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)]	● 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)]	● 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		● The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003
	Agriculture		● Agricultural Produce (Grading and Marking) Act, 1937

			● The General Grading and Marking Rules, 1988
	Food Processing Industries		● (The origin of the existing "Food Safety and Standards Act, 2006" was proposed by this Ministry.)
Atomic Energy Commission		DAE[(d)]	● The Atomic Energy Act, 1962
		AERB[(e)]	● 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.

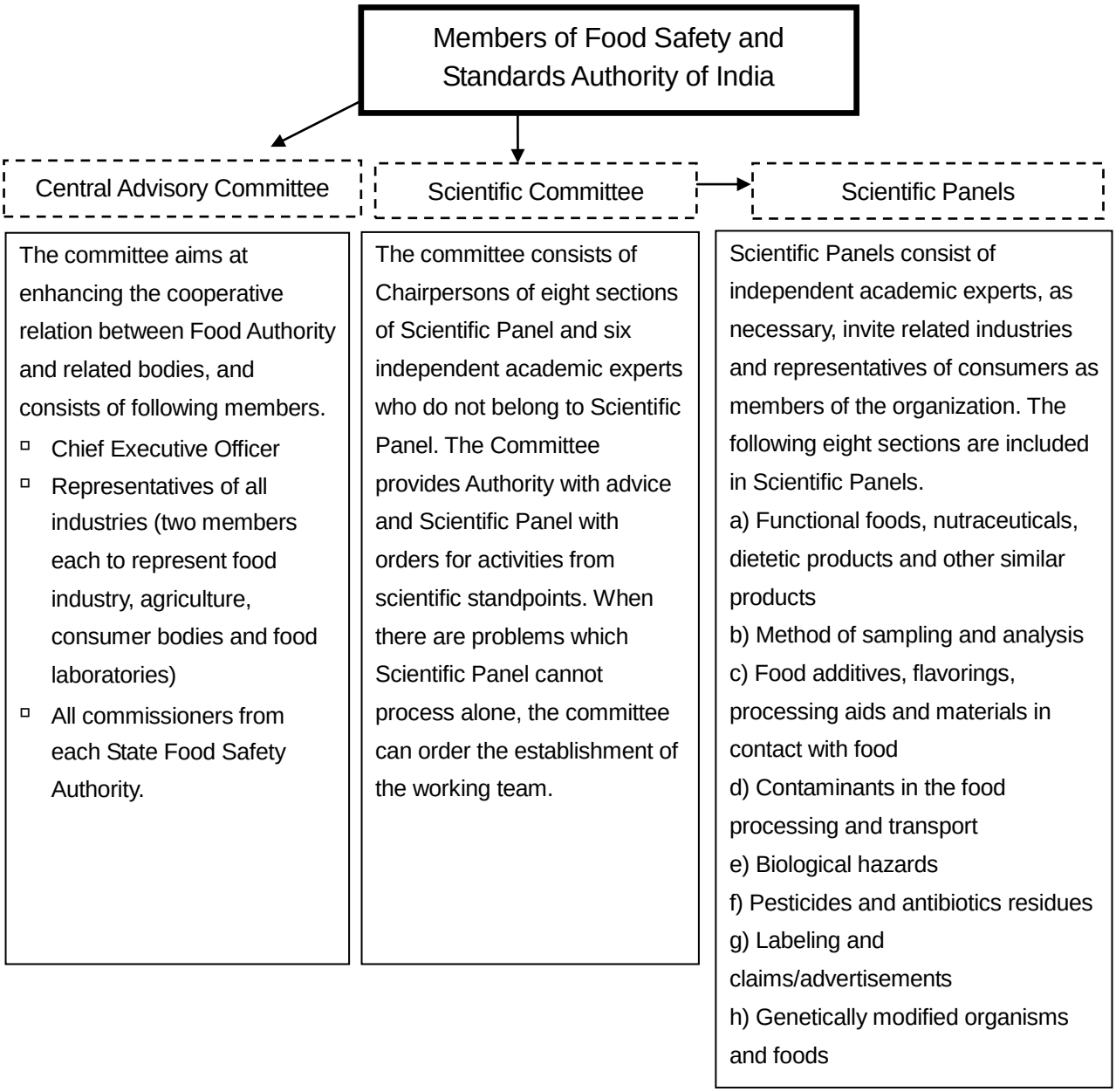

Figure 1: Outline of Food Safety and Standards Authority of India

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.

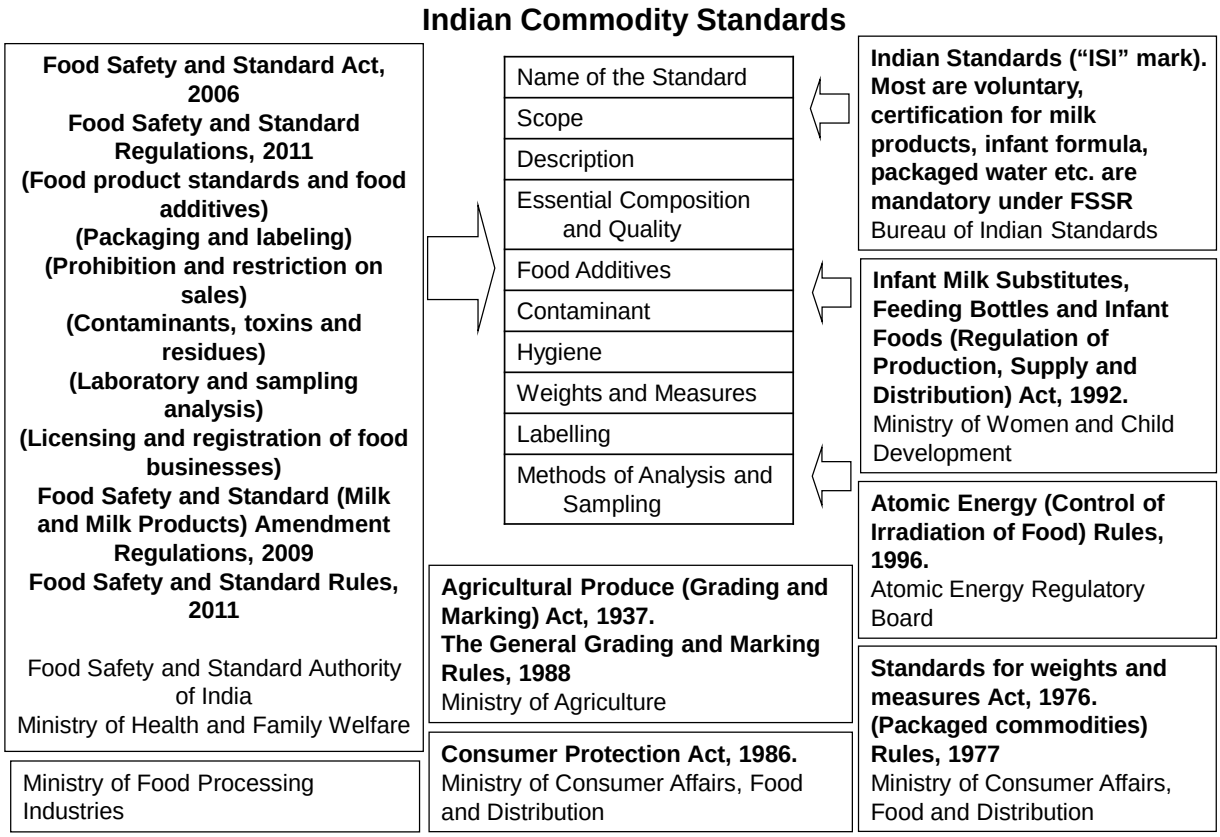

Figure 2: Summary of Food Standards and Relevant Laws in India

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)

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	IS 2346: 1992 Carbonated Beverages Specifications IS 12544: 1988 Carbonated Beverages - Non-alcoholic Beer - Specifications
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 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**

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)	Titratable 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 (*Eleusine coracana Gaertn*)	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. Chilies 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)**

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 Orthophenylphenol and Sodium orthophenylphenate	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 glaced 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 Ponceau 4R (Food Red 102) Erythrosine (Food Red 3)	14720 16255 45430	122 124 127
Yellow	Sunset Yellow FCF (Food Yellow 5) Tartrazine (Food Yellow 4)	15985 19140	110 102
Blue	Indigo Carmine (Food Blue 2) Brilliant Blue FCF (Food Blue 1)	73015 42090	132 133
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	Chlorophyl	75810
150b	Caramel	
160a	Carotenes (alpha, beta or gamma)	75130
160b	Annatto	75120
160c	Capsanthin or capsorubin	
160d	Lycopene	75125
160e	Beta-apo-8'-cartenal 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-phenylglicidate;
xi) Eugenol methyl ether;
xii) Methyl napthyl 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 BSLS 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	Dioctyl sodium sulfosuccinate	10 mg

5.2.6 *Foaming Agents*

999(i)	Quillaia extract type I	50 mg

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

Sl 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

Sl 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_{12}	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

Sl No.(1)	**Heavy metal (2)**	**Limit (3)**	**Method of test (4)**
i)	Arsenic, (as As), mg/l, max.	0.01	Appendix G
ii)	Cadmium, 9as 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 lines 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
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. **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. **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. **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. **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. **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 63^0C and not more than 65^0 C and held continuously at that temperature for at least 30 minutes or heated to at least 71.5^0 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 4^0C and kept at a temperature of not more than 10^0C until sale. Pasteurized milk shall, when subjected to the reductase test, not completely decolourize any methylene blue solution in less than 2½ hours. **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 100^0 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. **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 135^o- 150^oC for not less than 4 seconds and then be filled and sealed aseptically into sterile containers. **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. **10. Recombined Milk** Recombined Milk means the product prepared from the constituents of milk combined with water or

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.

Annex 1

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

Annex 2

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 THRERTO

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, neutraceuticals, 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	MoI
Nepal Standards (Certification mark) Rules 1983 NBSM	MoI
Standard weights and Measures Act 1968 NBSM	MoI
Standard weights and Measure Rules 1978 NBSM	MoI
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.
MoI: 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 factions 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 glace 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, *Gur* and *Khandsari* 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, *Palungo*, *Salgam* etc.	 550 3000 2000	
23.	Dried Ginger	2000	
24.	Processed meat (cooked picked) 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.

	Phosphorus	

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 conductive 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 confectionary, 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 %

- 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 perc ent
2.	Microbial count	
	(1) Total Plate Count	Not more than 1,000 per gram
	(2) *E. coli*	Absent in 25 gram
	(3) *Salmonella*	Absent in 25 gram
	(4) *Staphylococcus aureus*	Absent in 25 gram
	(5) *Clostridium perfringens*	Absent in 25 gram
	(6) *Clostridium botulinum*	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 35^0C for 10 days and 55^0C 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.

Annex- I

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	▫ Phytosanitary certificate for Import/Exported plants/plant products ▫ Pesticide Use Control ▫ Fertilizer Use Control
2	**Ministry of Food**	Directorate General of Food (DGF)	▫ 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.	▫ 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	▫ Fish Quality Control & Certification for export ▫ Same for the domestic market ▫ Animal Health ▫ Animal Product ▫ Imported Animal
6	**Ministry of Industries**	BSTI	▫ 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.

- **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

a) The common name,
b) The chemical name,
c) The net weight,
d) Adequate direction for use in accordance with the limits prescribed for such preservatives, and
e) 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 exceed 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:

a) The common name,
b) The chemical name,
c) The net weight,
d) Adequate directions for use in accordance with the limits prescribed for such preservatives, and
e) 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**

No	Foods	
47	**Food Grains**	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 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**	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.
49	**Wheat Flour or Maida**	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.
50	**Suji**	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.

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.

(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)