite, Food Grade
812:1983	Specification for Canned Tropical Fruit Cocktail
413:1983	Specification for Pasteurized Recombined Milk and Pasteurized, Homogenized Recombined Milk (First Revision)

851 : 1983	Specification for Phosphoric Acid (Food Grade)
808:1983	Specification for Resh Fish
777:1982	Specification for Instant Coffee
759:1982	Specification for Cloves, Whole and Ground (Powdered)
760:1982	Specification for Skimmed Milk Powder / Non - Fat Dried Milk
780:1982	Specification for Canned Papaya-Pineapple Salad
21:1982	Specification for Glucose Syrup (Liquid Glucose) (First Revision)
718 : 1981	Specification for Ginger, Whole and in Pieces
742:1981	Specification for Prawns / Shrimps Canned in Brine
664:1980	Specification for Canned Mushrooms (Agaricus)
596:1979	Specification for Jams (Fruit Preserves), Jellies and Marmalades
597:1979	Specification for Beer
548:1978	Specification for Fresh, Chilled and Frozen Lamb and Mutton
545:1978	Specification for Fresh, Chilled and Frozen Beef
547:1978	Specification for Fresh, Chilled and Frozen Pork
459:1976 *	Specification for Fresh Bananas
304:1975	Specification for Canned Rambutans
232:1974 *	Specification for Malaysian Mandarins for Fresh-Fruit Consumption
238:1974	Specification for Rice Bran Oil
79:1973	Specification for The Storage and Transport of Green Bananas

5. HALAL SYSTEM

Halal System is a system to examine raw materials of foods, production processes, quality of products permissible under Islamic Law, and to certify and label halal-compliant products. Currently, the Department of Islamic Development Malaysia (JAKIM) is responsible for evaluation for approval, and Halal Development Company (HDC) is for 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.

6. LAWS AND REGULATIONS RELATED TO FOOD ADDITIVES

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 Part 5, 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.

6.2 Food Additives Definitions & 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

- 1) Emulsifiers;
- 2) Antifoaming agents;
- 3) Stabilizers;
- 4) Thickeners;
- 5) Modified starches;
- 6) Gelling agents;
- 7) Acidity regulators;
- 8) Enzymes;
- 9) Solvents;
- 10) Glazing agents; and
- 11) 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.

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.

For flavourings, permitted flavouring substances that can be used in food include:

- 1) Those listed in one or more of the following publications:
 - a) FEMA GRAS (Generally Recognized As Safe (GRAS) flavouring substances published by the Flavor and Extract Manufacturers' Association of the United States (FEMA) contained in the Food Technology, a publication of the Institute of Food Technologists); or
 - b) Flavourings, List of Codex Specifications for Food Additives (CAC/MISC 6); or
- 2) Natural flavouring substance either in its raw state or after processing by traditional preparation process including drying, roasting, and fermentation.

6.4 Prohibited Substances to be used as Food Additives

Prohibited flavouring substances are found in the Eighth 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.

6.5 Specifications & Standards 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.

6.6 Application, Assessment and Approval of Food Additives

New food additives must first be evaluated by the Expert Committee on Food Additives and Contaminants and approved by the Food Safety and Quality Division (FSQD) within the Ministry of Health. 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 (WHO) 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

6.7 Labelling of Food Additives in Foods

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 "*contains (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*".

6.8 Summary of Food Additives

The definitions regarding food additives such as flavourings, processing aids, and carry-overs are summarized in Table 5. The descriptions of other items such as designated/existing food additives and prohibited substances are summarized in Table 6.

7. SPECIFICATIONS & STANDARDS AND METHODS OF ANALYSIS FOR GENERAL FOODS

Standards and methods of analysis for general foods are shown in Table 7. Standards and methods of analysis for the food categories taken up in the Case Study are described in the food categories, respectively.

8. CASE STUDIES

(1) Instant Noodles

Commodity Food Standards and Methods of Analysis:

Instant noodles are defined as "Pasta" including noodles, beehoon, laksa, macaroni and spaghetti in Food Regulations-1985. Instant Wheat Noodle (MS 526:2009) in MS is a standard which complied with Instant Noodles developed by Codex. Instant Noodles is also compared with Instant Beehoon (MS 1112:1988) (Table 8). These specifications and methods of analysis are described in Table 9.

Food Additives:

Standards for "Pasta" in Food Regulations-1985, and those for "Instant Wheat Noodle" (MS 526:2009) and "Instant Beehoon" (MS 1112:1988) in Malaysian Standards are described in Table 10. In each case, standards for use of food additives are regulated by the Food Regulations-1985, and MS Regulations do not exceed Food Regulations-1985 in the restrictions of the use of food additives.

(2) Carbonated Soft Drinks

Commodity Food Standards and Methods of Analysis:

There is no standard set either in Food Regulations-1985 or MS exclusively for Carbonated Soft Drinks. Both of them cover variety of food items like flavoured drinks. Specifications & standards are shown in Table 11, and methods of analysis in Table 12.

Food Additives:

Standards for "Flavoured Drink" in Food Regulations-1985, and those for "Ready-to-Drink Beverages" (MS 601:1994) in MS are described in Table 13. In each case, standards for use of food additives are regulated by the Food Regulations-1985, and MS do not exceed Food Regulations-1985 in the restrictions of the use of food additives.

(3) Prepared Frozen Foods

Commodity Food Standards and Methods of Analysis:

While there are some standards for frozen confection, frozen meats and frozen vegetables, no standards for prepared frozen foods more like Japanese ones. There are no any appropriate standards in MS, either; however, relatively similar standards are presented in Tables 14 and 15.

Food Additives:

There is no food category for “prepared frozen foods” in Malaysia. Standards for “Meat Frankfurters” (MS 1125:2003) and “Meat Burgers” (MS 1126:2003) in Food Regulations-1985 are described as examples. In each case, standards for use of food additives are regulated by the Food Regulations 1985, and MS do not exceed the Food Regulations in the restrictions of the use of food additives.

(4) Cow’s Milk

Commodity Food Standards and Methods of Analysis are summarized in Table 17. **Food Additives** are prohibited to use in Cow’s Milk according to Food Regulations-1985 (Table 18).

Table 5: Summary/Definition of Food Additives (General)

	Summary/Definitions	Reference
Related Legislation	Food Regulations 1985	http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21
Summary/Definitions (General)		
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 chemically-defined substance with flavouring properties either formed by chemical synthesis or obtained from materials of plant or animal origin. “Natural Flavouring Substance” means any flavouring substance obtained by physical processes may result in unavoidable but unintentional changes in the chemical structure of the component of the flavouring, or by enzymatic or microbiological processes from material of plant or animal origin, and is not synthetic flavouring substance or any flavouring substance formed by chemical synthesis.	Food Regulations 1985, Part V Regulation No. 22 (1) Food Regulations 1985, Part V Regulation No. 22 (2) 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)

Table 6: Summary/Definition of Food Additives (Specific)

		Summary/Definitions	Reference
Related Legislation		Food Regulations 1985	http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21
Summary (Specific)/Additional Laws			
1	List of Designated Food Additives	Includes preservative, antimicrobial agent, colouring substance, flavouring substance, flavour enhancer, 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		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
Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of Manufacturing of Food Additives		Found in Malaysian Standard 1282 Appendices 1-8 for acidity regulator; preservative; antioxidant; flavour enhancer; stabilizer, thickener and gelling agent; solvent; anticaking agent; and colouring substance.	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
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.	http://fsq.moh.gov.my/v3/index.php?option=com_k2&view=item&layout=item&id=224&Itemid=104

Table 7: Specifications & Standards and Methods of Analysis for General Foods

Related Legislation	Item	Specifications	Methods of Analysis	Reference
Food Regulations 1985	Incidental constituent	No person shall import prepare or advertise for sale or sell any food containing incidental constituent, except as otherwise specified in regulations 38, 38A, 39, 40 and 41	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Metal contaminants	<ol style="list-style-type: none"> 1. No person shall import prepare or advertise for sale or sell any food, specified in column (1) of Table I to the Fourteenth Schedule which contains the substances set out in the headings to columns (2) to (9) of the said Table in a proportion greater than the maximum permitted proportion specified opposite that food in the columns thereof applicable to the substances. 2. No person shall import, prepare or advertise for sale or sell the food additives specified in column (1) of Table II to the Fourteenth Schedule which contains the substances set out in the headings to column (2) to (8) of the said Table in a proportion greater than the maximum permitted proportion specified opposite that food additive in the columns thereof applicable to the substance. 	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	3-MCPD	No person shall import prepare or advertise for sale or sell any food, specified in column (1) of Table I to the Fourteenth A Schedule which contains 3-monochloropropane-1,2-diol (3-MCPD) in a proportion greater than the maximum permitted proportion specified opposite that food in column (2) of the Schedule.		
	Microorganisms and their toxins	<ol style="list-style-type: none"> 1. No person shall import, prepare or advertise for sale or sell any food ready for consumption that is contaminated with pathogenic microorganisms; 2. No person shall import, prepare or advertise for sale or sell any food, excluding water, specified in column (1) of Table I to the Fifteenth Schedule which contains bacteria in numbers greater than the numbers specified opposite that food in columns (2), (3) and (4) of the said Table for total plate, coliform and Escherichia coli count respectively. 3. No person shall import, prepare or advertise for sale or sell any food which contains the mycological contaminant specified in column (1) of Table II to the Fifteenth Schedule in proportion greater than the proportion specified opposite thereto in column (2) of the said Table. 		

	Drug residue	<ol style="list-style-type: none"> 1. No person shall import, sell, expose or offer for sale or delivery, any food intended for human consumption which contains drug residues greater than the amount set out in Table I, to the Fifteenth A Schedule. 2. Notwithstanding subregulation (1), either chlorotetracycline or oxytetracycline may be incorporated in ice used for preserving fresh fish, and unpeeled shrimps, provided that the concentration of one of these drugs shall not exceed 5 parts per million in the product. 3. Notwithstanding subregulation (1) and (2), no person shall import, sell, expose for sale or delivery, any food intended for human consumption which contains the drugs as set out in Table II to the Fifteenth A Schedule. 		
	Pesticide residue	<p>No person shall import, prepare for sale or sell any food:</p> <ol style="list-style-type: none"> a) containing pesticide residue in a proportion greater than the proportion specified for that food in relation to that pesticide residue as set out in the Sixteenth Schedule; b) containing pesticide residue in a proportion greater than the proportion specified for that food in relation to that pesticide residue as recommended in the Codex Alimentarius, where the pesticide is not specified in the Sixteenth Schedule; or c) containing more than 0.01 milligram per kilogram of any pesticide residue, where the pesticide residue is not specified for that food in the Sixteenth Schedule or Codex Alimentarius 		

Table 8: Case Study (1) Instant Noodles: Specifications & Standards

Standard Item	Food Regulations 1985 (as at 1st September 2009)	MS 526:2009	MS 1112:1988
Name of the Standard	Pasta	Instant Wheat Noodles	Instant Beehoon
Scope	<ul style="list-style-type: none"> ▪ Noodles, beehoon, laksa, macaroni and spaghetti 	<ul style="list-style-type: none"> ▪ Fried noodles, non-fried noodles 	<ul style="list-style-type: none"> ▪ Instant beehoon (Instant rice vermicelli)
Description	<ul style="list-style-type: none"> ▪ Any product that is obtained by extruding or moulding units of dough. 	<ul style="list-style-type: none"> ▪ A product prepared from wheat as the main ingredient and other flour/starches, with or without the addition of other ingredients and packed with suitable packaging material. It may be treated by alkaline agents. It is characterised by the use of pregelatinisation process and dehydration either by frying or by other 	<ul style="list-style-type: none"> ▪ Made up principally of rice flour and other wholesome food with or without the incorporation of seasoning.

<p>Essential Composition and Quality Factor</p>	<ul style="list-style-type: none"> ▪ Principally of a cereal meal ▪ May contain carbohydrate foods, egg solids, salt and any other food 	<p>methods.</p> <ul style="list-style-type: none"> ▪ Free from dirt, foreign matter and insects. ▪ Acceptable in term of appearance, texture, aroma, taste and colour and be free from any undesirable off-flavours and odours. ▪ To qualify for the concept of 'instant', the noodle shall be cooked or soaked in not more than four minutes in boiling water. ▪ Essential ingredients are: <ul style="list-style-type: none"> a) wheat flour and other flour or starches; b) water; and c) common salts or alkaline salts. The permitted alkaline salts are sodium, potassium, or calcium salt of carbonates, phosphates and/or hydroxides. ▪ Moisture: 10% (fried) , 14% (non-fried) ▪ Cooking or soaking time: 4 minutes (fried and non-fried) ▪ Protein content: 8.5% (fried and non-fried) ▪ Acid value: 2.0 mg KOH/g (fried), Not applicable (non-fried) 	<ul style="list-style-type: none"> ▪ In the form of solid strands and shall be free from mould, off-flavour, insect infestation or other spoilage. ▪ To qualify for the concept of 'instant', the product must be cooked in not more than four minutes in boiling water. ▪ Moisture: 12% ▪ Cooking time: 4 minutes ▪ Total protein: 5.7% ▪ Total ash: 1.0%
<p>Food Additives</p>	<ul style="list-style-type: none"> ▪ Permitted colouring substance ▪ Transglutaminase, sulphur dioxide or sulphites (as permitted food conditioner): <200 mg/kg ▪ Subject to general requirements concerning food additives. 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985. 	<ul style="list-style-type: none"> ▪ May contain food additives but not contain any added preservatives.
<p>Contaminants</p>	<ul style="list-style-type: none"> ▪ Arsenic (As): <1 mg/kg ▪ Lead (Pb) : <2 mg/kg ▪ Tin (Sn): <40 mg/kg ▪ Mercury (Hg): <0.05 mg/kg ▪ Cadmium (Cd): <1 mg/kg ▪ Antimony (Sb): < 1 mg/kg ▪ 3-monochloropropane-1,2-diol (3-MCPD) for all foods containing acid hydrolysed protein (solid foods): 0.05 mg/kg 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985. 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985.

Hygiene	<ul style="list-style-type: none"> ▪ Harmful, damaged packages prohibited ▪ No pathogenic microorganisms ▪ Aflatoxin or any other mycotoxins: <5 µg/kg ▪ Food Hygiene Regulations 2009 	<ul style="list-style-type: none"> ▪ Packed in suitable packaging materials which will safeguard the hygienic, nutritional, technological and organoleptic qualities of the product. ▪ Packaging materials shall be made of substances which are safe and suitable for their intended use. They should not impart any toxic substances or undesirable odour or flavour. ▪ Processed and packed under hygienic conditions in premises licensed in accordance with MS1514 – Good Manufacturing Practices. 	<ul style="list-style-type: none"> ▪ Processed and packed under hygienic conditions.
Weight and Measures	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified
Labelling	<ul style="list-style-type: none"> ▪ If labelled with the word “egg” or any word of similar meaning: >4% egg solids calculated on water-free basis ▪ Subject to general requirements for labelling ▪ Nutrition labelling is mandatory (regulation 18B of the Food Regulations 1985) 	<ul style="list-style-type: none"> ▪ The following information shall appear clearly on each package: <ul style="list-style-type: none"> a) name of product; b) name and address of the manufacturer and/or distributor or trade mark owner; c) net weight (in grams); d) list of ingredients and additives; e) date of manufacture or manufacturer’s code; f) date of expiry; and g) method of preparation. ▪ Shall comply with requirements specified in the Malaysian Food Act 1983 and Food Regulations 1985. 	<ul style="list-style-type: none"> ▪ The following information shall appear clearly on each package: <ul style="list-style-type: none"> a) name of product; b) list of ingredients and added additives; c) name of manufacturer and/or supplier; d) guaranteed net weight in grams; e) date of manufacture or manufacturer’s code; ▪ Shall comply with requirements specified in the Malaysian Food Act 1983 and Food Regulations 1985.
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Additives, contaminants, microorganisms, mycotoxins 	<ul style="list-style-type: none"> ▪ Moisture: oven-drying method ▪ Protein content: Kjeldahl method ▪ Acid value: Titrimetric method ▪ Cooking time 	<ul style="list-style-type: none"> ▪ Moisture: oven-drying method ▪ Protein content: Kjeldahl method ▪ Ash content: Direct method ▪ Cooking time

Table 9: Case Study (1) Instant Noodles: Specifications & Standards and Methods of Analysis

Related Legislation	Items	Specifications	Methods of Analysis	References
Food Regulations 1985	Food additives	Permitted colouring substance; transglutaminase: <200 mg/kg; sulphur dioxide: <200 mg/kg; sulphites: <200 mg/kg	International standards (AOAC, ISO, APHA, etc.)	
MS 526:2009 - Instant Noodles - Specification (Second Edition)	Moisture content	10% (Fried); 14% (Non-fried)	MS 526:2009, Appendix A	
	Cooking/soaking time	4 minutes	MS 526:2009, Appendix B	
	Protein content	8.50%	MS 526:2009, Appendix C	
	Acid value	2.0 mg KOH/g (Fried only)	MS 526:2009, Appendix D	
MS 1112:1988 - Instant Beehoon (Instant Rice Vermicelli) - Specification	Moisture content	12%	MS 1112:1988, Appendix A	
	Cooking/soaking time	4 minutes	MS 1112:1988, Appendix B	
	Protein content	5.70%	MS 1112:1988, Appendix C	
	Ash content	1.00%	MS 1112:1988, Appendix D	

Table 10: Case Study (1) Instant Noodles: Food Additives

	Description/Definitions	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	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		
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	Other additives are permitted in accordance with Food Regulations 1985.	

Table 11: Case Study (2) Carbonated Soft Drinks: Specifications & Standards

Standards Items	Food Regulations 1985 (as at 1 st September 2009)	MS 601:1994
Name of the Standard	Flavoured Drinks	Ready-To-Drink Beverages (carbonated and non-carbonated)
Scope	<ul style="list-style-type: none"> ▪ Flavoured drink 	<ul style="list-style-type: none"> ▪ Ready-to-drink beverages including fruit drinks and flavoured drinks
Descriptions	<ul style="list-style-type: none"> ▪ Flavoured drink shall be the soft drink composed of potable water and permitted flavouring substances, with or without sugar, glucose, high fructose glucose syrup or edible portions of extract of fruit or other plant substance. It may contain carbon dioxide. 	<ul style="list-style-type: none"> ▪ A non-alcoholic beverage and is saturated with carbon dioxide. It is prepared from comminuted fruit or fruit juices or concentrates and/or fruit or plant extracts, permitted sweeteners, potable water with or without the addition of the following ingredients: <ol style="list-style-type: none"> a) acidity regulators; b) permitted food conditioners; c) permitted flavouring substance; d) permitted preservatives; e) permitted colouring substance; f) permitted nutrient supplement like vitamin C; g) salts.
Essential Composition and Quality Factors	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Free from insect, rodent contamination and foreign particles as well as visibly free from seeds and skins. ▪ Have the flavour and aroma characteristic of the fruits, vegetables or flavours for which it is claimed or implied. Foreign flavours and odours shall not be present. ▪ Carbon dioxide – industrial grade free from hydrogen sulphide, sulphur dioxide and other noxious gases, mineral oils and also free from foreign odour. ▪ Flavouring agents: <ul style="list-style-type: none"> Comminuted fruit and fruit juices or concentrates – Extracted from natural and properly washed fruits and fit for consumption. They may either be freshly prepared or concentrated and preserved either by pasteurization or addition of permitted chemical preservatives. Essential oils and fruit/plant extracts – Essential oils and fruit/vegetable extracts are compounds obtained from fruit or plants and shall be safe for human consumption. ▪ Flavouring substances – Substance either naturally present in fruit/plant or added capable of imparting flavour to the product and shall be safe for consumption.
Food Additives	<ul style="list-style-type: none"> ▪ May contain permitted preservative, permitted colouring substances and permitted food conditioner including: 	<ul style="list-style-type: none"> ▪ Acid regulators - The following acids and the sodium, potassium, calcium salt of the acids may be used:

	<ul style="list-style-type: none"> ester gum <150 mg/litre; and β-cyclodextrin <500 mg/litre ▪ May contain caffeine-containing plant extract as permitted flavouring substance: < 200 mg/litre ▪ Preservative: <ul style="list-style-type: none"> Sulphur dioxide: <140 mg/kg Benzoic acid: <350 mg/kg Sorbic acid: <350 mg/kg ▪ Flavouring substance: <ul style="list-style-type: none"> Agaric acid: <20 mg/kg Total hydrocyanic acid: <1 mg/kg Pulegone: <1 mg/kg Quassin: <5 mg/kg Quinine: <85 mg/kg Thujones: <0.5 mg/kg ▪ Subject to general requirements concerning food additives. 	<ul style="list-style-type: none"> a) citric acid; b) phosphoric acid; c) lactic acid; d) malic acid; e) acetic acid; f) fumaric acid; g) tartaric acid. ▪ Food colours, nutritive and non-nutritive sweeteners as per Food Regulations. ▪ Mineral salts – sodium carbonate and sodium bicarbonate ▪ Preservatives: <ul style="list-style-type: none"> Sulphur dioxide: <140 ppm Benzoic acid: <350 ppm Sorbic acid: <350 ppm ▪ Flavouring agents (if used): <ul style="list-style-type: none"> Caffeine: <150 ppm Quinine: 40-85 ppm Vitamin C (ascorbic acid): 10 mg/100 ml
Contaminants	<ul style="list-style-type: none"> ▪ Arsenic (As): <0.1mg/kg ▪ Lead (Pb) : <0.2 mg/kg ▪ Tin (Sn): <40 mg/kg (<250 mg/kg if packed in can) ▪ Mercury (Hg): <0.05 mg/kg ▪ Cadmium (Cd): <1 mg/kg ▪ Antimony (Sb): < 0.15 mg/kg 	<ul style="list-style-type: none"> ▪ Metal contaminants: <ul style="list-style-type: none"> Copper: <1.0 ppm Arsenic: <0.02 ppm Lead: <0.2 ppm
Hygiene	<ul style="list-style-type: none"> ▪ Harmful, damaged packages prohibited ▪ Any glass bottle that has previously been used for another food ▪ No pathogenic microorganisms ▪ Aflatoxin or any other mycotoxins: <5 μg/kg ▪ Food Hygiene Regulations 2009 	<ul style="list-style-type: none"> ▪ Total colony count: <50 per ml ▪ Viable yeast and moulds: <10 per ml ▪ Presumptive coliform organism: negative ▪ Shall be prepared under strict hygienic conditions in accordance with Good Manufacturing Practices and relevant public health requirements currently enforced.
Weight and Measures	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified
Labelling	<ul style="list-style-type: none"> ▪ For the purpose of these Regulations, the word “beer”, “lager”, “champagne” or “wine” or other words suggesting that the product is an alcoholic beverage shall not appear on the label of any soft drink other than ginger beer, ginger ale and root beer. ▪ In the case of soft drink in bottles with applied ceramic labelling, the requirements of regulations 11 and 14 [general requirements for labelling relating to ‘Particulars in labelling’ 	<ul style="list-style-type: none"> ▪ Each container shall be suitably labelled with the following information: <ul style="list-style-type: none"> a) name and trade-mark of the product; b) name and address of the manufacturer and/or packer; c) guaranteed net volume in ml; d) list of ingredients in descending order of proportions; e) code number indicating batch and/or date of manufacture; ▪ Shall comply with requirements specified in the Malaysian Food Act

	<p>and 'Date marking'] may be printed in a reduced size of not smaller than 2 point lettering on the cap or crown of such bottle.</p> <ul style="list-style-type: none"> ▪ There shall be written in the label on a package containing flavoured syrup or flavoured cordial or flavoured drink the words "flavoured syrup" or "flavoured cordial" or "flavoured drink", or the name of such flavour in uniform lettering not less than 10 point conjoined with the words "flavoured syrup" or "flavoured cordial" or "flavoured drink", as the case may be. ▪ The label on the package of a flavoured syrup or flavoured drink shall not include – <ul style="list-style-type: none"> (a) any expression, pictorial representation or design that suggests or implies that the syrup or drink consists wholly or partly of fruit juice; or (b) a pictorial representation or design of a plant or part of a plant or a floral design that suggests or implies the presence of a plant in the syrup or drink ▪ There shall be written in the label on a package containing flavoured syrup or flavoured drink to which caffeine has been added a statement as to the presence of caffeine in that beverage. ▪ Flavoured syrup and flavoured drink to which a permitted fruit flavouring substance has been added shall be labelled in uniform lettering of not less than 10 point with the name of such fruit or fruits, immediately followed by the word "flavour" or "flavoured". ▪ Where fruit juice drink, fruit drink or flavoured drink is carbonated, there shall be written in the label on a package containing such drink – <ul style="list-style-type: none"> (a) the word "carbonated fruit juice drink" or "carbonated fruit drink" or "carbonated flavoured drink" as the case may be; or (b) the words "carbonated (state the name of the fruit) juice drink" or "carbonated (state the name of the fruit) fruit drink" or "carbonated (state the name of the flavour) flavoured drink", as the case may be. ▪ Where flavoured drink or botanical beverage contains quinine in a proportion exceeding 40 mg/litre – <ul style="list-style-type: none"> (a) the proportion of quinine added in mg/litre shall be stated on the label; and (b) such product may be labelled as "tonic water". 	<p>1983 and Food Regulations 1985.</p>
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	<ul style="list-style-type: none"> ▪ Subject to general requirements for labelling ▪ Nutrition labelling is mandatory (regulation 18B of the Food Regulations 1985) 	
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Additives, contaminants, microorganisms, mycotoxins 	<ul style="list-style-type: none"> ▪ Caffeine: HPLC method ▪ Quinine: spectrophotometric method ▪ Ascorbic acid (vitamin c): titrimetric method ▪ Copper, arsenic, lead: Atomic absorption spectrophotometric method ▪ Total colony count: pour plate method ▪ Yeast & moulds: pour plate method ▪ Coliforms: MPN method ▪ Sulphur dioxide: Rankin method ▪ Benzoic acid and sorbic acid: HPLC method

Table 12: Case Study (2) Carbonated Soft Drinks: Methods of Analysis

Related Legislation	Item	Specifications	Methods of Analysis	Reference
Food Regulations 1985	Food additives	Ester gum: <150 mg/l; Beta-cyclodextrin: <500 mg/l; Caffeine-containing plant extract as permitted flavouring substance: <200 mg/l; Sulphur dioxide: <140 mg/l; Benzoic acid: <350 mg/kg; Sorbic acid: <350 mg/kg; Agaric acid: <20 mg/kg; Total hydrocyanic acid: <1 mg/kg; Pulegone: <1 mg/kg; Quassin: <5 mg/kg; Quinine: <85 mg/kg; Thujones: <0.5 mg/kg	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Metal contaminant	Arsenic: <0.1 mg/kg; Lead: <0.2 mg/kg; Tin: <40 mg/kg; Mercury: <0.05 mg/kg; Cadmium: <1 mg/kg; Antimony: <0.15 mg/kg	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Pathogens	No pathogenic microorganisms	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Mycotoxins	Aflatoxin or other mycotoxins: < 5 µg/kg	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
MS 601:1994 - Specification for ready-to-drink beverages (carbonated and non-carbonated) (first revision)	Caffeine	max: 150 ppm (if used)	MS 601:1994, Appendix A	
	Quinine	40-85 ppm (if used)	MS 601:1994, Appendix B	
	Ascorbic acid	10 mg/100 ml (if used)	MS 601:1994, Appendix C	
	Copper	< 1.0 ppm	MS 601:1994, Appendix D	
	Arsenic	< 0.02 ppm	MS 601:1994, Appendix E	
	Lead	< 0.2 ppm	MS 601:1994, Appendix F	
	Total colony count	<50 cfu per ml	MS 601:1994, Appendix G	
	Viable yeast & moulds	<10 cfu per ml	MS 601:1994, Appendix H	
	Presumptive coliform organisms	Negative	MS 601:1994, Appendix J	
	Sulphur dioxide	< 140 ppm	MS 601:1994, Appendix K	
Benzoic & sorbic acid	< 350 ppm	MS 601:1994, Appendix M		

Table 13: Case Study (2) Carbonated Soft Drinks: Food Additives

	Summary/Definitions	References
Scope and/or Description	Flavoured Drinks	Food Regulations 1985, 354 and PartV
Positive and/or Negative List	Flavouring substances which were permitted in Food Regulations 1985 can be used. However, the use is limited when plant extract including caffeine is used as flavouring. May contain permitted preservative and food conditioner in accordance with Food Regulations 1985 following each prescribed use limitation.	
Use Limitations and/or Maximum Levels	<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 	
Scope and/or Description	Ready-To-Drink Beverages	MS 601:1994 Ready-to-drink beverages (carbonated and non-carbonated)
Positive and/or Negative List	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	
Use Limitation and/or Maximum Level	<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 14: Case Study (3) Prepared Frozen Foods: Specifications & Standards

Standard Item	Food Regulations 1985 (as at 1 st September 2009)	MS 1125:2003	MS 1126:2003
Name of the Standard	Food not elsewhere standardized	Meat Frankfurters	Meat Burgers
Scope	<ul style="list-style-type: none"> ▪ Food not elsewhere standardized 	<ul style="list-style-type: none"> ▪ Chilled and frozen meat frankfurters made from comminuted meat (beef, lamb and mutton, poultry, pork) with or without meat by-products in the form of a sausage 	<ul style="list-style-type: none"> ▪ Chilled and frozen meat burgers made from comminuted meat (beef, lamb and mutton, poultry, pork).
Descriptions	<ul style="list-style-type: none"> ▪ Food for which a standard has not been otherwise expressly prescribed by these Regulations. 	<ul style="list-style-type: none"> ▪ Frankfurters shall be sausages that are either raw or cooked with or without smoking. The product is prepared from comminuted meat, seasoned with salt, herbs and spices, mixed with food additives, filler and binders and packed into casings made from cellulose, collage or intestines of animals. The frankfurters unless otherwise specified shall be skinless or skin on and uniform in size and shape. 	<ul style="list-style-type: none"> ▪ Meat burgers shall be the meat product prepared from comminuted meat with or without the addition of fillers, binders, herbs and spices, salt, sweeteners and other food additives, and is sold in various shapes and sizes.
Essential Composition and Quality Factors	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ All meat including mechanically deboned meat used shall be obtained from healthy animals slaughtered in a hygienically-managed slaughter-house and poultry processing plant. ▪ Trimmings which are bruised or from damaged parts of bellies shall not be used. Feet and other by-products including brain, gastrointestinal tract, paunches, udders, sweetbreads (thymus, pancreas), tripe, spleen, lungs, salivary glands, lymphatic glands, testicles, uterus, ovaries, cartilage and bony tissue shall not be used. ▪ Fillers – textured vegetable proteins, cereal rusks, flours or other wholesome edible materials of farinaceous origin may be used. 	<ul style="list-style-type: none"> ▪ All meat including mechanically deboned meat used shall be obtained from healthy animals slaughtered in a hygienically-managed slaughter-house and poultry processing plant. ▪ Trimmings which are bruised or from damaged parts of bellies shall not be used. Feet and other by-products including brain, gastrointestinal tract, paunches, udders, sweetbreads (thymus, pancreas), tripe, spleen, lungs, salivary glands, lymphatic glands, testicles, uterus, ovaries, cartilage and bony tissue shall not be used. ▪ Fillers – textured vegetable proteins, cereal rusks, flours or other wholesome edible materials of farinaceous origin may be used. ▪ Binders – Other non-meat proteins from

		<ul style="list-style-type: none"> ▪ Binders – Other non-meat proteins from soya bean or dairy products may be used. ▪ Fat – only wholesome, edible vegetable or animal fat derived from the same species of animal used in the product, may be used. ▪ Herbs and spices – all herbs, spices and extracts used shall be clean, sound, wholesome, and shall comply with the requirements of Malaysian Food Act 1983 and Food Regulations 1985. ▪ Salt – edible white refined salt shall be used. ▪ Sweeteners – only sugar (sucrose) conforming to the requirements in “MS 82:1989 – Specifications for white refined sugar for industrial use” or dextrose or other permissible sweeteners shall be used. ▪ Finished product – either raw or thoroughly cooked or smoked, or flavoured and cooked and shall be delivered in good condition. They shall show no signs of deterioration at the time of delivery. ▪ Flavour and appearance – shall be palatable, have a pleasant flavour, an attractive appearance with no visible damage, objectionable colour and odour. ▪ Texture – shall be a good uniform texture, characteristic of the product. ▪ Freedom from defects – pieces of hair, bristle, skin and particles of bone shall not be present in the product. The product shall be free from dirt and from insect and rodent contamination or any other foreign matter. Poisonous or deleterious substance shall not be present. ▪ Contain $\geq 65\%$ by weight of meat. 	<p>soya bean or dairy products may be used.</p> <ul style="list-style-type: none"> ▪ Fat – only wholesome, edible vegetable or animal fat derived from the same species of animal used in the product, may be used. ▪ Herbs and spices – all herbs, spices and extracts used shall be clean, sound, wholesome, and shall comply with the requirements of Malaysian Food Act 1983 and Food Regulations 1985. ▪ Salt – edible white refined salt shall be used. ▪ Sweeteners – only sugar (sucrose) conforming to the requirements in “MS 82:1989 – Specifications for white refined sugar for industrial use” or dextrose or other permissible sweeteners shall be used. ▪ Finished product – uniform in size and shall be delivered in good condition. They shall show no signs of deterioration at the time of delivery. ▪ Flavour and appearance – shall be palatable, have a pleasant flavour, an attractive appearance with no visible damage, objectionable colour and odour. ▪ Texture – shall be a good uniform texture, characteristic of the product. ▪ Freedom from defects – pieces of hair, bristle, skin and particles of bone shall not be present in the product. The product shall be free from dirt and from insect and rodent contamination or any other foreign matter. Poisonous or deleterious substance shall not be present. ▪ Contain $\geq 65\%$ by weight of meat. ▪ Salt, sugar and seasoning all together shall not exceed 4% by weight. ▪ Moisture content: max. 60% by wet weight ▪ Total fat content: max. 30% by wet weight
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		<ul style="list-style-type: none"> ▪ May contain meat by-products which include hearts, tongues, diaphragm meat and weasands up to a limit of 15% calculated on the weight of all ingredients with the exception of the added water. ▪ Salt, sugar and seasoning all together shall not exceed 4% by weight. ▪ Moisture content: max. 60% by wet weight ▪ Total fat content: max. 30% by wet weight ▪ Protein content: min. 11% by wet weight 	<ul style="list-style-type: none"> ▪ Protein content: min. 15% by wet weight
Food Additives	<ul style="list-style-type: none"> ▪ May contain permitted nutrient supplement, permitted food conditioner, permitted flavouring substance, permitted colouring substance and permitted flavour enhancer. ▪ Shall not contain permitted non-nutritive sweetening substance. ▪ No person shall use permitted preservative in food not elsewhere standardized without the prior approval of the Director 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985. 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985.
Contaminants	<ul style="list-style-type: none"> ▪ Arsenic (As): <1 mg/kg ▪ Lead (Pb) : <2 mg/kg ▪ Tin (Sn): <40 mg/kg ▪ Mercury (Hg): <0.05 mg/kg ▪ Cadmium (Cd): <1 mg/kg ▪ Antimony (Sb): < 1 mg/kg ▪ 3-monochloropropane-1,2-diol (3-MCPD) for all foods containing acid hydrolysed protein (solid foods): 0.05 mg/kg 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985. 	<ul style="list-style-type: none"> ▪ In accordance with Malaysian Food Act 1983 and Food Regulations 1985.
Hygiene	<ul style="list-style-type: none"> ▪ Harmful, damaged packages prohibited ▪ No pathogenic microorganisms. ▪ Aflatoxin or any other mycotoxins: <5 µg/kg ▪ Food Hygiene Regulations 2009 	<ul style="list-style-type: none"> ▪ After processing, frankfurters may be chilled before freezing and the freezing completed at -12°C or lower within 24 hours. The product shall be stored at a temperature at or below -18°C throughout the storage period. ▪ Prepared and handled under strict 	<ul style="list-style-type: none"> ▪ After processing, the meat burgers may be chilled before freezing and the freezing completed at -12°C or lower within 8 hours. The product shall be stored at a temperature at or below -18°C throughout the storage period. ▪ Prepared and handled under strict hygienic

		<p>hygienic conditions in accordance to Good Manufacturing Practices as specified in MS 1514 and MS 1480.</p> <ul style="list-style-type: none"> ▪ Unless agreed otherwise between the purchaser and the manufacturer or the packer, frankfurters shall be packed in properly sealed bags/packaging material made of suitable food grade flexible transparent packaging material or in hermetically sealed containers. ▪ Mesophilic aerobic plate count (at 37°C for 48h): <math>10^4</math> (cooked), <math>10^5</math> (raw) per gram ▪ Coliform count (at 37°C for 48h): <math>50</math> per gram ▪ <i>E. coli</i>: negative ▪ Salmonellae: negative ▪ <i>S. aureus</i>: negative ▪ Clostridia: negative 	<p>conditions in accordance to Good Manufacturing Practices as specified in MS 1514 and MS 1480.</p> <ul style="list-style-type: none"> ▪ Unless agreed otherwise between the purchaser and the manufacturer or the packer, meat burgers shall be packed in properly sealed bags/packaging material made of suitable food grade flexible transparent packaging material or in hermetically sealed containers. ▪ Mesophilic aerobic plate count (at 37°C for 48h): <math>2.5 \times 10^5</math> per gram ▪ Coliform count (at 37°C for 48h): <math>100</math> per gram ▪ <i>E. coli</i>: negative ▪ Salmonellae: negative ▪ <i>S. aureus</i>: <math>100</math> per gram
Weight and Measures	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified 	<ul style="list-style-type: none"> ▪ Not specified
Labelling	<ul style="list-style-type: none"> ▪ There shall not be written in the label on a package containing food not elsewhere standardized or in an advertisement relating to that food any word or expression that compares a nutritional property or the ingredients of a food not elsewhere standardized with those of another food. ▪ Food not elsewhere standardized shall not be described or presented in such a manner or by such name or pictorial or other representation or devices as is suggestive of another article of food of which it is intended to be an imitation or substitute or which it resembles. ▪ The word "food not elsewhere standardized" shall not appear on the label of any package containing food 	<ul style="list-style-type: none"> ▪ Each package shall be suitably labelled with the following: <ul style="list-style-type: none"> a) the name of the product; b) a declaration of the presence of additives and a declaration indicating the common name of animal from which the meat is derived; c) name and address of the manufacturer and/or packer or the owner of the rights to manufacture or packing or the agent of any of them; d) minimum net weight in grams; e) list of ingredients in descending order of proportions used by weight in the product; f) storage instructions; g) for products which are not fully shelf-stable, i.e. which may be expected not to keep for at least one year in normal conditions of storage and sale, adequate 	<ul style="list-style-type: none"> ▪ Each package shall be suitably labelled with the following: <ul style="list-style-type: none"> a) the name of the product; b) a declaration of the presence of additives and a declaration indicating the common name of animal from which the meat is derived; c) name and address of the manufacturer and/or packer or the owner of the rights to manufacture or packing or the agent of any of them; d) minimum net weight in grams; e) list of ingredients in descending order of proportions used by weight in the product; f) storage instructions; g) for products which are not fully shelf-stable, i.e. which may be expected not to keep for at least one year in normal conditions of storage and sale, adequate

	<p>not elsewhere standardized.</p> <ul style="list-style-type: none"> ▪ Subject to general requirements for labelling ▪ Nutrient labelling is mandatory (regulation 18B of the Food Regulations 1985) 	<p>storage instructions shall be given on the label. These instructions shall state the recommended maximum temperature or conditions of storage and, in the case of products sold to the consumer, an indication of the recommended maximum period of storage in specified conditions shall be given;</p> <p>h) country of origin.</p> <ul style="list-style-type: none"> ▪ Shall comply with requirements specified in the Malaysian Food Act 1983 and Food Regulations 1985. 	<p>storage instructions shall be given on the label. These instructions shall state the recommended maximum temperature or conditions of storage and, in the case of products sold to the consumer, an indication of the recommended maximum period of storage in specified conditions shall be given;</p> <p>h) country of origin.</p> <ul style="list-style-type: none"> ▪ Shall comply with requirements specified in the Malaysian Food Act 1983 and Food Regulations 1985.
Methods of Analysis and Sampling	<ul style="list-style-type: none"> ▪ Additives, contaminants, microorganisms, mycotoxins 	<ul style="list-style-type: none"> ▪ Moisture content: oven-drying method (MS 954:Part 1:2000) ▪ Total fat content: acid hydrolysis method (MS 954: Part 4:1985) ▪ Protein content: Kjeldahl method (MS 954: Part 11:1986) ▪ Salmonellae: detection (MS 1110:Part 1:1988) ▪ Coliforms and <i>E. coli</i>: detection and enumeration (MS 1110:Part 2:1989) ▪ Mesophilic aerobic plate count: enumeration (MS 1110:Part 3:1989) ▪ <i>S. aureus</i>: detection and enumeration (MS 1110:Part 4:1989) ▪ Clostridia: detection (MS 1110:Part 5:1992) 	<ul style="list-style-type: none"> ▪ Moisture content: oven-drying method (MS 954:Part 1:2000) ▪ Total fat content: acid hydrolysis method (MS 954: Part 4:1985) ▪ Protein content: Kjeldahl method (MS 954: Part 11:1986) ▪ Salmonellae: detection (MS 1110:Part 1:1988) ▪ Coliforms and <i>E. coli</i>: detection and enumeration (MS 1110:Part 2:1989) ▪ Mesophilic aerobic plate count: enumeration (MS 1110:Part 3:1989) ▪ <i>S. aureus</i>: detection and enumeration (MS 1110:Part 4:1989) ▪ Clostridia: detection (MS 1110:Part 5:1992)

Table 15: Case Study (3) Prepared Frozen Foods: Methods of Analysis

Related Legislation	Items	Specifications	Methods of Analysis
MS 1125:2003 - Meat Frankfurters - Specifications	Moisture content	Max: 60% by wet weight	MS 954:Part 1:2000
	Total fat content	Max: 30% by wet weight	MS 954:Part 4:1985
	Protein content	Min: 11% by wet weight	MS 953:Part 11:1986
	Sampling	As described in Annex A	MS 1125:2003 Annex A
	Mesophilic aerobic plate count	<10 ⁴ cfu/g (cooked); <10 ⁵ cfu/g (raw), 37°C for 48h	MS 1110:Part 3:1989
	Coliform count	< 50 cfu/g, 37°C for 48h	MS 1110:Part 2:1989
	Salmonellae	absent per 25g	MS 1110:Part 1:1988
	<i>E. coli</i>	absent, MPN	MS 1110:Part 2:1989
	<i>S. aureus</i>	absent, MPN	MS 1110:Part 4:1989
MS 1126:2003 - Meat Burgers - Specifications	Moisture content	Max: 60% by wet weight	MS 954:Part 1:2000
	Total fat content	Max: 30% by wet weight	MS 954:Part 4:1985
	Protein content	Min: 15% by wet weight	MS 953:Part 11:1986
	Sampling	As described in Annex A	MS 1126:2003 Annex A
	Mesophilic aerobic plate count	< 2.5 x 10 ⁵ cfu/g, 37°C for 48h	MS 1110:Part 3:1989
	Coliform count	< 100 cfu/g, 37°C for 48h	MS 1110:Part 2:1989
	Salmonellae	absent per 25g	MS 1110:Part 1:1988
	<i>E. coli</i>	MPN, absent, MPN	MS 1110:Part 2:1989
	<i>S. aureus</i>	< 100 cfu/g, MPN	MS 1110:Part 4:1989

Table 16: Case Study (3) Prepared Frozen Foods: Food Additives

	Summary/Definitions	References
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		
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		

Table 17: Case Study (4) Cow's Milk: Specifications & Standards and Methods of Analysis

Related Legislation	Items	Specifications	Methods of Analysis	References
Food Regulations 1985	Milk fat	> 3.25%	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Non-fat milk solids	> 8.5%	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Added water, permitted food additive, other added substances or trace of antibiotic substance	Prohibited	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Reductase Test	Shall not completely decolorize any methylene blue solution in less than 4 hours	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Metal contaminants	Arsenic: < 0.5 mg/kg; Lead: < 1 mg/kg; Tin: < 40 mg/kg; Mercury: < 0.05 mg/kg; Cadmium: < 1 mg/kg; Antimony: < 1 mg/kg	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Total plate count	< 10 ⁵ cfu/g or /ml, 37°C for 48h (pasteurized milk only)	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Coliform count	< 50 cfu/g, 37°C for 48h (pasteurized milk only)	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
	Aflatoxin	< 0.5 µg/kg	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD

	Drug residues	<p>Albendazole: < 100µg/kg; Amoxicillin: < 4 µg/kg; Ampicillin: < 4 µg/kg; Avoparcin: < 10 µg/kg; Benzylpenicillin: 4 <µg/kg; Cefquinome: < 20 µg/kg; Ceftiofur sodium: < 100 µg/kg; Cloxacillin: < 30µ/kg; Colistin: < 50 µg/kg; Dexamethazone: < 0.3 µg/kg; Dicloxacillin: < 30 µg/kg; Dihydrostreptomycin: 200 µg/kg; Diminazene: < 150 µg/kg; Erythromycin: < 40 µg/kg; Febantel: < 100 µg/kg; Fenbendazole: < 100 µg/kg; Gentamicin: < 100 µg/kg; Isometamidium: < 100 µg/kg; Moxidectin: <500 µg/kg; Neomycin: < 500 µg/kg; Oxacillin: < 30 µg/kg; Oxfendazole: < 100 µg/kg; Oxibendazole: < 50 µg/kg; Oxytetracycline: < 100 µg/kg; Spectinomycin: < 200 µg/kg; Spiramycin: < 200 µg/kg; Streptomycin: < 200 µg/kg; Sulphadiazine: < 100 µg/kg; Sulphadimethoxine: < 10 µg/kg; Sulphadimidine: < 25 µg/kg; Sulphonamide: < 100 µg/kg; Tetracycline: < 100 µg/kg; Thiabendazole: < 100 µg/kg; Tilmicosin: < 50 µg/kg; Tylosin: < 50 µg/kg</p>	International standards (AOAC, ISO, APHA, etc)	Email communication with Malaysia FSQD
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Table 18: Case Study (4) Cow’s Milk: Food Additives

	Summary/Definitions	References
Scope and/or Description	Milk, raw milk or fresh milk	
Positive and/or Negative List	Food additives for this category are prohibited according to Food Regulations 1985.	Food Regulations 1985
Use Limitation and/or Maximum Level		

**5. International Conference
on Regulatory Framework and Case Studies of Food and Food Additives
in India, Bangladesh, Nepal, and Sri Lanka**

Regulatory Framework on Foods and Food Additives in India, Bangladesh, Nepal and Sri Lanka

Date: February 22, Friday, 2013 10:00-17:00

Place: KAIUN CLUB, 2F 2-6-4, Hirakawa-cho, Chiyoda-ku, Tokyo 102-0093 Japan
(<http://kaiunclub.org>)

Organizer: International Life Sciences Institute, Japan (ILSI Japan),
(<http://www.ilsijapan.org>)

Language: Japanese and English, Simultaneous Translation

Agenda

10:00-10:15 Opening Remark, Shuichi Kimura, Chairman, ILSI Japan

Session 1:

10:15-10:40 Message from the Ministry of Agriculture, Forestry and Fisheries,
Japan:

Ryosuke Ogawa, Counsellor for Export Promotion Division, Food
Industry Affairs Division (MAFF)

10:40-11:15 Keynote Speech: Regulatory Framework on Food and Food Additives
in India:

Pradip Kumar Chakraborty, Director (Zone/Product Approval),
Food Safety and Standards Authority of India (FSSAI),

11:15-11:55 Introduction of the MAFF Overseas Business Support Project for
Food Industry in East Asia by ILSI Japan

Hiroaki Hamano, Ryuji Yamaguchi, ILSI Japan

12:00-13:00 Lunch Break

Session 2:

13:00-13:40 Regulatory Framework on Foods and Food Additives in India,
Masanori Kohmura, Ajinomoto Co., Inc.

13:40-14:10 Laws and Regulations Relating to Foods in Sri Lanka, Bangladesh
and Nepal Rekha Sinha, Executive Director, ILSI India

14:10-14:50 Towards Harmonization of Food and Food Additive Standards in
ASEAN Teoh Keng Ngee, ILSI Southeast Asian Region

14:50-15:10 Refreshment (Coffee Break)

Session 3:

15:10-15:30 Market for Processed Foods in India

D.H. Pai Panandiker, Chairman, ILSI India

15:30-16:00 Case Study 1: Business Expansion of Ajinomoto Co., Inc. in India

Katsuo Hamano, Ajinomoto Co., Inc.

16:00-16:30 Case Study 2: International Business Operation of Yakult

Ryoichi Akahoshi, Yakult Honsha Co., Ltd.

16:30-16:55 Q&A and General Discussions,

16:55-17:00 Closing,

Ryuji Yamaguchi, Executive Director, ILSI Japan

Regulatory Framework on Food and Food Additives in India



Food Safety & Standards Authority of India (FSSAI)
Ministry of Health and Family Welfare
Government of India
New Delhi

**Regulatory Framework on Food and Food Additives
in India, Bangladesh, Nepal and Srilanka .**

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Introduction

- I would like to convey my sincere thanks to International Life Science Institute, Japan and India for conducting this International conference on “Regulatory Framework on Food and Food Additives in India, Bangladesh, Nepal and Sri Lanka”.
- With continuous innovation and research happening all over the world, a lot of new products and new ingredients can be seen coming into the food segment. A lot of food products imported into the country also contain ingredients as well as additives which are being introduced for the first time.

- India has various food products in each state and food innovation is taking place at higher rate.
- The consumer safety is of paramount importance. Main objective of Food Safety and Standards Authority of India is to ensure all products which are placed in the market are having appropriate safety. I hope all the speakers of the conference will give us adequate knowledge on regulatory framework on Food and Food Additives.
- India has more than 10,000 food products in trade.
- The Food Safety & Standards Regulation 2011 has given quality/safety specifications for nearly 330 products. Rest all products come under the category of Proprietary food.

- The Food Safety and Standards Act was enacted in 2006 in India. There are as many as 101 sections in the Food Safety And Standards Act, 2006.
- The Food Safety Rules & Regulations was implemented in India on 5th August, 2011. Before that, we had eight different Acts to regulate different types of food processing industries in the country. These are :
 - 1) The Prevention of Food Adulteration Act, 1954
 - 2) The Fruit Products Order, 1955
 - 3) The Milk and Milk Products Order, 1992
 - 4) The Meat Food Products Order, 1973
 - 5) The vegetable Oil Products (Control) Order, 1947

- 6) The Edible Oils Packaging (Regulation) Order, 1998.
- 7) The Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967.
- 8) Any other order issued under the Essential Commodities Act, 1955 relating to Food.

All these eight acts have been repealed in India from 5th August, 2011 and replaced by a single Act, The Food Safety And Standards Act, 2006.

Under Section 4 of the FSS Act, 2006 Government of India established 'Food Safety and Standards Authority of India' to exercise the powers conferred on and to perform the functions assigned to it under this Act.

Constitution of FSSAI

- The Food Safety and Standards Authority shall consist of a Chairperson and twenty-two members. There shall be a Chief Executive Officer of the Food Safety and Standards Authority, who shall be the legal representative of the Food Safety and Standards Authority and shall be responsible for the day to day administration of the Food Safety and Standards Authority.



- The Food Safety and Standards Authority established eight scientific panels and one scientific committee.
- The Food Safety and Standards Authority and State Food Safety Authorities shall monitor and verify that the relevant requirements of law are fulfilled by Food Business Operators at all stages of food business.

Special points under FSS Act 2006

- The unique thing in FSS Act, 2006 is Food Recall Procedures under Section 28.
- If a food business operator has reasons to believe that the food is not in compliance with this Act, or the rules or regulations, he/she shall immediately initiate procedure to withdraw the food from the market under the food recall procedure.
- There is a provision for emergency prohibition notices and orders under section 34 of this Act.
- Even the purchaser may have food analyzed under section 40 of this Act.

Provision for Penalty

- There are provisions relating to sub - standard food, misbranded food, food containing extraneous matter, food not of the nature or substance or quality demanded, unhygienic processing of food, possessing adulterant, unsafe food.
- Even there is provision relating to penalty for misleading advertisement. Degree of penalty ranges from INR 100,000 to 10,00,000.



- The Food Safety and Standards Rules, 2011 relates to enforcement structure and procedure, Adjudication and appeal to tribunal, various forms of appeal.



Important aspects of Food Safety and Standards Regulations, 2011

- Under the Food Safety and Standards Regulations, 2011 we have :
 - 1) Licensing and Registration of Food Businesses Regulations.
 - 2) Food Products Standards and Food Additives Regulations.
 - 3) Packaging and Labeling Regulations.
 - 4) Contaminants, Toxins and Residues Regulations.

- 5) Laboratory and Samples Analysis Regulations.
- 6) Prohibitions and Regulations on Sales Regulations.

Briefly, this is the regulatory framework on food in India. Detail Act, Rules and Regulations are available on our website: www.fssai.gov.in

FSSAI Detailed Website

Food Safety and Standards Authority of India
भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण

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Science in FSSAI
Imported Food
Int. Co-operation
Product Approval

Codex
[Codex India](#)

Licensing
[List of HS Code](#)
[Downloadable Forms](#)

What's New

Categorization of food products & development of Food Codes.(11-05-2012)

- Suggestions Invited
- Food Codes

New CEO takes over at FSSAI (10-05-2012)

Affidavit for Product Approval. (10-05-2012)

Minutes of seventh Meeting of Central Advisory Committee of FSSAI held on 27th April, 2012. (10-05-2012)

Ad-hoc guidelines for Alcoholic Beverages related to Import Food Clearance Process by FSSAI's Authorized Officers-reg. (03-05-2012)

Corrigendum-Guidelines related to Food Import Clearance Process by FSSAI's

Simplifying procedures for Registration & Licensing

The Food Safety and Standards Authority of India has been established under the Food Safety and Standards Act, 2006 as a statutory body for laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption....

[Continue Reading...](#)

Advice to Consumer

- Select fruits and vegetables without spots or necrosis (lesions) and any abnormality.
- Wash fruits and vegetables thoroughly with water (preferably) running potable water before eating and cooking.

Salient Features of Food Additives

- Use of food additives in food products is a major area of concern for the regulatory authority in India.
- The food products may contain additives as specified in the regulation.
- Use of food additives in traditional Indian foods, coloring matter, artificial sweeteners, preservatives, anti-oxidants, emulsifying and stabilizing agents, antifoaming agents in edible oils and fats, use of release agents in confectionary, flavoring agents and related substances, flavor enhancers, sequestering and buffering agents.

- Use of glycerol esters and wood resins, use of sucrose acetate Iso-butyrate, use of lactulose syrup, use of Dimethyl Dicarboxylate and other substances to be used in specified limits have been elaborated in Food Additives Regulations.
- Maximum permissible limit for the additives has been expressed mostly in parts per million i.e. mg/kg or in percentage % or in GMP.

Good Manufacturing Practices

- Good Manufacturing Practices (GMP) means the food additives used under the following conditions namely :
 - 1) The quantity of the additive added shall be limited to lowest possible level necessary to accomplish its desired effect.
 - 2) The quantity of the additive becomes a component of food and not intended to accomplish any physical or other technical effect.
 - 3) The additive is prepared and handled in the same way as a food ingredient.

Summary of list of Food Additives

Table 1:

- List of food additives for use in bread and biscuits have been specified in table 1 of the Food Additives Regulations.

Table 2:

- In table 2, permitted food additives for use in foods like snacks, sweets, instant mixes, rice and pulses based papads, ready to serve beverages, chewing gum, sugar based/ sugar free confectionary, chocolates, synthetic syrup, lozenges, have been specified.

Table 3:

- In table 3, food additives in foods not specified in table 2 like dairy based drinks, soups, custard powder, sausage etc have been specified.

Table 4:

- In table 4, list of food additives for use in edible oils and fats have been specified.

Table 5:

- List of food additives for use in fish and fish products have been specified in table 5.

Table 6:

- List of food additives for use in thermally processed fruits have been specified in table 6.

Table 7:

- In table 7, list of food additives in thermally processed vegetables have been specified.

Table 8:

- In table 8, list of food additives for use in food products like tamarind pulp, synthetic syrups, tomato puree and vinegar have been specified.

Table 9:

- In table 9, list of food additives for use in food products like Murrubba, squashes, fruit/vegetable juice, pulp etc have been specified.

Table 10:

- In table 10, list of food additives used in food products like jam/jellies, fruit marmalades, fruit drink etc have been specified.

Table 11:

- In table 11, list of food additives used in food products like dates, dry fruits and nuts have been specified.

Table 12:

- In table 12, list of food additives for use in sugars and salts have been specified.

Table 13:

- In table 13, list of food additives for use in cocoa powder, chocolate, sugar boiled confectionary, chewing gum/bubble gum have been specified.

Table 14:

- In table 14, list of food additives for use in milk products have been specified.

Table 15:

- In table 15, use of food additives in individual variety cheeses have been specified.

- As many as 555 food additives with International Numbering System (INS) have been listed in the food additives regulations only for identifying the food additives and their synonyms as published by the codex on 23/11/2005 Codex.
- In spite of specifying so many additives in 15 tables, lots of additives have not been specified in Food Safety and Standards Regulations, 2011
- In the absence of list of additives, we follow table 3 of GSFA published by the codex.
- Regulations on foods for special dietary uses, functional foods, nutraceuticals, health supplements is under draft stage.

- Nowadays, a lot of health supplements are being imported to India which contains a number of additives. We follow table 13.6 of GSFA which contains approved list of additives for health supplements.



Conclusions

- Food Safety and Standards Authority of India is in the process in reviewing various regulations including regulations for food additives
- However, harmonization with Codex Alimentarius Commission is under active consideration.
- We must have an uniform policy to permit food additives at least in Asian countries.

- Success of this conference lies on harmonization of food additives among India, Bangladesh, Sri Lanka and Nepal as food habits of the population of these countries are similar to some extent.
- This conference provides a platform where the representatives of these countries can interact amongst each other and coordinate the policies which will guide the future of the industry.
- It is a great honor and responsibility to be present in this conference and it is indeed a great learning chance for the participants by considering various perspectives offered by representatives of various countries.

*Thank
You*

農林水産省 東アジア食品産業海外展開支援事業

東アジアの食品等規格基準・分析方法等調査
と結果の共有化(第I~IV期)

実施主体:

特定非営利活動法人 国際生命科学研究機構
(ILSI Japan <http://www.ilsijapan.org>)

国際協力委員会 浜野 弘昭

農林水産省

東アジア食品産業海外展開支援事業

[趣旨]: 国内市場の量的飽和と成熟化に直面している我が国食品産業の経営体質、国際競争力の強化を図るため、人口増加と高い経済成長により魅力的な市場を形成しつつある東アジア地域(韓国、中国、ASEAN諸国およびインド地域)における事業の展開を促進する取り組みを支援する。

[調査概要]: 東アジア地域での食材、食品の流通を拡大するため、東アジア地域諸国における市場性(人口等)、日本の進出企業動向、今後の将来性等から、特に韓国、中国、シンガポール、マレーシア、フィリピン、インドネシア、タイ、ベトナム及びインド地域における、食品法体系、主たる食品等の規格基準やそれらの分析方法及び食品添加物規制を調査し、それらの相違点、及び今後統一或いは調和を図るための課題を抽出する。

農林水産省 東アジア食品産業海外展開支援事業
東アジアの食品等規格基準・分析方法等調査
と結果の共有化(第I～III期)

第I期:平成21(2009)年6月～平成22(2010)年3月

食品法体系と食品規格基準(即席めん、炭酸飲料、冷凍食品、牛乳)
コーデックス、日本、韓国、中国、マレーシア、シンガポール、フィリピン

第II期:平成22(2010)年6月～平成23(2011)年3月

分析方法
上記調査国に加えて、インドネシア、タイ、ベトナム

第III期:平成23(2011)年7月～平成24(2012)年3月

食品添加物に係る法体系と使用基準
コーデックス、日本、韓国、中国、及び上記 ASEAN 6か国

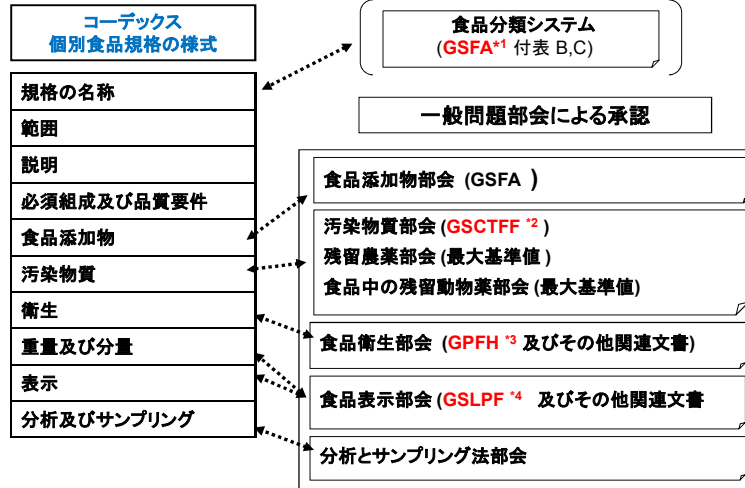
東アジアの食品等の規格基準、
分析方法の調査と結果の共有化

調査表：

コーデックスと日本

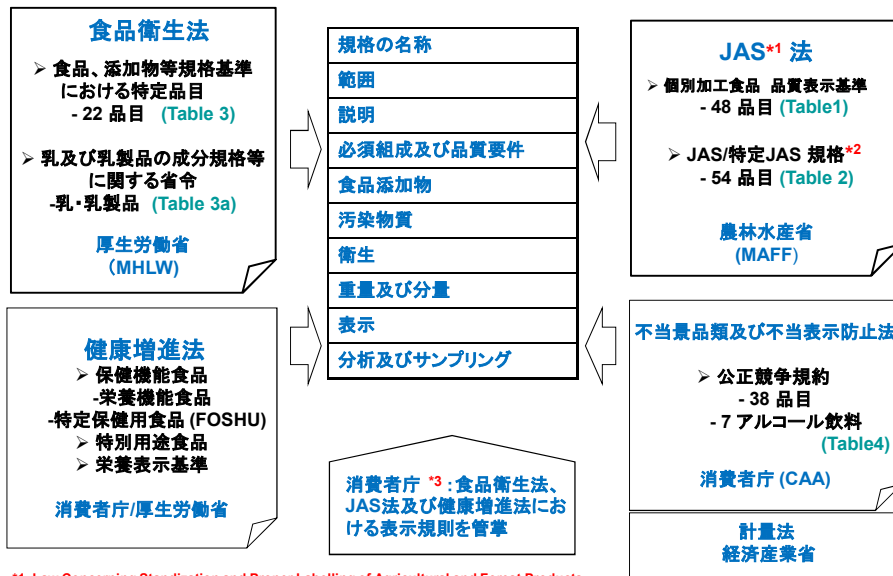
コーデックス個別食品規格の作成

コーデックス手続きマニュアル：第3節 コーデックス規格と関連文書の作成



- *1 Codex Stan 192-1955 食品添加物一般規格
- *2 Codex Stan 193-1995 食品及び飼料中の汚染物質一般規格
- *3 CAC/RCP1-1969 食品衛生一般原則
- *4 Codex Stan 1-1985 包装食品表示一般規格

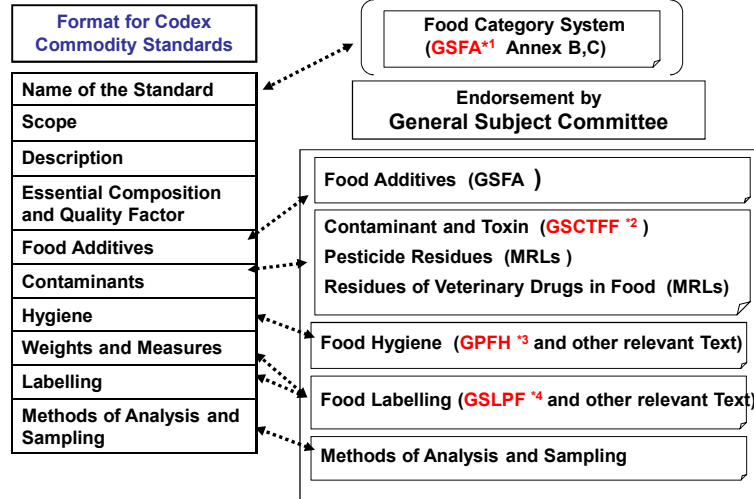
個別食品規格



- *1 Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products
- *2 voluntary (other than organic foods) standard with the certification system to attach the JAS Mark
- *3 New governmental organization started in September 2009

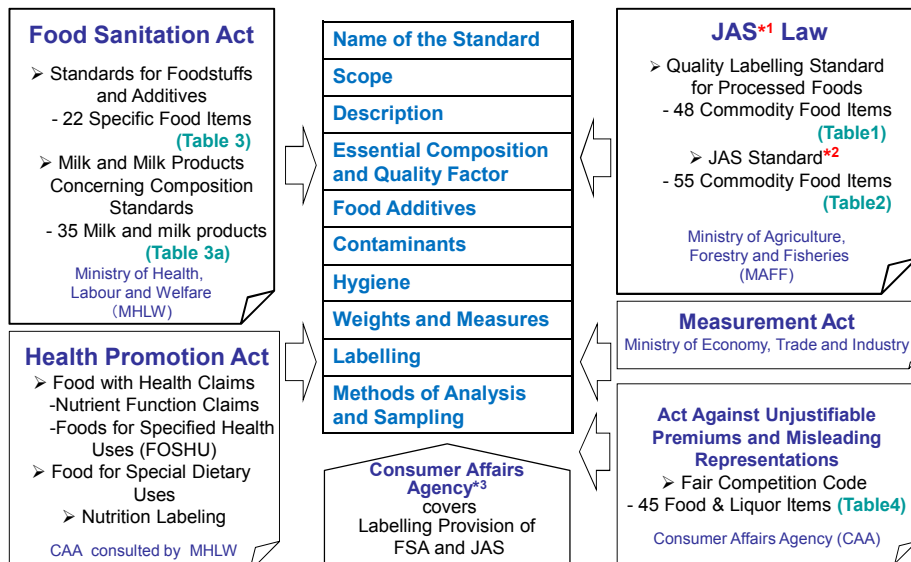
Codex Commodity Standards

Procedural Manual : Section III Elaboration of Codex Standards and Related Text

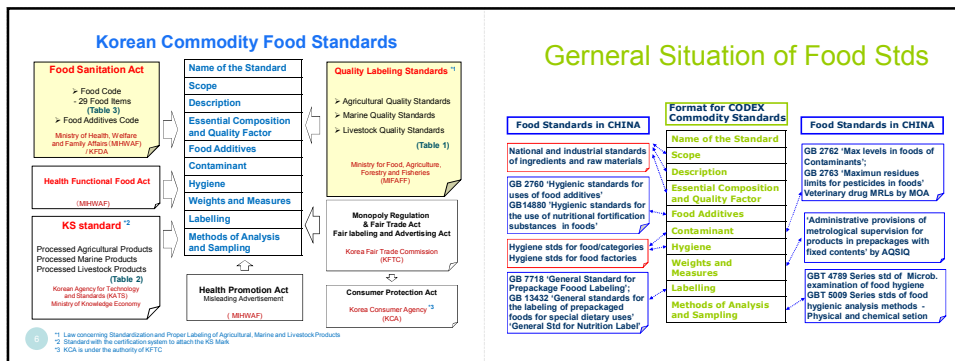


*1 Codex Stan 192-1955 General Standard for Food Additives
 *2 Codex Stan 193-1995 General Standard for Contaminants and Toxins in Foods and Feeds
 *3 CAC/RCPI-1969 General Principles of Food Hygiene
 *4 Codex Stan 1-1985 General Standards for the Labelling of Prepackaged Foods

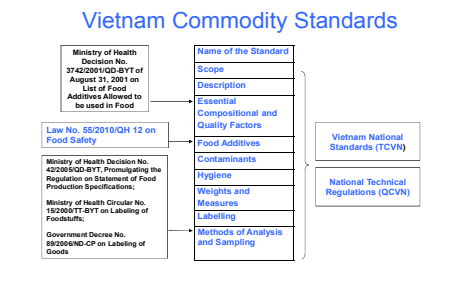
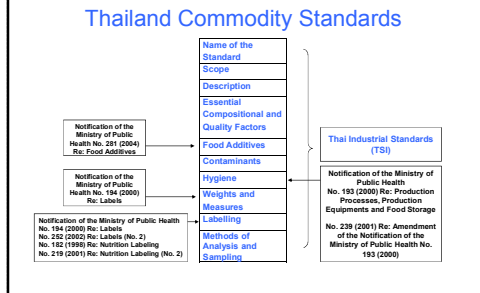
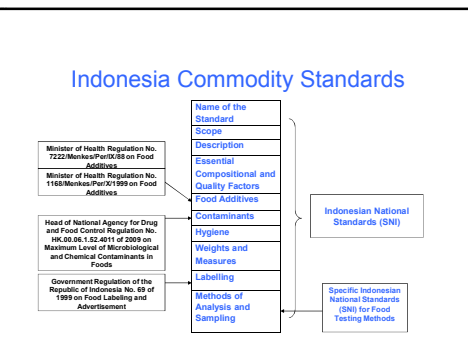
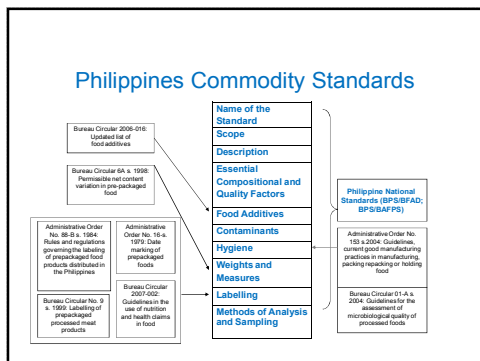
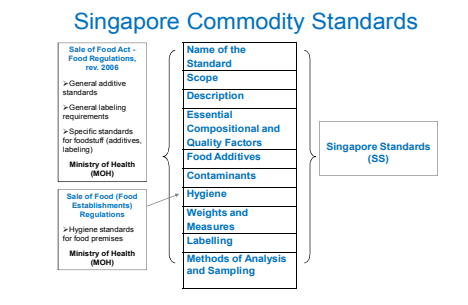
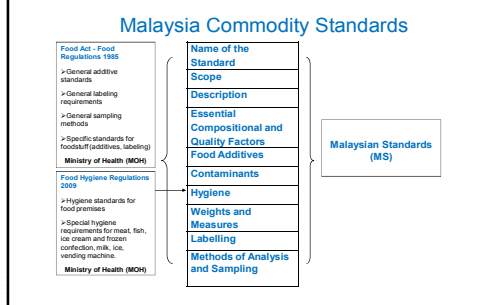
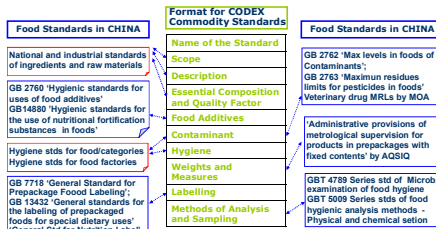
Commodity Food Standards for Japan



*1 Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products
 *2 voluntary (other than organic foods) standard with the certification system to attach the JAS Mark
 *3 New governmental organization started in September 2009



General Situation of Food Stds



**Workshop for the 1st Term Project on
“Investigation of Commodity Food Standards
and Methods of Analysis in Asia”**



**International Conference for Sharing
Information on Food Standards and
Resource and Environmental Conservation
for Food Industries in Asia Pacific**
**Challenges and Opportunities for Food Safety
& Human Health**

**International Conference for
Sharing Information on Food
Standards, Resource and
Environmental Conservation for
Food Industries in Asia-Pacific**



March 4, 2011
Pathumwan Princess Hotel
Bangkok, Thailand

Sponsor:
Ministry of Agriculture,
Forestry and Fisheries
(MAFF)
Japan

Supporters:
Food and Drug
Administration (FDA)
Thailand

National Bureau of Agri-
cultural Commodity and
Food Standards (ACFS)
Thailand

Organizer:



International Life Sciences Institute (ILSI) Japan

In collaboration with

ILSI Focal Point in China

ILSI Korea

ILSI Southeast Asia Region

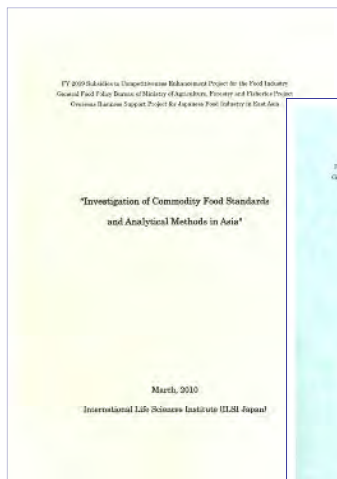


International Conference for Sharing Information on Food Standards in Asia

February 21, 2012,
Jakarta, Indonesia



Reports are available at:



<http://www.ilsijapan.org/English/ILSIJapan/COM/Com-W.php>

Diversity: Definition of Food Additives



Codex

Pluto is now out of the Solar System

Indonesia

Thailand

Malaysia

Vietnam

The Philippines

Singapore

China

Korea

Japan

平成24年度 東アジア食品産業海外展開支援事業
東アジアの食品等規格基準・分析方法等調査
と結果の共有化(第IV期)

『インド(地域)における食品関連法規に関する調査』

平成24年8月～平成25年3月

実施事業：『インド(地域)における食品関連法規に関する調査』①

事業の目的： 国内市場の量的飽和と成熟化に直面している我が国食品産業の経営体質の強化や国際競争力の強化に向け、経営基盤を強化するため、人口増加と高い経済成長により魅力的な市場を形成しつつある東アジア市場、特にインド地域における事業の展開を支援、促進する。

調査概要： インド地域(バングラデシュ、ネパール、スリランカを含む)での食品関連法規の体系、主たる食品等の規格基準とその分析方法や食品添加物の使用基準等の調査を ILSI India の協力を得て実施し、その結果は国際会議の開催、ILSI Japan ホームページ上等で情報共有し、課題の理解を深める。

なお、これまでに本調査事業において集積した東アジア地域(韓国、中国、ASEAN諸国及びインド地域)の食品関連法規に関する情報のデータベース化を行う。

実施事業：『インド(地域)における食品関連法規に関する調査』②

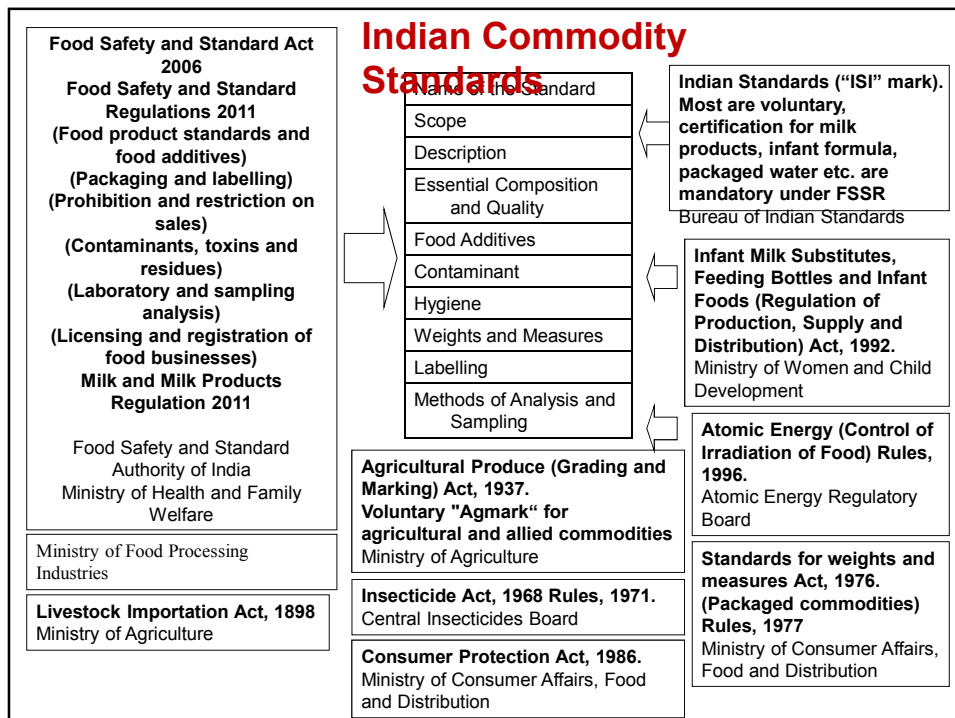
ILSI Japan の一組織である「国際協力委員会」内に調査対象とするそれぞれの専門分野(インド市場、食品規格基準、分析方法、食品添加物等)を担当する会員からなるプロジェクトチームを立ち上げ、各ILSI 支部(インド及び韓国、中国、東南アジア地域)と協力し、調査事業を進める。

実施主体	ILSI 支部	担当国
ILSI Japan (日本及びコーデックスを担当、調査全体の統括)	ILSI インド支部	インド(バングラデシュ、ネパール、スリランカを含む)
	ILSI 韓国支部	韓国
	ILSI 中国連絡事務所	中国(香港、台湾を除く)
	ILSI 東南アジア地域支部	マレーシア、シンガポール、フィリピン、インドネシア、タイ、ベトナム(ASEAN 諸国の内主要6か国)

実施事業：『インド(地域)における食品関連法規に関する調査』③

実施スケジュール：

- 予備調査、調査プログラム設計、調査票開発
2 か月 (平成24年8,9月)
- 調査対象国における調査、調査票の作成
3 か月 (平成24年10~12月)
- 調査票の集計、課題の抽出
2 か月 (平成25年1,2月)
- 国際会議の開催
平成25年2月22日 (東京)
- 報告書の作成
1 か月 (平成25年3月)



Reports for Bangladesh, Nepal and Sri Lanka

Bangladesh Country Report

1. Introduction to Regulatory Framework for Foods

Bangladesh is a developing country with a population of 150 million. It is a member of the World Trade Organization (WTO) and the South Asian Free Trade Zone (SAFTA). The government has established a Food Safety and Standards Authority of Bangladesh (FSSAI) to regulate food safety and quality. The FSSAI is a statutory body established under the Food Safety and Standards Act, 2009. The FSSAI is responsible for the regulation of food safety and quality in Bangladesh. The FSSAI is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

i. Administrative Authority

Food safety for persons is an essential part of public health. The government has established a Food Safety and Standards Authority of Bangladesh (FSSAI) to regulate food safety and quality. The FSSAI is a statutory body established under the Food Safety and Standards Act, 2009. The FSSAI is responsible for the regulation of food safety and quality in Bangladesh. The FSSAI is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

ii. Administration and Inspe

The FSSAI is a statutory body established under the Food Safety and Standards Act, 2009. The FSSAI is responsible for the regulation of food safety and quality in Bangladesh. The FSSAI is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

a. Ministry of Health and Family

Ministry of Health and Family Welfare, Government of Bangladesh, Dhaka. The Ministry of Health and Family Welfare is responsible for the regulation of food safety and quality in Bangladesh. The Ministry of Health and Family Welfare is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

b. Ministry of Local Government, R

Ministry of Local Government, Rural Development and Cooperatives, Government of Bangladesh, Dhaka. The Ministry of Local Government, Rural Development and Cooperatives is responsible for the regulation of food safety and quality in Bangladesh. The Ministry of Local Government, Rural Development and Cooperatives is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

c. Ministry of Law, Justice and Pa

Ministry of Law, Justice and Parliamentary Affairs, Government of Bangladesh, Dhaka. The Ministry of Law, Justice and Parliamentary Affairs is responsible for the regulation of food safety and quality in Bangladesh. The Ministry of Law, Justice and Parliamentary Affairs is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

d. Ministry of Food and Disaster

Ministry of Food and Disaster Relief, Government of Bangladesh, Dhaka. The Ministry of Food and Disaster Relief is responsible for the regulation of food safety and quality in Bangladesh. The Ministry of Food and Disaster Relief is a member of the International Food Safety and Health Council (IFSHC) and the International Commission on Food Safety and Health (ICFSH).

Nepal Report

Regulatory Frameworks And Institutional Provisions For The Quality Control O

Note: Nepal follows Hindu calendar ahead of international calendar. Year International calendar.

i. Administrative Authorities

Integration of food control system in Nepal (GSM-Then JMD Nepal) decided to a Department of Food which was put under irrigation. The department endeavored to control. As a result, Food Act enacted in institutional set up for food regulation. (usually, because even before sixties, there countries in the world including India. At that the focus on the quality of food is in addition guided by the profit motive food act enacted in India was given the n

During the decade while Nepal was in frameworks, very few operational model developed countries of the world including India. At that the focus on the quality of food is in addition guided by the profit motive food act enacted in India was given the n

Sri Lanka Report

Laws and Regulations Relating to Foods in Sri Lanka

I. Administrative Authorities

Administrative Authorities in Sri Lanka as shown in Table 1 are responsible for Food Administration of food categories and related stage of production. It may be noted that the Chief Food Authority Director General of Health Services is the apex body responsible for the country's food control administration.

Sector	Products	Imported	Domestic
Ministry/Department of Agriculture (MOA)	Primary products of agriculture	Food Control Administration of MOA (FCA)	MOA and FCA
Department of Animal Production & Health (DAPH)	Animal Husbandry Milk Products	DAPH and FCA	DAPH and FCA
Coconut Development Authority (CDA)	Coconuts & their products	FCA and CDA	FCA and CDA
Tea Board (TB)	Manufactured Tea	FCA and TB	FCA and TB
Ministry/Department of Fisheries (MOF)	Fish and Fish Related products	FCA	MOF and FCA
Sri Lanka Standards Institution (SLSI)	Nature voluntary & mandatory standards	FCA and SLSI	FCA

インド、バングラデシュ、ネパール、スリランカにおける食品及び食品添加物の法的枠組みと事例研究

10:00-10:15 開会の挨拶

木村 修一 (ILSI Japan会長)

Session 1:

10:15-10:40 農林水産省ご挨拶:

大臣官房参事官 農林水産省 食糧産業局 海外展開・輸出促進グループ長 小川良介

10:40-11:15 基調講演:

Dr. Pradip Chakraborty, Director, Food Safety and Standards Authority of India

11:15-11:55 農林水産省東アジア食品産業海外展開支援事業及びILSIの紹介

浜野弘昭、山口隆司 (ILSI Japan)

12:00-13:00 昼食

Session 2:

13:00-13:40 インドにおける食品及び食品添加物の法的枠組み 香村正徳 (味の素㈱)

13:40-14:10 バングラデシュ、ネパール、スリランカにおける食品及び食品添加物の法的枠組み

Ms. Rekha Sinha (ILSI India事務局長)

14:10-14:50 アセアン (ASEAN) における食品基準のハーモナイゼーション

Mr. Teoh Keng Ngee (ILSI SEAR)

14:50-15:10 休憩

Session 3:

15:10-15:30 インドにおける加工食品及び飲料市場について

Mr. D.H. Pai Panandiker (ILSI India会長)

15:30-16:00 事例研究 1:

味の素㈱

16:00-16:30 事例研究 2:

㈱ヤクルト本社

16:30-16:55 質疑応答及び総合討論

16:55-17:00 閉会の挨拶

山口隆司 (ILSI Japan事務局長)

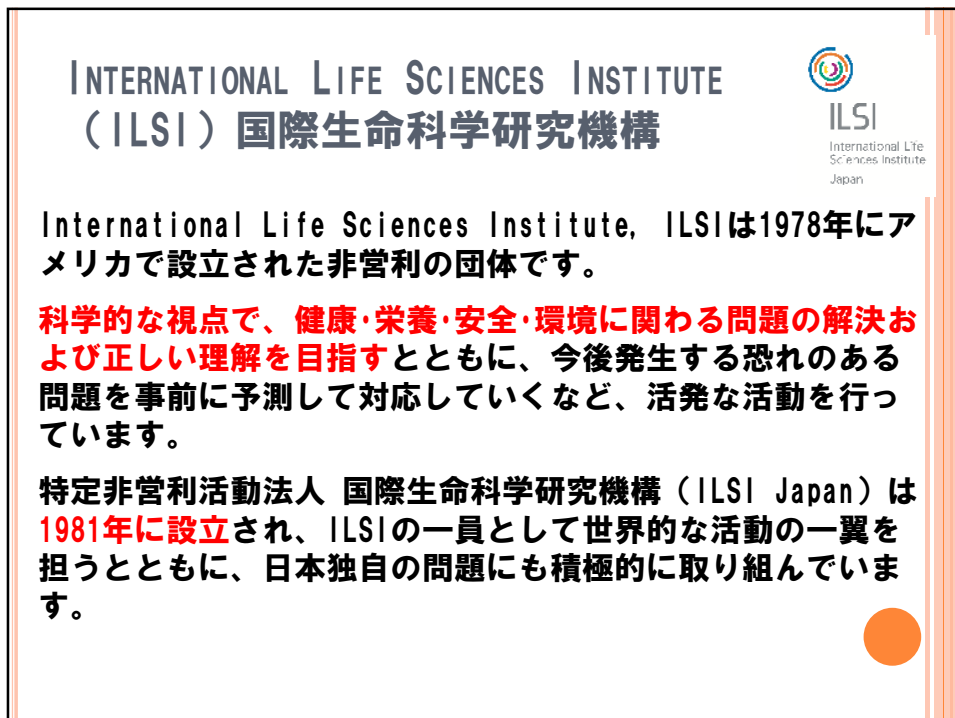
Data-base for the Information Collected and Updated (1st to 4th Term) (in preparation)



今後の事業展開について

- ◆ 調査テーマ/項目の拡大（表示等）
- ◆ 調査地域の拡大（東アジアから世界へ）
 - ◆ 情報の更新・データベースの拡充
- ◆ ILSI Japan の会員の参画・協力を！

About ILSI Japan



JAPAN	64
Europe	63
(HESI)	(47)
North Andean	46
Brasil	34
North America	34
Focal point in China	30
Southeast Asia Region	30
Korea	27
India	27
Mexico	21
Argentina	14
South Africa	8
South Andean	8
North Africa	7
TOTAL	460 (413)

ILSIの会員数は460社（2012年度）にも及び、世界規模で活動しています。長期間の研究を要する基礎的な課題は主として研究財団の各研究所が担当します。各研究所では、それぞれの分野における科学者の協力を得て、グローバルな視点から研究テーマを決め、世界的に優れた科学者に研究を委託します。また、**地域に特有な課題への対応は世界に広がる地域支部が担当しています。**

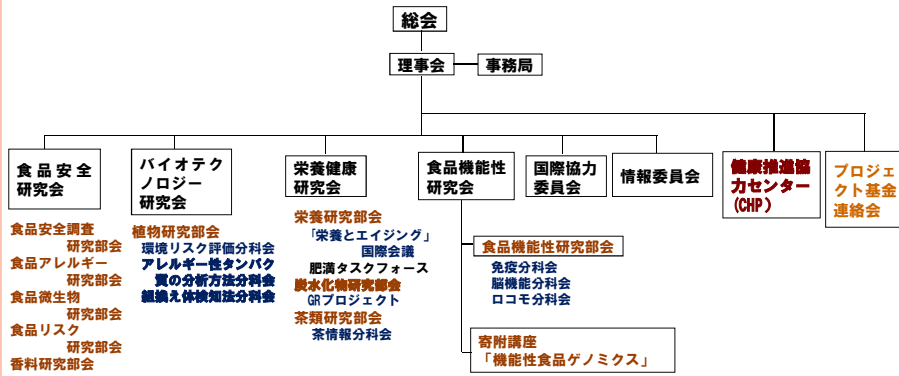
ILSIホームページ
<http://www.ilsi.org/>

WHAT'S ILSI? (INTERNATIONAL LIFE SCIENCES INSTITUTE)

ILSI本部

- 支部** 日本をはじめとする15の地域支部 環境保健科学研究所 (ILSI HESI)
- 国際機関委員会** 国際機関委員会 (IOC) 国際食品バイオテクノロジー委員会 (IFBIC)
- 研究財団** GM作物の環境リスクアセスメント研究所CERA) リスクサイエンス研究所 (RSIA) 栄養・健康推進協力センター (CNHP)

ILSI Japan の組織



ILSI Japanは2001年に特定非営利活動法人 (NPO法人) の認証を得ました。ILSI Japanの目的に賛同した64の団体 (2012年12月現在) が活動を支援しています。会員は上記の各委員会・研究会・研究部会に自由に参加し、科学の最新情報に触れながら問題解決を図ることができます。

ILSI JAPANの活動



調査・研究活動とその成果の発表

ILSI Japanの会員は、各研究部会に参加して、内外の最近の研究動向に直接ふれ、**共通の課題を研究**。研究テーマは研究部会会員によって決定。国内外の最新のデータを各機関から収集し、討議をして、その結果を発表しています。新しい研究テーマは大学などの研究機関に研究を依頼することもあります。そして研究部会の成果を最新の科学情報として会員の方々に提供するとともに、**関連する行政、学界、産業界に提言をし、政策の基礎や研究情報の拡大に貢献**しています。

科学情報の普及

機関誌「イルシー」(季刊)を発行しているほか、研究部会による研究成果を報告書として出版しています。また、シンポジウムや講演会、セミナーシリーズを開催し、多くの方々の参加を得、**最新の正しい科学情報の普及に努**めています。

国内外の関連機関との交流・連携

ILSI Japanが行なうシンポジウムは、国内外の関連機関と共催で開催する機会が多く、その度に国や国際機関、各種法人との連携も強まっています。コーデックスなど、国連の国際会議にオブザーバーとして参加し、情報交流、意見具申を行っています。また、本部や他の支部から刊行物がいち早く届き、関連事項についての世界の広範な最新情報を常時、入手しています。2001年7月に活動を開始したILSI CHP Japanは、アメリカの非営利法人 健康推進協力センター (ILSI CHP) と共に、世界的規模の公衆衛生に係る課題に取り組み、科学に基づいた予防・改善活動を行ってきました。国内では**Project PAN** (身体活動と栄養)、アジアでは**Project IDEA** (鉄欠乏性貧血症の撲滅活動)、**Project SWAN** (安全な水の供給と栄養・保健環境の改善) を、その分野の専門家の協力を得、適切な科学的検証を行いながら推進しています。2006年8月よりILSI Japanの一部門としてILSI Japan CHPと名称を改め、活動を続けています。

ご清聴ありがとうございました。



Regulatory Framework on Foods and Food Additives in India

ILSI Japan International Conference - Regulatory Framework on Foods and Food Additives in India, Bangladesh, Nepal and Sri Lanka-

Regulatory Framework on Food and Food Additives in India

- From the MAFF Investigation Project on the Food
Related Regulations in India -

ILSI Japan International Cooperation Committee
Ajinomoto Co., Inc.
Masanori Kohmura Ph.D

1. Food Administrative Bodies in India

Administrative body	Responsible agency	Related laws
Ministries of		
Health and Family Welfare	Food Safety and Standards Authority of India (FSSAI)	<ul style="list-style-type: none"> ● Food Safety and Standards Act, 2006 ● Food Safety and Standards Regulations, 2011 ● Food Safety and Standards Rules, 2011
Consumer Affairs, Food and Public Distribution	Bureau of Indian Standards (BIS)	<ul style="list-style-type: none"> ● The Bureau of Indian Standards Act, 1986 ● The Standards for Weights and Measures Act, 1976 ● The Standards for Weights and Measures Rules, 1977
Women and Child Development		<ul style="list-style-type: none"> ● The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003
Agriculture		<ul style="list-style-type: none"> ● Agricultural Produce (Grading and Marking) Act, 1937 ● The General Grading and Marking Rules, 1988
Food Processing Industries		
Atomic Energy Commission	DAE	● The Atomic Energy Act, 1962
	AERB	● Atomic Energy (Control of irradiation of Food) Rules, 1996

DAE : Department of Atomic Energy.
AERB : Atomic Energy Regulatory Board

2

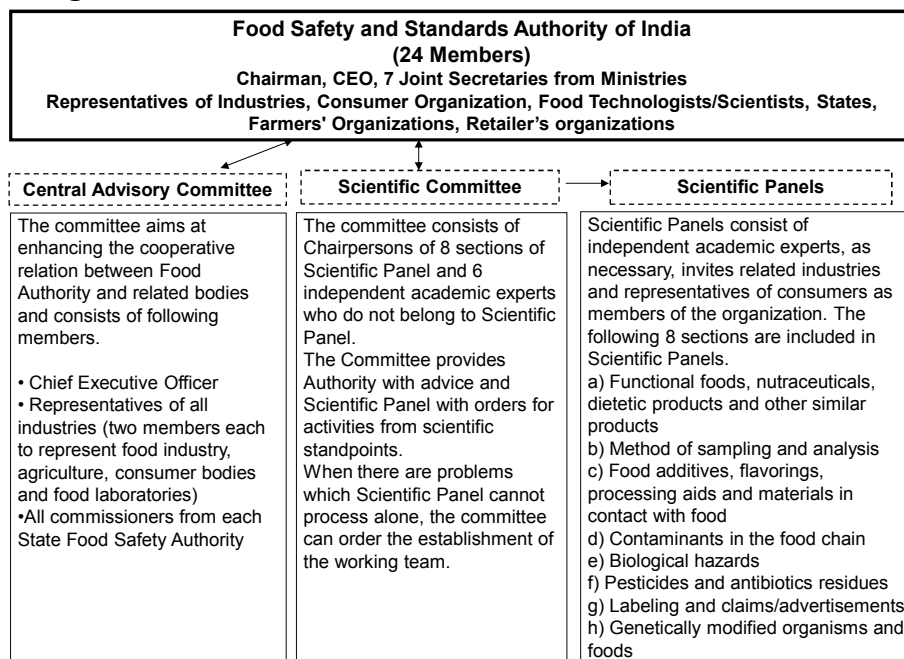
2. Food Safety and Standards Authority of India (FSSAI)

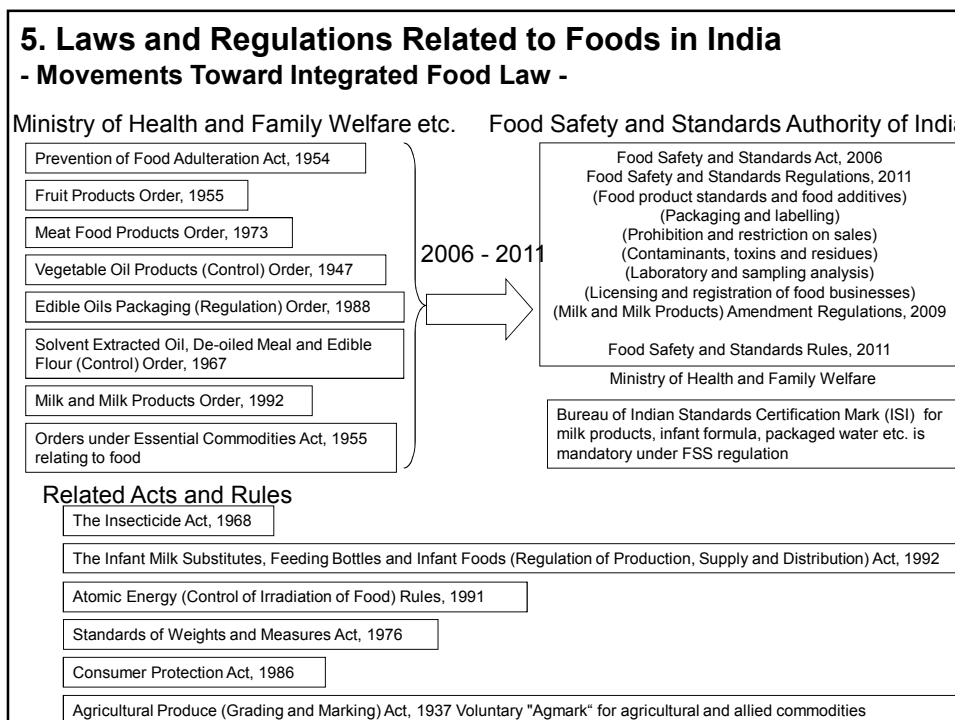
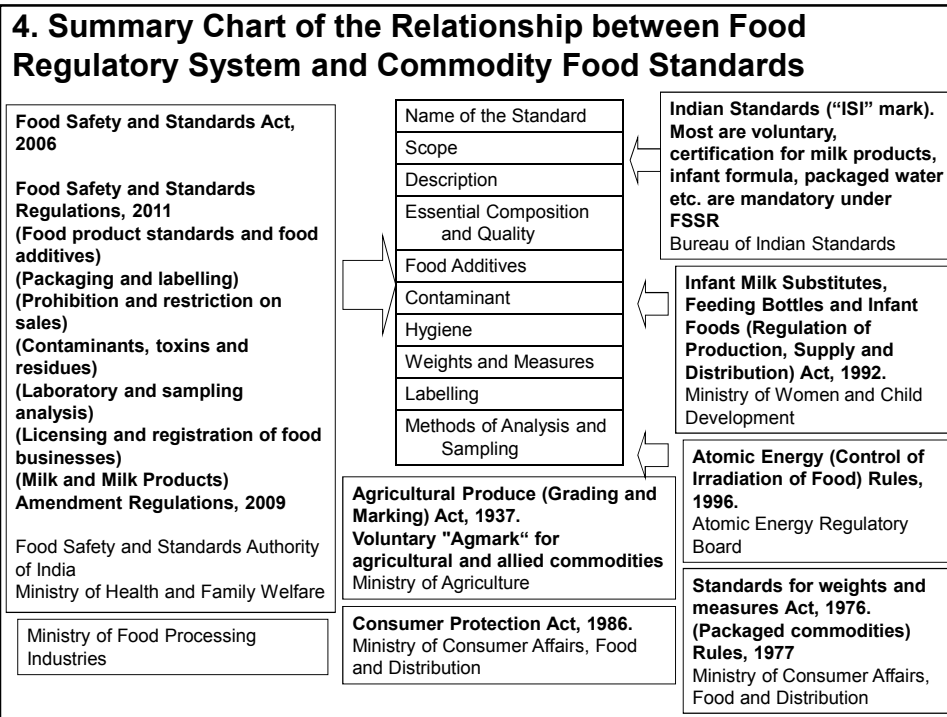
Roles of Food Safety and Standards Authority of India

1. Framing of regulations to lay down the standards and guidelines for food (食品の規格やガイドラインを制定するための規則の骨組みを作る).
2. Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses (食品ビジネスの食品安全マネジメントシステムの認証に携わる認証機関認定のための仕組みとガイドラインを制定する).
3. Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories (研究施設の認定と認定された研究施設の届出に関する手順とガイドラインを制定する).
4. 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 (中央政府や州政府が、食品の安全と栄養に直接的あるいは間接的に関わる分野の指針や規則を立案するにあたっての科学的アドバイスや技術的サポートを行なう).
5. Contribute to the development of International technical standards for food (食品の国際的技術基準の発展に貢献する).
6. Promote general awareness about food safety and food standards (食品安全や食品基準についての一般の認識を高める).

3

3. Organization Structure of FSSAI





6. Food Safety and Standards (FSS) Act, 2006

- 1. Establishment of Food Safety and Standards Authority of India (composition, functions, procedure and duties)**
- 2. General principles of food safety (not only the protection of human health, but also the protection of consumers' benefit including fair food transaction, appropriate risk management based on scientific reasons and preventive measures at appropriate level are set forth)**
- 3. General provisions as to articles of food**
 - a. Use of food additive or processing aid**
 - b. Contaminants, naturally occurring toxic substances, heavy metals, etc.**
 - c. Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts**
 - d. Genetically modified foods, organic foods, functional foods, proprietary foods, etc**
 - e. Packaging and labeling of foods**
 - f. Restrictions of advertisement and prohibition as to unfair trade practices**
- 4. Provisions relating to import**
- 5. Special responsibilities as to food safety (responsibilities of the food business operators, food recall procedure)**
- 6. Analysis of food (laboratories, auditors, analysts, procedure)**
- 7. Implementing sectors and their administrations, penalties, appeal organizations**

7

Example Provisions of the FSS Act, 2006

- 3. Definitions.**
 - 4. Establishment of FSSAI.**
 - 5. Composition of FA and qualifications for appointment of its Chairperson and other Members.**
 - 6. Selection Committee for selection of Chairperson and Members of FA.**
 - 11. Central Advisory Committee.**
 - 13. Scientific Panels.**
 - 14. Scientific Committee.**
 - 15. Procedure for Scientific Committee and Scientific Panel.**
 - 19. Use of food additive or processing aid.**
 - 20. Contaminants, naturally occurring toxic substances, heavy metals, etc**
 - 21. Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts.**
 - 22. Genetically modified foods, organic foods, functional foods, proprietary foods, etc.**
 - 23. Packaging and labelling of foods.**
 - 24. Restrictions of advertisement and prohibition as to unfair trade practices.**
 - 25. All imports of articles of food to be subject to this Act.**
- etc

7. Food Safety and Standards (FSS) Rules and Regulations

FSS Regulations, 2011

- Food product standards and food additives
- Packaging and labelling
- Prohibition and restriction on sales
- Contaminants toxins and residues
- Laboratory and sampling analysis
- Licensing and registration of food businesses

Enforced after 5th Aug 2011

FSS Rules, 2011

Example

2.1 - Qualification and duties
2.1.1: Commissioner of Food Safety (State Gov.)

2.1.2: Designated Officer

2.1.3: Food Safety Officer

2.1.4: Food Analyst

Enforced after 5th Aug 2011

Amendment Regulations, 2009

- Milk and Milk Products

Draft Regulations

- Food Authority's Food Recall Procedures
- Food for Special Nutritional or Dietary Uses
- Revised Energy Drinks, and Caffeine
- Revised Trans Fatty Acids in Partially Hydrogenated Vegetable Oils
- Food import
- Operationalizing the Regulation of GM Foods in India
- Labeling (claims)

8. Regulations on Food Additive

1. Definition of Food additive.

CHAPTER I, Article 3 of the FSS Act, 2006

(k) "food additive" means any substance not normally consumed as a food by itself or 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 by-products becoming a component of or otherwise affecting the characteristics of such food but does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities;

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8. Regulations on Food Additive

2. Functional Classes

Article 2.2.2, 5 Declaration regarding Food Additives of FSS (Packaging and labeling) Regulations, 2011.

(i) For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific names or recognized international numerical identifications: Acidity Regulator, Acids, Anticaking Agent, Antifoaming Agent, Antioxidant, Bulking Agent, Colour, Colour Retention Agent, Emulsifier, Emulsifying Salt, Firming Agent, Flour Treatment Agent, Flavour Enhancer, Foaming Agent, Gelling Agent, Glazing Agent, Humectant, Preservative, Propellant, Raising Agent, Stabilizer, Sweetener, Thickener:

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8. Regulations on Food Additive

Chapter 3: SUBSTANCES ADDED TO FOOD in the FSS (Food Product Standards and Food Additives) Regulations, 2011.

Colouring Matter, Artificial Sweeteners, Preservatives, Anti-oxidants, Emulsifying agents, Stabilising agents, Anticaking Agents, Antifoaming agents in edible oils and fats, Release agents, Flavouring Agents, Flavour Enhancers, Sequestering Agents and Buffering Agents

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8. Regulations on Food Additive

3. Definition of Processing aid

Article 19. Use of food additive or processing aid of the FSS Act, 2006

Explanation.- For the purposes of this section, “processing aid” means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, 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 nonintentional but unavoidable presence of residues or derivatives in the final product.

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8. Regulations on Food Additive

4. Approved Food Additives and its Use Standards

Article 19. Use of food additive or processing aid of the FSS Act, 2006

No article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of this Act and regulations made thereunder.

Article 3.1.1:1) of the FSS (Food Product Standards and Food Additives) Regulations, 2011. Use of Food Additives in Food Products:

The food products may contain food additives as specified in these Regulations and in Appendix A.

Appendix A consists of 15 tables of lists of food additives for use in food categories and a list of food categories with permitted food additives.

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8. Regulations on Food Additive

5. Food Additive Specifications

Article 3.2 of the FSS (Food Product Standards and Food Additives) Regulations, 2011. Standards of Additives

2.8: Sweetening agents including Honey. Specifications for 4 Artificial Sweeteners.

3.2.1: Food Colours. Specifications for 15 food colors.

Bureau of Indian Standards (BIS) set standards for 91 food additives. In the current regulatory frame work, BIS certification is voluntary, however, importer of specific food additives shall register to BIS.



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8. Regulations on Food Additive

6. New Food Additive Approval

There is no clear description on approval process for new food additive or revision of use level or food category in the FSS regulations.

However, application format and summary sheet for approval of food additives was announced by the Scientific Panel on Food Additives, flavouring, processing aids and materials in contact with food on April 4th, 2012. It stated that “Applicants should apply for the approval of food additives/enhancement of permitted food additives in other food products as well as increase the existing quantity of permitted food additives in the food product in the enclosed prescribed format. The application should be addressed to Director (PA), Food Safety and Standards Authority of India”

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8. Regulations on Food Additive

7. Labeling of Food Additives Used in Foods

Article 2.2.2: Labeling of Pre-packaged Food of FSS (Packaging and labeling) Regulations, 2011.

2. List of Ingredients, (d) Where an ingredient itself is the product of two or more ingredients, such a compound ingredients shall be declared in the list of ingredients, and shall be accompanied by a list, in brackets, of its ingredients in descending order of weight or volume, as the case may be: Provided that where a compound ingredient, constitutes less than five percent of the food, the list of ingredients of the compound ingredient, other than food additive, need not to be declared;

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8. Regulations on Food Additive

7. Labeling of Food Additives Used in Foods (2)

Article 2.2.2: Labeling of Pre-packaged Food of FSS (Packaging and labeling) Regulations, 2011.

5. Declaration regarding Food Additives, (i) For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific names or recognized international numerical identifications.

In addition, there are many specific labelling requirements relates to food additives

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8. Regulations on Food Additive

8. Carry Over Of Food Additives

Article 3.1.18 of the FSS (Food product standards and Food Additives) Regulation, 2011, **Carry Over of Food Additive.**

For the purpose of the standards specified in chapter 2 of these regulation the "Carry Over" principle applies to the presence of additives such as colours, flavouring agents, anti-oxidants anti-caking agents, emulsifying and stabilising agents, and preservatives in food, as a result of the use of raw material or other ingredients in which these additives were used. The presence of contaminants is not covered by this purpose. The presence of an additive in food through the application of the carry over principle is admissible in general unless otherwise specifically prohibited in the regulations provided the total additive including the carry over through the raw material or other ingredients does not exceed the maximum amount so permitted.

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9. Case Study

1. Instant Noodles

There is no food standard for "instant noodles" in both FSS (Food product standards and Food Additives) Regulations, 2011 and Indian Standards. Instant Noodles shall comply with the requirements set on "2.12: Proprietary Food" in FSS (Food product standards and Food Additives) Regulations, 2011.

	Food Safety and Standards Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) regulation, 2011 2.12: Proprietary Food	
Labeling	FSS (Packaging and Labeling) regulation, 2011 2.2: Labeling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food	
Food Additives	FSS (Food product standards and Food Additives) regulation, 2011 3.1: Food Additives	
Contaminant	FSS (Contaminants, Toxins and Residues) regulation, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene		

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9. Case Study

FSS (Food product standards and food additives) Regulations, 2011

2.12: Proprietary Food

2.12.1

1) Proprietary food means a food that has not been standardized under these regulations

2) In addition to the provisions including labelling requirements specified under these regulations, the proprietary foods shall also conform to the following requirements, namely:—

(i) the name describing as clearly as possible, the nature or composition of food and/or category of the food under which it falls in these regulations shall be mentioned on the label

(ii) the proprietary food product shall comply with all other regulatory provisions specified in these regulations and in Appendices A and B.

Veg and Non-Veg

1.2: Definitions—1.2.1: In these regulations unless the context otherwise requires:

7. “Non-Vegetarian Food” means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient;

11. “Vegetarian Food” means any article of Food other than Non- Vegetarian Food as defined in regulation 1.2.1 (7).

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9. Case Study

2.2.2: Labelling of Pre-packaged Foods

4. Declaration regarding Veg or Non veg –

(i) Every package of “Non Vegetarian” food shall bear a declaration to this effect made by a symbol and colour code as stipulated below to indicate that the product is Non-Vegetarian Food. The symbol shall consist of a brown colour filled circle having a diameter not less than the minimum size specified in the Table mentioned in the regulation 2.2.2 (4) (iv), inside a square with brown outline having sides double the diameter of the circle as indicated below:

(ii) Where any article of food contains egg only as Non-Vegetarian ingredient, the manufacturer, or packer or seller may give declaration to this effect in addition to the said symbol.

(iii) Every package of Vegetarian Food shall bear a declaration to this effect by a symbol and colour code as stipulated below for this purpose to indicate that the product is Vegetarian Food. The symbol shall consist of a green colour filled circle, having a diameter not less than the minimum size specified in the Table below, inside the square with green outline having size double the diameter of the circle, as indicated below:

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9. Case Study

2. Carbonated Soft Drinks

There are two standards relevant to the “Carbonated Soft Drinks” in FSS (Food product standards and food additives) Regulations, 2011.

2.3.30 Carbonated Fruit Beverages or Fruit Drinks

2.10.6 Beverages Non-Alcoholic-Carbonated

There are two standards relevant to the “Carbonated Soft Drinks” in Indian Standards

IS 2346-1992 Carbonated Beverages

IS 12544 1988 Carbonated Beverages - Non-alcoholic Beer

	Food Safety and Standards Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) regulation, 2011 2.3.30: Carbonated Fruit Beverages or Fruit Drinks 2.10.6: Beverages Non-Alcoholic-Carbonated	IS 2346-1992 Carbonated Beverages –Specification
Labeling	FSS (Packaging and Labeling) regulation, 2011 2.2: Labeling 2.2.1:General Requirements 2.2.2:Labelling of Pre-packaged Food	IS 12544 1988 Carbonated Beverages - Non-alcoholic Beer –Specification
Food Additives	FSS (Food product standards and Food Additives) regulation, 2011 3.1: Food Additives Appendix A:List of Food Additives	
Contaminant	FSS (Contaminants, Toxins and Residues) regulation, 2011 2.: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene	FSS (Food product standards and Food Additives) regulation, 2011 Appendix B:Microbiological Requirements	

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9. Case Study

2. Carbonated Soft Drinks

Method of Analysis :

Regulation applied	Item	Specification	Method of analysis	References
FSS (Food product standards and food additives) Regulation 2011 Carbonated beverage-Specification (IS 2346 : 1992 (reaffirmed 2009))	Arsenic	Max. 0.1 mg/kg		IS 11124 : 1984
	Lead	Max. 0.5 mg/kg		IS 6854 : 1973
	Copper	Max. 1.5 mg/kg		IS 6854 : 1973
	Iron	Max. 0.5 mg/kg		IS 6854 : 1973
	Total plate count	Not more than 50 cfu/ml		IS 5402 : 1969
	Coliform count	Absent in 100ml		IS 5401 : 1969
	Yeast and mold count	Not more than 2 cfu/ml		IS 5403 : 1969
	Saccharin	-	Volumetric method HPLC method	IS 2346 : 1992
	Gas volume	-		IS 2346 : 1992

9. Case Study

2. Carbonated Soft Drinks

Sampling methods

Regulation applied	No. of Bottles in the Production Lot	No. of Bottles to be selected	
		Microbiological tests	Other tests
FSS (Food product standards and food additives) Regulation 2011 Carbonated beverage-Specification (IS 2346 : 1992 (reaffirmed 2009))	Up to 1,300	12	18
	1,301 to 3,200	18	24
	3,201 to above	24	30
	References : IS 2346 : 1992 (Reaffirmed 2009) Annex D (Clause 9.1) - Bottles to be selected for testing shall be chosen at random utilizing random number tables (see IS 4905 : 1968).		

9. Case Study

3. Prepared Frozen Foods

There is no food standard for "Prepared Frozen Foods" in both FSS (Food product standards and food additives) Regulations, 2011 and Indian Standards.

"Prepared Frozen Foods" shall comply with the requirements set on "2.12:

Proprietary Food" in FSS (Food product standards and Food Additives) Regulations, 2011.

	Food Safety and Standards Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) regulation, 2011 2.12: Proprietary Food	
Labeling	FSS (Packaging and Labeling) regulation, 2011 2.2: Labeling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food	
Food Additives	FSS (Food product standards and Food Additives) regulation, 2011 3.1: Food Additives	
Contaminant	FSS (Contaminants, Toxins and Residues) regulation, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances	
Hygiene		26

9. Case Study

4. Cow's Milk

There is the standard relevant to the "Cow's Milk" in FSS (Food product standards and food additives) Regulations, 2011.

2.1.1 Milk

There are two standards relevant to the "Cow's Milk" in Indian Standards.

IS 4238:1967 Sterilized Milk

IS 13688:1999 Packaged Sterilized Milk

	Food Safety and Standards Regulations 2011	Indian Standards
Scope, Description, Essential Composition and Quality Factor	FSS (Food product standards and Food Additives) regulation, 2011 2.1: Dairy Products and Analogues 2.1.1: Milk	IS 4238-1967 Specification for Sterilized Milk
Labeling	FSS (Packaging and Labeling) regulation, 2011 2.2: Labeling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food	IS 13688:1999 Packaged Pasteurized Milk -Specification
Food Additives	FSS (Food product standards and Food Additives) regulation, 2011 3.1: Food Additives Appendix A: List of Food Additives Table 14 List of Food Additives for use in Milk products	
Contaminants	FSS (Contaminants, Toxins and Residues) regulation, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances, 2.3: Residues	
Hygiene	FSS (Food product standards and Food Additives) regulation, 2011 Appendix B: Microbiological Requirements Table 2 Microbiological Parameter for Milk products	

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9. Case Study

4. Cow's Milk

Sampling methods : Sterilized Milk

Regulation applied	No. of Containers in the Production Lot	No. of Containers to be selected	
		Bacterial spores	Creaming index, Turbidity and Sterility
FSS (Food product standards and Food Additives) regulation s, 2011 Specification for Sterilized Milk (IS 4238 : 1967 (reaffirmed 2010))	Up to 25	1	1
	26 to 100	2	5
	101 to 500	3	7
	501 to 1,000	3	9
	1,001 to 5,000	4	11
	5,001 to above	4	13
	References : IS 4238 : 1967 (Reaffirmed 2010) Appendix F (Sampling of Sterilized Milk)		

9. Case Study

4. Cow's Milk

Method of Analysis : Sterilized Milk

Regulation applied	Item	Specification	Method of analysis	References
FSS (Food product standards and Food Additives) Regulations, 2011 Specification for Sterilized Milk (IS 4238 : 1967 (reaffirmed 2010))	Creaming index	Max. 20	Centrifugation	IS 4238 : 1967 (Reaffirmed 2010)
	Turbidity test	To conform to test		IS 4238 : 1967 (Reaffirmed 2010)
	Sterility (a)	pH variation on 7days incubation : Max 0.3		IS 4238 : 1967 (Reaffirmed 2010)
	Sterility (b)	Titrateable acidity variation on 7 days incubation : Max. 0.02 g	Titration	IS 4238 : 1967 (Reaffirmed 2010)
	Bacterial Spores - aerobic	Max. 5 colonies / ml		IS 4238 : 1967 (Reaffirmed 2010)

Acknowledgement

This investigation was conducted by the project team for the investigation of Indian food regulation of ILSI Japan International Cooperation Committee in collaboration with ILSI India and supported by the Ministry of Ministry of Agriculture, Forestry and Fisheries.

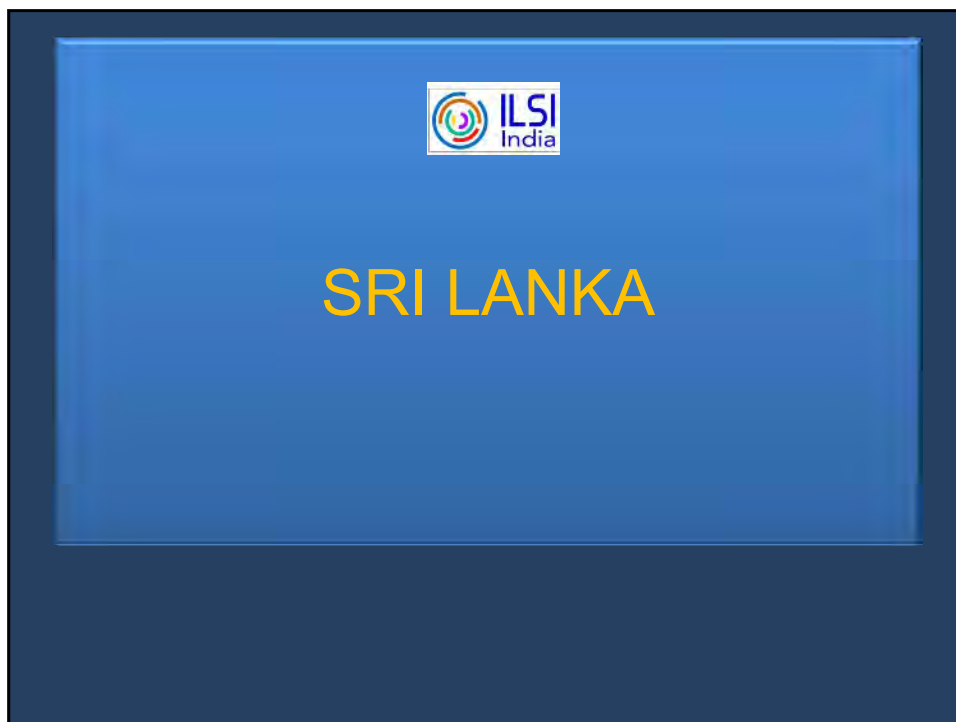
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**Thank you for your
kind attention**

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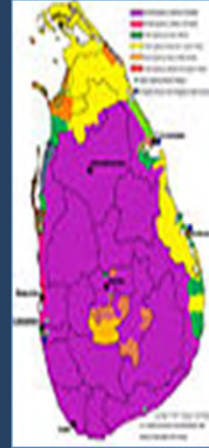


Country Fact Sheet



SRI LANKA

- **Sri Lanka is an Island in the Indian Ocean, off the south-eastern coast of India.** It is about the size of Ireland. It is about 28 kilometers (18 mi.) .
- **Population is about 20 million.** The Sinhalese, make up 74.9% of the population . Tamils are 15.4% . Most Sinhalese are Buddhist; most Tamils are Hindu.
- **Official Languages: Sinhala and Tamil.**



Administrative Authorities



Administrative Authorities in Sri Lanka as shown in the following Table are responsible for Food Administration of food categories and related stage of production.

Sector	Products	Imported	Domestic
Ministry Of Health/ Directorate General of Health Services	Food Products	Food Control Administration of *MoH (FCA)	FCA
Ministry/Department of Agriculture (MOA)	Primary products of agriculture	Food Control Administration of *MoH (FCA)	MOA and FCA
Department of Animal Production & Health (DAP &H)	Animal Husbandry Milk Products	DAP&H and FCA	DAP&H and FCA
Coconut Development Authority (CDA)	Coconuts & Their Products	FCA and CDA	FCA and CDA
Tea Board (TB)	Manufactured Tea	FCA and TB	FCA and TB
Ministry/Department of Fisheries (MDF)	Fish and Fish Related Products	FCA	MDF and FCA
Excise Department (ED)	Alcoholic Beverages	ED/Customs	ED
Ministry of Local Government (MoLG)	General Food Safety and Standards (implementation)		
Sri Lanka Standards Institution (SLSI) Established Under Sri Lanka Standards Institution Act No. 6 of 1984.	Formulation Of Voluntary & Mandatory Standards General National Standards Of Consumer And Industrial Products Including Food	SLSI	FCA and SLSI
Consumer Affairs Authority (CAA) Established Under the Consumer Affairs Authority Act No. 9 of 2003	Promotion of Effective Completion and Protection of Consumers: Regulation Of Internal Trade	FCA	CAA



Director General of Health Services

The Chief Food Authority is Director General of Health Services under Ministry of Health. It is the apex body responsible for the country's Food Control Administration (FCA). The Food Advisory Committee recommends the standards and regulations to be adopted by the Government.

Sri Lanka Standards Institute

Sri Lanka Standards institute (SLSI) plays an integral role with the FCA and in formulation of National Standards under the Food Act. The Standards of the SLSI are mostly voluntary. Some of them are declared mandatory for verification of standard parameters at the point of import.

The SLSI has mutual agreements with standards setting bodies of the exporting countries that certify the products exported from selected countries. Based on the certification of those bodies and verification checks carried out at national level the SLSI releases those products for further inspection and verification of FCA as far as food products are concerned

MAIN LEGISLATION

i) The Food Act No. 26 of 1980

•The Food Act No. 26 of 1980 amended by Food (Amendment) Act No. 20 of 1991 is the most important regulation and is administered by FCA of Ministry of Health.

Part I of the Food Act provides for prohibition in respect of food related to:

- a) Additives.
- b) Fitness for Human Consumption.
- c) Cleanliness.
- d) Adulteration.
- e) Sanitary conditions.

Part II of the Food Act includes provisions for establishment of Administration :

- a) Establishment of a Food Advisory Committee (FAC).
- b) Designating Director General of Health Services as the Chief Food Authority (CFA).
- e) Providing for Food Authorities under the Food Act; viz. Director General of Customs for imported foods; Chief Medical Officer of Health (CMOH) for the Colombo Municipal area; and Local Authorities (Urban Councils and Pradheshiya Sabhas etc.).

Part III of the Food Act provides for nature of offences under the Food Act and punishment.

Part IV of the Food Act provides protection for action taken in good faith; fines etc.

ii) Regulations have been made Under Section 32 Of
The Food Act

- 1) Miscellaneous Regulation
- 2) Hygiene
- 3) Food Standards
- 4) Non-nutritive sweeteners
- 5) Milk Standards
- 6) Additional Approved Analyst Regulations
- 7) Iodization of Salt
- 8) Microbiological Analyst
- 9) Labeling & Miscellaneous
- 10) Preservatives
- 11) Genetically Modified Foods
- 12) Bread Standards
- 13) Food (Labeling & Advertising) Regulation – 2005
- 14) Irradiation
- 15) Coloring Substances
- 16) Bottled or Package Water
- 17) Adoption of SL Standards
- 18) Antioxidants

Summary of Food Standards

- About 70 Commodities are covered under the Food Standards as per Regulations of 1991.
- These composite regulations are being gradually divided into separate categories such as 'oils and fats', Cereals, Pulses and Legumes, Spices and condiments etc., keeping in line with the Codex Guidelines and Standards.
- Most of these Regulations are in formulation stages and they will be published in Sinhala, Tamil and English languages once they are finalized by the Department of Legal Draftsman.

Laws and Regulations Related to Food Additives

OVERVIEW

▪According to Food Additives (General) Regulations yet to be published (currently in draft form) "Food additive" means any safe substance that is intentionally introduced into in a food in small quantities.

▪Food Additives can be used to affect the food's keeping quality, texture, consistency, appearance, odour, taste, alkalinity or acidity or to serve any other technological function.

They include :

- Preservative,
- Coloring Substance,
- Flavouring Substance,
- Flavour Enhancer
- Antioxidant,
- Emulsifying And Stabilizing Agent,
- Sweetener And Food Conditioner,

But do not include nutrient supplement, incidental constituent or common salt.

Food Additives: Highlights Of Provisions

- Functional classes of Food Additives as per the Table provided by the Codex are considered in the Sri Lankan standards with the relevant INS numbers.
- **Permitted Food Additives are prescribed with their Maximum Limits under the Food Additives Regulations in Sri Lanka. They are invariably based on the Codex Limits prescribed.**
- The recommended list of the Codex and evaluations carried out by Joint Expert Committee on Food Additives (JECFA) is consulted before approval of any Food Additive in Sri Lanka.
- **The labelling of food additives is governed by the Food (Labelling & Advertising) Regulation – 2005 in Sri Lanka.**
- Assessment of food additives as such is not carried in Sri Lanka and there has been no need for such assessments.

FLAVORS

As Per Draft Flavor Regulations



CATEGORIES

Negative List of Flavors

i. "Natural Aromatic Raw Material"	i. Aloin.
ii. "Natural Flavouring Concentrate"	ii. Beberine.
iii. "Natural Flavouring Substance"	iii. Beta- Azarone.
iv. "Nature-Identical Flavouring Substance"	iv. Cade oil.
v. "Artificial Flavouring Substance"	v. Calamus oil.
	vi. Coumarin and dihydrocoumarin.
	vii. Diethylene glycol.
	viii. Monoethyl ether.
	ix. Ethyl Methyl Ketone.
	x. Ethyl-3-Phenyglycidate.
	xi. Eugeny methyl ether.
	xii. Methyl Naphthyl ketone.
	xiii. Saffrole and Isosaffrole.
	xiv. Santonin.
	xv. Sassafras oil.
	xvi. Thujone, Isothujone, alpha and betathujone.
	xvii. Tonka bean.



There are a number of food products in which flavour enhancers are prohibited as per the draft regulations Schedule III.

List Of Plant Or Animal Sources For Flavoring Agents.

No such classification has been made in any of the regulations of Sri Lanka although the following provision has been made in the Food (Additives – Flavoring and Flavor enhancers) Regulations (Draft):

"The label on or attached to a package of a natural flavoring shall include the statement "NATURAL (here insert description of flavor) FLAVORING" or a similar statement."

Processing Aids

Currently NO Regulation is in place.

The Inventory of Processing Aids compiled and adopted by the Codex Alimentarius Commission is consulted.

- The inventory contains the following:
- Category – functional effect classification.
- Processing Aid – the chemical name and description of the substance used.
- Area of Utilization.
- Level of Residues.
- Interaction with food.
- JECFA evaluation.

Carry Over

- “Carry Over” is defined as the presence of food additives in food as a result of the use of raw material or other ingredients in which these additives were used.

PRESERVATIVES



- The present regulation for Food Preservatives is under revision.
- Schedule 1 of “Food Preservative Regulation” provides list of Permitted Food Preservatives along with INS number. 11 Food preservatives are permitted.

Column 1		Column II	
Permitted Preservative	INS No.	Alternative form in which the permitted preservative may be used (to be calculated as the permitted preservative shown in Column I)	INS No.
1. Sorbic acid	200	Sodium sorbate	201
		Potassium sorbate	202
2. Benzoic acid	210	Calcium sorbate	203
		Sodium benzoate	211
		Potassium benzoate	212
		Calcium benzoate	213
3. Sulphur dioxide	220	Sodium sulphite	221
		Sodium hydrogen sulphite	222
		Sodium metabisulphite	223
		Potassium metabisulphite	224
		Potassium sulphite	225
		Potassium hydrogen sulphite	228
		Calcium sulphite	226
Calcium hydrogen sulphite	227		
4. Biphenyl, Diphenyl	230		
5. Orthophenylphenol	231	Sodium orthophenylphenate	232
6. Nisin	234		
7. Potassium nitrite	249		
8. Sodium nitrite	250		
9. Sodium nitrate	251		
10. Potassium nitrate	252		
11. Propionic acid	280	Sodium propionate	281
		Calcium propionate	282
		Potassium propionate	283

Schedule II provides list of articles of Food which may contain Permitted Preservative and the Nature and Quantity of the Permitted Preservative in each case.

Permitted COLORS

A. Synthetic Colors As Per Coloring Substances Regulations

Color	Common Name	Color Index	INS Number
Red	Carmosine	14720	122
	Ponceau 4R	16255	124
	Erythrosine	45430	127
Yellow	Sunset Yellow FCF	15985	110
	Tartrazine	19140	102
Blue	Indigo Carmine	73015	132
	Brilliant Blue FCF	42090	133
Green	Green S	44090	142

Synthetic dyes specified in Table 1 shall conform to the following standard-

Pure dye minimum	85.0%
Water insoluble matter maximum	0.1%
Subsidiary dye maximum	4.0%
Ether extractable matter maximum	0.2%
Intermediates maximum	0.5%

B. Other Permitted Coloring Substances As Per Coloring Substances Regulations

<i>INS Number</i>	<i>Natural coloring substance</i>	<i>Color index</i>
100	Curcumin	75300
120	Cochineal (Carminic Acid)	75470
140	Chlorophyll	75810
150b	Caramel	
160a	Carotenes (alpha, beta or gamma)	75130
160b	Annato	75120
160c	Capsanthin or capsorubin	
160d	Lycopene	75125
160e	Beta-apo-8' – carotenal caroteonic acid	
161a	Flavoxanthin	75135
162	Beetroot red (betanin)	
163	Anthocyanins	
171	Titanium dioxide	77891

Commodity Standards Case Studies

1. Instant Noodles

- There is no standard for Instant noodles under the Food Act – this is not even considered as a possibility in the near future. SLSI is preparing draft standards. The texts are not yet available.
- **Reference can only be given to CODEX STAN 249-2006 which would be taken into consideration as a benchmark standard if and when such a standards framed.**

2. Carbonated Soft Drinks

- There is standard for Carbonated Soft Drinks. However SLSI is revising it and it will become the de facto standard under the Food Act once the standard is published under Food Act.

SLS 183



The draft SLS 183 prescribes the requirements and methods of sampling and testing for carbonated beverages and formulated caffeinated beverages. There are detailed requirements for ingredients to be used, flavors, preservatives, labeling, packaging, sampling and maintaining requirements for hygiene.

It allow:

➤ **Non-nutritive sweeteners:**

Aspartame	-600 mg/l(max)
Acesulfame-I	-350 mg/l(max)
Sucralose	-300 mg/l(max)
Neotame	- 20 mg/l(max)

➤ **Caffeine in Carbonated Beverages:** 150 mg/l when tested in accordance with the method prescribed in **AOA 979.08**.

➤ **Caffeine in Formulated Caffeinated Beverage:** Not less than 100 mg/l when tested in accordance with the method prescribed in **AOA 979.08**.



The formulated caffeinated beverages can contain:

- Thiamine
- Riboflavin
- Niacin
- Vitamin B₆
- Vitamin B_{1 2}
- Pantothenic acid
- Taurine
- Glucurcuronolactone
- Inositol

3. Prepared Frozen Foods

No standards relating to prepared frozen foods either under the Food Act or under the SLSI has been prepared and published so far.

4. Cow's Milk

There are definition and standards for Cow's Milk under the Food Act . These are being revised as per Draft Food (Milk and Milk Products) Regulations with Legal Departments. The requirements for additives and labeling are included in the regulations. Following categories of Cow's Milk are included:

1. Milk/Liquid Milk	8. Ultra Heat Treated Milk
2. Raw Or Fresh Liquid Milk	9. Flavored Milk
3. Standardized Milk	10. Recombined Milk
4. Semi-skimmed Milk Or Low Fat Milk	11. Reconstituted Milk
5. Skimmed Milk Or Non Fat Milk	12. Reconstituted Skimmed Milk
6. Pasteurized Milk	13. Toned Milk
7. Sterilized Milk	14. Lactose Hydrolyzed Milk

Shelf Life of Imported Food Items Under Food Act



- The Regulation specifies that all items of food imported into Sri Lanka shall at the point of entry into Sri Lanka, possess a minimum period of sixty per centum (60%) of unexpired shelf life.
- **Provided that the shelf life period specified above, shall not be enforced in respect of imported fresh fruits and vegetables and potatoes which have not been peeled or cut.**
- The period of shelf life of an item of imported food shall be determined on the basis of the date of manufacture and the date of expiry as declared by the manufacturer of the product and which is depicted on the label attached thereto
- For the purposes of these regulations, the expression "end of shelf life" shall be identified by the use of the words "date of expiry", "best before", "use by" or "use before" or other similar words which convey this meaning and which are used by a manufacturer of any food item being imported into Sri Lanka.
- For the purpose of these regulations "shelf life" means the period of time between the date of manufacture and its usability by the consumer, during which time the product is safe for human consumption and is of satisfactory quality in terms of nutritional value, flavor, texture and appearance.



BANGLADESH

Bangladesh

Officially The People's Republic of Bangladesh (গণ জাতী)

- Bangladesh is a country in **South Asia**. It faces the **Bay of Bengal** to its south, and is bordered by **India** on the north, west and east, as well as **Burma (Myanmar)** on the southeast.
- Bangladesh has the highest population density among large countries, 1,237.51 persons per square kilometer, and 12th overall, when small countries and city-states are included.¹
- Bangladesh has 7th largest population in the world - About 164.4 million.
- About 90% of Bangladeshis are **Muslims** and the remainder are mostly **Hindus**.
- Official language: **Bengali** (also known as Bangla).



Introduction To Regulatory Framework For Foods

- Bangladesh is yet to develop a unified Food Safety Administration System and to formulate a Food Safety Policy. But it has a National Food and Nutrition Policy where attention has been given on food safety.
- Significant activities in Food Safety and Quality Control are going on in the country. A number of Ministries, Departments and Agencies are involved in these activities with a major responsibility of the Ministry of Health and Family Welfare (MOHFW) which has a unique infrastructure to deliver its services throughout the country.

Major Stakeholder Ministries And Departments For Food Control

Food control in Bangladesh is a multi-sectorial responsibility.

Sl. No	Ministry	Department/Organization	Major activities
1.	Ministry of Agriculture	Plant Protection Wing, DAE	<ul style="list-style-type: none"> Phyto Sanitary certificate for Import/Exported plants/plant products Pesticide Use Control Fertilizer Use Control
2.	Ministry of Food	Directorate General of Food (DGF)	<ul style="list-style-type: none"> Quality Control of PFDS, Stock, Procured Food grains/Food Stuff, Imported food etc. Food Control in the Market (not doing at present)
3.	Ministry of Health & Family Welfare	Directorate General of Health; District & Upazila Health Administration and Institute of Public Health.	<ul style="list-style-type: none"> Food Quality and Sanitation Control in Upazila/District level Testing
4.	Ministry of LGRD	City Corporation & Pourashava Health Units	Have Sanitary Inspector, Labs and Public Analyst for food quality control in their command areas.
5.	Ministry of Fisheries & Livestock	A) Department of Fisheries (FIQC Wing) B) Department of Livestock	<ul style="list-style-type: none"> Fish Quality Control & Certification for export Same for the domestic market Animal Health Animal Product Imported Animal
6.	Ministry of Industries	BSTI	<ul style="list-style-type: none"> Frame Standards of Food Products Testing & Certification Marks and Surveillance.
7.	Ministry of Science, Information and Communication Technology	BAEC IFST, BCSIR	Test Radiation level of Imported Food items; Pesticides Residues Testing of Food Items; Research and Development
8.	Ministry of Education	DG, Primary, DG, Secondary, Text Book Board, Universities	Food safety, Nutrition & Environmental issues in the text book of all level of education
9.	Ministry of Information	PIB BTV Radio Bangladesh	Broad cast issues for awareness building
10.	Ministry of Home	Bangladesh Police	Assist the Inspection Agencies
11.	Ministry of Law, Justice & Parliamentary Affairs	-	Formulation, Vetting, Parliamentary Approval etc.

Major Laws & Regulations

There are several laws in Bangladesh for maintaining health and safety standards but there are 2 major regulations as follows:

1) The Bangladesh Pure Food Ordinance, 1959 Under Ministry of Health And Family Welfare

This is an ordinance to provide better control of the manufacture and sale of food for human consumption. Now, this Ordinance is under revision as 'The Bangladesh Pure Food (Amendment) Act'. Under this Act, it has been proposed to constitute a National Food Safety Council, headed by the Ministry of Health and Family Welfare as well as to establish Food Courts.

AND

The Bangladesh Pure Food Rules, 1967

The Pure Food Rules contain standards for 107 mandatory generic food standards. Now, these are under revision.

(2) The Bangladesh Standards And Testing Institution Ordinance, 1985 Amended By The Bangladesh Standards And Testing Institution (Amendment) Act, 2003 Under Ministry Of Industry

Under the Ordinance, the government has established the Bangladesh Standards and Testing Institution (BSTI). It certifies the quality of commodities, materials, whether for local consumption or for export and import.

POINTS TO NOTE

- All standards issued under Pure Food Rules are mandatory in nature and are enforced by BSTI.
- Carbonated water standards have been formulated and enforced under BSTI. These standards are based on Indian as well as CODEX guidelines.
- BSTI has adopted 153 Codex standards for food testing.

- **190 food standards developed by BSTI of which 52 should have compulsory certification marks.**
- **28 Codex standards have been adopted as Bangladesh standards.**
- **The BSTI conducts Surveillance including Surprise Inspections and tests Samples At The BSTI Laboratory**
- **BSTI is the legal entity for certification of products and services under its Marks certification scheme.**
- **The legal metrological testing facility is under the BSTI management.**
- **Most of the imports and exports requirements are covered under BSTI mandate. For specific inquiries BSTI need to be consulted. BSTI has provided regional testing facilities in the ports as well main business centers.**

Related Laws And Regulations

- Bangladesh - New food safety laws 17 Jan 2010
- [The Cantonments Pure Food Act - 19/07/1966](#)
- [The Pure Food Ordinance - 14/10/1959](#)
- [The Animal Slaughter \(Restriction\) and Meat Control Act - 23/04/1957](#)
- [The Food \(Special Courts\) Act - 13/11/1956](#)
- [The Seed Rules - 08/03/1998](#)
- [Protection and Conservation of Fish Rules / Act - 17/10/1985](#)
- [The Breast-Milk Substitutes \(Regulation of Marketing\) Ordinance - 24/05/1984](#)
The Ordinance aims at protection and encouragement of breastfeeding, banning advertising, import, distribution and sale of breast-milk substitutes.
- [The Marine Fisheries Rules - 05/09/1983](#)
- [The Marine Fisheries Ordinance - 19/07/1983](#)
- [The Fish & Fish Products \(Inspection & Quality Control\) Ordinance - 17/05/1983](#)
- [The Importers, Exporters and Indenters \(Registration\) Order - 22/10/1981](#)
- [The East Pakistan Fisheries \(Protection\) Ordinance - 24/03/1959](#)

Laws And Regulations On Food Additives

Overview

- No definite description exists under Bangladesh Pure Food Rules 1967 on Food Additives.
- There are provisions for use of Colors, Flavors, Preservatives and Sweeteners.
- Functional Classes have been prescribed.
- Stabilizers or emulsifying agents are permitted.
- Antioxidants are permitted.

Flavors Under Pure Food Rules

- There is definition for Flavoring Compounds in food .
- Foods containing Flavors have to be labeled.
- Food containing added natural flavouring compounds shall be labelled in the legend with 'NATURAL FLAVOUR' or 'CONTAIN NATURAL FLAVOURING' provided that only those flavouring compounds which have been obtained from fruits or plants by extraction with suitable harmless solvents or by distillation or by expression, or by any other suitable process are used.
- Food containing artificial flavouring compound shall be labelled with the legend 'ARTIFICIAL FLAVOUR' or 'IMITATION FLAVOUR' provided that where a food contains a mixture of both natural and artificial flavouring compounds it shall be labelled as 'ARTIFICIAL FLAVOUR' provided further that those flavoring compounds which have been obtained by Chemical synthesis shall be considered as artificial.

Processing Aids

No description available under the Bangladesh Pure Food Laws 1967.

Carry Over

No description available under the Bangladesh Pure Food Laws 1967.

Functional Classes

Under Bangladesh Pure Food Laws, 1967, following functional classes of foods Additives have been listed:

List Of Food Categories

- Milk and Milk Products.
- Edible Oils and Oil Products.
- Tea, Coffee, Roasted Coffee and Grounded Coffee.
- Sugars and Sugary Products
Honey.
- Food Grains, Cereals and Their Products.
- Starchy Products.
- Non Alcoholic Beverages.
- Spices.
- Fruits, Vegetables and Miscellaneous Products.
- Edible Fats.
- Biscuits, Bread and Confectionery Product.
- Dried Fish.
- Ice.

Additives

- Flavoring Agents.
- Coloring Matters.
- Class I And Class II Preservatives.
- Antioxidants.
- Stabilizers.
- Non Nutritive Constituents.
- Common Salt.
- Baking Powder.
- Edible Gelatin

Colouring Matter In Food

Coal-tar Dyes



<u>Colour Index No.</u>	<u>Colour Index Name</u>	<u>Common Name</u>	<u>Chemical Class</u>
73015	Food Blue 1	Indigo Carmine	Indigoid
42090	Food Blue 2	Brilliant Blue F.C.F	Triarylmethane
69800	Food Blue 4	Indanthrone	Anthraquinone
42051	Food Blue 5	Patent Blue V	Triarylmethane
42640	Food Violent 2	Violet 6b	Triarylmethane
42580	Food Violent 3	Violets B.N.P.	Do.
42085	Food Green 1	Sulpho Green 2 B.A.	Do.
42095	Food Green 2	Acid Brilliant Green	Do.
42053	Food Green 3	A.F. Green No. 3	Do.
15985	Food Yellow 3	Sunset Yellow F.C.F	Monoazo
19140	Food Yellow 4	Tartrazine	Do.
.....	Food Brown 1	Brown F.K.	Disazo
.....	Food Brown 2	Chocolate Brown	Monoazo
		F.B.	
20285	Food Brown 3	Chocolate Brown	Disazo
		H.T.	
14700	Food Red 1	Ponceau S.X.	Monoazo
16185	Food Red 9	Amaranth	Do.
45430	Food Red 14	Brythrosine B.S.	Xanthene
28440	Food Black 1	Black P.N.	Disazo

*The colour index, second edition, 1956, Society of Dyers and Colorists, England.



- The maximum limit of permissible colour which may be added to any food shall be one grain per pound of food.
- The following natural colouring matters may be used in or, upon any article of food-
 - cochineal, carmine, caramel, Carotenes, chlorophyll, curcumin, lactoflavin, annatto, ratanjot, saffron.
- Inorganic colouring matters or pigments shall not be added to any article of food.
- ✓ The use of artificial or synthetic colouring matters in raw foodstuffs which are consumed after cooking in the usual way is prohibited.
- No person shall sell a coal-tar colour or a mixture of coal-tar colors unless the label on the package carries-
 - The common name (s) of the coal-tar colour (s).
 - The lot number of coal-tar colour; and
 - The words "Food Colour".

➤ Negative List

Use of permitted coal-tar dyes in or upon any food other than those shown below is prohibited-

- Ice-cream
- Dairy products except milk, dahi, butter, ghee, chhana, condensed milk, cream, and baby food
- Smoked fish
- Egg preparation
- Sweets including pastry and Other confectionaries
- Fruit Products
- Non-alcoholic beverages except tea, cocoa and coffee
- Custard powder
- Jelly crystals
- Soup powder and
- Luncheon meat
- Processed or preserved vegetables
- Flavoring agents

Preservatives Under Food Rules, 1967

Class I Preservative shall be-

Common salt
Sugar
Dextrose
Glucose
Wood smoke
Spices
Vinegar or acetic acid
Honey
Hops
Commercial salt petre; and
Alcohol or potable spirit, and

Class II preservative shall be –

Benzoic acid including salts thereof,
Sulphurous acid including salts thereof,
Nitrites of sodium or potassium in respect of
food like ham, pickle, meat, and
Sorbic acid including salts thereof.

The use of Class II preservatives is restricted to 26 specified group of foods and proportions in which they can be used has also been specified.

Use of more than one class II in any food is prohibited.

Antioxidants In Food

Antioxidants shall not be added to any food other than :

- **Edible oils and fats from animal, vegetable and fish, vitamin oils or concentrates,**
and
- **Products consisting essentially of fat such as margarine or the like.**

Stabilisers In Food



The use of stabilizers or emulsifying agents, singly or in combination is permitted:

- Agar Agar.
- Carob bean.
- Irish moss or carrageen or chondrus.
- Guar gum.
- Sodium alginate.
- Monoglycerides or diglycerides of fatty acids.
- Brominated vegetable oils.
- Gum Acacia.
- Provided that where a standard for the nature, substance and quality of a----- prescribes a limit, that shall not be exceed by the stabilizer.

Non-Nutritive Constituents



- The following non-nutritive sweeteners or their salts-may be used:

- ❖ Calcium cyclobexyl-sulphate; and
- ❖ Sodium cyclohexyl-sulphate.

Non-nutritive sweeteners and sugar shall not be used in combination in any food.

Negative List For Food Additives



Negative List is Not clearly specified Under Bangladesh Food Laws, 1967. However, products are considered injurious to health if they contain the following metal or metalloids in excess of the tolerance limit showing against each-

Aluminum	Maximum	250	parts	per	million
Antimony	“	2.0	“	“	“
Arsenic Liquid	“	0.1	“	“	“
Arsenic Solid	“	2	“	“	“
Boron	“	80	“	“	“
Cadmium	“	6	“	“	“
Zinc	“	100	“	“	“
Copper	“	10	“	“	“
Tin	“	100	“	“	“
Fluorine	“	1.5	“	“	“
Silver	“	1	“	“	“
Lead Liquid	“	2	“	“	“
Lead Solid	“	20	“	“	“

Labeling Of Food Additives



- Most of the labelling requirements are in conformity to regional requirements and are guided by general principles of Codex Labeling norms. The labels are in Bangla and English dialects with general information on Brand Name, Manufacture details, weight/ volume, price and date of manufacture. Labeling of additives is as per generic guidelines. Currently BSTI is developing the labelling policy.

Labelling Under Bangladesh Pure Food Rules, 1967

Container of food which contains preservative shall not be marked "pure"- the word "Pure" shall not be used on the label of the container of any food which contains preservative.

No preservative shall be sold for use in food unless the label carries-

- The common name.
- The chemical name.
- The net weight.
- Adequate directions for use in accordance with the limits prescribed for such preservatives; and
- The name and address of the manufacturer.

Commodity Standards **Case Studies**

1. Instant Noodles

- Under Bangladesh Pure Food Rules, 1967, NO specific standard for Instant Noodles are prescribed. However, standards for cereal products, local products and vermicelli are provided.

2. Carbonated Soft Drinks

- Under The Bangladesh Pure Food Rules 1967 Standards for Non alcoholic Beverages, which include Aerated water and Soda water, are prescribed. These are mandatory and enforced by government agencies.

3. Prepared Frozen Foods

There are NO standards Under the Bangladesh Pure Food Rules, 1967, for Frozen Foods including fish, meat and poultry products.

4. Cow's Milk

- Under The Bangladesh Pure Food Rules 1967, Milk and Products standardization have been prescribed. These standards include cow's milk along with other local processed milk products manufactured and traded in the country. All these standards are mandatory and enforced by government agencies.

Nepal

Nepal

- The Federal Democratic Republic of Nepal, is located in **South Asia** in the **Himalayas** and bordered to the north by the **People's Republic of China**, and to the south, east, and west by the **Republic of India**.
- Population of approximately 27 million .
- Nepal is the world's 93rd largest country by land mass and the 41st most populous country.
- **Hinduism** is practised by about 81% of Nepalese, **Buddhism** is linked historically with Nepal and is practiced by 9%,
- Official Language: Nepali



Introduction

- In the course of formulating food regulatory framework in Nepal in 1960s, many of the technical aspects were referred from Prevention of Food Adulteration Act of India or PFA. These days, the trend of updating of regulation is mainly guided by the Codex guidelines.

Legislations And Agencies Food Safety

Act/Rules and implementing Departments	Related Ministries
Food Act 1966 DFTQC	Ministry of Agriculture Development
Food Regulation 1970 DFTQC	Ministry of Agriculture Development
Consumer protection Act 1998 DoC	Ministry of Commerce and Supplies
Consumer protection Rules 2000 DoC	Ministry of Commerce and Supplies
Slaughterhouse and Meat Inspection Act 1998 DLS	Ministry of Agriculture Development
Slaughterhouse and Meat Inspection Rules 2000 DLS	Ministry of Agriculture Development
Local self-governance Act 1999 Local Govts	Ministry of Local Development
Local self-government Rules 2000 Local Govts	Ministry of Local Development
Nepal Standards (Certification mark) Act 1980 NBSM	Ministry of Industries
Nepal Standards (Certification mark) Rules 1983 NBSM	Ministry of Industries
Standard weights and Measures Act 1968 NBSM	Ministry of Industries
Standard weights and Measure Rules 1978 NBSM	Ministry of Industries
Animal health and livestock service act 1998 DLS	Ministry of Agriculture Development
Animal health and Livestock service Rules 2000 DLS	Ministry of Agriculture Development
Breast feeding substances (Sales & Distribution control) Act 1992 DH/DFTQC	Ministry of Health & Population. / Ministry of Agriculture Development
Breast feeding substances (Sales & Distribution control) Rules 1994 Department of Health /: Department of Food Technology & Quality Control.	Ministry of Health & Population. /Ministry of Agriculture Development
Iodized Salt (Production Sale and Distribution) Act 1999 Department of Health Department of Food Technology & Quality Control.	Ministry of Health & Population/ /Ministry of Agriculture Development
Feed Act 1976: Department of Food Technology & Quality Control.	Ministry of Agriculture Development
Pesticide Regulation Act 1991 DoA	MoAD

Main Legislation



- **Food Act 2023 (1966) & Food Rules 2027 (1970).**
- **The Administrative Authority for Food Act and Rules is Ministry of Agriculture Development.**
- **Note: Nepal follows Hindu calendar (Bikram Sambat) which is approximately 57 years ahead of international calendar. Year 2027 in Nepali calendar would be 1970 in International calendar.**



- **The Food Act provides for definitions of food and food adulteration, administrative infrastructure, offences and penalties and establishment of Department of Food Technology and Quality Control and setting up of Food Standardization Committee.**
- **The Food Rules provide for Food Additives, Contaminants, Inspections, Method of Sampling, Food Labelling, Use of Color and Preservatives etc.**



**Department Food Technology
And Quality Control (DFTQC)**
Website: [Www.Dftqc.Gov.Np/](http://www.Dftqc.Gov.Np/)

- The Department of Food Technology and Quality Control (DFTQC) functioning under Ministry of Agriculture Development (MoAD), Government of Nepal is the agency responsible for administering the food control programme in Nepal.
- DFTQC delivers its activities through three Divisions and two sections as given below:
 - ✓ Quality Control Division.
 - ✓ Central Food Laboratory.
 - ✓ Food Technology and Training Division.
 - ✓ National Nutrition Programme.
 - ✓ SPS Enquiry Point.



The Functions Of DFTQC, As Specified In Food Act, Are As Follows:

- To analyse appeal (requested) samples.
- To assist the Food Standardisation Board in generating scientific data to set Standards for food.
- To conduct food inspector training program and issue licenses for food inspectors.
- To regulate imports of food products from the perspective of quality control.
- To facilitate export of food products from the perspective of food safety and quality.
- To provide laboratory services to food quality control programmes including industries and import export trades as requested.

Quality Control Division



This is the division responsible to execute the functions and activities specifically focused to food quality control (implementation of Food Act & Regulation). The activities include:

- Food Inspection.
- Industry Licencing.
- Consumer Awareness.
- Food Standardization And Compliance.

Food Standard Fixation Committee



There is a Food Standardization Fixation Committee. The major function of the Food Standardisation Committee is to make recommendations to the Government on the development of, or amendment to standards taking account of Codex practices, scientific justification and production practices. The Board is chaired by the Secretary of the Ministry of Agriculture Development and consists of representatives from several ministries, industry and consumer association.

Mandatory Food Standards In Nepal

- Generic Standards
- **The standards of food commodities either common staple or their products, are included in the generic standards.**
- **Eleven groups of food commodities are included in mandatory standards in Nepal – Table 1.**

Table 1. Mandatory Standards For Food Commodities Of Nepal

S. N.	Food Group	No. Of Food commodity
1	Milk & Milk Products	18
2	Fats & Oils	16
3	Fruits & Vegetable Products	17
4	Spices & Condiments	22
5	Tea, Coffee, Cocoa and their Products	3
6	Salt	2
7	Cereal, Pulses & their Products	23
8	Processed Drinking Water	1
9	Non-Alcoholic Beverage	1
10	Sweetening Agent	3
11	Sweets and Confectionaries	3
	Total	109

- The standards so far prepared and executed up to now are published in Nepali Language. For specific compositional and technical parameters the English version is also given in the brackets.
- The need is felt by the concerned stakeholders to have an authentically translated version of standards in English. Food safety and quality document being a regulatory document needs to be translated by authorized institutions. Some efforts could be expected towards this direction in near future.

Laws And Regulations Related To Food Additives

- Standard published by Indian PFA (now FSSAI) and CODEX are frequently referred standard for additives in Nepal.

Flavors

- **NO details on qualitative and quantitative terms are given in Nepalese food standard.**
- **Natural and artificial flavors in processed foods are referred in Codex and PFA publication.**

Processing Aids

- **NO specific definitions and quantitative limits are available in the existing Food Act and Regulation regarding processing aids.**

Carry Over

No specific requirements available but generally guided by Codex requirements.

Functional Classes

- **Only few classes such as Food Colors (natural and artificial), Preservatives(class I and Class II) and few Vitamins and Minerals are given with quantitative limits in Food Regulation and Standards in Nepal.**

Color

- “Color” means any natural or artificial colour to be mixed in a food.
- **Coal Tar Colours (Synthetic Dyes) Are Allowed To Be Used In Food as per food specified in schedule 10 only.**

Table 2. List Of Coal Tar Colours Permitted To Be Used In Food

Type	Colour Index No. 1956	Common name	Other name
Red	16185	Amaranth	Food Red 9
Red	16255	Ponceau 4R	
Red	45430	Erythrosine	Food red 14
Red	14720	Carmoisine (Azo Rubin)	
Red	16045	Fast red E	
Yellow	19140	Tartrazine	Food yellow 4
Yellow	15985	Sunset yellow FCF	
Blue	73015	Indigo carmine	Food blue 1
Blue	42090	Brilliant blue FCF	
Green	44090	Wool green B.S.	
Green	42053	Fast green FCF	

Maximum Limit of Permitted Colour: The above-mentioned Coal Tar Colours may be added to any food that is ready for consumption not in excess of 200 milligram per kilogram.

Restriction on the Use of Coal Tar Colours: The Coal Tar Colours can be used only in the following food:

- (1) All kinds of ice-cream.
- (2) Cheese.
- (3) Different preparations from egg.
- (4) Biscuit, cake, pastry, and other sweets.
- (5) Non-alcoholic beverages except tea, coffee, coca cola.
- (6) Custard powder.
- (7) Jelly powder.
- (8) Processed or preserved fruits and green vegetables.
- (9) Soup powder.
- (10) Flavouring agents.

Prohibition of the use of Coal Tar Colours: Even the specified Coal Tar Colours are not allowed to be used in any food to be eaten after cooking.

Natural Colours Allowed To Be Used In Food

Type	Colour Index	Common Name
Yellow	75.120	Annato
-do-	75.130	Carotene or β -carotene
-do-	75.100	Saffron
-do-	-	Riboflavin or lactoflavin
-do-	75.150	Turmeric or curcumin
-do-	-	Lentophil
Gray	-	Caramel
Red	75.470	Cochineal, carmine or carmine acid
-do-	-	Ratanjot, hamatoxilin
-do-	-	Arrayal (atsin)
-do-	75.520	Alkanet, alkaline
Green	75.810	Chlorophyll

There are restriction on use of Inorganic Colors and Pigments

No inorganic colors or pigments are permitted to be used in food preparations.

Use Of Preservative In Food

First Class Preservatives

- **Common salt.**
- **Sugar/sugar candy.**
- **Dextrose.**
- **Glucose.**
- **Wood smoke.**
- **Spices.**
- **Vinegar or acetic acid.**
- **Honey.**
- **Hops, and**
- **Alcohol.**

Second Class Preservatives

- **Sodium or potassium nitrites.**
- **Benzoic acid and salts thereof.**
- **Sulphurous acid and sulphur dioxide.**

The quantities of preservatives and the food in which they can be used have been mentioned in the Rules.

The use of more than one Second Class Preservative in any food is prohibited.

Vitamins And Minerals

- **Vitamins and Minerals are allowed to be added in foods and the limits have been prescribed.**

Labelling Requirements

- Where a color or a preservative is added to a food, any statement or any kind of symbol or sign indicating such addition has be mentioned on the label.
- The label of a food claimed to contain vitamins, minerals or other nutritional substances have to specify it on the label.

There are following provisions:

- (a) One shall not claim that a food sold by him/her contains such vitamins and/or other nutritional substances without specifying the same on the label of that food.
- (b) An advertisement or publicity statement shall not mention that a food contains such vitamins and/or other nutritional substances without specifying the quantity of such vitamins and/or other nutritional substances.

Revision

- The original Food Act does not cover the mandatory requirements and regulation mechanisms for functional foods, nutraceuticals, GM foods and many other dimensions of newer food processing technologies. To address these issues, the existing Food Act has to be replaced with newer version, which has already been drafted and is under the process of promulgation by legislature.

Nepal Bureau Of Standards And Metrology (NBSM)
Under Ministry of Industry

- **Besides Department of Food Technology and Quality Control, Nepal Bureau of Standards and Metrology has been also working in the field of food quality assurance. It provides voluntary quality certification mark called NS.**
- **There are 106 standards for food products and 13 for food packaging Materials.**

Case Studies

1. Instant Noodles

- **There are standards for Instant noodle .**
- **It means the product prepared from refined wheat flour which is cooked in the shape of curled or twisted thread or in any other shape. The product may contains vegetable oil, seasonings, eggs, mushrooms, vegetables, chicken or its extract, shrimp etc. and may be added with permitted flavor. The product shall not contain any mold and insect infestations, parts or whole, and shall meet the specified requirements:-**

2. Processed Milk

- **There are standards for Processed milk.**
- **Processed milk means the liquid milk containing not less than 3.0 percent milk fat and 8.0 percent milk-solid-not-fat (SNF) by adjusting either or not by the partial removal of milk fat and either or not by the solubilization of skimmed milk powder and processed by pasteurization or sterilization. The milk processed by pasteurization process can be labeled as "pasteurized milk" and that processed by sterilization can be labeled as "sterilized milk".**

3. Carbonated Water

- **There are standards for Carbonated Water (nonalcoholic beverage).**

- **Carbonated Water (nonalcoholic beverage) means the beverage prepared by mixing one or more ingredients which is packed and sealed in bottle or can impregnated with carbon dioxide under pressure.**

4. Frozen Foods

- **There are no provisions for Frozen Foods.**

- **ACKNOWLEDGEMENT & THANKS**

I would like to thank the following EXPERTS for their contribution in preparing Country Reports of Sri Lanka, Bangladesh and Nepal:

- **Sri Lanka: Dr. S. Nagaiah, Consultant / Food Control Administration Unit, Ministry Of Health**
- **Bangladesh: Dr. G.M. Tewari, Consultant**
- **Nepal: Dr. Ganesh Dawadi, Deputy Director General, Dept. of Food Technology & Quality Control**

THANK YOU



Towards Harmonization of Food and Food Additive Standards in ASEAN



Towards Harmonization of Food and Food Additive Standards in ASEAN

Teoh Keng Ngee
Manager, Scientific
Programs



ILSI
Southeast
Asia Region

ASEAN

(Association of South East Asian Nations)



- Formed on August 8, 1967 by 5 Founding Members (*Indonesia, Malaysia, Philippines, Singapore, Thailand*) through ASEAN Declaration (Bangkok)
- Original purpose: maintain regional security & stability (*newly independent nations, threat of regional tension & disputes, wider threat of communism*)



ILSI
Southeast
Asia Region

ASEAN Development

- Expansion of membership: Brunei (1984), Vietnam (1995), Lao PDR & Myanmar (1997), Cambodia (1999)
- As ASEAN 'matures', shift from **security** towards **economic** focus
- Move from regional **cooperation** towards regional **integration** objective
- ASEAN Free Trade Area (AFTA) (1992), realized in 2010 for ASEAN -6
- Formalization of ASEAN through **ASEAN Charter** in 2008
- Towards **ASEAN Community** 2015 -> comprising 1) **ASEAN Security Community**
2) **ASEAN Socio-Cultural Community** & 3) **ASEAN Economic Community**



ASEAN Today

- 10 Member States with a combined total population of 600 million
- Rapidly growing economic region:

Country	2012 Real GDP Growth Rate (%)
Brunei Darussalam	2.7
Cambodia	6.5
Indonesia	6.0
Lao PDR	8.3
Malaysia	4.4
Myanmar	6.2
Philippines	4.8
Singapore	2.1
Thailand	5.6
Vietnam	5.1



(Source: CIA World Fact Book)

ASEAN Economic Community (AEC)

- One of the pillars of the ASEAN Community to be established by 2015

- Objectives of the AEC, to be:

- 1) A single market and production base;
- 2) A highly competitive economic region;
- 3) A region of equitable economic development; and
- 4) A region fully integrated into the global economy

- Aim to make AEC a region with **free movement of goods**, services, investment, skilled labour and freer flow of capital, through cooperation on human resource development, enhancing infrastructure and communications connectivity, **integrating industries across the region** & **enhancing private sector involvement**, etc.



ASEAN Guiding Principles

- Guiding principles of ASEAN since its foundation:

- 1) respect for independence, sovereignty & equality
- 2) non-aggression & peaceful settlement of disputes
- 3) non-interference in internal affairs
- 4) consultation & consensus

- Collectively known as “The ASEAN Way”

- These principles are enshrined in the ASEAN Charter
(therefore they are not likely to change in the foreseeable future)



Differences between ASEAN & EU economic integration

ASEAN	EU
Established post-WW II & de-colonization period with focus on security cooperation at the beginning and only later on economic integration	Established post-WW II with economic integration agenda from the beginning
Relations-based decision making through informal discussions between leaders	Rules-based decision making through formal negotiations between leaders
ASEC is purely an administrative institution	EC has mandate to initiate EU legislation
Voluntary adoption of rules based on national processes	Mandatory adoption of EU legislation once issued
No cases brought up for dispute settlement	Dispute settlements have helped spur harmonization



Harmonization of Food Standards in ASEAN

- Harmonization of ASEAN food standards led by the [ASEAN Consultative Committee on Standards and Quality \(ACCSQ\) Prepared Foodstuff Product Working Group \(PFPWG\)](#) through:
 - a) Mutual Recognition Arrangements for inspection & certification procedures (based on Codex Alimentarius guidelines)
 - b) Adoption of ASEAN harmonized technical standards or Codex standards (e.g. labeling, food additives, contaminants, contact materials, etc.)

- Capacity building efforts to strengthen ASEAN food control systems & infrastructures led by the [ASEAN Expert Group on Food Safety \(AEGFS\)](#), through [ASEAN Food Safety Improvement Plan \(AFSIP\)](#) on areas including:
 - a) Risk assessment
 - b) Laboratory capacity
 - c) Risk communication
 - d) Consumer education
 - e) Food safety legislation
 - f) Inspection & certification

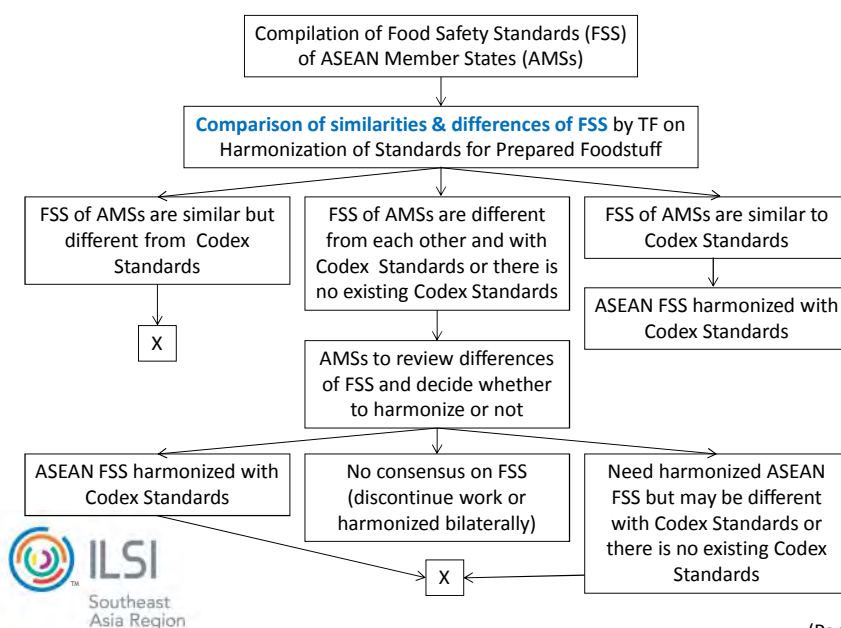


Science as a Basis for Harmonization of ASEAN Food Standards and Controls

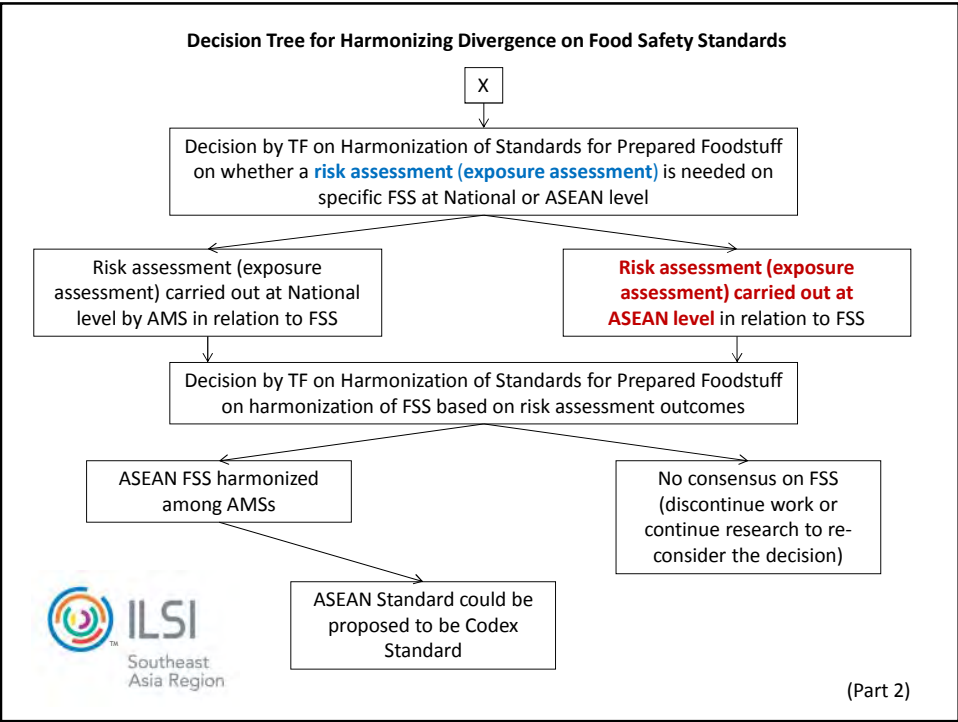
- There is general agreement among ASEAN food safety authorities to use risk assessment as a basis for food safety standards harmonization when clear agreement is not possible (ref: PFPWG Decision Tree)
- However, lack of scientific capacity, data & infrastructure in the region leave gaps to be filled and acts as barrier in applying science-based decision making



Decision Tree for Harmonizing Divergence on Food Safety Standards



(Part 1)



Food Additive Standards in ASEAN

- Each ASEAN country has specific regulatory bodies responsible for control of use of food additives:

Country	Regulatory Body
Brunei Darussalam	Food Safety & Quality Control Division, Ministry of Health
Cambodia	Department of Drug and Food, Ministry of Health; CAMCONTROL
Indonesia	Ministry of Health; National Agency for Drug and Food Control
Lao PDR	Food and Drug Department, Ministry of Health
Malaysia	Food Safety & Quality Division, Ministry of Health
Myanmar	Food and Drug Administration
Philippines	Food and Drug Administration
Singapore	Agri-Food & Veterinary Authority
Thailand	Food and Drug Administration
Vietnam	Vietnam Food Administration



Food Additive Standards in ASEAN

- Most ASEAN countries have regulations that control use of food additives:

Country	Regulatory Body
Brunei Darussalam	Public Health (Food) Regulations
Cambodia	NA
Indonesia	Minister of Health Regulation No. 33 of 2012 on Food Additives
Lao PDR	Decision on the Control on Production, Exportation-Importation of Food No. 856/MoH
Malaysia	Food Regulations 1985
Myanmar	NA
Philippines	AO No. 88As. 1984 on Regulatory Guidelines Concerning Food Additives; FDA Circular No. 2006-016 on Updated List of Food Additives
Singapore	Food Regulations
Thailand	Notification of the Minister of Public Health No. 281 B.E. 2547 (2004) on Food Additives
Vietnam	Minister of Health Decision No. 3742/2001/QĐ-BYT on List of Additives Permitted for Use in Food



Harmonization of Food Additive Standards in ASEAN

- Current harmonization of food standards, including for food additives, at ASEAN-level is based on 'vertical' approach (by commodity) rather than 'horizontal' approach, for e.g.

Step 1: selection of food category to be harmonized for food additives & contaminants (e.g. confectionary)

Step 2: identification of differences in food additive & contaminant standards for the food category

Step 3: agreement among TF on Harmonization of Standards for Prepared Foodstuff which food additives and/or contaminants to be harmonized according to PFPWG Decision Tree



ILSI SEAR'S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

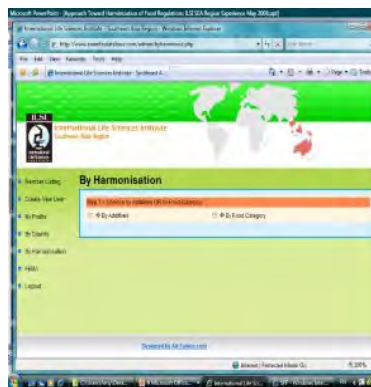
1) ASEAN Food Safety Standards Harmonization Workshop Series

- Organized workshop series with food safety authorities from AMSs since 2001:
 - initially started with FAO & WHO to determine whether possible for AMSs to harmonize food safety standards with Codex Standards, focusing on food additives
 - serves as a platform for different stakeholders (government, academia & industry) to discuss and share scientific issues and identify capacity gaps that are relevant to food safety standards harmonization
- Main recommendations/outcomes/outputs in 2012:
 - **ASEAN Food Safety Standards Database**
 - ASEAN Risk Profiles for Contaminants (*in progress*)
 - Case Studies on Food Descriptions Used in Contaminant Standards of AMSs (*in progress*)



ASEAN Food Safety Standards Database

- In 2003, ILSI Southeast Asia Region developed a pilot database to support work on harmonization of food additive standards by ASEAN countries
- Includes information on food additive standards:
 - 45 selected additives (preservatives, sweeteners & colours)
 - includes data from 10 ASEAN countries
 - food categorization based on Codex General Standard for Food Additives



ASEAN Food Safety Standards Database

Timeline	Activity
Jan 2011	Decision to hand over AFSSD to ACCSQ PFPWG at 9 th ASEAN Food Safety Standards Harmonization Workshop
Feb 2011 - Dec 2011	Revamping and upgrading of AFSSD to meet current technical needs for food safety standards harmonization
Feb 2012	Shared at 10 th ASEAN Food Safety Standards Harmonization Workshop
June 2012	Shared at 15 th ACCSQ PFPWG and adopted by ACCSQ PFPWG for their use in the work on food safety standards harmonization



Website: www.aseanfssdatabase.com

Members
Database Search
Profiles
Administrators
GSFA Codex *
GSFA Categories *
Additives Manager *

Members Login
Hi Super User,
[Log out](#)

About the ASEAN Food Safety Standards Database

ILSI
Southeast Asia Region

The ASEAN Food Safety Standards Database is an initiative of the Working Group on ASEAN Food Safety Standards Harmonization.

The Working Group on ASEAN Food Safety Standards Harmonization consists of government authorities from Southeast Asian countries that make up the Association of Southeast Asian Nations (ASEAN), as well as regional and academic stakeholders. The main objective of the Working Group is to identify ways to harmonize food safety standards among ASEAN countries so that they are aligned with international standards whenever possible, such as Codex Alimentarius. Members of the Working Group meet annually to discuss harmonization efforts at the ASEAN Food Safety Standards Harmonization Workshop, which is facilitated by the International Life Sciences Institute (ILSI) Southeast Asia Region.

Currently, the ASEAN Food Safety Standards Database contains information on food additive standards in the ten ASEAN countries.

Participating Countries

- Brunei Darussalam
- Indonesia
- Malaysia
- Philippines
- Thailand
- Cambodia
- Laos
- Myanmar
- Singapore
- Vietnam

Disclaimer

(C) 2012 International Life Sciences Institute - ASEAN Food Safety Standards Database
Disclaimer: This database is made available solely for the purpose of information. It has no legal value. Users are

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ILSI ASEAN Food Safety Standards Database
International Life Sciences Institute
Southeast Asia Region

Members
Database Search
Profiles
Members Login
Hi demo, Logout

Search
[PLACEHOLDER TEXT]: Describe the search function here

Additives
[- ACIDITY REGULATOR -]
Acetic acid, glacial
Ammonium acetate
Ammonium carbonate
Ammonium dihydrogen phosphate
Ammonium hydrogen carbonate
Ammonium hydroxide
Ammonium lactate
Ascorbic acid, L-
Calcium acetate
Calcium carbonate
Calcium dihydrogen diphosphate
Calcium gluconate
Calcium hydrogen phosphate
Calcium hydroxide
Calcium lactate
Calcium malate, DL-
Calcium oxide
Calcium polyphosphate
Carrauba wax
Citric acid
Diammonium hydrogen phosphate
Dicalcium diphosphate
Dipotassium dihydrogen phosphate
Dipotassium tartrate
Disodium dihydrogen phosphate
Disodium diphosphate
Fumaric acid
Glucose delta-lactone
Hydrochloric acid
L(+)-Tartaric acid
Lactic acid, L-, D-, DL-

Food Categories
01.0.0.0 - DAIRY PRODUCTS AND ANALOGUES, EXCLUDING...
01.1.0.0 - MILK and dairy-based drinks
01.1.1.0 - MILK AND BUTTERMILK (PLAIN)
01.1.1.1 - Milk (plain)
01.1.1.2 - Buttermilk (plain)
01.1.2.0 - DAIRY-BASED DRINKS, FLAVOURED AND/OR FER...
01.2.0.0 - Fermented and renneted milk products (plain), exc...
01.2.1.0 - FERMENTED MILKS (PLAIN)
01.2.1.1 - Fermented milks (plain), not heat-treated after fe...
01.2.1.2 - Fermented milks (plain), heat-treated after ferme...
01.2.2.0 - RENNETED MILK (PLAIN)
01.3.0.0 - Condensed milk and analogues (plain)
01.3.1.0 - CONDENSED MILK (PLAIN)
01.3.2.0 - BEVERAGE WHITENERS
01.4.0.0 - Cream (plain) and the like
01.4.1.0 - PASTEURIZED CREAM (PLAIN)
01.4.2.0 - STERILIZED AND LIGHT CREAMS, WHIPPING CRY...

Countries
Brunei
Cambodia
Indonesia
Laos
Malaysia
Myanmar
Philippines
Singapore
Thailand
Vietnam
Select All | Unselect All

Select food additive
Organized according to functional classes
Select food category
Select country

Search

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ILSI ASEAN Food Safety Standards Database
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Members
Database Search
Profiles
Members Login
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Search
Search Criteria
Food Categories: ALL
Additive/Substance: Preservative/Benzoates
Countries: ALL

Legend
GCSFA Value
Green: All GCSFA
Red: Not GCSFA
Green: Not GCSFA
Green: Not GCSFA
Orange: Harmonized with GCSFA
White: Harmonized with GCSFA (partial countries)

Results

Food No./Description	GCSFA (Code) (100-199)	Brunei	Cambodia	Indonesia	Laos	Malaysia	Myanmar	Philippines	Singapore	Thailand
01.0.0.0 DAIRY PRODUCTS AND ANALOGUES, EXCLUDING PRODUCTS OF FOOD CATEGORY 02.0	100 ppm	200 ppm (+10ppm)	60 ppm (-40ppm)	90 ppm (-10ppm)	200 ppm (+10ppm)	60 ppm (-40ppm)	NP	NP	NP	NP
01.1.0.0 Milk and dairy-based drinks	50 ppm	60 ppm (+10ppm)	60 ppm (+10ppm)	60 ppm (+10ppm)	60 ppm (+10ppm)	60 ppm (+10ppm)	60 ppm (+10ppm)	60 ppm (+10ppm)	NP	60 ppm (+10ppm)
01.1.1.0 MILK AND BUTTERMILK (PLAIN)	NP	80 ppm	80 ppm	80 ppm	80 ppm	80 ppm	80 ppm	80 ppm	NP	80 ppm
01.1.1.1 Milk (plain)	NP	NP	NP	NP	NP	80 ppm	NP	NP	NP	NP
01.1.1.2 Buttermilk (plain)	NP	NP	NP	NP	NP	80 ppm	NP	NP	NP	NP
01.1.2.0 DAIRY-BASED DRINKS, FLAVOURED AND/OR FERMENTED (e.g., ...)	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP

Indicates specific notes/conditions of use (roll over to reveal)

Red indicates all countries not harmonized with GCSFA
Blue indicates some (not all) countries harmonized with GCSFA
Green indicates all countries harmonized with GCSFA

Arrows to indicate whether lower or higher than GCSFA value

Management of the Database

- **Administrator (ILSI Southeast Asia Region):**
 - Update values for GSFA additives when changes occur at CCFA
 - Update GSFA food categories when changes occur at CCFA
 - Update database to include new food additives (if any)
 - Maintenance and further upgrading of the database software
 - Pay for the web hosting of the database
 - Administer user access to the database (report to ACCSQ PFPWG on list of users, see who has accessed it and from where)
- **Moderators (ASEAN Focal Points):**
 - Modify national data for own country
 - Able to add country-specific custom categories
 - Not able to modify another country's data



Current Status of the Database

- Population of data for Codex GSFA has been completed
- Collection of data on national food additive standards via identified National Focal Points, starting with 'priority' food additives (e.g. **colours**, **preservatives**, **sweeteners**)
- Data collected from AMSs on **colours** as of Dec 2012
- Second template on **preservatives** sent out via ASEC to AMSs in Jan 2013
- Decision regarding opening of database to wider audience to be decided by ACCSQ PFPWG (AMSs are generally supportive when the timing is appropriate)



ILSI SEAR'S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

2) Training Workshops on Risk Assessment of Food Additives

- Organized in Philippines (February 24, 2012) and Thailand (February 27, 2012) for national food safety authorities and risk assessors
- Discussed topics including general principles for risk assessment of food additives, exposure assessment and provided specific case studies on steviol glycosides, etc.

2) ASEAN Food Consumption Data and Exposure Assessment Workshop

- Organized in Malaysia (October 10-13, 24, 2012) inviting food consumption data experts and risk assessors from all ASEAN countries
- Discussed development of harmonized food consumption data among ASEAN countries for use in exposure assessment, including for during approval of food additives



ILSI SEAR'S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

- ILSI SEAR seeks to continue playing a role in supporting ASEAN efforts in harmonization of food safety based on scientific principles and evidence
- This may be achieved through:
 - sharing of latest scientific information and technical knowledge on identified and emerging food safety concerns
 - helping to develop and build capacity in relation to food safety and risk assessment infrastructures within ASEAN (e.g. ASEAN Food Safety Standards Database, ASEAN Risk Profiles, ASEAN Food Consumption Data, etc.)
- Nevertheless, harmonization of food safety standards in ASEAN will be a long and challenging process





Thank you

Website: www.ilsis.org/SEA_Region

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Scientific Program Manager
ILSI Southeast Asia Region
E-mail: kengngtee@ilsisea.org.sg



<u>MARKET FOR PROCESSED FOODS</u>	
GLOBAL MARKET	¥ 400 trillion
GLOBAL EXPORTS	¥ 24 trillion
INDIAN MARKET	¥ 7.7 trillion
INDIA'S EXPORTS	¥ 600 billion

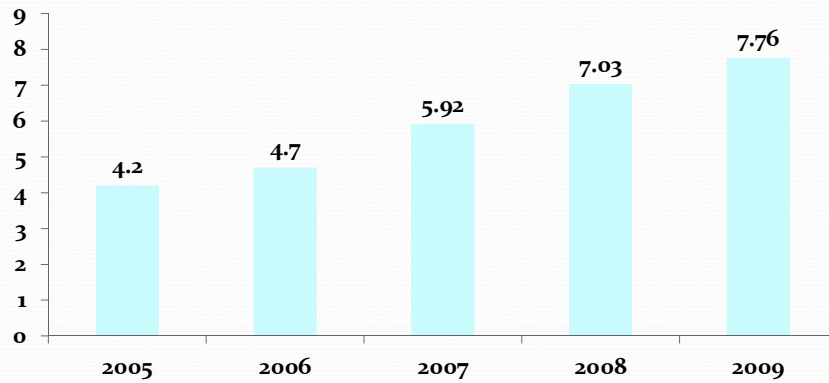
PROCESSING OF AGRICULTURAL PRODUCTION

Malaysia	80
Philippines	78
Brazil	70
China	40
Thailand	30
India	20

PRODUCTION OF SELECT AGRICULTURAL COMMODITIES

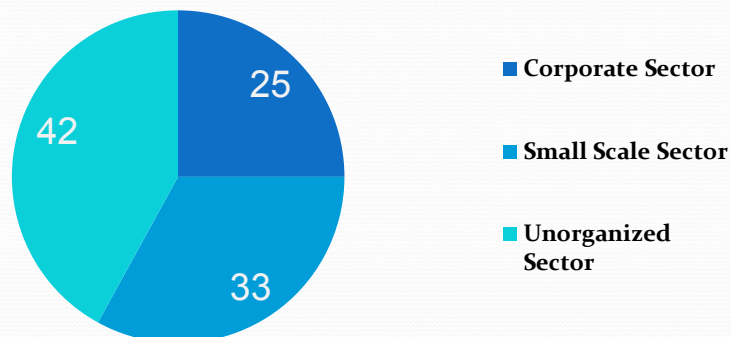
Fruits	80 mil tons
Vegetables	140 mil tons
Milk	115 mil tons
Fish	8 mil tons
Poultry	0.8 mil tons
Eggs	60 billion
Food grains	250 mil tonnes

GROWTH OF FOOD PROCESSING INDUSTRY (In Trillion Yen)

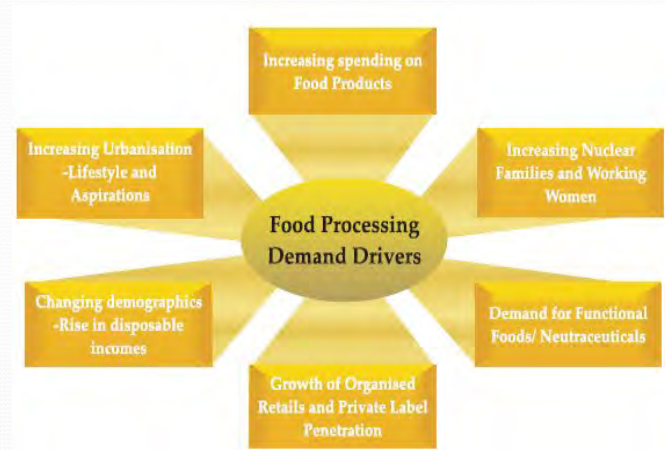


SECTORWISE SHARE IN FOOD INDUSTRY

Share (%)



DRIVERS OF DEMAND FOR PROCESSED FOODS



MARKET SIZE OF CORPORATE SECTOR IN PROCESSED FOODS 2010-11

Food	Japanese Yen
Milk Powder and Condensed Milk	58.5 billion
Infant Milk Products	59 billion
Malted Milk Foods	62.8 billion
Ice-cream	21 billion
Flour Milling	215.6 billion
Biscuits	217 billion
Bread	13.3 billion
Breakfast Cereals	1.6 billion

Food	Japanese Yen
Wafer and Potato Chips	29 billion
Fruits Juices	36.1billion
Sauces/Ketchups/jams	17.4 billion
Sugar	1.03 trillion
Confectionery	134 billion
Vegetable Oil	1.8 trillion
Soya Products	339.5 billion
Poultry Products	116.9 billion
Marine Products	1.56 trillion
Soft Drinks	227 billion

味の素(株)のインドにおける事業展開
Business Expansion of Ajinomoto
Co., Inc. in India

2013年2月22日
February 22, 2013

味の素(株) 濱野勝男
Ajinomoto Co. Inc., Katsuo Hamano

1

サブタイトル
Sub title

- うまみ調味料「味の素」の普及と
インドビジネスの可能性
Activities to promote Umami
seasoning “AJI-NO-MOTO” and
Business potentiality in India

2

目次

Contents

1. うまみ調味料「味の素」の普及

Promoting Umami seasoning “AJI-NO-MOTO”

- インド味の素社の成り立ちと立ち上げ期
Business history of Ajinomoto India Pvt. Ltd.
- リテイル営業の開始
Starting sales activity for retail market
- リテイル営業の進化
Developing sales activity for retail market

3

2. 今後のインドビジネスの可能性

Business potentiality in India

- 魅力あるインド市場、人材
Promising market and manpower
- 日本人の人材に求められること
Necessities for human resource from
Japanese business person

4

1. うまみ調味料「味の素」の普及

Promoting Umami seasoning “AJI-NO-MOTO”



5

インド味の素社の成り立ちと立ち上げ期

Business history of Ajinomoto India Pvt. Ltd.

- 2003年タミルナドゥ州チェンナイ市内に設立
AIPL was established in Chennai city of Tamil Nadu in Y2003
- 味の素(株)とタイ味の素(株)が出資
Investor: Ajinomoto (Tokyo and Thailand)
- MSGを輸入し、リパック工場にて製造、販売
AIPL imports MSG, repacks it as small size and sells in all over India

6

- 社長はインド人、取締役は日本人
Managing director is Indian, director is Japanese
- 従業員は約300名(含む契約社員)
The number of employee is around 300 including ISR, factory worker
- 2005年の洪水で事務所移転、2011年の事務所内床の沈下により再度移転(2度の被害に遭う)
AIPL transferred office and factory at 2 times by calamity such as flood in Y2005 and subsidence of office floor in Y2011



7

リテイル営業の開始 Starting sales activity for retail market

- 創立以来外食用品種を発売。2005年よりリテイル品種(小袋サイズ)の「味の素」の販売を開始し、2007年より本格的にエリアを拡大。

AIPL launched “AJI-NO-MOTO” 500g for food service since 2003, and started sales of small size of “AJI-NO-MOTO” in Y2005, and then accelerated area expansion in Y2007



8

- 味の素リテイルウェイの浸透のため、営業同行、営業研修とOJTを強化

In order to make sales person understand “Ajinomoto Retail Way”, I focused on OJT (On the Job Training) by going retail market together and doing sales seminar



Going together



Attaching sticker



Sales seminar

9

- PUSH型からPULL型営業へ変更

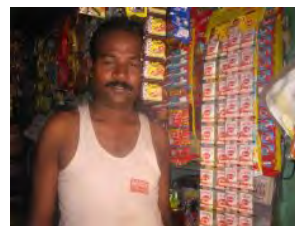
Changed sales stile from “PUSH-selling” to “PULL selling”

cf. 理由

- ・返品防止
- ・売掛金の防止
- ・店頭での新鮮な商品

Reason:

- Avoid return goods
- Avoid Account Receivables
- Maintain fresh product at retailer



10

- 店頭での在庫消化のため、営業活動の中に販促/普及活動を組み込む

In order to improve off-take at retail counter, we emphasized sales promotion activity in sales person mind



Caravan activity

In-shop activity

Sampling

11

- キーメニューを“ラッサム”に特化し、消費者への普及を図る

We focused on “Rasam” soup as a key menu and tried its penetration to consumer



Veg-Meals in South India



Rasam soup

12

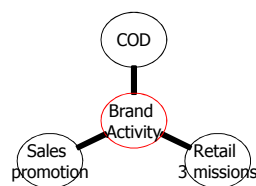
リテイル営業の進化

Developing sales activity for retail market

- "ブランド活動" を中核とした営業活動への変更
We changed from sales activity into "Brand Activity" as a core activity

例) 評価項目・販促活動を変更

Ex. Changed evaluation point and sales promotion activity



Manner	Discipline	Principle	Evaluation by customer	Sales Control
Brand Activity				

13

- 売掛金の大幅(70%)削減とフォーム(州税)の回収
Reduced 70% of Account Receivables and trying to collect forms (f-form, c-form)
- 卸店経由の販売から自社デポ直販方式へ変更中
Changing sales system from distributor to own depot by direct sales

14

- 新商品「Hapima」(スパイスミックス)を発売し、南インドを中心に販売中

We launched “Hapima” masala and are selling in south India



15

2. 今後のインドビジネスの可能性 Business potentiality in India



16

魅力あるインド市場、人材 Promising market and manpower

- 11億人の巨大な人口(胃袋)
A large number (1.1 billion) of population (stomach)
- 家計所得増/簡便化/品質志向によるFMCGへ購買が増加
Increasing purchase of FMCG (Fast Moving Consumer Goods) by income increase, simplification and quality-oriented

17

- 教育水準の向上による優秀な人材の増加
Increasing the number of talented people by upgrading the standard level of education
- 一方で、就業経験のある人材の離職率が増加
On the other hand, it is increasing a job separation rate of manpower who have an experience of working in other company

18

日本人の人材に求められること Necessities for human resource from Japanese business person

- 新興国で何をすべきか
What do we have to do in an newly emerging countries?
- 現地の消費者の幸福に貢献する新たな価値の提供
Producing a new value which will contribute to happy life
of consumer in each countries
- ブランドを育てる(ファンを増やす)
Creating and raising brand (increasing fans)
- 人を育てる(自分の分身を作る)
Training human resource (as the other self)
- 元気な会社にする
Making our company be active

19

これによって、
By these necessities,

- 売上と利益をあげる
We will increase net sales and profit
- 社会に貢献する(納税、雇用)
We will contribute to society in those countries
(tax payment and employment)

20

- 求められる人材像

Required person

- サバイバルができる人
Survive in the tough situation
- 人が好きでコミュニケーションできる人
Like people and good communication
- 胃袋が強い人
Strong stomach
- 熱く語れる人(信念、ビジョン)
Talk about faith and vision earnestly
- 即断即決即実践、率先垂範できる人
Decide promptly, take the initiative and set a good example for others
- 現場によく足を運び現場発想ができる人
Go to field market frequently and think by field-oriented
- 経験・勘・度胸のある人
Well-experienced, Intuition and Boldness
- 人と金をマネジメントできる人
Manage people and money

21

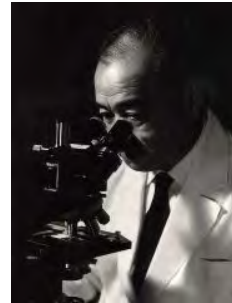
ご清聴ありがとうございました

Thank you very much!



22

ヤクルトの国際事業



2013年2月22日
(株)ヤクルト本社国際事業本部
理事 赤星 良一

Yakult

Yakult

- ヤクルト菌の誕生
- 代田稔博士の願い
- 国際事業への進出と展開
- インドコルカタ大規模臨床試験
- マイクロビオタ・プロバイオティクス科学財団設立
- ヤクルト菌の普及と健康の輪
- YL組織の構築と女性労働市場の創出

ヤクルトの生い立ち

- ・ 1899年 代田稔 長野県上田市に生まれる
- ・ 栄養失調と感染症によって多くの友人が亡くなっていく
- ・ 三高から京都帝大医学部に進学
- ・ 研究目標を赤痢やコレラ等の感染症の菌を殺すから感染しにくい体にするに変更
- ・ 治療医学から予防医学に
- ・ コレクションの中から、乳酸菌に効果があることを発見
- ・ 1930年 乳酸菌の強化培養(胃液、胆汁液)に成功



[F:¥DrShirotaShort2.mpg](#)

ヤクルト誕生

- ・ 1935年 シロタ株をヤクルトの商標で発売
- ・ 代田保護菌普及会の使命は「**世界の人々の健康を守る**」



- ・ 代田稔博士の哲学
「予防医学」
「健腸長寿」
「誰もが手に入れられる価格で」

国際事業の変遷

第1段階 求められて

- 1964年 台湾
- 1968年 ブラジル
- 1969年 香港
- 1971年 タイ
- 1971年 韓国
- 1978年 フィリピン
- 1979年 シンガポール
- 1981年 メキシコ



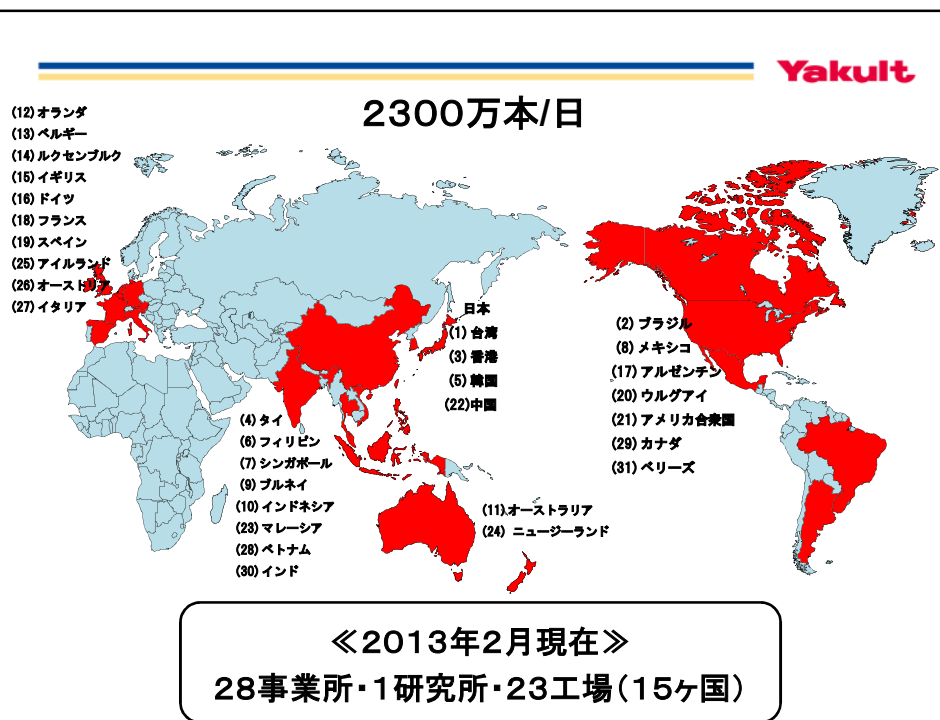
第2段階 積極的な戦略を持って

- 1991年 インドネシア
- 1994年 オーストラリア
- 1994年 オランダ
- 1995年 ベルギー
- 1996年 イギリス
- 1996年 ドイツ
- 1997年 アルゼンチン



第3段階 人口大国での基盤作りとビジネスモデルの拡大

- 2002年 中国
- 2004年 マレーシア
- 2005年 オーストリア
- 2005年 イタリア
- 2007年 アメリカ
- 2007年 ベトナム
- 2008年 インド



岡山大学インド感染症共同研究センター



平成17~18年度に日本政府が建設したNICEDの研究棟

岡山大学インド感染症共同研究センター



竹田美文



G. B. Nair

プロバイオティクスは腸管感染症を 予防することができるか

大規模無作為二重盲検試験

- ・調査地域: **コルカタ市**
- ・調査対象: **1～5歳の乳幼児 約4,000人**
- ・試験品: **乳酸菌シロタ株飲料**



飲用サンプルの冷蔵輸送(ヨーロッパヤクルト ⇒ Niced)

Yakult

(製造後1 ~ 3)

ヨーロッパ工場 (オランダ) ⇒ 出荷

[E:ヤクルト試験.mpg](#)

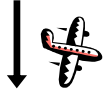


アムステルダム空港 ⇒ 保冷コンテナに積替え・輸出通関



(製造後 4)

フランクフルト空港 ⇒ ルフトハンザ航空にてコルカタへ



(製造後 5)

インド・コルカタ空港 ⇒ コルカタ空港着

⇒ 輸入通関後、冷蔵トラックへ積込・配送



(製造後 6)

Niced ⇒ 引渡 (土曜日AM6:00)

Yakult

2つの経営方針

• 農耕型経営

「畑を耕し、種を蒔き、辛抱強く水を遣り、品種改良を続け、長い期間を経た末に漸く収穫期を迎える」「この収穫で新たな畑を耕す」

• 使命型経営

「代田保護菌普及会」が「世界の人々の健康を守る」という代田博士と同じ使命感を持ってヤクルトの普及に努める

2008年 インド工場竣工



マイクロビオタ・
プロバイオティック科学財団

Yakult



Yakult

ヤクルトレディの育成



Yakult

キラナショップ



宅配



スーパーマーケット



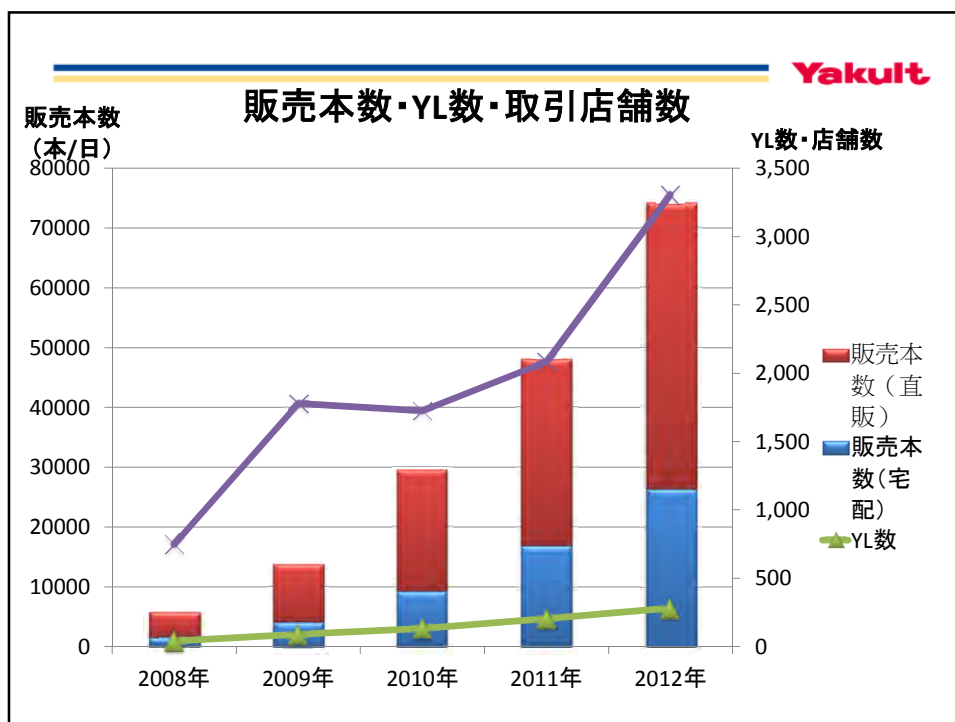
ホテル



- 05年 現地法人設立
- 06年 工場着工
(デリー郊外のライ)
- 08年 工場稼働、生産開始
デリーにて販売開始
- 09年 ムンバイにて販売開始
- 10年 バンガロールにて販売開始
- 12年 ハイデラバードにて販売開始
- 12年 チェンナイにて販売開始
- 13年 コルカタ等へ市場拡大を検討

進出都市 ⇒ ○

進出予定都市 ⇒ ○



Yakult

インドにおける社員数推移

(単位: 人)

部門	2008年	2009年	2010年	2011年	2012年	
人事・総務・ 経理・購買	8	11	11	11	17	
営業	宅配部門	26	32	36	56	69
	直販部門	14	25	28	22	29
	その他	1	2	0	0	0
	小計	41	59	64	78	98
学術広報	3	4	3	3	4	
工場	39	27	27	27	31	
合計	91	101	105	119	150	

※12月末時点の数値。

