

# International Food Regulatory System

**C O D E X**

**A L I M E N T A R I U S**

**International Food Standards**



**World Health  
Organization**



**Food and Agriculture  
Organization of  
the United Nations**

# Codex Alimentarius Commission (CAC)

- **The FAO** (Food and Agriculture Organization) **and the WHO** (World Health Organization) **jointly established the Codex Alimentarius Commission** (CAC) in 1962 to implement the joint FAO/WHO food Standards Programme.
- The aim of the commission is to protect the health of consumers by ensuring observance of fair practices in food trade.
- The CAC consults with the Directors-General of the FAO and the WHO on all matters pertaining to the implementation of the joint FAO/WHO Food Standards Programme.
- Codex Alimentarius includes general standards, which have across-the-board application to all foods and are not product-specific.

# General standards or recommendations

1. Food labelling
  2. Food additives
  3. Contaminants
  4. Methods of analysis and sampling
  5. Food hygiene
  6. Nutrition and foods for special dietary uses
  7. Food import and export inspection and certification systems
  8. Residues of veterinary drugs in foods
  9. Pesticide residues in foods
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- Most standards take a number of years to develop.
  - Once adopted by the Commission, a Codex standard is added to the Codex Alimentarius.
  - It has become incumbent on signatory countries of the SPC agreement to implement these standards.

# Purpose of the Codex Alimentarius

1. Collection of internationally adopted food standards and related texts presented in a uniform manner.
2. Protecting consumers' health and ensuring fair practices in the food trade.
3. Guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

## Nature of Codex Standards

1. Codex standards and related texts are not a substitute for, or alternative to national legislation.
  2. Every country's laws and administrative procedures contain provisions with which it is essential to comply.
  3. Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented.
  4. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the sections listed therein.
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# International Dairy Federation (IDF)



- IDF is the pre-eminent source of scientific and technical expertise for all stakeholders of the dairy chain.
- Membership covers 56 countries and is growing. The mission of IDF is to represent the dairy sector worldwide by providing the best global source of scientific expertise and knowledge in support of the development and promotion of quality milk and dairy products to deliver consumers with nutrition, health and well-being.
- IDF publishes jointly with the ISO, standards method of sampling and analysis of milk and milk products.

# Work areas of IDF





# International Organization for Standardization (ISO)

- The name ISO, derived from the Greek isos, meaning "equal".
- ISO is a network of the national standards institutes of **158 countries**
- One member per country, with a **Central Secretariat in Geneva, Switzerland**, that coordinates the system.
- ISO is a non-governmental organization that forms a bridge between the public and private sectors.
- It is the world's largest developer and publisher of International Standards.
- In French ISO was known as "OIN" (Organization internationale de normalization).



# ISO standards

## **1. ISO 9000 family- Quality management system:**

The ISO 9000 family is the world's best-known quality management standard for companies and organizations of any size.

## **2. ISO/IEC 27000 family: Information security management systems:**

Providing security for any kind of digital information, the ISO/IEC 27000 family of standards is designed for any size of organization.

## **3. ISO 14000 family: Environmental management:**

Improve your environmental performance with this family of standards.

## **4. ISO 31000: 2018: Risk Management**

Manage the risks that could jeopardize your company's performance with this ISO standard.

## **5. ISO 50001:2018- Energy management:**

ISO's standard for helping organizations manage their energy performance.



**6. ISO 26000: 2010 – Social Responsibility:**

Help your organization to operate in a socially responsible way with this standard.

**7. ISO/IEC 17025 – Testing and calibration laboratories:**

Testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods

**8. ISO 37001: 2016 – Anti Bribery Management systems:**

Prevent, detect and address bribery.

**9. ISO 45001 – Occupational Health and safety:**

Reduce workplace risks and make sure that everyone gets home safely with ISO 45001.

**10. ISO 22000 – Food Safety Management system:**

Inspire confidence in your food products with this family of standards.



# Characteristics of ISO standards are

## **1. Democratic:**

Every full member of ISO has the right to take part in the development of any standard which it judges to be important to its country's economy. No matter what the size or strength of that economy, each participating member in ISO has one vote. Each country is on an equal footing to influence the direction of ISO's work at the strategic level, as well as the technical content of its individual standards.

## **2. Voluntary**

ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce the implementation of its standards. ISO does not regulate or legislate. However, countries may decide to adopt ISO standards - mainly those concerned with health, safety or the environment - as regulations or refer to them in legislation, for which they provide the technical basis. In addition, although ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9001 quality management systems, or of dimensions of freight containers and bank cards. ISO itself does not regulate or legislate.



### **3. Market-driven**

- ISO only develops standards for which there is a market requirement. The work is mainly carried out by experts from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use.

### **4. By Consensus**

- ISO standards are based on international consensus among the experts in the field.
- Consensus, like technology, evolves and ISO takes account both of evolving technology and of evolving interests by requiring a periodic review of its standards at least every five years to decide whether they should be maintained, updated or withdrawn. In this way, ISO standards retain their position as the state of the art.

### **5. Globally relevant**

- ISO standards are technical agreements which provide the framework for compatible technology worldwide. They are designed to be globally relevant - useful everywhere in the world. ISO standards are useful everywhere in the world.



**FDA**

# Food and Drug Administration (FDA or USFDA)

- The FDA is formed in 1906 and has its headquarters at White Oak, Maryland.
- The agency also has 223 field offices and 13 laboratories located throughout the 50 states.
- FDA is an agency of the United States Department of Health and Human Services.
- The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.
- The FDA also enforces other laws, which include sanitation requirements on interstate travel and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.



# Organizations of FDA

The FDA comprises several offices and centers. Major are

- Center for Biologics Evaluation and Research
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Division of Manufacturing and Product Quality
- Division of New Drugs and Labeling Compliance
- Division of Scientific Investigations
- Division of Drug Marketing, Advertising and Communications<sup>8</sup>
- Informatics and Computational Safety Analysis Staff (ICSAS)
- Center for Food Safety and Applied Nutrition
- Center for Tobacco Products
- Center for Veterinary Medicine
- National Center for Toxicological Research
- Office of Regulatory Affairs



# What does FDA regulates ?

- The FDA regulates more than \$1 trillion worth of consumer goods, about 25% of consumer expenditures in the United States.
- This includes \$466 billion in food sales, \$275 billion in drugs, \$60 billion in cosmetics and \$18 billion in vitamin supplements.
- Much of the expenditures are for goods imported into the United States; the FDA is responsible for monitoring a third of all imports.
- Most federal laws concerning the FDA are part of the Food, Drug and Cosmetic Act.

# Regulatory programs of FDA

## i) Food and dietary supplements

- The Center for Food Safety and Applied Nutrition (CFSAN) is the branch of the FDA that ensures the safety and accurate labelling of nearly all food products in the United States.
- One exception is **meat products derived from traditional domesticated animals**, such as cattle and chickens, which fall under the **jurisdiction of the United States Department of Agriculture Food Safety and Inspection Service**.
- CFSAN also sets the requirements for nutrition labelling of most foods. Both food standards and nutrition labelling requirements are part of the Code of Federal Regulations.
- **Bottled water** is regulated in America **by the FDA**. State governments also regulate bottled water. **Tap water** is regulated by **state and local regulations**, as well as the **United States Environmental Protection Agency (EPA)**.

## **ii) Drugs**

The Centre for Drug Evaluation and Research has different requirements for the three main types of drug products:

- new drugs,
- generic drugs and
- over-the-counter drugs.

A drug is considered "new" if it is made by a different manufacturer, uses different excipients or inactive ingredients, is used for a different purpose, or undergoes any substantial change.

## **iii) Vaccines, blood and tissue products, and biotechnology**

- The Centre for Biologics Evaluation and Research is the branch of the FDA responsible for ensuring the safety and efficacy of biological therapeutic agents.
- These include blood and blood products, vaccines, allergenics, cell and tissue-based products, and gene therapy products.

#### **iv) Medical and radiation-emitting devices**

- The Centre for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices.
- Medical device starting from toothbrush to complex devices such as implantable brain pacemakers and some non medical devices that emit certain types of electromagnetic radiation are overseen by CDRH.

#### **V) Cosmetics**

- Cosmetics are regulated by the Centre for Food Safety and Applied Nutrition, the same branch of the FDA that regulates food.
- Cosmetic products are not in general subject to premarket approval by the FDA unless they make "structure or function claims", which make them into drugs.
- However, all colour additives must be specifically approved by the FDA before they can be included in cosmetic products sold in the U.S.
- The labelling of cosmetics is regulated by the FDA, and cosmetics that have not been subjected to thorough safety testing must bear a warning to that effect.

## **vi) Veterinary products**

- The Centre for Veterinary Medicine (CVM) is the branch of the FDA that regulates food, food additives, and drugs that are given to animals, including food animals and pets.
- CVM does not regulate vaccines for animals; these are handled by the United States Department of Agriculture.

## **vii) Tobacco products**

- Since the Family Smoking Prevention and Tobacco Control Act became law in 2009, the FDA also has had the authority to regulate tobacco products.
- In 2009, Congress passed a law requiring colour warnings on cigarette packages and on printed advertising, in addition to text warnings from the U.S. Surgeon General.
- The nine new graphic warning labels were announced by the FDA in June 2011 and are required to appear on packaging by September 2012.

# What Doesn't FDA Regulate?

FDA does not regulate:

- advertising (except for prescription drugs, medical devices, and tobacco products)
- alcoholic beverages
- some consumer products, such as paint, child-resistant packages, baby toys, and household appliances (except for those that give off radiation)
- illegal drugs of abuse, such as heroin and marijuana
- health insurance
- meat and poultry (except for game meats, such as venison, ostrich, and snake)
- restaurants and grocery stores

# FDA and India

FDA's activities in India are to ensure that food and medical products exported from India to the U.S. are safe, are good quality, and are effective.

## **FDA activities in India include:**

- **Engaging with Indian counterpart regulatory authorities** to ensure the timely exchange of information regarding clinical trials that are conducted that support marketing applications in the U.S.
- **Partnering with Indian counterpart agencies** on various bilateral and regional capacity building initiatives
- **Working with regulated product industries in India** that wish to export their products to the U.S. to assure their understanding of our standards and expectations regarding FDA-regulated products
- **Coordinating and collaborating daily on product quality and safety issues** with other U.S. government agencies

THANK YOU