



Chemical Quality Assurance (DTC- 311)



INTERNATIONAL REGULATIONS:

CODEX, IDF, ISO, FDA, EEC

Dr. Binita Rani
Associate Professor
Department of Dairy Chemistry
SGIDT, BASU, Patna

Codex Alimentarius Commission (CAC)

- The FAO and the WHO jointly established the Codex Alimentarius Commission (CAC) in **1962** to => implement the **joint FAO/WHO food Standards Programme**.
- **Aim** of the commission is to => **protect the health of consumers** by ensuring observance of fair practices in food trade.
- It promotes co-ordination of work on formulation of food standards undertaken by **international governmental and non-governmental organizations**.

- It shall be responsible for => making proposals to, and shall be consulted by, the Directors-General of the **FAO** and the **WHO** on => all matters pertaining to **implementation of the joint FAO/WHO Food Standards Programme.**
- In addition to **commodity standards**, Codex Alimentarius includes => **general standards**, which have across-the-board application to **all foods** and are **not product-specific.**

There are **general standards or recommendations** for:

- Food labeling;
- Food additives;
- Contaminants;
- Methods of analysis and sampling;
- Food hygiene;
- Nutrition and foods for special dietary uses;
- Food import and export inspection and certification systems;
- Residues of veterinary drugs in foods;
- Pesticide residues in foods.

- Most **standards** take a **number of years** to develop.
- Once adopted by the Commission, a **Codex standard** is added to the **Codex Alimentarius**.
- The Codex Alimentarius has become customary for => **health authorities, government food control officials, manufacturers, scientists and consumer advocates** to ask first of all: **What does the Codex Alimentarius have to say?**
- Adoption of HACCP standards, formulated by CAC, under the sanitary and phytosanitary (**SPC**) measures has made the **HACCP system an instrument of food safety**.
- It has become incumbent on signatory countries of the SPC agreement to **implement these standards**.

International Dairy Federation (IDF)

IDF publishes jointly with the ISO, **standard method of sampling and analysis of milk and milk products.**



Work Areas of IDF

International Organization for Standardization (ISO)

- 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**.
- **Nongovernmental organization** that forms => a **bridge** between the **public and private sectors**.
- World's **largest** developer and publisher of **International Standards**.
- It enables a **consensus** to be reached on solutions that meet both the **requirements of business** and the **broader needs of society**.

- "International Organization for Standardization" would have **different acronyms** in different languages e.g. "IOS" in English, "OIN" in French (Organisation internationale de normalisation).
- Its founders decided to give it also a short, all-purpose name. They chose **"ISO"**, derived from the Greek **isos**, meaning **"equal"**.
- Whatever the country, whatever the language, the short form of the organization's name is always **ISO**.

Characteristics of ISO standards :

1. Democratic

2. Voluntary

3. Market-driven

4. By Consensus

5. Globally relevant

Food and Drug Administration (FDA or USFDA):

- FDA is an agency of => the United States Department of Health and Human Services.
- Responsible for => protecting and promoting public health through => regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

- It 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**.
- It 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**.
- In **2008**, the FDA started opening offices in **foreign countries**, including => China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

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)
- Center for Food Safety and Applied Nutrition
- Center for Tobacco Products
- Center for Veterinary Medicine
- Division of Manufacturing and Product Quality
- Division of New Drugs and Labeling Compliance
- Division of Scientific Investigations
- Division of Drug Marketing, Advertising and Communications
- Informatics and Computational Safety Analysis Staff (ICSAS)
- National Center for Toxicological Research
- Office of Regulatory Affairs

What does FDA regulates

- It 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 (FDA regulates in the following areas):

- 1. Food and dietary supplements**
- 2. Drugs**
- 3. Vaccines, blood and tissue products, and biotechnology**
- 4. Medical and radiation-emitting devices**
- 5. Cosmetics**
- 6. Veterinary products**
- 7. Tobacco products**

What doesn't FDA regulate?

FDA does not regulate:

- advertising (except prescription drugs, medical devices, 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, eg., venison, ostrich, and snake)
- restaurants and grocery stores

FDA shares the responsibility for regulating these products with other government agencies:

pesticides (FDA, the U.S. Department of Agriculture, and the Environmental Protection Agency regulate these)

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, good quality, and effective.**

To this end, 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 that have complementary missions to assess conditions and events in those areas that might have an impact on the safety and quality of FDA-regulated products being exported to the U.S.

- Increased FDA inspections of **relevant high-risk facilities**; and by working with **private- and public-sector entities** that wish to engage with FDA on third-party certification efforts regarding these products.

European Economic Community (EEC)

(sometimes simply known as the **European Community**, also known as the **Common Market** in the English-speaking world)

- was an **international organisation** created with a view to => bring about **economic integration** (including a common market) among its six original members—Belgium, France, Germany, Italy, Luxembourg and the Netherlands.

Aims and achievements

Main aim was to => "preserve peace and liberty and to lay the foundations of an ever closer union among the peoples of Europe".

Calling for **balanced economic growth**, this was to be accomplished through:

- The establishment of a **customs union** with a common external tariff
- **Common policies** for agriculture transport and trade
- **Enlargement of the EEC** to the rest of Europe

For the customs union, the treaty provided for a **10% reduction in custom duties** and up to **20% of global import quotas**.

The background features abstract, overlapping geometric shapes in various shades of blue, ranging from light sky blue to deep navy blue. These shapes are primarily located on the right side of the frame, creating a modern, layered effect. The rest of the background is plain white.

THANKS