

## **In India FSSAI (Food Safety and Standards Authority of India) regulate the food safety and standards**

Section 92 (1) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards in consistent with this Act and Rules made there under. After the enactment of the FSS Act, 2006 FSSAI has drafted six principal regulations through extensive consultation and deliberations/ meetings with various stakeholders. These regulations have been notified in the gazette of India on 1st August, 2011 and came into force on 5th August, 2011.

These regulations/standards are further reviewed and several new regulations are notified taking into account the latest developments in food science, food consumption pattern, new products and additives, advancement in the processing technology and food analytical methods and also with a view to bridge the gap between national and international standards for food products.

That formulation and revision of regulations/ standards involves several stages. After recommendation by the Scientific Panel, following the due process laid down including validation by the Scientific Committee a regulations/ standards are approved by the Food Authority. After soliciting comments of stakeholders and their considerations, final notification is issued for implementation.

In addition to the Six principal regulations notified on 1st August 2011, following new regulations are notified. These include:

1. Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016
2. Food Safety and Standards (Food Recall Procedure) Regulation, 2017
3. Food Safety and Standards (Import) Regulation, 2017
4. Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.
5. Food Safety and Standards (Organic Food) Regulation, 2017.

### **About**

## **FSSAI: Laws and Regulations**

1. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011

2. Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011
3. Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011
4. Food Safety and Standards (Packaging and Labelling) Regulation, 2011
5. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
6. Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011
7. Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
8. Food Safety and Standards (Food Recall Procedure) Regulation, 2017
9. Food Safety and Standards (Import) Regulation, 2017
10. Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
11. Food Safety and Standards (Organic Food) Regulation, 2017
12. Food Safety and Standards (Alcoholic Beverages) Regulation, 2018
13. Food Safety and Standards (Fortification of Food) Regulation, 2018
14. Food Safety and Standards (Food Safety Auditing) Regulation, 2018
15. Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018
16. Food Safety and Standards (Advertising and Claims) Regulation, 2018
17. Food Safety and Standards (Packaging) Regulation, 2018
18. Food Safety and Standards (Recovery and Distribution of Surplus food) Regulation, 2019
- 19. Food Safety and Standards Authority of India Business Transaction Regulations, 2010**

# **International Consideration:**

## **(Food safety agencies and regulations)**

Each nation administers its own food laws and standards. The challenge is for businesses that export and import food among the nations -- how do they meet the variety of national standards. The purpose of this page is to focus some attention on the food standards of other nations as well as international standards that strive to harmonize global food standards. This page does not offer a detailed discussion of each nation's standards, but instead provides links to their web sites. The information on these web sites is an opportunity to view how other nations address food safety concerns and to note both the similarities and differences among the national standards.

.Canada - Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/toce.shtml>

" The CFIA develops and delivers programs and services designed to protect Canadians from preventable food safety hazards, to ensure that food safety emergencies are effectively managed, and that the public is aware of--and contributes to--food safety. "

*Excerpt from* <http://www.inspection.gc.ca/english/fssa/fssae.shtml>

**List of Acts and Regulations** at <http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/list-of-acts-and-regulations/eng/1419029096537/1419029097256>

Canadian definition of **adulterated**: <http://laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html#h-4>

*Note the reference to HACCP.*

.European Union

- REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT; see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>
- "The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety."  
See <http://www.efsa.europa.eu/en/aboutefsa.htm>

.Norway -- Norwegian Food Safety Authority

<https://www.mattilsynet.no/language/english/>

"The Norwegian Food Safety Authority is a governmental body. Our goal is that consumers should have healthy and safe food and safe drinking water. We promote human, plant, fish and animal health, environmentally friendly production, and ethically acceptable farming of animals and fish. The Norwegian

Food Safety Authority also performs duties relating to cosmetics and medicines, and inspects animal health personnel."

Taken from <http://www.mattilsynet.no/english/about>

.United Kingdom -- Food Standards Agency <http://www.foodstandards.gov.uk/>

"The Food Standards Agency is an independent food safety watchdog set up by an Act of Parliament in 2000 to protect the public's health and consumer interests in relation to food."

Taken from <http://www.foodstandards.gov.uk/aboutus/>

- Australia and New Zealand -- Food Standards Australia New Zealand <http://www.foodstandards.gov.au/>

France -- <http://www.securitesanitairesaliments.agriculture.gouv.fr/>

Netherlands -- <https://english.nvwa.nl/>

- "The task of the Food and Consumer Product Safety Authority is to protect human and animal health. It monitors food and consumer products to safeguard public health and animal health and welfare. The Authority controls the whole production chain, from raw materials and processing aids to end products and consumption."

Japan -- <http://www.mhlw.go.jp/english/topics/foodsafety/>

India -- <http://fssai.gov.in/home>

- "The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption."

Kenya -- Kenya Bureau of Standards (KEBS) at <http://www.kebs.org/>; also note

- " Food and Agriculture Department ... is responsible for the development of standards covering food technologies, food safety, fertilizers, agricultural produce, livestock and livestock products, poultry and poultry products, etc."  
See <http://www.kebs.org/index.php?view=stdoverview>

Uzbekistan

- Ministry of Agriculture -- [www.agro.uz](http://www.agro.uz)

- The Agency "UZSTANDART" -- [www.standart.uz](http://www.standart.uz)
- UzGo'shtSut Sanoat (Meat and Milk Industry) -- No web page
- Sifat Markazi (Quality Center) -- [www.sifat.uz](http://www.sifat.uz)
- Association of Oil-Fat and Food Industry -- [www.uzmaslojir.uz](http://www.uzmaslojir.uz)
- Davlat Don Inspeksiyasi (Wheat Inspection) -- [www.uzddi.uz](http://www.uzddi.uz)
- Pharmaceutical Industry "Uzpharmsanoat" -- <http://uzpharmsanoat.uz/en/>
- State Patent Office -- <http://www.patent.uz/eng/index.htm>
- Customs Committee -- [www.customs.uz](http://www.customs.uz)

Taiwan -- Just establishing (2014) a food safety agency -- <http://www.mohw.gov.tw/EN/Ministry/Index.aspx>

China -- see <https://www.ag.ndsu.edu/academic-sites/foodlaw/safe-408-608/chinafoodlaw>

Uganda

- Uganda National Bureau of Standards -- <http://www.unbs.go.ug/>
- "Microbiology laboratory -- UNBS is mandated with ensuring that and regulating the quality of foods and other consumable (edible ) products such as water, fruit juices etc."
- "Chemistry laboratory -- The chemistry laboratory provides services that help prevent contaminated and adulterated foods products from entering the market."

## International Food Safety Standards

*Participating (buying or selling; importing or exporting) in the world food market requires that one meets the expectations of trading partners; that is, **food exporters must comply with the standards imposed by the importing nation where the food will be consumed.** Consequently, a firm intending to export its product must comply with both the domestic **and** foreign laws.*

- *This duplication of regulation adds cost and complexity. If the national standards differ, the firm is forced to devise a process that complies with both -- or perhaps abandons the attempt to export to the targeted market.*
- *If the national standards are the same, the duplication still arguably adds unnecessary cost and burdens trade because the firm must repeat the process of demonstrating to the regulatory agency of both nations that the food is in compliance.*

*To ease the process, nations began to agree to accept imported food if 1) it met the standards of the exporting nation **and** 2) the standards and their administration in the exporting nation were determined by the importing nation to be equivalent to the standards of the importing nation. Thus, importing nations reviewed the laws and administration of the laws of the exporting nations to determine if there*

is **equivalency**. The assumption was that if there is equivalency of the laws and administration of the laws, a nation would accept imported foods that complied with the standards of the exporting nation.

- An example would be USDA "Eligibility of foreign countries for importation of products into the United States" at **9 CRR 327.2**.
- **Example of a report** following a USDA FSIS on-site audit of France's meat and poultry inspection system in 2007.
- How easy would it be for an importing nation to prevent competing imports by determining that there was "no equivalency" with an exporting nation?

Despite the benefit of eliminating the need for a firm to proceed through two nearly identical regulatory processes, the governments' efforts of determining equivalency remained a one-on-one (**bi-lateral**) process. For example, ten nations wanting to trade with each of the other nine nations would involve 45 equivalency determinations.

Nations soon devised a **multi-lateral** approach to the question of equivalency. This vision was based on the observation that if the standards for nation A are equivalent to the standards for nation B, and the standards for nation B are equivalent to the standards for nation C, logic would suggest that the standards for nations A and C should also be equivalent. Therefore, why not have the three nations enter into one multi-lateral agreement about equivalency, rather than three bilateral agreements? Why not also allow other nations to be part of such a multi-lateral agreement? Why stop there? Why not allow any nation that wants to trade with any other nation to do so as long as both nations agree to abide by the group's multi-lateral standards? Thus **international food standards** began to emerge.

The agreed-upon standards are ostensibly based on science, yet the politics of influencing trade and competition among nations have not been eliminated. Food standards are recognized as necessary, but it is still difficult to **distinguish between "food standards to assure safety" versus "standards to control trade."** Although international standards for food are not as developed as some national standards, expectations are that international food standards will continue to be refined.

International standards are likely to impact domestic standards. That is, if a nation wants its firms to participate in the world food trade, the firms will need to comply with the emerging, albeit voluntary, international standards. And because many businesses will not know for certain which of their product will be sold and consumed domestically and which will be sold internationally, the business will likely need to adhere to the international standards for all product. It is easy to envision that the international standards will not only be the standard for traded food, but also for food throughout nations involved in international trade -- which is nearly all nations.

- *Despite the support for multi-lateral agreements, the nations accept there will be times when unique standards will be justified. Thus the goal for the multi-lateral agreements may not be to achieve identical standards, but at least **harmonized** standards.*
- *Will international food standards emerge as a de-facto preemption of national standards?*

*This page considers emerging international standards and how individual countries may proceed in the coming years.*

### **Background -- Organizations**

*International standards - although voluntary - are emerging from the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations and from the World Trade Organization (WTO).*

*"The **Food and Agriculture Organization** of the United Nations leads international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy. FAO is also a source of knowledge and information. We help developing countries and countries in transition modernize and improve agriculture, forestry and fisheries practices and ensure good nutrition for all. Since our founding in 1945, we have focused special attention on developing rural areas, home to 70 percent of the world's poor and hungry people."*

*Excerpt from **FAO at Work***

*Also see **FAO Food Safety and Quality***

*"The **World Health Organization** is the United Nations specialized agency for health. It was established on 7 April 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."*

*Excerpt from **About WHO***

*"The **Codex Alimentarius Commission** was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations."*

*Excerpt from Codex Alimentarius **Welcome***

*Additional explanations of the Codex*

- **FAO Understanding the Codex Alimentarius**
  - *"The Codex Alimentarius ... has become the seminal global reference point for consumers, food producers and processors, national food control agencies and the international food trade. The code has had an enormous impact on the thinking of food producers and processors as well as on the awareness of the end users - the consumers."*
- **USDA Codex Alimentarius**
  - *USDA has lead responsibility for representing the US at Codex sessions: "[t]he U.S. Codex Office, located in FSIS, USDA, is the U.S. Contact Point for the Codex Alimentarius Commission and its activities."*

*"The **World Trade Organization (WTO)** is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business."*

*Excerpt from What is the WTO?*

*"The World Trade Organization came into being in 1995. One of the youngest of the international organizations, the WTO is the successor to the General Agreement on Tariffs and Trade (GATT) established in the wake of the Second World War."*

*Excerpt from The WTO in Brief: Part 1*

### **Background -- Activities**

*"Article 20 of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism. In addition, there are two specific WTO agreements dealing with food safety and animal and plant health and safety, and with product standards."*

*"A separate agreement on food safety and animal and plant health standards (the Sanitary and Phytosanitary Measures Agreement or SPS) sets out the basic rules."*

***The Codex standards for food are set by committees comprised of representaives from member nations.***

*"**General Subject Committees** are so called because their work has relevance for all Commodity Committees and, since this work applies across the board to all commodity standards, General Subject Committees are sometimes referred to as "horizontal committees". There are nine such committees:"*



*"Commodity Committees have responsibility for developing standards for specific foods or classes of food. In order to distinguish them from the "horizontal committees" and recognize their exclusive responsibilities, they are often referred to as "vertical" committees. There are 16 such committees:"*

*Excerpt from **The Codex system: FAO, WHO and the Codex Alimentarius Commission***

*Process for setting standards*

*"The Procedure for the Elaboration of Codex Standards describes the way by which Codex standards are prepared and the various Steps in the process which ensure comprehensive review of draft standards by governments and other interested parties. It was comprehensively revised in 1993 to provide a uniform elaboration procedure for all Codex standards and related texts. The Procedure was further revised in 2004 to introduce the strategic planning process and critical review."*

*Excerpt from **Codex Alimentarius Commission - 15th Procedural Manual**, p.4 of pdf file.*

*The standards should not be used as barriers to trade*

*"Under the WTO agreements, countries cannot normally discriminate between their trading partners... Imported and locally-produced goods should be treated equally"*

*Excerpts from **Understanding the WTO: BASICS Principles of the trading system***

*WTO's objective of trade neutrality is consistent with Codex*

*"The officials and experts who laid the foundations and determined the direction taken by activities of the Joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission were first and foremost concerned with protecting the health of consumers and ensuring fair practices in the food trade. They felt that, if all countries harmonized their food laws and adopted internationally agreed standards, such issues would be dealt with naturally. Through harmonization, they envisaged fewer barriers to trade and a freer movement of among countries, which would be to the benefit of farmers and their families and would also help to reduce hunger and poverty."*

*Taken from **Codex and the international food trade***

*But there are exceptions; one is national health concerns*

*"Article 20 of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as*

*disguised protectionism. In addition, there are two specific WTO agreements dealing with food safety and animal and plant health and safety, and with product standards."*

*"Member countries are encouraged to use international standards, guidelines and recommendations where they exist. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary."*

Taken from **Understanding the WTO: THE AGREEMENTS Standards and safety**

*Regional approach to distinct needs and concerns*

*Consistent with the idea that some areas have distinct needs, Codex encourages that distinct needs be identified and addressed by nations in the region, rather than individual nations. The hope is that a regional approach should lead to fewer issues than if distinct standards are established by individual nations. However, a regional approach does not prohibit individual nations from addresses their needs.*

*"The [Codex Regional] Coordinating Committee[s are] responsible for defining problems and needs concerning food standards and food control of all Codex member countries of the region."*

- See **The Codex system: FAO, WHO and the Codex Alimentarius Commission** (FAO)
- Also see **Regional Coordinating Committees** (FSIS) for a list of regional coordinating committee and **Regionalism: friends or rivals?** (WTO) for a brief discussion of the role of regional trading agreements.

## ***International Organization for Standardization (ISO)***

*Another entity that deserves some introduction is the International Organization for Standardization or ISO. Read the "Overview of the ISO System" at **International Organization for Standardization** Standards being developed by agreement among businesses with emphasis on testing procedures and manufacturing processes, rather than product characteristics. These standards are being referenced in business agreements.*

- ISO has addressed **food products** (TC 34)
- ISO also has published standards to address food safety. See
  - **ISO 22000:2005**-- Food safety management systems -- Requirements for any organization in the food chain

- *"ISO 22000:2005 specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption." Even though this statement does not explicitly reference Codex and HACCP, prior statements included explicit reference.*
- **ISO/TS 22004:2005** -- *Food safety management systems -- Guidance on the application of ISO 22000:2005*
- **ISO/TS 22003:2007** -- *Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems*
- **ISO 22005:2007** -- *Traceability in the feed and food chain -- General principles and basic requirements for system design and implementation*
- **ISO 24276:2006** -- *Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- General requirements and definitions*