5. International Conference
on Regulatory Framework and Case Studies of Food and Food Additives
in India, Bangladesh, Nepal, and Sri Lanka
Regulatory Framework on Foods and Food Additives in India, Bangladesh, Nepal and Sri Lanka

Date: February 22, Friday, 2013  10:00-17:00
Place: KAIUN CLUB, 2F 2-6-4, Hirakawa-cho, Chiyoda-ku, Tokyo 102-0093 Japan (http://kaiunclub.org)
Organizer: International Life Sciences Institute, Japan (ILSI Japan), (http://www.ilsijapan.org)
Language: Japanese and English, Simultaneous Translation

Agenda

10:00-10:15  Opening Remark,  Shuichi Kimura, Chairman, ILSI Japan

Session 1:
10:15-10:40  Message from the Ministry of Agriculture, Forestry and Fisheries, Japan:
Ryosuke Ogawa, Counsellor for Export Promotion Division, Food Industry Affairs Division (MAFF)
10:40-11:15  Keynote Speech: Regulatory Framework on Food and Food Additives in India:
Pradip Kumar Chakraborty, Director (Zone/Product Approval), Food Safety and Standards Authority of India (FSSAI),
11:15-11:55  Introduction of the MAFF Overseas Business Support Project for Food Industry in East Asia by ILSI Japan
Hiroaki Hamano, Ryuji Yamaguchi, ILSI Japan

12:00-13:00  Lunch Break

Session 2:
13:00-13:40  Regulatory Framework on Foods and Food Additives in India,
Masanori Kohmura, Ajinomoto Co., Inc.
13:40-14:10  Laws and Regulations Relating to Foods in Sri Lanka, Bangladesh and Nepal
Rekha Sinha, Executive Director, ILSI India
14:10-14:50  Towards Harmonization of Food and Food Additive Standards in ASEAN
Teoh Keng Ngee, ILSI Southeast Asian Region

14:50-15:10  Refreshment (Coffee Break)
Session 3:
15:10-15:30  Market for Processed Foods in India
             D.H. Pai Panandiker, Chairman, ILSI India
15:30-16:00  Case Study 1: Business Expansion of Ajinomoto Co., Inc. in India
             Katsuo Hamano, Ajinomoto Co., Inc.
16:00-16:30  Case Study 2: International Business Operation of Yakult
             Ryoichi Akahoshi, Yakult Honsha Co., Ltd.

16:30-16:55  Q&A and General Discussions,

16:55-17:00  Closing,  Ryuji Yamaguchi, Executive Director, ILSI Japan
Introduction

- I would like to convey my sincere thanks to International Life Science Institute, Japan and India for conducting this International conference on “Regulatory Framework on Food and Food Additives in India, Bangladesh, Nepal and Sri Lanka”.

- With continuous innovation and research happening all over the world, a lot of new products and new ingredients can be seen coming into the food segment. A lot of food products imported into the country also contain ingredients as well as additives which are being introduced for the first time.
India has various food products in each state and food innovation is taking place at higher rate.

The consumer safety is of paramount importance. Main objective of Food Safety and Standards Authority of India is to ensure all products which are placed in the market are having appropriate safety. I hope all the speakers of the conference will give us adequate knowledge on regulatory framework on Food and Food Additives.

India has more than 10,000 food products in trade.

The Food Safety & Standards Regulation 2011 has given quality/safety specifications for nearly 330 products. Rest all products come under the category of Proprietary food.

The Food Safety and Standards Act was enacted in 2006 in India. There are as many as 101 sections in the Food Safety And Standards Act, 2006.

The Food Safety Rules & Regulations was implemented in India on 5th August, 2011. Before that, we had eight different Acts to regulate different types of food processing industries in the country. These are:

1) The Prevention of Food Adulteration Act, 1954
2) The Fruit Products Order, 1955
3) The Milk and Milk Products Order, 1992
4) The Meat Food Products Order, 1973
5) The vegetable Oil Products (Control ) Order, 1947
8) Any other order issued under the Essential Commodities Act, 1955 relating to Food.

All these eight acts have been repelled in India from 5th August, 2011 and replaced by a single Act, The Food Safety And Standards Act, 2006.

Under Section 4 of the FSS Act, 2006 Government of India established ‘Food Safety and Standards Authority of India’ to exercise the powers conferred on and to perform the functions assigned to it under this Act.

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**Constitution of FSSAI**

- The Food Safety and Standards Authority shall consist of a Chairperson and twenty-two members. There shall be a Chief Executive Officer of the Food Safety and Standards Authority, who shall be the legal representative of the Food Safety and Standards Authority and shall be responsible for the day to day administration of the Food Safety and Standards Authority.
The Food Safety and Standards Authority established eight scientific panels and one scientific committee.

The Food Safety and Standards Authority and State Food Safety Authorities shall monitor and verify that the relevant requirements of law are fulfilled by Food Business Operators at all stages of food business.

**Special points under FSS Act 2006**

- The unique thing in FSS Act, 2006 is Food Recall Procedures under Section 28.
- If a food business operator has reasons to believe that the food is not in compliance with this Act, or the rules or regulations, he/she shall immediately initiate procedure to withdraw the food from the market under the food recall procedure.
- There is a provision for emergency prohibition notices and orders under section 34 of this Act.
- Even the purchaser may have food analyzed under section 40 of this Act.
Provision for Penalty

- There are provisions relating to sub-standard food, misbranded food, food containing extraneous matter, food not of the nature or substance or quality demanded, unhygienic processing of food, possessing adulterant, unsafe food.
- Even there is provision relating to penalty for misleading advertisement. Degree of penalty ranges from INR 100,000 to 10,00,000.

- The Food Safety and Standards Rules, 2011 relates to enforcement structure and procedure, Adjudication and appeal to tribunal, various forms of appeal.
Important aspects of Food Safety and Standards Regulations, 2011

- Under the Food Safety and Standards Regulations, 2011 we have:

1) Licensing and Registration of Food Businesses Regulations.
2) Food Products Standards and Food Additives Regulations.
3) Packaging and Labeling Regulations.
4) Contaminants, Toxins and Residues Regulations.

5) Laboratory and Samples Analysis Regulations.
6) Prohibitions and Regulations on Sales Regulations.

Briefly, this is the regulatory framework on food in India. Detail Act, Rules and Regulations are available on our website: [www.fssai.gov.in](http://www.fssai.gov.in)
Salient Features of Food Additives

- Use of food additives in food products is a major area of concern for the regulatory authority in India.
- The food products may contain additives as specified in the regulation.
- Use of food additives in traditional Indian foods, coloring matter, artificial sweeteners, preservatives, anti-oxidants, emulsifying and stabilizing agents, antifoaming agents in edible oils and fats, use of release agents in confectionary, flavoring agents and related substances, flavor enhancers, sequestering and buffering agents.
Use of glycerol esters and wood resins, use of sucrose acetate Iso-butyrate, use of lactulose syrup, use of Dimethyl Dicarbonate and other substances to be used in specified limits have been elaborated in Food Additives Regulations.

Maximum permissible limit for the additives has been expressed mostly in parts per million i.e. mg/kg or in percentage % or in GMP.

Good Manufacturing Practices

Good Manufacturing Practices (GMP) means the food additives used under the following conditions namely:

1) The quantity of the additive added shall be limited to lowest possible level necessary to accomplish its desired effect.

2) The quantity of the additive becomes a component of food and not intended to accomplish any physical or other technical effect.

3) The additive is prepared and handled in the same way as a food ingredient.
Summary of list of Food Additives

Table 1:
- List of food additives for use in bread and biscuits have been specified in table 1 of the Food Additives Regulations.

Table 2:
- In table 2, permitted food additives for use in foods like snacks, sweets, instants mixes, rice and pulses based papads, ready to serve beverages, chewing gum, sugar based/sugar free confectionary, chocolates, synthetic syrup, lozenges, have been specified.

Table 3:
- In table 3, food additives in foods not specified in table 2 like dairy based drinks, soups, custard powder, sausage etc have been specified.

Table 4:
- In table 4, list of food additives for use in edible oils and fats have been specified.
Table 5:
- List of food additives for use in fish and fish products have been specified in table 5.

Table 6:
- List of food additives for use in thermally processed fruits have been specified in table 6.

Table 7:
- In table 7, list of food additives in thermally processed vegetables have been specified.

Table 8:
- In table 8, list of food additives for use in food products like tamarind pulp, synthetic syrups, tomato puree and vinegar have been specified.

Table 9:
- In table 9, list of food additives for use in food products like Murrubba, squashes, fruit/vegetable juice, pulp etc have been specified.
Table 10:
- In table 10, list of food additives used in food products like jam/jellies, fruit marmalades, fruit drink etc have been specified.

Table 11:
- In table 11, list of food additives used in food products like dates, dry fruits and nuts have been specified.

Table 12:
- In table 12, list of food additives for use in sugars and salts have been specified.

Table 13:
- In table 13, list of food additives for use in cocoa powder, chocolate, sugar boiled confectionary, chewing gum/bubble gum have been specified.
Table 14:

- In table 14, list of food additives for use in milk products have been specified.

Table 15:

- In table 15, use of food additives in individual variety cheeses have been specified.

- As many as 555 food additives with International Numbering System (INS) have been listed in the food additives regulations only for identifying the food additives and their synonyms as published by the codex on 23/11/2005 Codex.
- In spite of specifying so many additives in 15 tables, lots of additives have not been specified in Food Safety and Standards Regulations, 2011
- In the absence of list of additives, we follow table 3 of GSFA published by the codex.
- Regulations on foods for special dietary uses, functional foods, nutraceuticals, health supplements is under draft stage.
Nowadays, a lot of health supplements are being imported to India which contains a number of additives. We follow table 13.6 of GSFA which contains approved list of additives for health supplements.

**Conclusions**

- Food Safety and Standards Authority of India is in the process in reviewing various regulations including regulations for food additives
- However, harmonization with Codex Alimentarius Commission is under active consideration.
- We must have an uniform policy to permit food additives at least in Asian countries.
• Success of this conference lies on harmonization of food additives among India, Bangladesh, Sri Lanka and Nepal as food habits of the population of these countries are similar to some extent.
• This conference provides a platform where the representatives of these countries can interact amongst each other and coordinate the policies which will guide the future of the industry.
• It is a great honor and responsibility to be present in this conference and it is indeed a great learning chance for the participants by considering various perspectives offered by representatives of various countries.
農林水産省 東アジア食品産業海外展開支援事業

東アジアの食品等規格基準・分析方法等調査と結果の共有化（第I～IV期）

実施主体:
特定非営利活動法人 国際生命科学研究機構 (ILSI Japan http://www.ilsijapan.org)
国際協力委員会 浜野 弘昭

農林水産省 東アジア食品産業海外展開支援事業

〔趣旨〕: 国内市場の量的飽和と成熟化に直面している我が国食品産業の経営体質、国際競争力の強化を図るため、人口増加と高い経済成長により魅力的な市場を形成しつつある東アジア地域（韓国、中国、ASEAN諸国およびインド地域）における事項の展開を促進する取り組みを支援する。

〔調査概要〕: 東アジア地域での食材、食品の流通を拡大するため、東アジア地域諸国における市場性（人口等）、日本の進出企業動向、今後の将来性を含める、特に韓国、中国、シンガポール、マレーシア、フィリピン、インドネシア、タイ、ベトナム及びインド地域における、食品法体系、主たる食品等の規格基準やそれらの分析方法及び食品添加物規制を調査し、それらの相違点及び今後統一あるいは調和を図るための課題を抽出する。
農林水産省 東アジア食品産業海外展開支援事業
東アジアの食品等規格基準・分析方法等調査
と結果の共有化（第I〜III期）

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<td>食品法体系と食品規格基準（即席めん、炭酸飲料、冷凍食品、牛乳）コーデックス、日本、韓国、中国、マレーシア、シンガポール、フィリピン</td>
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<th>平成22(2010)年6月〜平成23(2011)年3月</th>
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|  | 分析方法
上記調査国に加えて、インドネシア、タイ、ベトナム |

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<td>食品添加物に係る法体系と使用基準コーデックス、日本、韓国、中国、及び上記ASEAN 6か国</td>
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東アジアの食品等の規格基準、分析方法の調査と結果の共有化

調査表：コーデックスと日本
<table>
<thead>
<tr>
<th>規格名称</th>
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<td>必須組成及び品質要件</td>
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<td>重量及び分量</td>
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<td>分析及びサンプリング</td>
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**コーデックス個別食品規格の作成**

- **コーデックス**
  - 個別食品規格の作成

- **一般問題部会による承認**

- **食品添加物部会 (GSFA)**
- **汚染物質部会 (GSCTFF)**
- **残留農薬部会**
  - 最大基準値
- **食品中の残留動物薬部会**
  - 最大基準値
- **食品衛生部会 (GPFH)**
  - 及びその他関連文書
- **食品表示部会 (GSLPF)**
  - 及びその他関連文書
- **分析とサンプリング法部会**

*1 Codex Stan 192-1955 食品添加物一般規格
*2 Codex Stan 193-1995 食品及び飼料中の汚染物質一般規格
*3 CAC/RCP1-1969 食品衛生一般原則
*4 Codex Stan 1-1985 包装食品表示一般規格

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**個別食品規格**

**食品衛生法**
- 食品、添加物等規格基準における特定品目 - 22 品目 (Table 3)
- 乳及び乳製品の成分規格等に関する省令 - 乳・乳製品 (Table 3a)
- 厚生労働省 (MHLW)

**健康増進法**
- 健康機能食品
- 特定健康機能食品
- 特定保健用食品 (FOSHU)
- 健康増進食品
- 健康表示食品
- 消費者庁/厚生労働省

**JAS*1 法**
- 個別加工食品 品質表示基準 - 48 品目 (Table 1)
- JAS/特定JAS 規格*2 - 54 品目 (Table 2)
- 農林水産省 (MAFF)

**不当表示及び不正表示防止法**
- 公正競争規約 - 38 品目
- 7 アルコール飲料 (Table 4)
- 消費者庁 (CAA)

**消費者庁*3 食品衛生法、JAS及び健康増進法における表示規則を管掌**

**計量法**
- 経済産業省

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

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

<table>
<thead>
<tr>
<th>Name of the Standard</th>
<th>Scope</th>
<th>Description</th>
<th>Essential Composition and Quality Factor</th>
<th>Food Additives (GSFA)</th>
<th>Contaminants and Toxin (GSCTFF)</th>
<th>Pesticide Residues (MRLs)</th>
<th>Residues of Veterinary Drugs in Food (MRLs)</th>
<th>Food Hygiene (GPFH)</th>
<th>Food Labelling (GSLPF)</th>
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**Endorsement by General Subject Committee**

- **Food Category System (GSFA)**
  - Annex B,C

- **Format for Codex Commodity Standards**

- **Codex Commodity Standards**

*1 Codex Stan 192-1955 General Standard for Food Additives
*2 Codex Stan 193-1995 General Standard for Contaminants and Toxins in Foods and Feeds
*3 CAC/RCP1-1969 General Principles of Food Hygiene
*4 Codex Stan 1-1985 General Standards for the Labelling of Prepackaged Foods

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## Commodity Food Standards for Japan

**Food Sanitation Act**
- Standards for Foodstuffs and Additives
  - 22 Specific Food Items
    - Table 3
- Milk and Milk Products Concerning Composition Standards
  - 35 Milk and milk products
    - Table 3a
  - Ministry of Health, Labour and Welfare (MHLW)

**Health Promotion Act**
- Food with Health Claims
  - Nutrient Function Claims
  - Foods for Specified Health Uses (FOSHU)
- Food for Special Dietary Uses
- Nutrition Labeling

**Consumer Affairs Agency (CAA)** consulted by MHLW

**JAS Law**
- Quality Labelling Standard for Processed Foods
  - 48 Commodity Food Items
    - Table 1
  - JAS Standard
  - 55 Commodity Food Items
    - Table 2
  - Ministry of Agriculture, Forestry and Fisheries (MAFF)

**Measurement Act**
- Ministry of Economy, Trade and Industry

**Act Against Unjustifiable Premiums and Misleading Representations**
- Fair Competition Code
  - 45 Food & Liquor Items
  - Table 4
  - Consumer Affairs Agency (CAA)

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*1 Law Concerning Standardization and Proper Labeling of Agricultural and Forest Products
*2 Voluntary (other than organic foods) standard with the certification system to attach the JAS Mark
*3 New governmental organization started in September 2009
Workshop for the 1st Term Project on "Investigation of Commodity Food Standards and Methods of Analysis in Asia"

International Conference for Sharing Information on Food Standards and Resource and Environmental Conservation for Food Industries in Asia-Pacific

Challenges and Opportunities for Food Safety & Human Health

March 4, 2011
Park Hyatt Hotel
Bangkok, Thailand
International Conference for Sharing Information on Food Standards in Asia

February 21, 2012, Jakarta, Indonesia

Reports are available at:

http://www.ilsijapan.org/English/ILSJJapan/COM/Com-W.php
Diversity: Definition of Food Additives

Pluto is now out of the Solar System

Codex
Indonesia
Thailand
Malaysia
Vietnam
The Philippines
Singapore
China
Korea
Japan

平成24年度 東アジア食品産業海外展開支援事業
東アジアの食品等規格基準・分析方法等調査
と結果の共有化（第IV期）

『インド（地域）における食品関連法規に関する調査』
平成24年8月～平成25年3月
実施事業：『インド（地域）における食品関連法規に関する調査』①

事業の目的：国内市場の量的飽和と成熟化に直面している我が国食品産業の経営体質の強化や国際競争力の強化に向け、経営基盤を強化するため、人口増加と高い経済成長により魅力的な市場を形成しつつある東アジア市場、特にインド地域における事業の展開を支援、促進する。

調査概要：インド地域（パキスタンを含む）での食品関連法規の体系、主たる食品等の規格基準とその分析方法や食品添加物の使用基準等の調査をILSI Indiaの協力を得て実施し、その結果は国際会議の開催、ILSI Japanホームページ等で情報共有し、課題の理解を深める。

なお、これまでに本調査事業において集積した東アジア地域（韓国、中国、ASEAN諸国及びインド地域）の食品関連法規に関する情報のデータベース化を行う。

実施事業：『インド（地域）における食品関連法規に関する調査』②

ILSI Japanの一組織である「国際協力委員会」内に調査対象とするそれぞれの専門分野（インド市場、食品規格基準、分析方法、食品添加物等）を担当する会員からなるプロジェクトチームを立ち上げ、各ILSI支部（インド及び韓国、中国、東南アジア地域）と協力し、調査事業を進める。

<table>
<thead>
<tr>
<th>実施主体</th>
<th>ILSI 部支部</th>
<th>担当国</th>
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<tr>
<td>ILSI Japan</td>
<td>ILSI インド支部</td>
<td>インド（パキスタンを含む）</td>
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<td>ILSI 韓国支部</td>
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<td></td>
<td>ILSI 中国連絡事務所</td>
<td>中国（香港、台湾を除く）</td>
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<td>ILSI 東南アジア地域支部</td>
<td>マレーシア、シンガポール、フィリピン、インドネシア、タイ、ベトナム（ASEAN諸国内主要6か国）</td>
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実施事業：『インド（地域）における食品関連法規に関する調査』③

実施スケジュール：
予備調査、調査プログラム設計、調査票開発
2か月（平成24年8,9月）
調査対象国における調査、調査票の作成
3か月（平成24年10～12月）
調査票の集計、課題の抽出
2か月（平成25年1,2月）
国際会議の開催
平成25年2月22日（東京）
報告書の作成
1か月（平成25年3月）
Bangladesh Country Report

Nepal Report

Regulatory Frameworks and Institutional Provisions for the Quality Control of Food Products

Sri Lanka Report

Laws and Regulations Relating to Foods in Sri Lanka

インド、バングラデシュ、ネパール、スリランカにおける食品及び食品添加物の法的枠組みと事例研究

10:00-10:15 開会の挨拶 木村修一（ILSI Japan会長）

Session 1:
10:15-10:40 農林水産省のご挨拶：大臣官房参事官 農林水産省食糧産業局海外展開・輸出促進グループ長 小川良介
10:40-11:15 基調講演：Dr. Pradip Chakraborty, Director, Food Safety and Standards Authority of India
11:15-11:55 農林水産省東アジア食品産業海外展開支援事業及びILSIの紹介：浜野弘昭、山口隆司（ILSI Japan）
12:00-13:00 午食

Session 2:
13:00-13:40 インドにおける食品及び食品添加物の法的枠組み：香村正徳（味の素㈱）
13:40-14:10 バングラデシュ、ネパール、スリランカにおける食品及び食品添加物の法的枠組み：Ms. Rekha Sinha（ILSI India）
14:10-14:50 アเซアン（ASEAN）における食品基準のハーモナイゼーション：Mr. Teoh Keng Ngee（ILSI SEAR）
14:50-15:10 休憩

Session 3:
15:10-15:30 インドにおける加工食品及び飲料市場について：Mr. D.H. Pai Panandiker（ILSI India会長）
15:30-16:00 事例研究 1：味の素㈱
16:00-16:30 事例研究 2：ヤクルト本社
16:30-16:55 質疑応答及び総合討論
16:55-17:00 閉会の挨拶 山口隆司（ILSI Japan事務局長）
今後の事業展開について

◆ 調査テーマ/項目の拡大（表示等）
◆ 調査地域の拡大（東アジアから世界へ）
◆ 情報の更新・データベースの拡充

◆ ILSI Japan の会員の参画・協力を！
国際生命科学研究機構（ILSI）について

ILSI Japan
事務局長 山口

科学的な視点で、健康・栄養・安全・環境に関わる問題の解決および正しい理解を目指すとともに、今後発生する恐れのある問題を事前に予測して対応していくなど、活発な活動を行っています。

特定非営利活動法人 国際生命科学研究機構（ILSI Japan）は1981年に設立され、ILSIの一員として世界的な活動の一翼を担うとともに、日本独自の問題にも積極的に取り組んでいます。
ILSIの会員数は460社（2012年度）にも及び、世界規模で活動しています。長期の研究を要する基礎的な課題は主として研究財団の各研究所が担当します。各研究所では、それぞれの分野における科学者の協力を得て、グローバルな視点から研究テーマを決め、世界的に優れた科学者に研究を委託します。また、地域に特有な課題への対応は世界に広がる地域支部が担当しています。

ILSIホームページ
http://www.ilsi.org/
ILSI Japanは2001年に特定非営利活動法人（NPO法人）の認証を得ました。ILSI Japanの目的に賛同した64の団体（2012年12月現在）が活動を支えています。会員は上記の各委員会・研究会・研究部会に自由に参加し、科学の最新情報を触れながら問題解決を図ることができます。

ILSI Japanの活動

- 調査・研究活動とその成果の発表
  ILSI Japanの会員は、各研究部会に参加して、内外の最近の研究動向に直接ふれ、分野の課題を研
  究。研究テーマは研究部会委員会によって決定。国内外の最新のデータを集める国際会議に参加し、
  敬意を表しています。新しい研究テーマは大学などの研究機関に研究を依頼することもあります。研究
  会は会員が各自に提案するものであり、会員は自由に研究をし、研究の基
  本的知識を伝えることに貢献しています。

- 国内外の関連機関との交流・連携
  ILSI Japanは、国際的な協力機関と連携し、科学に基づいた健康政策の推進を
  行っています。各国の国際会議に参加し、情報交流を行っています。また、ILSI Japan CHP Japanは、
  国際的な健康政策の推進を目的として活動を続けています。

- 科学情報の普及
  ILSI Japanは、関連機関との交流を経て、科学の最新情報を会員に提供し、関連事項についての世
  界の広範な最新情報を常時、提供しています。
ご清聴ありがとうございました。
ILSI Japan International Conference
- Regulatory Framework on Foods and Food Additives in India, Bangladesh, Nepal and Sri Lanka-

Regulatory Framework on Food and Food Additives in India

- From the MAFF Investigation Project on the Food Related Regulations in India -

ILSI Japan International Cooperation Committee
Ajinomoto Co., Inc.
Masanori Kohmura Ph.D

1. Food Administrative Bodies in India

<table>
<thead>
<tr>
<th>Administrative body</th>
<th>Responsible agency</th>
<th>Related laws</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministries of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health and Family Welfare</td>
<td>Food Safety and Standards Authority of India (FSSAI)</td>
<td>• Food Safety and Standards Act, 2006</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Food Safety and Standards Regulations, 2011</td>
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<tr>
<td></td>
<td></td>
<td>• Food Safety and Standards Rules, 2011</td>
</tr>
<tr>
<td>Consumer Affairs, Food and Public Distribution</td>
<td>Bureau of Indian Standards (BIS)</td>
<td>• The Bureau of Indian Standards Act, 1986</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The Standards for Weights and Measures Act, 1976</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The Standards for Weights and Measures Rules, 1977</td>
</tr>
<tr>
<td>Women and Child Development</td>
<td></td>
<td>• The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003</td>
</tr>
<tr>
<td>Agriculture</td>
<td></td>
<td>• Agricultural Produce (Grading and Marking) Act, 1937</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The General Grading and Marking Rules, 1988</td>
</tr>
<tr>
<td>Food Processing Industries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atomic Energy Commission</td>
<td>DAE</td>
<td>• The Atomic Energy Act, 1962</td>
</tr>
<tr>
<td></td>
<td>AERB</td>
<td>• Atomic Energy (Control of irradiation of Food) Rules, 1996</td>
</tr>
</tbody>
</table>

DAE : Department of Atomic Energy
AERB : Atomic Energy Regulatory Board
2. Food Safety and Standards Authority of India (FSSAI)

Roles of Food Safety and Standards Authority of India

1. Framing of regulations to lay down the standards and guidelines for food (食品の規格やガイドラインを制定するための規則の骨組みを作る).
2. Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses (食品ビジネスの食品安全管理システムの認証に携わる認証機関認定のための仕組みとガイドラインを制定する).
3. Laying down procedures and guidelines for accreditation of laboratories and notification of the accredited laboratories (研究施設の認定と認定された研究施設の届出に関する手順とガイドラインを制定する).
4. To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition (中央政府や州政府が、食品の安全と栄養に直接的あるいは間接的に関わる分野の指針や規則を立案するにあたっての科学的アドバイスや技術的サポートを行う).
5. Contribute to the development of International technical standards for food (食品の国際的技術基準の発展に貢献する).
6. Promote general awareness about food safety and food standards (食品安全や食品基準についての一般の認識を高める).

3. Organization Structure of FSSAI

The committee aims at enhancing the cooperative relation between Food Authority and related bodies and consists of following members.

- Chief Executive Officer
- Representatives of all industries (two members each to represent food industry, agriculture, consumer bodies and food laboratories)
- All commissioners from each State Food Safety Authority

Scientific Panel:

- The committee consists of Chairpersons of 8 sections of Scientific Panel and 6 independent academic experts who do not belong to Scientific Panel.
- The Committee provides Authority with advice and Scientific Panel with orders for activities from scientific standpoints.
- When there are problems which Scientific Panel cannot process alone, the committee can order the establishment of the working team.

Scientific Panels consist of independent academic experts, as necessary, invites related industries and representatives of consumers as members of the organization. The following 8 sections are included in Scientific Panels.

- a) Functional foods, nutraceuticals, dietetic products and other similar products
- b) Method of sampling and analysis
- c) Food additives, flavorings, processing aids and materials in contact with food
- d) Contaminants in the food chain
- e) Biological hazards
- f) Pesticides and antibiotics residues
- g) Labeling and claims/advertisements
- h) Genetically modified organisms and foods
4. Summary Chart of the Relationship between Food Regulatory System and Commodity Food Standards

<table>
<thead>
<tr>
<th>Name of the Standard</th>
<th>Scope</th>
<th>Description</th>
<th>Essential Composition and Quality</th>
<th>Food Additives</th>
<th>Contaminant</th>
<th>Hygiene</th>
<th>Weights and Measures</th>
<th>Labelling</th>
<th>Methods of Analysis and Sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian Standards (&quot;ISI&quot; mark). Most are voluntary, certification for milk products, infant formula, packaged water etc. are mandatory under FSSR</td>
<td>Bureau of Indian Standards</td>
<td>Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992.</td>
<td>Ministry of Women and Child Development</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Laws and Regulations Related to Foods in India

- Movements Toward Integrated Food Law -

<table>
<thead>
<tr>
<th>Related Acts and Rules</th>
<th>Ministry of Health and Family Welfare etc.</th>
<th>Food Safety and Standards Authority of India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of Food Adulteration Act, 1954</td>
<td>Food Safety and Standards Act, 2006</td>
<td>Food Safety and Standards Regulations, 2011 (Food product standards and food additives)</td>
</tr>
<tr>
<td>Fruit Products Order, 1955</td>
<td>Food Safety and Standards Act, 2006</td>
<td>Food Safety and Standards Regulations, 2011 (Prohibitions and restrictions on sales)</td>
</tr>
<tr>
<td>Vegetable Oil Products (Control) Order, 1947</td>
<td>(Laboratory and sampling analysis)</td>
<td>Laboratory and sampling analysis (Licensing and registration of food businesses)</td>
</tr>
<tr>
<td>Milk and Milk Products Order, 1992</td>
<td>(Packaging and labelling)</td>
<td>Milk and Milk Products Amendment Regulations, 2009</td>
</tr>
<tr>
<td>Orders under Essential Commodities Act, 1955 relating to food</td>
<td>(Contaminants, toxins and residues)</td>
<td>Milk and Milk Products Amendment Regulations, 2009</td>
</tr>
</tbody>
</table>

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1. Establishment of Food Safety and Standards Authority of India (composition, functions, procedure and duties)

2. General principles of food safety (not only the protection of human health, but also the protection of consumers’ benefit including fair food transaction, appropriate risk management based on scientific reasons and preventive measures at appropriate level are set forth)

3. General provisions as to articles of food
   a. Use of food additive or processing aid
   b. Contaminants, naturally occurring toxic substances, heavy metals, etc.
   c. Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts
   d. Genetically modified foods, organic foods, functional foods, proprietary foods, etc
   e. Packaging and labeling of foods
   f. Restrictions of advertisement and prohibition as to unfair trade practices

4. Provisions relating to import

5. Special responsibilities as to food safety (responsibilities of the food business operators, food recall procedure)

6. Analysis of food (laboratories, auditors, analysts, procedure)

7. Implementing sectors and their administrations, penalties, appeal organizations

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Example Provisions of the FSS Act, 2006

3. Definitions.
4. Establishment of FSSAI.
5. Composition of FA and qualifications for appointment of its Chairperson and other Members.
6. Selection Committee for selection of Chairperson and Members of FA.
11. Central Advisory Committee.
15. Procedure for Scientific Committee and Scientific Panel.
19. Use of food additive or processing aid.
20. Contaminants, naturally occurring toxic substances, heavy metals, etc.
21. Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts.
22. Genetically modified foods, organic foods, functional foods, proprietary foods, etc.
23. Packaging and labelling of foods.
24. Restrictions of advertisement and prohibition as to unfair trade practices.
25. All imports of articles of food to be subject to this Act.
   etc
7. Food Safety and Standards (FSS) Rules and Regulations

**Draft Regulations**
- Food Authority’s Food Recall Procedures
- Food for Special Nutritional or Dietary Uses
- Revised Energy Drinks, and Caffeine
- Revised Trans Fatty Acids in Partially Hydrogenated Vegetable Oils
- Food Import
- Operationalizing the Regulation of GM Foods in India
- Labeling (claims)

**FSS Regulations, 2011**
- Food product standards and food additives
- Packaging and labelling
- Prohibition and restriction on sales
- Contaminants toxins and residues
- Laboratory and sampling analysis
- Licensing and registration of food businesses

Enforced after 5th Aug 2011

**Amendment Regulations, 2009**
- Milk and Milk Products

**FSS Rules, 2011**

Example
2.1 - Qualification and duties
2.1.1: Commissioner of Food Safety (State Gov.)
2.1.2: Designated Officer
2.1.3: Food Safety Officer
2.1.4: Food Analyst

Enforced after 5th Aug 2011

8. Regulations on Food Additive

1. Definition of Food additive.

**CHAPTER I, Article 3 of the FSS Act, 2006**

(k) “food additive” means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities;
### 8. Regulations on Food Additive

#### 2. Functional Classes

**Article 2.2.2, 5 Declaration regarding Food Additives** of FSS (Packaging and labeling) Regulations, 2011.

(i) For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific names or recognized international numerical identifications: Acidity Regulator, Acids, Anticaking Agent, Antifoaming Agent, Antioxidant, Bulking Agent, Colour, Colour Retention Agent, Emulsifier, Emulsifying Salt, Firming Agent, Flour Treatment Agent, Flavour Enhancer, Foaming Agent, Gelling Agent, Glazing Agent, Humectant, Preservative, Propellant, Raising Agent, Stabilizer, Sweetener, Thickener:

<table>
<thead>
<tr>
<th>Class Title</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidity Regulator</td>
<td>Ascorbic Acid</td>
</tr>
<tr>
<td>Anticaking Agent</td>
<td>Silicon Dioxide</td>
</tr>
<tr>
<td>Antioxidant</td>
<td>Butylated Hydroxyanisole (BHA)</td>
</tr>
<tr>
<td>Bulking Agent</td>
<td>Guar Gum</td>
</tr>
<tr>
<td>Colour</td>
<td>Artificial Food Color</td>
</tr>
<tr>
<td>Colour Retention Agent</td>
<td>Ethyl Vanillate</td>
</tr>
<tr>
<td>Emulsifier</td>
<td>Monoglycerides</td>
</tr>
<tr>
<td>Emulsifying Salt</td>
<td>Sodium Stearoyl 2-Lactate</td>
</tr>
<tr>
<td>Firming Agent</td>
<td>Calcium Caseinate</td>
</tr>
<tr>
<td>Flour Treatment Agent</td>
<td>Enzyme Preparations</td>
</tr>
<tr>
<td>Flavour Enhancer</td>
<td>Monosodium Glutamate (MSG)</td>
</tr>
<tr>
<td>Foaming Agent</td>
<td>Sodium Lauryl Sulfate</td>
</tr>
<tr>
<td>Gelling Agent</td>
<td>Carboxymethylcellulose (CMC)</td>
</tr>
<tr>
<td>Glazing Agent</td>
<td>Carnauba Wax</td>
</tr>
<tr>
<td>Humectant</td>
<td>Glycerol</td>
</tr>
<tr>
<td>Preservative</td>
<td>Potassium Sorbate</td>
</tr>
<tr>
<td>Propellant</td>
<td>Carbon Dioxide</td>
</tr>
<tr>
<td>Raising Agent</td>
<td>Sodium Bicarbonate</td>
</tr>
<tr>
<td>Stabilizer</td>
<td>Gelatin</td>
</tr>
<tr>
<td>Sweetener</td>
<td>Aspartame</td>
</tr>
<tr>
<td>Thickener</td>
<td>Xanthan Gum</td>
</tr>
</tbody>
</table>

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### 8. Regulations on Food Additive

**Chapter 3: Substances Added to Food** in the FSS (Food Product Standards and Food Additives) Regulations, 2011.

8. Regulations on Food Additive

3. Definition of Processing aid

**Article 19. Use of food additive or processing aid** of the FSS Act, 2006
Explanation.- For the purposes of this section, “processing aid” means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the nonintentional but unavoidable presence of residues or derivatives in the final product.

8. Regulations on Food Additive

4. Approved Food Additives and its Use Standards

**Article 19. Use of food additive or processing aid** of the FSS Act, 2006
No article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of this Act and regulations made thereunder.

**Article 3.1.1:1** of the FSS (Food Product Standards and Food Additives) Regulations, 2011. **Use of Food Additives in Food Products:**
The food products may contain food additives as specified in these Regulations and in Appendix A.
Appendix A consists of 15 tables of lists of food additives for use in food categories and a list of food categories with permitted food additives.
8. Regulations on Food Additive

5. Food Additive Specifications

Article 3.2 of the FSS (Food Product Standards and Food Additives) Regulations, 2011. Standards of Additives

2.8: Sweetening agents including Honey. Specifications for 4 Artificial Sweeteners.

3.2.1: Food Colours. Specifications for 15 food coulors.

Bureau of Indian Standards (BIS) set standards for 91 food additives. In the current regulatory framework, BIS certification is voluntary, however, importer of specific food additives shall register to BIS.

8. Regulations on Food Additive

6. New Food Additive Approval

There is no clear description on approval process for new food additive or revision of use level or food category in the FSS regulations.

However, application format and summary sheet for approval of food additives was announced by the Scientific Panel on Food Additives, flavouring, processing aids and materials in contact with food on April 4th, 2012. It stated that “Applicants should apply for the approval of food additives/enhancement of permitted food additives in other food products as well as increase the existing quantity of permitted food additives in the food product in the enclosed prescribed format. The application should be addressed to Director (PA), Food Safety and Standards Authority of India”
7. Labeling of Food Additives Used in Foods

Article 2.2.2: Labeling of Pre-packaged Food of FSS (Packaging and labeling) Regulations, 2011.

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

8. Regulations on Food Additive

7. Labeling of Food Additives Used in Foods (2)

Article 2.2.2: Labeling of Pre-packaged Food of FSS (Packaging and labeling) Regulations, 2011.

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

In addition, there are many specific labelling requirements relates to food additives
8. Regulations on Food Additives

8. Carry Over Of Food Additives

Article 3.1.18 of the FSS (Food product standards and Food Additives) Regulation, 2011, Carry Over of Food Additive.

For the purpose of the standards specified in chapter 2 of these regulation the "Carry Over" principle applies to the presence of additives such as colours, flavouring agents, anti-oxidants anti-caking agents, emulsifying and stabilising agents, and preservatives in food, as a result of the use of raw material or other ingredients in which these additives were used. The presence of contaminants is not covered by this purpose. The presence of an additive in food through the application of the carry over principle is admissible in general unless otherwise specifically prohibited in the regulations provided the total additive including the carry over through the raw material or other ingredients does not exceed the maximum amount so permitted.

9. Case Study

1. Instant Noodles

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

<table>
<thead>
<tr>
<th>Scope, Description, Essential Composition and Quality Factor</th>
<th>Food Safety and Standards Regulations 2011</th>
<th>Indian Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS (Food product standards and Food Additives) regulation, 2011 2.12: Proprietary Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>FSS (Packaging and Labeling) regulation, 2011</td>
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<tr>
<td>2.2: Labelling</td>
<td>2.2.1: General Requirements</td>
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<td>2.2.2: Labelling of Pre-packaged Food</td>
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<tr>
<td>Food Additives</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
<td></td>
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<tr>
<td>3.1: Food Additives</td>
<td></td>
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<tr>
<td>Contaminant</td>
<td>FSS (Contaminants, Toxins and Residues) regulation, 2011</td>
<td></td>
</tr>
<tr>
<td>2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances</td>
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<td></td>
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<tr>
<td>Hygiene</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. Case Study

FSS (Food product standards and food additives) Regulations, 2011

2.12: Proprietary Food
2.12.1
1) Proprietary food means a food that has not been standardized under these regulations
2) In addition to the provisions including labelling requirements specified under these regulations, the proprietary foods shall also conform to the following requirements, namely:—
(i) the name describing as clearly as possible, the nature or composition of food and/or category of the food under which it falls in these regulations shall be mentioned on the label
(ii) the proprietary food product shall comply with all other regulatory provisions specified in these regulations and in Appendices A and B.

Veg and Non-Veg
1.2: Definitions—1.2.1: In these regulations unless the context otherwise requires:
7. “Non-Vegetarian Food” means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient;
11. “Vegetarian Food” means any article of Food other than Non- Vegetarian Food as defined in regulation 1.2.1 (7).

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

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

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

2. Carbonated Soft Drinks

There are two standards relevant to the “Carbonated Soft Drinks” in FSS (Food product standards and food additives) Regulations, 2011.

2.3.30 Carbonated Fruit Beverages or Fruit Drinks

2.10.6 Beverages Non-Alcoholic-Carbonated

There are two standards relevant to the “Carbonated Soft Drinks” in Indian Standards

IS 2346-1992 Carbonated Beverages

IS 12544 1988 Carbonated Beverages - Non-alcoholic Beer

<table>
<thead>
<tr>
<th>Food Safety and Standards Regulations 2011</th>
<th>Indian Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope, Description, Essential Composition and Quality Factor</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
</tr>
<tr>
<td>Labeling</td>
<td>FSS (Packaging and Labeling) regulation, 2011</td>
</tr>
<tr>
<td>Food Additives</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
</tr>
<tr>
<td>Contaminant</td>
<td>FSS (Contaminants, Toxins and Residues) regulation, 2011</td>
</tr>
<tr>
<td>Hygiene</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulation applied</th>
<th>Item</th>
<th>Specification</th>
<th>Method of analysis</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS (Food product standards and food additives) Regulation 2011 Carbonated beverage-Specification (IS 2346 : 1992 (reaffirmed 2009))</td>
<td>Arsenic</td>
<td>Max. 0.1 mg/kg</td>
<td>IS 11124 : 1984</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lead</td>
<td>Max. 0.5 mg/kg</td>
<td>IS 6854 : 1973</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Copper</td>
<td>Max. 1.5 mg/kg</td>
<td>IS 6854 : 1973</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Iron</td>
<td>Max. 0.5 mg/kg</td>
<td>IS 6854 : 1973</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total plate count</td>
<td>Not more than 50 cfu/ml</td>
<td>IS 5402 : 1969</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coliform count</td>
<td>Absent in 100ml</td>
<td>IS 5401 : 1969</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yeast and mold count</td>
<td>Not more than 2 cfu/ml</td>
<td>IS 5403 : 1969</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Saccharin</td>
<td>-</td>
<td>Volumetric method HPLC method</td>
<td>IS 2346 : 1992</td>
</tr>
<tr>
<td></td>
<td>Gas volume</td>
<td>-</td>
<td></td>
<td>IS 2346 : 1992</td>
</tr>
</tbody>
</table>
9. Case Study

2. Carbonated Soft Drinks

Sampling methods

<table>
<thead>
<tr>
<th>Regulation applied</th>
<th>No. of Bottles in the Production Lot</th>
<th>No. of Bottles to be selected</th>
<th>Microbiological tests</th>
<th>Other tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS (Food product standards and food additives) Regulation 2011 Carbonated beverage-Specification (IS 2346 : 1992 (reaffirmed 2009))</td>
<td>Up to 1,300</td>
<td>12</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,301 to 3,200</td>
<td>18</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3,201 to above</td>
<td>24</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

- Bottles to be selected for testing shall be chosen at random utilizing random number tables (see IS 4905 : 1968).

9. Case Study

3. Prepared Frozen Foods

There is no food standard for “Prepared Frozen Foods” in both FSS (Food product standards and food additives) Regulations, 2011 and Indian Standards.

<table>
<thead>
<tr>
<th>Food Safety and Standards Regulations 2011</th>
<th>Indian Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope, Description, Essential Composition and Quality Factor</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011 2.12: Proprietary Food</td>
</tr>
<tr>
<td>Labeling</td>
<td>FSS (Packaging and Labeling) regulation, 2011 2.2: Labeling 2.2.1: General Requirements 2.2.2: Labelling of Pre-packaged Food</td>
</tr>
<tr>
<td>Food Additives</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011 3.1: Food Additives</td>
</tr>
<tr>
<td>Contaminant</td>
<td>FSS (Contaminants, Toxins and Residues) regulation, 2011 2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances</td>
</tr>
<tr>
<td>Hygiene</td>
<td></td>
</tr>
</tbody>
</table>
9. Case Study

4. Cow’s Milk

There is the standard relevant to the “Cow’s Milk” in FSS (Food product standards and food additives) Regulations, 2011.

2.1.1 Milk

There are two standards relevant to the “Cow’s Milk” in Indian Standards.

IS 4238:1967 Sterilized Milk

IS 13688:1999 Packaged Sterilized Milk

<table>
<thead>
<tr>
<th>Scope, Description, Essential Composition and Quality Factor</th>
<th>Food Safety and Standards Regulations 2011</th>
<th>Indian Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.2.1: General Requirements</td>
<td>IS 13688:1999 Packaged Pasteurized Milk -Specification</td>
</tr>
<tr>
<td>Food Additives</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.1: Food Additives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Appendix A: List of Food Additives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Table 14 List of Food Additives for use in Milk products</td>
<td></td>
</tr>
<tr>
<td>Contaminants</td>
<td>FSS (Contaminants, Toxins and Residues) regulation, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.1: Metal Contaminants, 2.2: Crop contaminants and naturally occurring toxic substances, 2.3: Residues</td>
<td></td>
</tr>
<tr>
<td>Hygiene</td>
<td>FSS (Food product standards and Food Additives) regulation, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Appendix B: Microbiological Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Table 2 Microbiological Parameter for Milk products</td>
<td></td>
</tr>
</tbody>
</table>

9. Case Study

4. Cow’s Milk

Sampling methods: Sterilized Milk

<table>
<thead>
<tr>
<th>Regulation applied</th>
<th>No. of Containers in the Production Lot</th>
<th>No. of Containers to be selected</th>
<th>Bacterial spores</th>
<th>Creaming index, Turbidity and Sterility</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS (Food product standards and Food Additives) regulation 5, 2011 Speciation for Sterilized Milk (IS 4238 : 1967 (reaffirmed 2010))</td>
<td>Up to 25</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>26 to 100</td>
<td>2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>101 to 500</td>
<td>3</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>501 to 1,000</td>
<td>3</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,001 to 5,000</td>
<td>4</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5,001 to above</td>
<td>4</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>

References: IS 4238 : 1967 (Reaffirmed 2010) Appendix F (Sampling of Sterilized Milk)
# 9. Case Study

## 4. Cow’s Milk

Method of Analysis: Sterilized Milk

<table>
<thead>
<tr>
<th>Regulation applied</th>
<th>Item</th>
<th>Specification</th>
<th>Method of analysis</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS (Food product</td>
<td>Creaming index</td>
<td>Max. 20</td>
<td>Centrifugation</td>
<td>IS 4238 : 1967</td>
</tr>
<tr>
<td>standards and Food</td>
<td>Turbidity test</td>
<td>To conform to test</td>
<td>IS 4238 : 1967</td>
<td></td>
</tr>
<tr>
<td>Additives) Regulations, 2011</td>
<td>Sterility (a)</td>
<td>pH variation on 7days incubation : Max 0.3</td>
<td>IS 4238 : 1967</td>
<td></td>
</tr>
<tr>
<td>Specification for Sterilized Milk (IS 4238 : 1967 (reaffirmed 2010))</td>
<td>Sterility (b)</td>
<td>Titratatable acidity variation on 7 days incubation : Max. 0.02 g</td>
<td>IS 4238 : 1967</td>
<td></td>
</tr>
<tr>
<td>Bacterial Spores - aerobic</td>
<td>Max. 5 colonies / ml</td>
<td></td>
<td>IS 4238 : 1967</td>
<td></td>
</tr>
</tbody>
</table>

---

### Acknowledgement

This investigation was conducted by the project team for the investigation of Indian food regulation of ILSI Japan International Cooperation Committee in collaboration with ILSI India and supported by the Ministry of Ministry of Agriculture, Forestry and Fisheries.

The project team for the investigation of Indian food regulation of ILSI Japan International Cooperation Committee

- Fumiko Sekiya, Takasago International Corp.
- Hiroaki Hamano, ILSI Japan
- Kiyohisa Kaneko, Coca-Cola(Japan)Company Ltd.
- Masanori Kohmura, Ajinomoto Co., Inc.
- Matsuhiro Katashima, Kao Corp.
- Ryouichi Akahoshi, Yakult Honsha Co. Ltd.
- Toshihisa Oota, Yakult Honsha Co. Ltd.
- Umeki Youichro, Du Pont Kabushiki Kaisha
- Yoshiharu Kuma
- Yumi Asada, Unilever Japan Service
Thank you for your kind attention
Country Fact Sheet

SRI LANKA

- Sri Lanka is an Island in the Indian Ocean, off the south-eastern coast of India. It is about the size of Ireland. It is about 28 kilometers (18 mi.)

- Population is about 20 million. The Sinhalese, make up 74.9% of the population. Tamils are 15.4%. Most Sinhalese are Buddhist; most Tamils are Hindu.

- Official Languages: Sinhala and Tamil.

Administrative Authorities

Administrative Authorities in Sri Lanka as shown in the following Table are responsible for Food Administration of food categories and related stage of production.
<table>
<thead>
<tr>
<th>Sector</th>
<th>Products</th>
<th>Imported</th>
<th>Domestic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry Of Health  Directorate General of Health Services</td>
<td>Food Products</td>
<td>Food Control Administration of MoH (FCA)</td>
<td>FCA</td>
</tr>
<tr>
<td>Ministry/Department of Agriculture (MOA)</td>
<td>Primary products of agriculture</td>
<td>Food Control Administration of MoH (FCA)</td>
<td>MOA and FCA</td>
</tr>
<tr>
<td>Department of Animal Production &amp; Health (DAP &amp;H)</td>
<td>Animal Husbandry Milk Products</td>
<td>DAP&amp;H and FCA</td>
<td>DAP&amp;H and FCA</td>
</tr>
<tr>
<td>Coconut Development Authority (CDA)</td>
<td>Coconuts &amp; Their Products</td>
<td>FCA and CDA</td>
<td>FCA and CDA</td>
</tr>
<tr>
<td>Tea Board (TB)</td>
<td>Manufactured Tea</td>
<td>FCA and TB</td>
<td>FCA and TB</td>
</tr>
<tr>
<td>Ministry/Department of Fisheries (MoF)</td>
<td>Fish and Fish Related Products</td>
<td>FCA</td>
<td>MDF and FCA</td>
</tr>
<tr>
<td>Excise Department (ED)</td>
<td>Alcoholic Beverages</td>
<td>ED/Customs</td>
<td>ED</td>
</tr>
<tr>
<td>Ministry of Local Government (MoLG)</td>
<td>General Food Safety and Standards (Implementation)</td>
<td>SLSI</td>
<td>FCA and SLSI</td>
</tr>
<tr>
<td>Consumer Affairs Authority (CAA) Established Under the Consumer Affairs Authority Act No. 9 of 2003</td>
<td>Promotion of Effective Completion and Protection of Consumers: Regulation Of Internal Trade</td>
<td>FCA</td>
<td>CAA</td>
</tr>
</tbody>
</table>

**Director General of Health Services**

The Chief Food Authority is Director General of Health Services under Ministry of Health. It is the apex body responsible for the country’s Food Control Administration (FCA). The Food Advisory Committee recommends the standards and regulations to be adopted by the Government.

**Sri Lanka Standards Institute**

Sri Lanka Standards institute (SLSI) plays an integral role with the FCA and in formulation of National Standards under the Food Act. The Standards of the SLSI are mostly voluntary. Some of them are declared mandatory for verification of standard parameters at the point of import.

The SLSI has mutual agreements with standards setting bodies of the exporting countries that certify the products exported from selected countries. Based on the certification of those bodies and verification checks carried out at national level the SLSI releases those products for further inspection and verification of FCA as far as food products are concerned.
MAIN LEGISLATION

i) The Food Act No. 26 of 1980
   • The Food Act No. 26 of 1980 amended by Food (Amendment) Act No. 20 of 1991 is the most important regulation and is administered by FCA of Ministry of Health.

   Part I of the Food Act provides for prohibition in respect of food related to:
   a) Additives.
   b) Fitness for Human Consumption.
   c) Cleanliness.
   d) Adulteration.
   e) Sanitary conditions.

   Part II of the Food Act includes provisions for establishment of Administration:
   a) Establishment of a Food Advisory Committee (FAC).
   b) Designating Director General of Health Services as the Chief Food Authority (CFA).

   e) Providing for Food Authorities under the Food Act; viz. Director General of Customs for imported foods; Chief Medical Officer of Health (CMOH) for the Colombo Municipal area; and Local Authorities (Urban Councils and Pradheshiya Sabhas etc.).

   Part III of the Food Act provides for nature of offences under the Food Act and punishment.

   Part IV of the Food Act provides protection for action taken in good faith; fines etc.
Regulations have been made Under Section 32 Of The Food Act

1) Miscellaneous Regulation
2) Hygiene
3) Food Standards
4) Non-nutritive sweeteners
5) Milk Standards
6) Additional Approved Analyst Regulations
7) Iodization of Salt
8) Microbiological Analyst
9) Labeling & Miscellaneous
10) Preservatives
11) Genetically Modified Foods
12) Bread Standards
13) Food (Labeling & Advertising) Regulation – 2005
14) Irradiation
15) Coloring Substances
16) Bottled or Package Water
17) Adoption of SL Standards
18) Antioxidants

Summary of Food Standards

• About 70 Commodities are covered under the Food Standards as per Regulations of 1991.

• These composite regulations are being gradually divided into separate categories such as ‘oils and fats’, Cereals, Pulses and Legumes, Spices and condiments etc., keeping in line with the Codex Guidelines and Standards.

• Most of these Regulations are in formulation stages and they will be published in Sinhala, Tamil and English languages once they are finalized by the Department of Legal Draftsman.
**Laws and Regulations Related to Food Additives**

**OVERVIEW**

*According to Food Additives (General) Regulations yet to be published (currently in draft form) “Food additive” means any safe substance that is intentionally introduced into a food in small quantities.*

*Food Additives can be used to affect the food’s keeping quality, texture, consistency, appearance, odour, taste, alkalinity or acidity or to serve any other technological function. They include:*

- Preservative,
- Coloring Substance,
- Flavouring Substance,
- Flavour Enhancer,
- Antioxidant,
- Emulsifying And Stabilizing Agent,
- Sweetener And Food Conditioner,

*But do not include nutrient supplement, incidental constituent or common salt.*

---

**Food Additives: Highlights Of Provisions**

- Functional classes of Food Additives as per the Table provided by the Codex are considered in the Sri Lankan standards with the relevant INS numbers.

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

- The recommended list of the Codex and evaluations carried out by Joint Expert Committee on Food Additives (JECFA) is consulted before approval of any Food Additive in Sri Lanka.

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

- Assessment of food additives as such is not carried in Sri Lanka and there has been no need for such assessments.
FLAVORS
As Per Draft Flavor Regulations

<table>
<thead>
<tr>
<th>CATEGORIES</th>
<th>Negative List of Flavors</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. “Natural Aromatic Raw Material”</td>
<td>i. Aloin.</td>
</tr>
<tr>
<td>ii. “Natural Flavouring Concentrate”</td>
<td>ii. Beberine.</td>
</tr>
<tr>
<td>iii. “Natural Flavouring Substance”</td>
<td>iii. Beta- Azarone.</td>
</tr>
<tr>
<td>v. “Artificial Flavouring Substance”</td>
<td>v. Calamus oil.</td>
</tr>
<tr>
<td>ix. Ethyl Methyl Ketone.</td>
<td>ix. Ethyl Methyl Ketone.</td>
</tr>
<tr>
<td>x. Ethyl-3-Phenylglicidate.</td>
<td>x. Ethyl-3-Phenylglicidate.</td>
</tr>
<tr>
<td>xi. Eugenyl methyl ether.</td>
<td>xi. Eugenyl methyl ether.</td>
</tr>
<tr>
<td>xii. Methyl Naphthyl ketone.</td>
<td>xii. Methyl Naphthyl ketone.</td>
</tr>
<tr>
<td>xiii. Saffrole and Isosaffrole.</td>
<td>xiii. Saffrole and Isosaffrole.</td>
</tr>
<tr>
<td>xv. Sassafras oil.</td>
<td>xv. Sassafras oil.</td>
</tr>
<tr>
<td>xvi. Thujone, Isothujone, alpha and betathujone.</td>
<td>xvi. Thujone, Isothujone, alpha and betathujone.</td>
</tr>
<tr>
<td>xvii. Tonka bean.</td>
<td>xvii. Tonka bean.</td>
</tr>
</tbody>
</table>

There are a number of food products in which flavour enhancers are prohibited as per the draft regulations Schedule III.

List Of Plant Or Animal Sources For Flavoring Agents.

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

“The label on or attached to a package of a natural flavoring shall include the statement “NATURAL (here insert description of flavor) FLAVORING” or a similar statement.”
Processing Aids

Currently NO Regulation is in place.

The Inventory of Processing Aids compiled and adopted by the Codex Alimentarius Commission is consulted.

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

Carry Over

- “Carry Over” is defined as the presence of food additives in food as a result of the use of raw material or other ingredients in which these additives were used.
• The present regulation for Food Preservatives is under revision.

• Schedule 1 of “Food Preservative Regulation” provides list of Permitted Food Preservatives along with INS number. 11 Food preservatives are permitted.

<table>
<thead>
<tr>
<th>Permitted Preservative</th>
<th>Column I</th>
<th>Column II</th>
<th>Column III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>INS No.</td>
<td>Alternative form in which the permitted preservative may be used (to be calculated as the permitted preservative shown in Column I)</td>
<td>INS No.</td>
</tr>
<tr>
<td>1. Sorbic acid</td>
<td>200</td>
<td>Sodium sorbate</td>
<td>201</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potassium sorbate</td>
<td>202</td>
</tr>
<tr>
<td>2. Benzoic acid</td>
<td>210</td>
<td>Calcium sorbate</td>
<td>203</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sodium benzoate</td>
<td>211</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potassium benzoate</td>
<td>212</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calcium benzoate</td>
<td>213</td>
</tr>
<tr>
<td>3. Sulphur dioxide</td>
<td>220</td>
<td>Sodium sulphite</td>
<td>221</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sodium hydrogen sulphite</td>
<td>222</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sodium metabisulphite</td>
<td>223</td>
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<td></td>
<td></td>
<td>Potassium metabisulphite</td>
<td>224</td>
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<td></td>
<td></td>
<td>Potassium sulphite</td>
<td>225</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potassium hydrogen sulphite</td>
<td>228</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calcium sulphite</td>
<td>226</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calcium hydrogen sulphite</td>
<td>227</td>
</tr>
<tr>
<td>4. Biphenyl, Diphenyl</td>
<td>230</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Orthophenylphenol</td>
<td>231</td>
<td>Sodium orthophenylphenate</td>
<td>232</td>
</tr>
<tr>
<td>6. Nisin</td>
<td>234</td>
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<td></td>
</tr>
<tr>
<td>7. Potassium nitrite</td>
<td>249</td>
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</tr>
<tr>
<td>8. Sodium nitrite</td>
<td>250</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Sodium nitrate</td>
<td>251</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Potassium nitrate</td>
<td>252</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Propionic acid</td>
<td>280</td>
<td>Sodium propionate</td>
<td>281</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calcium propionate</td>
<td>282</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potassium propionate</td>
<td>283</td>
</tr>
</tbody>
</table>
Schedule II provides list of articles of Food which may contain Permitted Preservative and the Nature and Quantity of the Permitted Preservative in each case.

### Permitted COLORS

#### A. Synthetic Colors

As Per Coloring Substances Regulations

<table>
<thead>
<tr>
<th>Color</th>
<th>Common Name</th>
<th>Color Index</th>
<th>INS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Carmosine</td>
<td>14720</td>
<td>122</td>
</tr>
<tr>
<td></td>
<td>Ponceau 4R</td>
<td>16255</td>
<td>124</td>
</tr>
<tr>
<td></td>
<td>Erythrosine</td>
<td>45430</td>
<td>127</td>
</tr>
<tr>
<td>Yellow</td>
<td>Sunset Yellow FCF</td>
<td>15985</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>Tartrazine</td>
<td>19140</td>
<td>102</td>
</tr>
<tr>
<td>Blue</td>
<td>Indigo Carmine</td>
<td>73015</td>
<td>132</td>
</tr>
<tr>
<td></td>
<td>Brilliant Blue FCF</td>
<td>42090</td>
<td>133</td>
</tr>
<tr>
<td>Green</td>
<td>Green S</td>
<td>44090</td>
<td>142</td>
</tr>
</tbody>
</table>

Synthetic dyes specified in Table 1 shall conform to the following standard:

- Pure dye minimum: 85.0%
- Water insoluble matter maximum: 0.1%
- Subsidiary dye maximum: 4.0%
- Ether extractable matter maximum: 0.2%
- Intermediates maximum: 0.5%
### B. Other Permitted Coloring Substances

As Per Coloring Substances Regulations

<table>
<thead>
<tr>
<th>INS Number</th>
<th>Natural coloring substance</th>
<th>Color index</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Curcumin</td>
<td>75300</td>
</tr>
<tr>
<td>120</td>
<td>Cochineal (Carmine Acid)</td>
<td>75470</td>
</tr>
<tr>
<td>140</td>
<td>Chlorophyll</td>
<td>73810</td>
</tr>
<tr>
<td>150b</td>
<td>Caramel</td>
<td></td>
</tr>
<tr>
<td>160a</td>
<td>Carotenes (alpha, beta or gamma)</td>
<td>75130</td>
</tr>
<tr>
<td>160b</td>
<td>Annato</td>
<td>75120</td>
</tr>
<tr>
<td>160c</td>
<td>Capsanthin or capsorubin</td>
<td></td>
</tr>
<tr>
<td>160d</td>
<td>Lycopene</td>
<td>75125</td>
</tr>
<tr>
<td>160e</td>
<td>Beta-apo-8’ – cartenal carotenic acid</td>
<td></td>
</tr>
<tr>
<td>161a</td>
<td>Flavoxanthin</td>
<td>75135</td>
</tr>
<tr>
<td>182</td>
<td>Beetroot red (betaxanthin)</td>
<td></td>
</tr>
<tr>
<td>163</td>
<td>Anthocyanins</td>
<td></td>
</tr>
<tr>
<td>171</td>
<td>Titanium dioxide</td>
<td>77891</td>
</tr>
</tbody>
</table>

---

### Commodity Standards

Case Studies
1. **Instant Noodles**

   • There is no standard for Instant noodles under the Food Act – this is not even considered as a possibility in the near future. SLSI is preparing draft standards. The texts are not yet available.

   • Reference can only be given to CODEX STAN 249-2006 which would be taken into consideration as a benchmark standard if and when such a standards framed.

2. **Carbonated Soft Drinks**

   • There is standard for Carbonated Soft Drinks. However SLSI is revising it and it will become the de facto standard under the Food Act once the standard is published under Food Act.
The draft SLS 183 prescribes the requirements and methods of sampling and testing for carbonated beverages and formulated caffeinated beverages. There are detailed requirements for ingredients to be used, flavors, preservatives, labeling, packaging, sampling and maintaining requirements for hygiene.

It allow:

- **Non-nutritive sweeteners:**
  - Aspartame - 600 mg/l (max)
  - Acesulfame-I - 350 mg/l (max)
  - Sucralose - 300 mg/l (max)
  - Neotame - 20 mg/l (max)

- **Caffeine in Carbonated Beverages:** 150 mg/l when tested in accordance with the method prescribed in AOA 979.08.

- **Caffeine in Formulated Caffeinated Beverage:** Not less than 100 mg/l when tested in accordance with the method prescribed in AOA 979.08.

The formulated caffeinated beverages can contain:

- Thiamine
- Riboflavin
- Niacin
- Vitamin B₆
- Vitamin B₁₂
- Pantothenic acid
- Taurine
- Glucururonolactone
- Inositol
3. Prepared Frozen Foods

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

4. Cow’s Milk

There are definition and standards for Cow’s Milk under the Food Act. These are being revised as per Draft Food (Milk and Milk Products) Regulations with Legal Departments. The requirements for additives and labeling are included in the regulations. Following categories of Cow’s Milk are included:

<table>
<thead>
<tr>
<th>1. Milk/Liquid Milk</th>
<th>8. Ultra Heat Treated Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Raw Or Fresh Liquid Milk</td>
<td>9. Flavored Milk</td>
</tr>
<tr>
<td>4. Semi-skimmed Milk Or Low Fat Milk</td>
<td>11. Reconstituted Milk</td>
</tr>
<tr>
<td>5. Skimmed Milk Or Non Fat Milk</td>
<td>12. Reconstituted Skimmed Milk</td>
</tr>
<tr>
<td>7. Sterilized Milk</td>
<td>14. Lactose Hydrolyzed Milk</td>
</tr>
</tbody>
</table>
Shelf Life of Imported Food Items Under Food Act

• The Regulation specifies that all items of food imported into Sri Lanka shall at the point of entry into Sri Lanka, possess a minimum period of sixty per centum (60%) of unexpired shelf life.

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

• The period of shelf life of an item of imported food shall be determined on the basis of the date of manufacture and the date of expiry as declared by the manufacturer of the product and which is depicted on the label attached thereto.

• For the purposes of these regulations, the expression “end of shelf life” shall be identified by the use of the words “date of expiry”, “best before”, “use by” or “use before” or other similar words which convey this meaning and which are used by a manufacturer of any food item being imported into Sri Lanka.

• For the purpose of these regulations “shelf life” means the period of time between the date of manufacture and its usability by the consumer, during which time the product is safe for human consumption and is of satisfactory quality in terms of nutritional value, flavor, texture and appearance.
Bangladesh
Officially The People’s Republic of Bangladesh (গণ জাতীয় রাষ্ট্র)

- Bangladesh is a country in South Asia. It faces the Bay of Bengal to its south, and is bordered by India on the north, west and east, as well as Burma (Myanmar) on the southeast.
- Bangladesh has the highest population density among large countries, 1,237.51 persons per square kilometer, and 12th overall, when small countries and city-states are included.
- Bangladesh has 7th largest population in the world - About 164.4 million.
- About 90% of Bangladeshis are Muslims and the remainder are mostly Hindus.
- Official language: Bengali (also known as Bangla).

Introduction To Regulatory Framework For Foods

- Bangladesh is yet to develop a unified Food Safety Administration System and to formulate a Food Safety Policy. But it has a National Food and Nutrition Policy where attention has been given on food safety.
- Significant activities in Food Safety and Quality Control are going on in the country. A number of Ministries, Departments and Agencies are involved in these activities with a major responsibility of the Ministry of Health and Family Welfare (MOHFW) which has a unique infrastructure to deliver its services throughout the country.
Major Stakeholder Ministries And Departments For Food Control

Food control in Bangladesh is a multi-sectorial responsibility.

<table>
<thead>
<tr>
<th>Sl No</th>
<th>Ministry</th>
<th>Department/Organization</th>
<th>Major activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ministry of Agriculture</td>
<td>Plant Protection Wing, DAE</td>
<td>• Phyto Sanitary certificate for Import/Exported plants/plant products&lt;br&gt;• Pesticide Use Control&lt;br&gt;• Fertilizer Use Control</td>
</tr>
<tr>
<td>2.</td>
<td>Ministry of Food</td>
<td>Directorate General of Food (DGF)</td>
<td>• Quality Control of FODS, Stocks, Processed Food grains/Food Stuff, Imported Food etc. &lt;br&gt;• Food Control in the Market (not doing at present)</td>
</tr>
<tr>
<td>3.</td>
<td>Ministry of Health &amp; Family Welfare</td>
<td>Directorate General of Health, District &amp; Upazila Health Administration and Institute of Public Health</td>
<td>• Food Quality and Sanitation Control in Upazila/District level&lt;br&gt;• Testing</td>
</tr>
<tr>
<td>4.</td>
<td>Ministry of LGRD</td>
<td>City Corporation &amp; Pourashawa Health Units</td>
<td>Have Sanitary Inspector, Labs and Public Analyst for food quality control in their command areas.</td>
</tr>
<tr>
<td>5.</td>
<td>Ministry of Fisheries &amp; Livestock</td>
<td>A) Department of Fisheries (FQCI, Wing)</td>
<td>• Fish Quality Control &amp; Certification for export&lt;br&gt; • Same for the domestic market</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B) Department of Livestock</td>
<td>• Animal Health&lt;br&gt;• Animal Products&lt;br&gt;• Imported Animal</td>
</tr>
<tr>
<td>6.</td>
<td>Ministry of Industries</td>
<td>BDTI</td>
<td>• Frame Standards of Food Products&lt;br&gt; • Testing &amp; Certification Marks and Surveillance</td>
</tr>
<tr>
<td>7.</td>
<td>Ministry of Science, Information and Communication Technology</td>
<td>BAEC</td>
<td>Text Radiation level of imported Food Items, Pesticides Residues&lt;br&gt; • Testing of Food Items; Research and Development</td>
</tr>
<tr>
<td>8.</td>
<td>Ministry of Education</td>
<td>DG, Primary, DG, Secondary, Text Book Board, Universities</td>
<td>Food Safety, Nutrition &amp; Environmental issues in the text book of all level of education</td>
</tr>
<tr>
<td>9.</td>
<td>Ministry of Information</td>
<td>PIB, RTV</td>
<td>Broadcast issues for awareness building</td>
</tr>
<tr>
<td>10.</td>
<td>Ministry of Home</td>
<td>Bangladesh Police</td>
<td>Assist Inspection Agencies</td>
</tr>
<tr>
<td>11.</td>
<td>Ministry of Law, Justice &amp; Parliamentary Affairs</td>
<td>-</td>
<td>Copyright, vetting, Parliamentary Approval etc.</td>
</tr>
</tbody>
</table>
Major Laws & Regulations

There are several laws in Bangladesh for maintaining health and safety standards but there are 2 major regulations as follows:

1) The Bangladesh Pure Food Ordinance, 1959 Under Ministry of Health And Family Welfare

   This is an ordinance to provide better control of the manufacture and sale of food for human consumption. Now, this Ordinance is under revision as 'The Bangladesh Pure Food (Amendment) Act'. Under this Act, it has been proposed to constitute a National Food Safety Council, headed by the Ministry of Health and Family Welfare as well as to establish Food Courts.

   AND

The Bangladesh Pure Food Rules, 1967

   The Pure Food Rules contain standards for 107 mandatory generic food standards. Now, these are under revision.

(2) The Bangladesh Standards And Testing Institution Ordinance, 1985 Amended By The Bangladesh Standards And Testing Institution (Amendment) Act, 2003 Under Ministry Of Indutsry

Under the Ordinance, the government has established the Bangladesh Standards and Testing Institution (BSTI). It certifies the quality of commodities, materials, whether for local consumption or for export and import.

POINTS TO NOTE

- All standards issued under Pure Food Rules are mandatory in nature and are enforced by BSTI.
- Carbonated water standards have been formulated and enforced under BSTI. These standards are based on Indian as well as CODEX guidelines.
- BSTI has adopted 153 Codex standards for food testing.
• 190 food standards developed by BSTI of which 52 should have compulsory certification marks.
• 28 Codex standards have been adopted as Bangladesh standards.
• The BSTI conducts Surveillance including Surprise Inspections and tests Samples At The BSTI Laboratory
• BSTI is the legal entity for certification of products and services under its Marks certification scheme.
• The legal metrological testing facility is under the BSTI management.
• Most of the imports and exports requirements are covered under BSTI mandate. For specific inquiries BSTI need to be consulted. BSTI has provided regional testing facilities in the ports as well main business centers.

Related Laws And Regulations

• Bangladesh - New food safety laws 17 Jan 2010
• The Cantonments Pure Food Act - 19/07/1966
• The Pure Food Ordinance - 14/10/1959
• The Animal Slaughter (Restriction) and Meat Control Act - 23/04/1957
• The Food (Special Courts) Act - 13/11/1956
• The Seed Rules - 08/03/1998
• Protection and Conservation of Fish Rules / Act - 17/10/1985
• The Breast-Milk Substitutes (Regulation of Marketing) Ordinance - 24/05/1984
  The Ordinance aims at protection and encouragement of breastfeeding, banning advertising, import, distribution and sale of breast-milk substitutes.
• The Marine Fisheries Rules - 05/09/1983
• The Marine Fisheries Ordinance - 19/07/1983
• The Fish & Fish Products (Inspection & Quality Control) Ordinance - 17/05/1983
• The Importers, Exporters and Indenters (Registration) Order - 22/10/1981
• The East Pakistan Fisheries (Protection) Ordinance - 24/03/1959
Laws And Regulations On Food Additives

Overview

- No definite description exists under Bangladesh Pure Food Rules 1967 on Food Additives.

- There are provisions for use of Colors, Flavors, Preservatives and Sweeteners.

- Functional Classes have been prescribed.

- Stabilizers or emulsifying agents are permitted.

- Antioxidants are permitted.

Flavors Under Pure Food Rules

- There is definition for Flavoring Compounds in food.

- Foods containing Flavors have to be labeled.

- Food containing added natural flavouring compounds shall be labelled in the legend with ‘NATURAL FLAVOUR’ or ‘CONTAIN NATURAL FLAVOURING’ provided that only those flavouring compounds which have been obtained from fruits or plants by extraction with suitable harmless solvents or by distillation or by expression, or by any other suitable process are used.

- Food containing artificial flavouring compound shall be labelled with the legend ‘ARTIFICIAL FLAVOUR’ or ‘IMITATION FLAVOUR’ provided that where a food contains a mixture of both natural and artificial flavouring compounds it shall be labelled as ‘ARTIFICIAL FLAVOUR’ provided further that those flavoring compounds which have been obtained by Chemical synthesis shall be considered as artificial.
Processing Aids
No description available under the Bangladesh Pure Food Laws 1967.

Carry Over
No description available under the Bangladesh Pure Food Laws 1967.

Functional Classes
Under Bangladesh Pure Food Laws, 1967, following functional classes of foods Additives have been listed:

- Milk and Milk Products.
- Edible Oils and Oil Products.
- Tea, Coffee, Roasted Coffee and Grounded Coffee.
- Sugars and Sugary Products Honey.
- Food Grains, Cereals and Their Products.
- Starchy Products.
- Non Alcoholic Beverages.
- Spices.
- Fruits, Vegetables and Miscellaneous Products.
- Edible Fats.
- Biscuits, Bread and Confectionery Product.
- Dried Fish.
- Ice.

- Flavoring Agents.
- Coloring Matters.
- Class I And Class II Preservatives.
- Antioxidants.
- Stabilizers.
- Non Nutritive Constituents.
- Common Salt.
- Baking Powder.
- Edible Gelatin
**Colouring Matter In Food**

**Coal-tar Dyes**

<table>
<thead>
<tr>
<th>Colour Index No.</th>
<th>Colour Index Name</th>
<th>Common Name</th>
<th>Chemical Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>73015</td>
<td>Food Blue 1</td>
<td>Indigo Carmine</td>
<td>Indigoid</td>
</tr>
<tr>
<td>42090</td>
<td>Food Blue 2</td>
<td>Brilliant Blue F.C.F</td>
<td>Triarylmethane</td>
</tr>
<tr>
<td>69800</td>
<td>Food Blue 4</td>
<td>Indanthrone</td>
<td>Anthraquinone</td>
</tr>
<tr>
<td>42051</td>
<td>Food Blue 5</td>
<td>Patent Blue V</td>
<td>Triarylmethane</td>
</tr>
<tr>
<td>42640</td>
<td>Food Violent 2</td>
<td>Violet 6b</td>
<td>Triarylmethane</td>
</tr>
<tr>
<td>42580</td>
<td>Food Violent 3</td>
<td>Violets B.N.P.</td>
<td>Do.</td>
</tr>
<tr>
<td>42085</td>
<td>Food Green 1</td>
<td>Sulpho Green 2 B.A.</td>
<td>Do.</td>
</tr>
<tr>
<td>42095</td>
<td>Food Green 2</td>
<td>Acid Brilliant Green</td>
<td>Do.</td>
</tr>
<tr>
<td>42053</td>
<td>Food Green 3</td>
<td>A.F. Green No. 3</td>
<td>Do.</td>
</tr>
<tr>
<td>15585</td>
<td>Food Yellow 3</td>
<td>Sunset Yellow F.C.F.</td>
<td>Monoazo</td>
</tr>
<tr>
<td>19140</td>
<td>Food Yellow 4</td>
<td>Tartrazine</td>
<td>Do.</td>
</tr>
<tr>
<td>20285</td>
<td>Food Brown 3</td>
<td>Brown F.K.</td>
<td>Disazo</td>
</tr>
<tr>
<td>14700</td>
<td>Food Red 1</td>
<td>Ponceau S.X.</td>
<td>Monoazo</td>
</tr>
<tr>
<td>16185</td>
<td>Food Red 9</td>
<td>Amaranth</td>
<td>Do.</td>
</tr>
<tr>
<td>45480</td>
<td>Food Red 14</td>
<td>Brachysin B.S.</td>
<td>Xanthene</td>
</tr>
<tr>
<td>28440</td>
<td>Food Black 1</td>
<td>Black P.M.</td>
<td>Disazo</td>
</tr>
</tbody>
</table>


- The maximum limit of permissible colour which may be added to any food shall be one grain per pound of food.

- The following natural colouring matters may be used in or, upon any article of food:
  - cochineal, carmine, caramel, Carotenes, chlorophyll, curcumin, lactoflavin, annatto, ratanjot, saffron.

- Inorganic colouring matters or pigments shall not be added to any article of food.

- The use of artificial or synthetic colouring matters in raw foodstuffs which are consumed after cooking in the usual way is prohibited.

- No person shall sell a coal-tar colour or a mixture of coal-tar colors unless the label on the package carries:
  - The common name (s) of the coal-tar colour (s).
  - The lot number of coal-tar colour; and
  - The words “Food Colour”.
Negative List

Use of permitted coal-tar dyes in or upon any food other than those shown below is prohibited:

- Ice-cream
- Dairy products except milk, dahi, butter, ghee, chhana, condensed milk, cream, and baby food
- Smoked fish
- Egg preparation
- Sweets including pastry and Other confectionaries
- Fruit Products
- Non-alcoholic beverages except tea, cocoa and coffee
- Custard powder
- Jelly crystals
- Soup powder and
- Luncheon meat
- Processed or preserved vegetables
- Flavoring agents

Preservatives Under Food Rules, 1967

<table>
<thead>
<tr>
<th>Class I Preservative shall be-</th>
<th>Class II preservative shall be –</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common salt</td>
<td>Benzoic acid including salts thereof,</td>
</tr>
<tr>
<td>Sugar</td>
<td>Sulphurous acid including salts thereof,</td>
</tr>
<tr>
<td>Dextrose</td>
<td>Nitrites of sodium or potassium in respect of food like ham, pickle, meat, and</td>
</tr>
<tr>
<td>Glucose</td>
<td>Sorbic acid including salts thereof.</td>
</tr>
<tr>
<td>Wood smoke</td>
<td></td>
</tr>
<tr>
<td>Spices</td>
<td></td>
</tr>
<tr>
<td>Vinegar or acetic acid</td>
<td></td>
</tr>
<tr>
<td>Honey</td>
<td></td>
</tr>
<tr>
<td>Hops</td>
<td></td>
</tr>
<tr>
<td>Commercial salt petre; and</td>
<td></td>
</tr>
<tr>
<td>Alcohol or potable spirit, and</td>
<td></td>
</tr>
</tbody>
</table>
The use of Class II preservatives is restricted to 26 specified group of foods and proportions in which they can be used has also been specified.

Use of more than one class II in any food is prohibited.

**Antioxidants In Food**

Antioxidants shall not be added to any food other than:

- Edible oils and fats from animal, vegetable and fish, vitamin oils or concentrates, and
- Products consisting essentially of fat such as margarine or the like.
Stabilisers In Food

The use of stabilizers or emulsifying agents, singly or in combination is permitted:

- Agar Agar.
- Carob bean.
- Irish moss or carragheen or chondrus.
- Guar gum.
- Sodium alginate.
- Monoglycerides or diglycerides of fatty acids.
- Brominated vegetable oils.
- Gum Acacia.

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

Non-Nutritive Constituents

- The following non-nutritive sweeteners or their salts-may be used:

  - Calcium cyclobexyl-sulphate; and
  - Sodium cyclohexyl-sulphate.

Non-nutritive sweeteners and sugar shall not be used in combination in any food.
Negative List For Food Additives

Negative List is Not clearly specified Under Bangladesh Food Laws, 1967. However, products are considered injurious to health if they contain the following metal or metalloids in excess of the tolerance limit showing against each-

<table>
<thead>
<tr>
<th>Metal</th>
<th>Maximum</th>
<th>parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
<td>250</td>
<td>2.0</td>
</tr>
<tr>
<td>Antimony</td>
<td>0.1</td>
<td>2.0</td>
</tr>
<tr>
<td>Arsenic Liquid</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Arsenic Solid</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Boron</td>
<td>80</td>
<td>2.0</td>
</tr>
<tr>
<td>Cadmium</td>
<td>6.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Zinc</td>
<td>100</td>
<td>2.0</td>
</tr>
<tr>
<td>Copper</td>
<td>10</td>
<td>2.0</td>
</tr>
<tr>
<td>Tin</td>
<td>100</td>
<td>2.0</td>
</tr>
<tr>
<td>Fluorine</td>
<td>1.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Silver</td>
<td>10</td>
<td>2.0</td>
</tr>
<tr>
<td>Lead Liquid</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Lead Solid</td>
<td>20</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Labeling Of Food Additives

- Most of the labelling requirements are in conformity to regional requirements and are guided by general principles of Codex Labeling norms. The labels are in Bangla and English dialects with general information on Brand Name, Manufacture details, weight/volume, price and date of manufacture. Labeling of additives is as per generic guidelines. Currently BSTI is developing the labelling policy.
Labelling Under Bangladesh Pure Food Rules, 1967

Container of food which contains preservative shall not be marked “pure” - the word “Pure” shall not be used on the label of the container of any food which contains preservative.

No preservative shall be sold for use in food unless the label carries:
• The common name.
• The chemical name.
• The net weight.
• Adequate directions for use in accordance with the limits prescribed for such preservatives; and
• The name and address of the manufacturer.

Commodity Standards
Case Studies
1. Instant Noodles

• Under Bangladesh Pure Food Rules, 1967, NO specific standard for Instant Noodles are prescribed. However, standards for cereal products, local products and vermicelli are provided.

2. Carbonated Soft Drinks

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

There are NO standards Under the Bangladesh Pure Food Rules, 1967, for Frozen Foods including fish, meat and poultry products.

4. Cow’s Milk

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

- The Federal Democratic Republic of Nepal, is located in South Asia in the Himalayas and bordered to the north by the People’s Republic of China, and to the south, east, and west by the Republic of India.
- Population of approximately 27 million.
- Nepal is the world's 93rd largest country by land mass and the 41st most populous country.
- Hinduism is practised by about 81% of Nepalese, Buddhism is linked historically with Nepal and is practiced by 9%.
- Official Language: Nepali
Introduction

• In the course of formulating food regulatory framework in Nepal in 1960s, many of the technical aspects were referred from Prevention of Food Adulteration Act of India or PFA. These days, the trend of updating of regulation is mainly guided by the Codex guidelines.

Legislations And Agencies

<table>
<thead>
<tr>
<th>Act/Rules and implementing Departments</th>
<th>Related Ministries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Act 1966 DTFC</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Food Regulation 1970 DTFC</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Consumer protection Act 1966 DTFC</td>
<td>Ministry of Commerce and Supplies</td>
</tr>
<tr>
<td>Consumer protection Rules 1966 DTFC</td>
<td>Ministry of Commerce and Supplies</td>
</tr>
<tr>
<td>Slaughterhouse and Meat Inspection Act 1966 DLS</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Slaughterhouse and Meat Inspection Rules 1966 DLS</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Local self-government Act 1999 Local Govt</td>
<td>Ministry of Local Development</td>
</tr>
<tr>
<td>Local self-government Rules 2000 Local Govt</td>
<td>Ministry of Local Development</td>
</tr>
<tr>
<td>Nepal Standards (Certification mark) Act 1993 NBSM</td>
<td>Ministry of Industries</td>
</tr>
<tr>
<td>Standard weights and Measures Act 1968 NBSM</td>
<td>Ministry of Industries</td>
</tr>
<tr>
<td>Standard weights and Measures Rules 1979 NBSM</td>
<td>Ministry of Industries</td>
</tr>
<tr>
<td>Animal health and treatment service Act 1995 DLS</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Animal health and treatment service Rules 1995 DLS</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Breast feeding substances (Sales &amp; Distribution control) Act 1994 DoF&amp;RC</td>
<td>Ministry of Health &amp; Population</td>
</tr>
<tr>
<td>Ministry of Agriculture Development</td>
<td></td>
</tr>
<tr>
<td>Pesticide Regulation Act 1991 DoA MoAD</td>
<td></td>
</tr>
<tr>
<td>Feed Act 1976: Department of Food Technology &amp; Quality Control</td>
<td>Ministry of Agriculture Development</td>
</tr>
<tr>
<td>Pesticide regulations Act 1991 LDC</td>
<td></td>
</tr>
</tbody>
</table>
Main Legislation


- The Administrative Authority for Food Act and Rules is Ministry of Agriculture Development.

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

- The Food Act provides for definitions of food and food adulteration, administrative infrastructure, offences and penalties and establishment of Department of Food Technology and Quality Control and setting up of Food Standardization Committee.

- The Food Rules provide for Food Additives, Contaminants, Inspections, Method of Sampling, Food Labelling, Use of Color and Preservatives etc.
The Department of Food Technology and Quality Control (DFTQC) functioning under Ministry of Agriculture Development (MoAD), Government of Nepal is the agency responsible for administering the food control programme in Nepal.

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

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

The Functions Of DFTQC, As Specified In Food Act, Are As follows:

- To analyse appeal (requested) samples.
- To assist the Food Standardisation Board in generating scientific data to set Standards for food.
- To conduct food inspector training program and issue licenses for food inspectors.
- To regulate imports of food products from the perspective of quality control.
- To facilitate export of food products from the perspective of food safety and quality.
- To provide laboratory services to food quality control programmes including industries and import export trades as requested.
Quality Control Division

This is the division responsible to execute the factions and activities specifically focused to food quality control (implementation of Food Act & Regulation). The activities include:

• Food Inspection.
• Industry Licencing.
• Consumer Awareness.
• Food Standardization And Compliance.

Food Standard Fixation Committee

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

- **Generic Standards**

- The standards of food commodities either common staple or their products, are included in the generic standards.

- Eleven groups of food commodities are included in mandatory standards in Nepal – Table 1.

---

### Table 1. Mandatory Standards For Food Commodities Of Nepal

<table>
<thead>
<tr>
<th>S. N.</th>
<th>Food Group</th>
<th>No. Of Food commodity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Milk &amp; Milk Products</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>Fats &amp; Oils</td>
<td>16</td>
</tr>
<tr>
<td>3</td>
<td>Fruits &amp; Vegetable Products</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>Spices &amp; Condiments</td>
<td>22</td>
</tr>
<tr>
<td>5</td>
<td>Tea, Coffee, Cocoa and their Products</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>Salt</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>Cereal, Pulses &amp; their Products</td>
<td>23</td>
</tr>
<tr>
<td>8</td>
<td>Processed Drinking Water</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>Non-Alcoholic Beverage</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>Sweetening Agent</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>Sweets and Confectionaries</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>109</strong></td>
</tr>
</tbody>
</table>
• The standards so far prepared and executed up to now are published in Nepali Language. For specific compositional and technical parameters the English version is also given in the brackets.

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

Laws And Regulations Related To Food Additives

• Standard published by Indian PFA (now FSSAI) and CODEX are frequently referred standard for additives in Nepal.
Flavors

- NO details on qualitative and quantitative terms are given in Nepalese food standard.

- Natural and artificial flavors in processed foods are referred in Codex and PFA publication.

Processing Aids

- NO specific definitions and quantitative limits are available in the existing Food Act and Regulation regarding processing aids.
**Carry Over**

No specific requirements available but generally guided by Codex requirements.

**Functional Classes**

- Only few classes such as Food Colors (natural and artificial), Preservatives (class I and Class II) and few Vitamins and Minerals are given with quantitative limits in Food Regulation and Standards in Nepal.
**Color**

- “Color” means any natural or artificial colour to be mixed in a food.

- **Coal Tar Colours (Synthetic Dyes) Are Allowed To Be Used In Food as per food specified in schedule 10 only.**

### Table 2. List Of Coal Tar Colours Permitted To Be Used In Food

<table>
<thead>
<tr>
<th>Type</th>
<th>Colour Index No. 1956</th>
<th>Common name</th>
<th>Other name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>16185</td>
<td>Amaranth</td>
<td>Food Red 9</td>
</tr>
<tr>
<td>Red</td>
<td>16255</td>
<td>Ponceau 4R</td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>45430</td>
<td>Erythrosine</td>
<td>Food red 14</td>
</tr>
<tr>
<td>Red</td>
<td>14720</td>
<td>Carmoisine (Azo Rubin)</td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>16045</td>
<td>Fast red E</td>
<td></td>
</tr>
<tr>
<td>Yellow</td>
<td>19140</td>
<td>Tartrazine</td>
<td>Food yellow 4</td>
</tr>
<tr>
<td>Yellow</td>
<td>15985</td>
<td>Sunset yellow FCF</td>
<td></td>
</tr>
<tr>
<td>Blue</td>
<td>73015</td>
<td>Indigo carmine</td>
<td>Food blue 1</td>
</tr>
<tr>
<td>Blue</td>
<td>42090</td>
<td>Brilliant blue FCF</td>
<td></td>
</tr>
<tr>
<td>Green</td>
<td>44090</td>
<td>Wool green B.S.</td>
<td></td>
</tr>
<tr>
<td>Green</td>
<td>42053</td>
<td>Fast green FCF</td>
<td></td>
</tr>
</tbody>
</table>
Maximum Limit of Permitted Colour: The above-mentioned Coal Tar Colours may be added to any food that is ready for consumption not in excess of 200 milligram per kilogram.

Restriction on the Use of Coal Tar Colours: The Coal Tar Colours can be used only in the following food:

(1) All kinds of ice-cream.
(2) Cheese.
(3) Different preparations from egg.
(4) Biscuit, cake, pastry, and other sweets.
(5) Non-alcoholic beverages except tea, coffee, coca cola.
(6) Custard powder.
(7) Jelly powder.
(8) Processed or preserved fruits and green vegetables.
(9) Soup powder.
(10) Flavouring agents.

Prohibition of the use of Coal Tar Colours: Even the specified Coal Tar Colours are not allowed to be used in any food to be eaten after cooking.

<table>
<thead>
<tr>
<th>Type</th>
<th>Colour Index</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>75.120</td>
<td>Annato</td>
</tr>
<tr>
<td>-do--</td>
<td>75.130</td>
<td>Carotine or β-carotine</td>
</tr>
<tr>
<td>-do--</td>
<td>75.100</td>
<td>Saffron</td>
</tr>
<tr>
<td>-do--</td>
<td></td>
<td>Riboflavin or lactoflavin</td>
</tr>
<tr>
<td>-do--</td>
<td>75.150</td>
<td>Turmeric or curcumin</td>
</tr>
<tr>
<td>-do--</td>
<td></td>
<td>Lentophil</td>
</tr>
<tr>
<td>Gray</td>
<td></td>
<td>Caramel</td>
</tr>
<tr>
<td>Red</td>
<td>75.470</td>
<td>Cochineal, carmine or carmine acid</td>
</tr>
<tr>
<td>-do--</td>
<td></td>
<td>Ratanjot, hamatoxilin</td>
</tr>
<tr>
<td>-do--</td>
<td></td>
<td>Arrayal (atsin)</td>
</tr>
<tr>
<td>-do--</td>
<td>75.520</td>
<td>Alkanet, alkaline</td>
</tr>
<tr>
<td>Green</td>
<td>75.810</td>
<td>Chlorophyll</td>
</tr>
</tbody>
</table>
There are restrictions on the use of inorganic colors and pigments.

No inorganic colors or pigments are permitted to be used in food preparations.

**Use Of Preservative In Food**

**First Class Preservatives**
- Common salt.
- Sugar/sugar candy.
- Dextrose.
- Glucose.
- Wood smoke.
- Spices.
- Vinegar or acetic acid.
- Honey.
- Hops, and
- Alcohol.

**Second Class Preservatives**
- Sodium or potassium nitrites.
- Benzoic acid and salts thereof.
- Sulphurous acid and sulphur dioxide.
The quantities of preservatives and the food in which they can be used have been mentioned in the Rules.

The use of more than one Second Class Preservative in any food is prohibited.

**Vitamins And Minerals**

- Vitamins and Minerals are allowed to be added in foods and the limits have been prescribed.
Labelling Requirements

• Where a color or a preservative is added to a food, any statement or any kind of symbol or sign indicating such addition has be mentioned on the label.

• The label of a food claimed to contain vitamins, minerals or other nutritional substances have to specify it on the label.

There are following provisions:

(a) One shall not claim that a food sold by him/her contains such vitamins and/or other nutritional substances without specifying the same on the label of that food.

(b) An advertisement or publicity statement shall not mention that a food contains such vitamins and/or other nutritional substances without specifying the quantity of such vitamins and/or other nutritional substances.

Revision

• The original Food Act does not cover the mandatory requirements and regulation mechanisms for functional foods, 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.
Nepal Bureau Of Standards And Metrology (NBSM)
Under Ministry of Industry

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

• There are 106 standards for food products and 13 for food packaging Materials.

Case Studies
1. Instant Noodles

• There are standards for Instant noodle.

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

2. Processed Milk

• There are standards for Processed milk.

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

• There are standards for Carbonated Water (nonalcoholic beverage).

• Carbonated Water (nonalcoholic beverage) means the beverage prepared by mixing one or more ingredients which is packed and sealed in bottle or can impregnated with carbon dioxide under pressure.

4. Frozen Foods

• There are no provisions for Frozen Foods.
• ACKNOWLEDGEMENT & THANKS

I would like to thank the following EXPERTS for their contribution in preparing Country Reports of Sri Lanka, Bangladesh and Nepal:

- Sri Lanka: Dr. S. Nagaiah, Consultant / Food Control Administration Unit, Ministry Of Health
- Bangladesh: Dr. G.M. Tewari, Consultant
- Nepal: Dr. Ganesh Dawadi, Deputy Director General, Dept. of Food Technology & Quality Control

THANK YOU
Towards Harmonization of Food and Food Additive Standards in ASEAN

ASEAN
(Association of South East Asian Nations)

- Formed on August 8, 1967 by 5 Founding Members (Indonesia, Malaysia, Philippines, Singapore, Thailand) through ASEAN Declaration (Bangkok)

- Original purpose: maintain regional security & stability (newly independent nations, threat of regional tension & disputes, wider threat of communism)
ASEAN Development


- As ASEAN ‘matures’, shift from security towards economic focus

- Move from regional cooperation towards regional integration objective

- ASEAN Free Trade Area (AFTA) (1992), realized in 2010 for ASEAN -6

- Formalization of ASEAN through ASEAN Charter in 2008

- Towards ASEAN Community 2015 -> comprising 1) ASEAN Security Community 2) ASEAN Socio-Cultural Community & 3) ASEAN Economic Community

ASEAN Today

- 10 Member States with a combined total population of 600 million

- Rapidly growing economic region:

<table>
<thead>
<tr>
<th>Country</th>
<th>2012 Real GDP Growth Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei Darussalam</td>
<td>2.7</td>
</tr>
<tr>
<td>Cambodia</td>
<td>6.5</td>
</tr>
<tr>
<td>Indonesia</td>
<td>6.0</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>8.3</td>
</tr>
<tr>
<td>Malaysia</td>
<td>4.4</td>
</tr>
<tr>
<td>Myanmar</td>
<td>6.2</td>
</tr>
<tr>
<td>Philippines</td>
<td>4.8</td>
</tr>
<tr>
<td>Singapore</td>
<td>2.1</td>
</tr>
<tr>
<td>Thailand</td>
<td>5.6</td>
</tr>
<tr>
<td>Vietnam</td>
<td>5.1</td>
</tr>
</tbody>
</table>

(Source: CIA World Fact Book)
ASEAN Economic Community (AEC)

- One of the pillars of the ASEAN Community to be established by 2015

- Objectives of the AEC, to be:

1) A single market and production base;
2) A highly competitive economic region;
3) A region of equitable economic development; and
4) A region fully integrated into the global economy

- Aim to make AEC a region with free movement of goods, services, investment, skilled labour and freer flow of capital, through cooperation on human resource development, enhancing infrastructure and communications connectivity, integrating industries across the region & enhancing private sector involvement, etc.

ASEAN Guiding Principles

- Guiding principles of ASEAN since its foundation:

1) respect for independence, sovereignty & equality
2) non-aggression & peaceful settlement of disputes
3) non-interference in internal affairs
4) consultation & consensus

- Collectively known as “The ASEAN Way”

- These principles are enshrined in the ASEAN Charter (therefore they are not likely to change in the foreseeable future)
Differences between ASEAN & EU economic integration

<table>
<thead>
<tr>
<th></th>
<th>ASEAN</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Established post-WW II &amp; de-colonization period with focus on security cooperation at the beginning and only later on economic integration</td>
<td>Established post-WW II with economic integration agenda from the beginning</td>
<td></td>
</tr>
<tr>
<td>Relations-based decision making through informal discussions between leaders</td>
<td>Rules-based decision making through formal negotiations between leaders</td>
<td></td>
</tr>
<tr>
<td>ASEC is purely an administrative institution</td>
<td>EC has mandate to initiate EU legislation</td>
<td></td>
</tr>
<tr>
<td>Voluntary adoption of rules based on national processes</td>
<td>Mandatory adoption of EU legislation once issued</td>
<td></td>
</tr>
<tr>
<td>No cases brought up for dispute settlement</td>
<td>Dispute settlements have helped spur harmonization</td>
<td></td>
</tr>
</tbody>
</table>

Harmonization of Food Standards in ASEAN

- Harmonization of ASEAN food standards led by the ASEAN Consultative Committee on Standards and Quality (ACCSQ) Prepared Foodstuff Product Working Group (PFPWG) through:
  a) Mutual Recognition Arrangements for inspection & certification procedures (based on Codex Alimentarius guidelines)
  b) Adoption of ASEAN harmonized technical standards or Codex standards (e.g. labeling, food additives, contaminants, contact materials, etc.)

- Capacity building efforts to strengthen ASEAN food control systems & infrastructures led by the ASEAN Expert Group on Food Safety (AEGFS), through ASEAN Food Safety Improvement Plan (AFSIP) on areas including:
  a) Risk assessment
  b) Laboratory capacity
  c) Risk communication
  d) Consumer education
  e) Food safety legislation
  f) Inspection & certification
Science as a Basis for Harmonization of ASEAN Food Standards and Controls

- There is general agreement among ASEAN food safety authorities to use risk assessment as a basis for food safety standards harmonization when clear agreement is not possible (ref: PFPWG Decision Tree)

- However, lack of scientific capacity, data & infrastructure in the region leave gaps to be filled and acts as barrier in applying science-based decision making.
Decision Tree for Harmonizing Divergence on Food Safety Standards

Decision by TF on Harmonization of Standards for Prepared Foodstuff on whether a risk assessment (exposure assessment) is needed on specific FSS at National or ASEAN level

- Risk assessment (exposure assessment) carried out at National level by AMS in relation to FSS
- Risk assessment (exposure assessment) carried out at ASEAN level in relation to FSS

Decision by TF on Harmonization of Standards for Prepared Foodstuff on harmonization of FSS based on risk assessment outcomes

- ASEAN FSS harmonized among AMSs
- No consensus on FSS (discontinue work or continue research to reconsider the decision)

ASEAN Standard could be proposed to be Codex Standard

(Food Additive Standards in ASEAN)

- Each ASEAN country has specific regulatory bodies responsible for control of use of food additives:

<table>
<thead>
<tr>
<th>Country</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei Darussalam</td>
<td>Food Safety &amp; Quality Control Division, Ministry of Health</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Department of Drug and Food, Ministry of Health; CAMCONTROL</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Ministry of Health; National Agency for Drug and Food Control</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Food and Drug Department, Ministry of Health</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Food Safety &amp; Quality Division, Ministry of Health</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Philippines</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Singapore</td>
<td>Agri-Food &amp; Veterinary Authority</td>
</tr>
<tr>
<td>Thailand</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Vietnam Food Administration</td>
</tr>
</tbody>
</table>
Food Additive Standards in ASEAN

- Most ASEAN countries have regulations that control use of food additives:

<table>
<thead>
<tr>
<th>Country</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei Darussalam</td>
<td>Public Health (Food) Regulations</td>
</tr>
<tr>
<td>Cambodia</td>
<td>NA</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Minister of Health Regulation No. 33 of 2012 on Food Additives</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Decision on the Control on Production, Exportation-Importation of Food No. 856/MoH</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Food Regulations 1985</td>
</tr>
<tr>
<td>Myanmar</td>
<td>NA</td>
</tr>
<tr>
<td>Philippines</td>
<td>AO No. 88As. 1984 on Regulatory Guidelines Concerning Food Additives; FDA Circular No. 2006-016 on Updated List of Food Additives</td>
</tr>
<tr>
<td>Singapore</td>
<td>Food Regulations</td>
</tr>
<tr>
<td>Thailand</td>
<td>Notification of the Minister of Public Health No. 281 B.E. 2547 (2004) on Food Additives</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Minister of Health Decision No. 3742/2001/QD-BYT on List of Additives Permitted for Use in Food</td>
</tr>
</tbody>
</table>

Harmonization of Food Additive Standards in ASEAN

- Current harmonization of food standards, including for food additives, at ASEAN-level is based on ‘vertical’ approach (by commodity) rather than ‘horizontal’ approach, for e.g.

  **Step 1:** selection of food category to be harmonized for food additives & contaminants (e.g. confectionary)

  **Step 2:** identification of differences in food additive & contaminant standards for the food category

  **Step 3:** agreement among TF on Harmonization of Standards for Prepared Foodstuff which food additives and/or contaminants to be harmonized according to PFPWG Decision Tree
ILSI SEAR’S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

1) ASEAN Food Safety Standards Harmonization Workshop Series

- Organized workshop series with food safety authorities from AMSs since 2001:
  - Initially started with FAO & WHO to determine whether possible for AMSs to harmonize food safety standards with Codex Standards, focusing on food additives
  - Serves as a platform for different stakeholders (government, academia & industry) to discuss and share scientific issues and identify capacity gaps that are relevant to food safety standards harmonization

- Main recommendations/outcomes/outputs in 2012:
  - ASEAN Food Safety Standards Database
  - ASEAN Risk Profiles for Contaminants (in progress)
  - Case Studies on Food Descriptions Used in Contaminant Standards of AMSs (in progress)

ASEAN Food Safety Standards Database

- In 2003, ILSI Southeast Asia Region developed a pilot database to support work on harmonization of food additive standards by ASEAN countries

- Includes information on food additive standards:
  - 45 selected additives (preservatives, sweeteners & colours)
  - Includes data from 10 ASEAN countries
  - Food categorization based on Codex General Standard for Food Additives
ASEAN Food Safety Standards Database

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2011</td>
<td>Decision to hand over AFSSD to ACCSQ PFPWG at 9th ASEAN Food Safety Standards Harmonization Workshop</td>
</tr>
<tr>
<td>Feb 2011 - Dec 2011</td>
<td>Revamping and upgrading of AFSSD to meet current technical needs for food safety standards harmonization</td>
</tr>
<tr>
<td>Feb 2012</td>
<td>Shared at 10th ASEAN Food Safety Standards Harmonization Workshop</td>
</tr>
<tr>
<td>June 2012</td>
<td>Shared at 15th ACCSQ PFPWG and adopted by ACCSQ PFPWG for their use in the work on food safety standards harmonization</td>
</tr>
</tbody>
</table>

Website: www.aseanfssdatabase.com
Management of the Database

- **Administrator (ILSI Southeast Asia Region):**
  - Update values for GSFA additives when changes occur at CCFA
  - Update GSFA food categories when changes occur at CCFA
  - Update database to include new food additives (if any)
  - Maintenance and further upgrading of the database software
  - Pay for the web hosting of the database
  - Administer user access to the database (report to ACCSQ PFPWG on list of users, see who has accessed it and from where)

- **Moderators (ASEAN Focal Points):**
  - Modify national data for own country
  - Able to add country-specific custom categories
  - Not able to modify another country’s data

Current Status of the Database

- Population of data for Codex GSFA has been completed

- Collection of data on national food additive standards via identified National Focal Points, starting with ‘priority’ food additives (e.g. colours, preservatives, sweeteners)

- Data collected from AMSs on colours as of Dec 2012

- Second template on preservatives sent out via ASEC to AMSs in Jan 2013

- Decision regarding opening of database to wider audience to be decided by ACCSQ PFPWG (AMSs are generally supportive when the timing is appropriate)
ILSI SEAR’S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

2) Training Workshops on Risk Assessment of Food Additives

- Organized in Philippines (February 24, 2012) and Thailand (February 27, 2012) for national food safety authorities and risk assessors
- Discussed topics including general principles for risk assessment of food additives, exposure assessment and provided specific case studies on steviol glycosides, etc.

2) ASEAN Food Consumption Data and Exposure Assessment Workshop

- Organized in Malaysia (October 10-13, 24, 2012) inviting food consumption data experts and risk assessors from all ASEAN countries
- Discussed development of harmonized food consumption data among ASEAN countries for use in exposure assessment, including for during approval of food additives

ILSI SEAR’S Role & Activities in Supporting Food Safety Standards Harmonization in ASEAN

- ILSI SEAR seeks to continue playing a role in supporting ASEAN efforts in harmonization of food safety based on scientific principles and evidence
- This may be achieved through:
  - sharing of latest scientific information and technical knowledge on identified and emerging food safety concerns
  - helping to develop and build capacity in relation to food safety and risk assessment infrastructures within ASEAN (e.g. ASEAN Food Safety Standards Database, ASEAN Risk Profiles, ASEAN Food Consumption Data, etc.)
- Nevertheless, harmonization of food safety standards in ASEAN will be a long and challenging process
Thank you

Website: www.ilsi.org/SEA_Region

Mr. Keng Ngee Teoh
Scientific Program Manager
ILSI Southeast Asia Region
E-mail: kengngee@ilsisea.org.sg
Market for Processed Foods in India

MARKET FOR PROCESSED FOODS IN INDIA

BY

D H PAI PANANDIKER
CHAIRMAN, ILSI-INDIA

MARKET FOR PROCESSED FOODS

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLOBAL MARKET</td>
<td>¥ 400 trillion</td>
</tr>
<tr>
<td>GLOBAL EXPORTS</td>
<td>¥ 24 trillion</td>
</tr>
<tr>
<td>INDIAN MARKET</td>
<td>¥ 7.7 trillion</td>
</tr>
<tr>
<td>INDIA’S EXPORTS</td>
<td>¥ 600 billion</td>
</tr>
</tbody>
</table>
### PROCESSING OF AGRICULTURAL PRODUCTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaysia</td>
<td>80</td>
</tr>
<tr>
<td>Philippines</td>
<td>78</td>
</tr>
<tr>
<td>Brazil</td>
<td>70</td>
</tr>
<tr>
<td>China</td>
<td>40</td>
</tr>
<tr>
<td>Thailand</td>
<td>30</td>
</tr>
<tr>
<td>India</td>
<td>20</td>
</tr>
</tbody>
</table>

### PRODUCTION OF SELECT AGRICULTURAL COMMODITIES

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits</td>
<td>80 mil tons</td>
</tr>
<tr>
<td>Vegetables</td>
<td>140 mil tons</td>
</tr>
<tr>
<td>Milk</td>
<td>115 mil tons</td>
</tr>
<tr>
<td>Fish</td>
<td>8 mil tons</td>
</tr>
<tr>
<td>Poultry</td>
<td>0.8 mil tons</td>
</tr>
<tr>
<td>Eggs</td>
<td>60 billion</td>
</tr>
<tr>
<td>Food grains</td>
<td>250 mil tonnes</td>
</tr>
</tbody>
</table>
GROWTH OF FOOD PROCESSING INDUSTRY (In Trillion Yen)

<table>
<thead>
<tr>
<th>Year</th>
<th>Share (Trillion Yen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>4.2</td>
</tr>
<tr>
<td>2006</td>
<td>4.7</td>
</tr>
<tr>
<td>2007</td>
<td>5.92</td>
</tr>
<tr>
<td>2008</td>
<td>7.03</td>
</tr>
<tr>
<td>2009</td>
<td>7.76</td>
</tr>
</tbody>
</table>

SECTORWISE SHARE IN FOOD INDUSTRY

- Corporate Sector: 42%
- Small Scale Sector: 25%
- Unorganized Sector: 33%
DRIVERS OF DEMAND FOR PROCESSED FOODS

- Increasing spending on Food Products
- Increasing Urbanisation -Lifestyle and Acquisitions
- Changing demographics -Rise in disposable incomes
- Growth of Organised Retail and Private Label Penetration
- Demand for Functional Foods/ Nutraceuticals
- Increasing Nuclear Families and Working Women

MARKET SIZE OF CORPORATE SECTOR IN PROCESSED FOODS 2010-11

<table>
<thead>
<tr>
<th>Food</th>
<th>Japanese Yen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk Powder and Condensed Milk</td>
<td>58.5 billion</td>
</tr>
<tr>
<td>Infant Milk Products</td>
<td>59 billion</td>
</tr>
<tr>
<td>Malted Milk Foods</td>
<td>62.8 billion</td>
</tr>
<tr>
<td>Ice-cream</td>
<td>21 billion</td>
</tr>
<tr>
<td>Flour Milling</td>
<td>215.6 billion</td>
</tr>
<tr>
<td>Biscuits</td>
<td>217 billion</td>
</tr>
<tr>
<td>Bread</td>
<td>13.3 billion</td>
</tr>
<tr>
<td>Breakfast Cereals</td>
<td>1.6 billion</td>
</tr>
<tr>
<td>Food</td>
<td>Japanese Yen</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Wafer and Potato Chips</td>
<td>29 billion</td>
</tr>
<tr>
<td>Fruits Juices</td>
<td>36.1 billion</td>
</tr>
<tr>
<td>Sauces/Ketchups/jams</td>
<td>17.4 billion</td>
</tr>
<tr>
<td>Sugar</td>
<td>1.03 trillion</td>
</tr>
<tr>
<td>Confectionery</td>
<td>134 billion</td>
</tr>
<tr>
<td>Vegetable Oil</td>
<td>1.8 trillion</td>
</tr>
<tr>
<td>Soya Products</td>
<td>339.5 billion</td>
</tr>
<tr>
<td>Poultry Products</td>
<td>116.9 billion</td>
</tr>
<tr>
<td>Marine Products</td>
<td>1.56 trillion</td>
</tr>
<tr>
<td>Soft Drinks</td>
<td>227 billion</td>
</tr>
</tbody>
</table>
Case Study 1: Business Expansion of Ajinomoto Co., Inc. in India

味の素㈱のインドにおける事業展開
Business Expansion of Ajinomoto Co., Inc. in India

2013年2月22日
February 22, 2013

味の素㈱　瀬野勝男
Ajinomoto Co. Inc., Katsuo Hamano

サブタイトル
Sub title

• うまみ調味料「味の素」の普及と
インドビジネスの可能性
Activities to promote Umami seasoning “AJI-NO-MOTO” and Business potentiality in India
目次
Contents

1. うまみ調味料「味の素」の普及
   Promoting Umami seasoning “AJI-NO-MOTO”
   • インド味の素社の成り立ちと立ち上げ期
     Business history of Ajinomoto India Pvt. Ltd.
   • リテイル営業の開始
     Starting sales activity for retail market
   • リテイル営業の進化
     Developing sales activity for retail market

2. 今後のインドビジネスの可能性
   Business potentiality in India
   • 魅力あるインド市場、人材
     Promising market and manpower
   • 日本人の人材に求められること
     Necessities for human resource from Japanese business person
1. うまみ調味料「味の素」の普及
Promoting Umami seasoning “AJI-NO-MOTO”

インド味の素社の成り立ちと立ち上げ期
Business history of Ajinomoto India Pvt. Ltd.

・2003年タミルナドゥ州チェンナイ市内に設立
  AIPL was established in Chennai city of Tamil Nadu in Y2003

・味の素㈱とタイ味の素㈱が出資
  Investor: Ajinomoto (Tokyo and Thailand)

・MSGを輸入し、リパック工場にて製造、販売
  AIPL imports MSG, repacks it as small size and sells in all over India
Managing director is Indian, director is Japanese.
The number of employee is around 300 including ISR, factory worker.
AIPL transferred office and factory at 2 times by calamity such as flood in Y2005 and subsidence of office floor in Y2011.

Starting sales activity for retail market

AIPL launched “AJI-NO-MOTO” 500g for food service since 2003, and started sales of small size of “AJI-NO-MOTO” in Y2005, and then accelerated area expansion in Y2007.
• 味の素リテイルウェイの浸透のため、営業同行、営業研修とOJTを強化
In order to make sales person understand “Ajinomoto Retail Way”, I focused on OJT (On the Job Training) by going retail market together and doing sales seminar

Going together  Attaching sticker  Sales seminar

• PUSH型からPULL型営業へ変更
Changed sales stile from “PUSH-selling” to “PULL selling”

cf. 理由  Reason:
・返品防止  Avoid return goods
・売掛金の防止  Avoid Account Receivables
・店頭での新鮮な商品  Maintain fresh product at retailer
• In order to improve off-take at retail counter, we emphasized sales promotion activity in sales person mind

Caravan activity  In-shop activity  Sampling

• We focused on “Rasam” soup as a key menu and tried its penetration to consumer

Veg-Meals in South India  Rasam soup
Developing sales activity for retail market

- "Brand activity" as a core activity
  
  We changed from sales activity into “Brand Activity” as a core activity

- Example) Changed evaluation point and sales promotion activity

<table>
<thead>
<tr>
<th>Manner</th>
<th>Discipline</th>
<th>Principle</th>
<th>Evaluation by customer</th>
<th>Sales Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>COD</td>
<td>Brand</td>
<td>Activity</td>
<td>Retail 3 missions</td>
<td></td>
</tr>
</tbody>
</table>

- Reduced 70% of Account Receivables and trying to collect forms (f-form, c-form)

- Changing sales system from distributor to own depot by direct sales
We launched “Hapima” masala and are selling in south India

2. 今後のインドビジネスの可能性
Business potentiality in India
魅力あるインド市場、人材
Promising market and manpower

• 11億人の巨大な人口（胃袋）
  A large number (1.1 billion) of population (stomach)
• 家計所得増/簡便化/品質志向によるFMCGへ
  購買が増加
  Increasing purchase of FMCG (Fast Moving Consumer Goods) by income increase, simplification and quality-oriented

• 教育水準の向上による優秀な人材の増加
  Increasing the number of talented people by upgrading the standard level of education

• 一方で、就業経験のある人材の離職率が増加
  On the other hand, it is increasing a job separation rate of manpower who have an experience of working in other company
Japan's demand for human resources

Necessities for human resource from Japanese business person

• What do we have to do in a newly emerging country?
  Producing a new value which will contribute to happy life of consumer in each countries
• Creating and raising brand (increasing fans)
• Training human resource (as the other self)
• Making our company be active

By these necessities, we will increase net sales and profit.
We will contribute to society in those countries (tax payment and employment)
求められる人材像

Required person

- サバイバルができる人
  Survive in the tough situation
- 人が好きでコミュニケーションできる人
  Like people and good communication
- 胃袋が強い人
  Strong stomach
- 熱く語れる人（信念、ビジョン）
  Talk about faith and vision earnestly
- 即断即決即実践、率先垂範できる人
  Decide promptly, take the initiative and set a good example for others
- 現場によく足を運び現場発想ができる人
  Go to field market frequently and think by field-oriented
- 経験・勘・度胸のある人
  Well-experienced, Intuition and Boldness
- 人と金をマネジメントできる人
  Manage people and money

ご清聴ありがとうございました
Thank you very much!
ヤクルトの国際事業

2013年2月22日
㈱ヤクルト本社国際事業本部
理事 赤星 良一

ヤクルト菌の誕生
代田稔博士の願い
国際事業への進出と展開
インドコルカタ大規模臨床試験
マイクロビオタ・プロバイオティクス科学財団設立
ヤクルト菌の普及と健康の輪
YL組織の構築と女性労働市場の創出
ヤクルトの生い立ち

・ 1899年 代田稔 長野県上田市に生まれる
・ 栄養失調と感染症によって多くの友人が亡くなっていく。
・ 三高から京都帝大医学部に進学
・ 研究目標を赤痢やコレラ等の感染症の菌を殺すから感染しにくい体にするに変更
・ 治療医学から予防医学に
・ コレクションの中から、乳酸菌に効果があることを発見
・ 1930年 乳酸菌の強化培養(胃液、胆汁液)に成功

ヤクルト誕生

・ 1935年 シロタ株をヤクルトの商標で発売
・ 代田保護菌普及会の使命は「世界の人々の健康を守る」

・ 代田稔博士の哲学
  「予防医学」
  「健腸長寿」
  「誰もが手に入れられる価格で」
国際事業の変遷

第1段階  求められて

• 1964年 台湾
• 1968年 ブラジル
• 1969年 香港
• 1971年 タイ
• 1971年 韓国
• 1978年 フィリピン
• 1979年 シンガポール
• 1981年 メキシコ

第2段階  積極的戦略を持って

• 1991年 インドネシア
• 1994年 オーストラリア
• 1994年 オランダ
• 1995年 ベルギー
• 1996年 イギリス
• 1996年 ドイツ
• 1997年 アルゼンチン
第3段階 人口大国での基盤作りとビジネスモデルの拡大

- 2002年 中国
- 2004年 マレーシア
- 2005年 オーストリア
- 2005年 イタリア
- 2007年 アメリカ
- 2007年 ベトナム
- 2008年 インド

2300万本/日

≪2013年2月現在≫
28事業所・1研究所・23工場（15ヶ国）
岡山大学インド感染症共同研究センター

平成17〜18年度に日本政府が建設したNICEDの研究棟

岡山大学インド感染症共同研究センター

竹田美文  G. B. Nair
プロバイオティクスは腸管感染症を予防することができるか

大規模無作為二重盲検試験

・調査地域：コルカタ市
・調査対象：1〜5歳の乳幼児 約4,000人
・試験品：乳酸菌シロタ株飲料

一部の地域で残る生活様式
飲用サンプルの冷蔵輸送（ヨーロッパヤクルト⇒NICED）

(製造後1～3)
ヨーロッパ工場（オランダ）⇒出荷

ヨーロッパ工場（オランダ）⇒出荷

アムステルダム空港⇒保冷コンテナに積替え・輸出通関

(製造後4)
フランクフルト空港⇒ルフトハンザ航空にてコルカタへ

(製造後5)
インド・コルカタ空港⇒輸入通関後、冷蔵トラックへ積込・配送

NICED⇒引渡（土曜日AM6:00）

2つの経営方針

・ 農耕型経営
「畑を耕し、種を蒔き、辛抱強く水を遣り、品種改良を続け、長い期間を経た末に漸く収穫期を迎える」「この収穫で新たな畑を耕す」

・ 使命型経営
「代田保護菌普及会」が「世界の人々の健康を守る」という代田博士と同じ使命感を持ってヤクルトの普及に努める
2008年 インド工場竣工

マイクロビオタ・プロバイオティック科学財団
ヤクルトレディの育成

キラナショップ

宅配
スーパーマーケット

ホテル

05年 現地法人設立
06年 工場着工
(デリー郊外のライ)
08年 工場稼動、生産開始
デリーにて販売開始
09年 ムンバイにて販売開始
10年 バンガロールにて販売開始
12年 ハイデラバードにて販売開始
12年 チェンナイにて販売開始
13年 コルカタ等へ市場拡大を検討
### インドにおける社員数推移

<table>
<thead>
<tr>
<th>（単位：人）</th>
<th>2008年</th>
<th>2009年</th>
<th>2010年</th>
<th>2011年</th>
<th>2012年</th>
</tr>
</thead>
<tbody>
<tr>
<td>部門</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>人事・総務・経理・購買</td>
<td>8</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>営業</td>
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<td></td>
<td></td>
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<tr>
<td>宅配部門</td>
<td>26</td>
<td>32</td>
<td>36</td>
<td>56</td>
<td>69</td>
</tr>
<tr>
<td>直販部門</td>
<td>14</td>
<td>25</td>
<td>28</td>
<td>22</td>
<td>29</td>
</tr>
<tr>
<td>その他</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>小計</td>
<td>41</td>
<td>59</td>
<td>64</td>
<td>78</td>
<td>98</td>
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<td>学術広報</td>
<td>3</td>
<td>4</td>
<td>3</td>
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<tr>
<td>工場</td>
<td>39</td>
<td>27</td>
<td>27</td>
<td>27</td>
<td>31</td>
</tr>
<tr>
<td>合計</td>
<td>91</td>
<td>101</td>
<td>105</td>
<td>119</td>
<td>150</td>
</tr>
</tbody>
</table>

※12月末時点の数値。
インドの人達に健康を

ありがとうございました

ありがとうございました