INTRODUCTION TO FOOD LAW

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For use in FDSC 3202

Department of Food Science
The University of Arkansas
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INTRODUCTION

This book is designed for the course ‘FDSC 3202 Introduction to Food Law’ and contains information and principles to enable an understanding of the basic legal concepts for students intending to work in the food industry. It is important that students should be familiar with basic information, including appropriate citation references. Nevertheless, students should also be able to apply knowledge in problem solving and learn how to use the food law and regulations literature and computer technology to solve specific problems. Students should also develop the career skills necessary to maintain current awareness of food law and regulatory developments to evaluate their significance for the industry.

Thinking, reasoning skills and applying knowledge to solve legal problems is a key part of the course. In-class exercises with questions at the end of each chapter and professional articles challenge students to do this. These notes are to be used with Federal Food Drug & Cosmetic Act, Code of Federal Regulations and regulatory agency website and other internet resources which should be used with other course materials. The computer internet is vital in researching legal literature and maintaining awareness of new developments in food law and regulations. Web site addresses have been included in the text to enable easy access to valuable sites but web sites addresses do change without warning and students should use search engines to locate new addresses if they encounter problems.

Remember, the knowledge and skills acquired in this course are used regularly by food science professionals in making corporate decisions related to: product development, labeling, food safety and marketing. The course will provide the opportunity to learn the basic principles of food law and the skills to maintain a current awareness of developments that will enhance your food industry career prospects and be valuable throughout your professional life.
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INTRODUCTION:

Food and drug laws have been necessary for two main reasons:

1. **Food Safety** - In the past, naturally occurring toxins from molds or rodent remains constituted a health threat. More recently, toxic dyes and preservatives were used in food processing. As insecticides and pesticides became available, the possibility of residues remaining on raw materials also constituted a danger to health. Now there is legislation protecting the consumer from poisonous substances in food and rigorous testing of any new food additive is necessary before it achieves legal status. More recently, bioterrorism has become an issue of concern.

2. **Quality or Standard of Acceptance** - In addition to being safe, commercially prepared foods have in the past had to conform to standards for that particular product. That standard included specific ingredients and the physical and chemical characteristics of the food. In this way the marketing of imitation or low quality goods is avoided. Furthermore, it is ensured that a product of a certain name, e.g. tomato juice, always has similar characteristics irrespective of the company it is marketed by.

HISTORY:

Food laws were in existence in early Hebrew and Egyptian civilizations and throughout European history. The first English food law was enacted by King John in 1202 to prohibit the addition of ground beans or peas to flour for used to make bread.

The history of food law in the United States dates back to colonial times. Food surpluses were traded abroad and standards for exported goods were introduced to make products more desirable to importers. For example, legislation was introduced to deter the addition of ground chalk or beans to milled flour.

Massachusetts was a leading colony in food legislation. As early as the 1640's and 1650's, it...
introduced laws relating to the inspection of animal products and the weight of a penny loaf of bread. However, Massachusetts did not pass a general food law until 1784. This law was the first of its kind, but non-specific in nature, ruling "against selling unwholesome provisions." This legislation pertained only to the state of Massachusetts. Other states developed their food laws independently. Coastal states exporting abroad had the most stimulus to develop a legal framework.

Unfortunately or by design, because each state developed its laws independently, a product sold in one state may be illegal in another. As a result, it was difficult for food to pass freely across state lines. However, reciprocal agreements between some states did exist, but there was a need to make food law a federal issue. Only this would promote unhampered interstate trade.

At the beginning of the twentieth century, three main problems needed to be addressed at the federal level.

1. Adulteration of food.

Poisonous food colors and preservatives containing lead, arsenic, mercury, formaldehyde and other toxic substances were commonly added to food. Furthermore, infestation rodent contamination, filth and decayed organic matter also endangered the food supply.

2. Misbranding of food.

Description on the label of a food container may not have been a reliable description of the food. A blatant example was a product sold as 'fruit jelly,' that contained only water, glucose, grass seed and artificial color. In addition, labels did not need to list the weight of ingredients.

3. False advertising.

Misleading advertising was common in the publicizing of 'patent cures' and remedies. False claims were common and went unchallenged.

Dr. Harvey W. Wiley brought the need of federal food laws to public attention by dramatically demonstrating the effects of ingesting toxic preservatives. He fed measured amounts of commonly used food additives to 12 men to demonstrate their effects. They became known as "The Poison Squad".

**PURE FOOD AND DRUG ACT 1906:**

As a result of the efforts of Wiley and others, the first national law dealing with food safety,
interstate trade and foreign commerce was passed. This law prevented "the manufacture, sale and transport of adulterated and misbranded food, medicine, and liquor." This applied to D.C. and territories of the U.S. and transport across state boundaries.

The main weaknesses of this legislation were:

1. It did not apply to articles manufactured and sold within a state boundary, and was not pre-emptive over state law.
2. It was difficult to enforce, as there was no objective quality control procedures.
3. It was necessary to show intent to adulterate or misbrand i.e. prove fraud.

There were two revisions of the 1906 act.

1. Gould amendment 1913 "net weight amendment"
   It became necessary for the 'weight, measure or numerical count to be conspicuously marked on the label' of every food item.
2. McNary-Mapes amendment 1930
   This introduced standards of quality and standards of fill for canned goods. The amendment allowed 10% headspace in a can to allow for stirring and expansion.

1938 FEDERAL FOOD DRUG AND COSMETIC ACT

HISTORY:

After the initial federal legislation in 1906, there was much resistance by industrial interests to further legal changes. However, after a large number of deaths as a result of the additive, "Elixir of Sulfanilamide", a major law was passed which formed the basis of current food legislation. The 1938 Food Drug and Cosmetic Act made a number of favorable changes.

1. Cosmetic and therapeutic devices were regulated for the first time.
2. Proof of fraud was no longer required to stop false claims for drugs.
3. Drug manufacturers were required to provide scientific proof that new products could be safely used before putting them on the market.
4. Addition of poisonous substances to foods was prohibited except where unavoidable or
required in production. Safe tolerances were authorized for residues of such substances, for example pesticides.

5. Specific authority was provided for factory inspections.

6. Food standards were required when needed 'to promote honesty and fair dealings in the interest of consumers.'

7. Federal court injunctions against violations were added to the previous legal remedies of product seizures and criminal prosecutions." - From HEW Publication no. FDA 79-1054

Amendments to the Act continue to be made in response to technological and social changes and other developments.

FORCES AFFECTING LEGISLATION:

Food legislation is an ever-changing process. Social, political, and economic forces are constantly influencing legal developments. These forces can be classified into three groups:

1. The Consumers - the public who wants food.

2. The Industry - the food producers.

3. The Government - the protectors of the food supply.

All three groups interact in the development of food law. This is seen in the evolution of the 1906 Act. Wiley, in government, worked toward effective legislation. The industry resisted these efforts until public opinion was stimulated to support new laws. However, not all regulations originated with government or the consumer. Around 1930, canned shrimp was being seized and destroyed by Food and Drug Administration because methods of detecting shrimp decomposition had been greatly improved. The industry was not capable of improving the practices of poorly supervised packing operations so they requested that an inspection law be passed so that guidelines would be available. The Seafood Inspection Act was passed in 1934.

With the development of 'consumerism,' the three factions are sometimes in conflict with each other. Subsequently, there is debate about the nature and quantity of present legislation. It is the responsibility of government to ensure safe and wholesome food for consumers while not making
legislation so repressive as to increase food costs or seriously reduce the supply.

Many Acts have been passed since 1938 that have modified the FDC&A as a result of societal forces affecting legislation. The following are such acts that have been passed by Congress over the last 20 years.

1990 Nutrition Labeling and Education Act, which radically changed the US food labels;
1994 Dietary Supplement Health and Education Act, that regulates dietary supplements;
1996 Food Quality Protection Act, which repealed the application of the Delaney Clause to pesticides;
1997 FDA Modernization Act which expedited certain administrative processes;
2002 Bioterrorism Act which mandates food facility registration, are examples of new legislation that resulted from the interaction of social, scientific, political and economic forces and,
2004 Food Allergen, Labeling and Consumer Protection Act, mandates that the label identifies common food allergens, if present e.g. nuts, fish, eggs and milk.
2011 FDA Food Safety Modernization Act, This is the most sweeping reform of food safety laws since 1938, was signed into law by President Obama on January 4, 2011. It aims to ensure that the food supply in the United States is safe by shifting the focus from responding to contamination to preventing contamination.

THE ROLE OF GOVERNMENT:

The control and regulation of food in the United States fits in the established legal and governmental framework. An understanding of this system is important in appreciating how food laws are produced and enforced.

Legislative Branch

"All legislative powers herein granted shall be vested in the Congress of the United States of America, which shall consist of a Senate and House of Representatives." Article I, the Constitution. Congress passes those laws that are enforced.

Executive Branch

"The executive power shall be vested in a President of the United States of America." Article II, the Constitution. The President is the 'chief executive' of the federal government with the role of enforcement
of legislation. However, the authority to implement laws is delegated to government departments and agencies. The administration consists of the Cabinet; the White House staff, executive agencies, which are advisory councils in specialized areas; and 50 independent government agencies. The Environmental Protection Agency (EPA) and Federal Trade Commission (FTC) are two of these independent agencies. In addition, there are the government departments. The Department of Agriculture and Department of Health and Human Services are involved with the enforcement of food legislation.

**Judicial Branch**

“The judicial power of the United States Government shall be vested in one Supreme Court, and in such inferior courts as the Congress may, from time to time, ordain and establish.” Article III, the Constitution. The Supreme Court delegates power to lower courts, but it can review its decisions. It is the role of the courts to interpret the law and settle legal disputes.

**State Governments**

State Government follows the Federal pattern, but Federal legislation pre-empts that of the state.

**FEDERAL FOOD, DRUG AND COSMETIC ACT AND GOVERNMENT OPERATION**

The diagram explains how the FFD&CA is administrated. Congress passed the act and the authority to enforce it was given to the government. This authority was delegated to the Department of Health and Human Services and ultimately to the Food and Drug Administration (FDA). On identifying a violation, the FDA can notify the U.S. Attorney who may then file charges with the U.S. District Court. The Court can then take legal measures. The FDA can take more lenient action by issuing a warning or allow a hearing before filing charges. The matter then passes through the judicial system.
POSSIBLE COURSES OF ACTION IN ENFORCING FEDERAL FOOD, DRUG, AND COSMETIC ACT

Your Hamburger: 41,000 Regulations

The hamburger, staple of the quick, inexpensive meal, is the subject of 41,000 federal and state regulations, many of those stemming from 200 laws and 111,000 precedent-setting court cases.

These rules, cited in a three-volume study by Colorado State University, touch on everything involved in meat production—grazing practices of cattle, conditions in slaughterhouses and methods used to process meat for sale to supermarkets, restaurants and fast-food outlets. Together, they add an estimated 8 to 11 cents per pound to the cost of hamburger.

The chart on this page gives just a sampling of the rules and regulations governing the burger you buy at the corner sandwich stand.

Pesticides—No more than 5 parts of the pesticide DDT per million parts of fat in the meat.

Bun—Enriched bun must contain at least 1.8 milligrams of thiamine, 1.1 milligrams of riboflavin and at least 8 but not more than 12.5 milligrams of iron.

Content—It must be fresh or frozen chopped beef and not contain added water, binders or extenders.

Growth promoters—Use of growth-stimulating drugs must end two weeks before slaughter.

Fat—No more than 30 percent fat content.

Pickle—Slices must be between 1/8 and 3/8 inches thick.

Lettuce—Must be fresh, not soft, overgrown, burst or “rubby.”

Tomato—Must be mature but not overripe or soft.

Ketchup—To be considered Grade A fancy, it must flow no more than 9 centimeters in 30 seconds at 69 degrees Fahrenheit.

Mayonnaise—May be seasoned or flavored as long as the substances do not color it to look like egg yolk.

Cheese—Must contain at least 50 percent milk fat and, if made with milk that is not pasteurized, must be cured for 60 or more days at a temperature of at least 35 degrees Fahrenheit.

Inspections—As many as six inspections under Federal Meat Inspection Act can occur as meat is checked before and after slaughter and at boning, grinding, fabrication and packaging stages.
THE BRANCHES

Executive
The President is the administrative head of the executive branch of the Government, which includes numerous agencies, both temporary and permanent, as well as the 13 executive departments.

Legislative
Congress, the legislative branch of the Government, is comprised of the elected representatives of the people in the Senate and the House of Representatives.

Judicial
Article III, section 1, of the Constitution of the United States provides that "the judicial power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.

THE LAWS

The agencies of the executive branch make administrative law. It is comprised of rules (also called regulations), and they have the force of law and are subject to review by the federal courts. Rules are frequently promulgated to implement legislation.

Congress enacts law through legislation by passing bills, and this is called statutory law. Congress often delegates through legislation the power of issuing regulations and of adjudication to administrative bodies.

Courts, in deciding controversies, make common law, which is also known as case law or judicial authority.
A. REGULATORY AGENCIES:

I. Government

The primary organization involved in enforcing food legislation is the Food and Drug Administration (FDA). It is concerned with enforcing the FFDCA. However, other organizations do have regulatory authority that affects the food industry. These include the Department of Agriculture and public health organizations. A discussion of these agencies follows.

The computer internet provides an opportunity for organizations to provide additional information on the world wide web (www). The URL (Uniform Resource Locator) address of an agency is stated in bold type, when available.

1. Food and Drug Administration (FDA) http://www.fda.gov/

   The United States Department of Agriculture (USDA) was originally responsible for food and drug law (1938-40). The Federal Security Agency acquired this responsibility in 1940 until it became part of the Department of Health Education and Welfare (HEW). Currently, food and drug law falls under the jurisdiction of the Department of Health and Human Services (HHS) (http://www.hhs.gov/) and is administered by the FDA.

   The FDA has authority to supervise and police the food industries involved in interstate commerce. This includes pre-market approval of food additives, factory inspections and ensuring the industry complies with minimum standards of acceptability and quality. They are particularly concerned with processing procedures, adulteration, and misbranding. Below is a more detailed list of their responsibilities:

   Examples of important activities:

   1. It makes periodic inspections of food establishments and examines samples of their
products for adulteration or misbranding. The 2011 FDA Food Safety Modernization Act mandates more factory inspection of those that pose a greater safety risk.

2. It establishes standards of identity, quality, and fill of containers of food products.

3. It develops and enforces regulations for proper food labeling.

4. It assists the food industry in voluntary compliance with the law and issues regulations designed to prevent violations.

5. It makes decisions on the safety of food additives and regulates the conditions of their usage.

6. It determines the safety of food colors and tests batches of those subject to certification.

7. It enforces safe limits on the amount of pesticide residues that may remain on food crops, if any.

8. It regulates drugs and feeds that are for human food-producing animals.

9. It enforces sanitation and safety regulations for food and water served to passengers traveling in regular interstate vehicles.

10. It monitors food supply to detect possible contamination with industrial chemicals or other deleterious substances and takes proper regulatory actions.

11. It maintains adequate communication with and extends maximal cooperation to state authorities and other federal agencies in urgent situations such as massive food contamination by floods, explosions, fires, and food poisoning.

12. It inspects the import of food products to assure compliance with domestic federal laws.

13. It warns the general public when a hazardous food product is identified.

14. It initiates court proceedings against firms and individuals that have violated the law(s).

In spite of its broad authority concerning the U.S. food supply, the following are some examples that define what the agency cannot do:
1. In general, the FDA can only regulate food manufacturers or firms that engage their products in interstate commerce. State officials have direct control over those products processed and sold solely within the state.

2. Although the FDA has authority over the safety of a food product before or after it enters interstate commerce, it cannot prevent a person from selling a worthless or harmful product. After such a product has been marketed, the FDA can challenge its value and safety and the agency bears the burden of proof. However, the 2011 FDA Food Safety Modernization Act gives FDA authority to prohibit entry of food into US that has been produced by an overseas company that has refused US inspection.

3. The FDA's authority in dealing with a food product it regulates is as follows:
   a. It can obtain a court order to seize a lot of defective food products.
   b. Before the 2011 FDA Food Safety Modernization Act FDA could not request a recall or legally seize certain food products if new scientific evidence shows that they may be hazardous or unacceptable although their interstate shipment and marketing were legal previously.

4. The FDA cannot regulate local and state food service sanitation, such as restaurants, delicatessens, drive-ins, fast-food counters, vending machines, and others.

5. The FDA cannot regulate food prices and food advertising.

6. The FDA cannot regulate cigarettes.

7. The FDA cannot regulate any food items containing more than 2% poultry and/or 3% meat product. The USDA regulates such products.

8. The FDA cannot regulate the quality as well as the sanitation of Grade A pasteurized fluid milk. It cooperates with and assists state authorities that have primary responsibility over the product.

9. The FDA can regulate unsolicited food products or related literature in the mail, if they are deceptive. The U.S. Post Office also has direct regulatory authority.

10. The FDA cannot regulate pesticide usage. This is the responsibility of the Environmental...
II. Statutes administered

1. The Tea Importation Act of 1897 as amended
2. Filled Milk Act of 1923
3. Import Milk Act of 1927
5. The Public Health Service Act of 1944
6. Poultry Products Inspection Act of 1957, as amended (one provision)
7. The Fair Packaging and Labeling Act of 1966
10. The Nutritional Labeling and Education Act 1990
11. The Dietary Supplement Health and Education Act 1994
12. The Food Quality Protection Act 1996
13. The FDA Modernization Act
14. The Bioterrorism Act 2002
15. 2004 Food Allergen, Labeling and Consumer Protection Act
16. 2011 FDA Food Safety Modernization Act

2. United States Department of Agriculture (USDA) [http://www.usda.gov/]

The USDA inspects and regulates meat, poultry, and other animal products, e.g. eggs and certain dairy foods. It is also responsible for many food and nutrition programs. USDA grading of foods is also an important function. The organization is divided into four services.

A. Food and Nutrition Service

   Activities

   1. The food stamp program
   2. National school lunch and breakfast program
   3. Commodity distribution programs

B. Agricultural Research Service (ARS)

   1. Conducts research in the areas of:
      -- Crop and animal production, protection, processing, and distribution
-- Food safety and quality
-- Natural resources conservation

2. Cooperative State Research Service
   -- Administers federal funding for research at the agricultural experiment stations
   -- Plans and coordinates federal-state research programs
   -- Administers competitive research grants program
   -- Administers federal funding for State Extension service
   -- Plans and coordinates Federal-State Extension programs

C. Food Safety and Inspection Service  http://www.fsis.usda.gov/
   Activities:
   1. Inspects and analyzes domestic and imported meat and poultry food products
   2. Establishes standards and approves labels for processed meat and poultry products
   3. Provides assistance in labeling, training, sanitation, etc.
   4. Codex alimentarius commission
      -- Established by Food and Agricultural Organization (FAO) of the United Nations
      and World Health Organization (WHO)
      -- Purpose: The protection of consumer health and facilitation of world trade by the
      establishment of uniform international food standards

Statutes Administered
   1. Federal Meat Inspection Act of 1967 (1906)
   2. Poultry Products Inspection Act of 1957

D. Agricultural Marketing Service (AMS)  http://www.ams.usda.gov/
   Activities:
   1. Development of quality grade standards
   2. Provide voluntary grade standards for meat, poultry, eggs, dairy products, fruits and
      vegetables
   3. Administers marketing regulatory programs

Protects the public consumer and businessman alike against anti-competitive behavior and unfair deceptive business or trade practices.

A. Bureau of Competition:
   1. Makes rules and regulations for various trade practices
   2. Investigates and litigates deceptive or unfair trade practices
   3. Advise and coordinate consumers, businessmen and government for better understanding
   4. Provide consumer education programs to detect deceptive trade practices

B. Bureau of Consumer Protection
   1. FTC has primary authority over advertising (Excluding labeling) of foods
   2. FDA has primary jurisdiction over labeling of foods
   3. FTC & FDA cooperate where both agencies are involved

   1. Activities:
      a. To maximize voluntary compliance with the laws and to minimize willful or involuntary violations
      b. To suppress the traffic in illicit distilled spirits
      c. Determines and assures full collections of revenue due from alcohol industries
      d. Prevent commercial bribery, consumer deception, and improper trade practices
      e. Assist in the resolution of problems relating to industrial development, ecology, revenue protection, and public health
   2. Statutes Administered:
      a. Internal Revenue Codes of 1918 and 1954
      b. Federal Alcohol Administration Act

5. U.S. Department of Commerce

National Bureau of Statistics; National Oceanic and Atmospheric Administration
National Marine Fisheries Service

Activities:
1. Voluntary in-plant inspection for fishery products and sanitation
2. Develops grade standards for fishery products
3. Voluntary inspection service to importers and exporters
4. Cooperate with FDA and USDA in inspection evaluation and use of food inspectors

Bureau of Industrial Economics (BIE)

-- Provided a wide range of services to business, including all types of food establishments.

6. U.S. Department of Labor

Occupational Safety and Health Administration (OSHA)

Activities:
1. Develops and promulgates occupational safety and health hazards
2. Develops and issues regulations
3. Conducts investigation and inspections to determine compliance
4. Issues citations and proposes penalties for non-compliance of regulations

Statue Administered:

Occupational Safety and Health Act (OSHA)

7. Public Health Service

Activities:
1. Stimulate and assist states and communities with health resources and development of education for the health profession.
2. Assist with delivery of health services to all U.S. citizens.
3. To conduct and support research in the medical and related sciences and disseminate scientific information.
4. To protect the health of the nation against impure and unsafe foods, drugs, cosmetics and other potential hazards.
5. Provide national leadership for the control and prevention of communicable diseases and other public health functions (CDC)

Despite the number of organizations, this course will be primarily involved with the role of FDA and USDA.


This is the latest federal agency and is concerned with national security, including bioterrorism which involves detection of intentionally adulterated foods.

FDA and USDA

In 1998 the National Academy of Sciences released a report recommending that a single agency be responsible for food safety. This was a controversial suggestion from both a political and philosophical point of view and the debate continues to this today.

1. Companies have a working knowledge of the FDA and USDA but a new agency would have to develop a new working relationship with industry that would present the food industry with uncertainty and the unknown. Many companies may be resistant to change. Some believe that change would automatically create more bureaucracy and increased costs.

2. Some believe in a single food regulatory agency in principle but the problems arise due to the different philosophy and structure of the FDA and USDA. The FDA is used to police the food industry and enforce legislation that could result in bringing a company to court. In addition, FDA is understaffed and overworked. However, USDA has a dual role to serve the industry and enforce USDA regulations. In addition, political interaction conflict between USDA and FDA may itself be a factor against formation of single agency.

II. NON-GOVERNMENT (INDEPENDENT) AGENCIES

Environmental Protection Agency (EPA)  http://www.epa.gov/

Protects and enhances our environment today and for future generations, control and abate pollution in the areas of air, water, solid waste, pesticides, noise, and radiation.

Activities:

1. Responsible for pesticide activities-tolerance levels and monitoring
2. Responsible for the planning, evaluation, and operation of toxic regulatory control programs
3. Responsible for water pollution abatement and control
4. Responsible for drinking water activities
5. Responsible for solid waste management activities
6. Responsible for radiation activities

Statutes administered:
2. Safe Drinking Water Act
3. Clean Air Act
4. Noise Control Act of 1972
6. Federal Insecticide, Fungicide, and Rodenticide Act
7. Federal Food, Drug, and Cosmetic Act

State and Local Laws and Regulations
I. The Arkansas Food, Drug, and Cosmetic Act: Administered by Arkansas Department of Agriculture
II. County City Regulations

[Material from this section on regulatory agencies is largely quotations from 'Statutes and Regulations Pertaining to Food and Food Products. Products.']
B. LITERATURE RELATING TO FOOD LAW

STATUTORY LAW - Legislation passed by Congress


All statutory laws in force in the United States are published in the United States Code. This publication contains almost all federal law which relates to the food industry. It is divided into Titles. The following are important titles relating to the food industry.

Title 7  Agriculture
  - United States Grain Standards Act
  - Federal, Insecticide, Fungicide and Rodenticide Act

Title 15  Commerce and Trade
  - Federal Trade Commission Act
  - Fair Packaging Act

Title 21  Food and Drugs
  - Tea Importation Act
  - Filled Milk Act
  - Import Milk Act
  - Butter Act
  - Dry Milk Solids Act
  - Wholesome Meat Act
  - Wholesome Poultry Products Act
  - Egg Products Inspection Act
  - Federal Food, Drug, and Cosmetic Act - Chapter 9

Title 21 is the most important title for food industrialists.


This the US code with additional notes to supplement the law itself.

United States Code Service (U.S.C.S.)

In this publication, the law is illustrated with reference to specific cases, which is described with reference to each point of law.

Proposed federal legislation being considered in Washington  http://thomas.loc.gov/

This address allows you access to legislation being debated in the House and discover what food
related issues are being currently considered.

ADMINISTRATIVE LAW (Regulations)


Statutory Laws differ from administrative law in that the statutory law describes in principle what is required whereas administrative law, or regulations, describe practically how it can be complied with. The administrative law is found in the Code of Federal Regulations (CFR). The CFR consists of titles; titles are divided into parts; parts are divided into sections. The important titles for the food industry are Title 7, Agriculture, and Title 21, Food and Drugs (See Appendix).

There is an official system of coding of CFR's. The following is an example of a citation; 21 CFR 101.9(c)(6)(ii). This is explained as follows:

21 - Title 21 Food and Drugs
CFR - Code of Federal Regulations
101 - part 101, Food Labeling
.9 - Section 9, Nutritional labeling of food
(c) - Paragraph (c), The declaration of nutritional information on the label
(6) - Subparagraph (6), "Fat content" or "Fat"
(ii) - Subdivision (ii) when cholesterol content is declared . . .

Find this reference in the CFR
1. Find the volume CFR 21 parts 100-169.
2. Find the pages with 101.9 in the upper corner.
3. Find paragraph c, subparagraph 6, subdivision ii.

Federal Register  https://www.federalregister.gov/

The Code of Federal Regulations are published annually whereas the Federal Register is a daily news bulletin on regulations. The Federal Register (FR) is a daily update of the CFR.

Regulations cannot become effective, or be repealed until they are published in the Federal
Register. Proposed changes are announced in the FR to allow interested parties to respond before final regulations are published in the FR. This is the 'Proposal and Comment' process and has the following steps each of which are published in the FR:

1. Advance notice of proposed rule making
2. The proposal, comment is solicited by the FDA
3. Final regulation.

EXECUTIVE ACTION

FDA Enforcement Report  http://www.fda.gov/safety/recalls/enforcementreports/

This is a weekly publication describing legal action taken by the FDA and measures taken by industry to recall defective products.

FDA Consumer  http://www.fda.gov/fdac/default.htm

The FDA Consumer is the official magazine of the FDA and provides information for the public relating to food and health, in addition to legal information.

JUDICIAL ACTIONS

Law Courts

Federal Judiciary:  http://www.uscourts.gov/

Court decisions of the Supreme Court, appeals courts and district courts are each reported in separate law journals. In addition to the government publication, there are commercial publishers (West Pub. Co.) who also produce law journals. The advantage of the commercially produced journals is that they are published faster than the government reports, and often provide additional footnotes. Most of the law library consists of reports of judicial actions. Court decisions are important because they create the criteria for deciding similar cases in the future. A guide to finding specific cases can be found at http://findlaw.com/casecode/

Supreme Court Cases

These are reported by the government in U.S. Reports (U.S.) and published commercially as the
Supreme Court Reporter (S.Ct.). Lawyers editions (L.Ed.) of the latter provide additional information.

**Appeals Court Cases**

Government reports are found in Court of Appeals of the Federal Courts (F.) while the Federal Reporter (F.2d) is a publication of appeal court cases by West Pub. Co.

**District Court Cases**

These are reported in the Federal Supplement (F. Supp.).

Cases are quoted, as for example, U.S. v. Coca Cola 241 U.S. 265. To find this case, locate volume 241 of U.S. Reports and turn to page 265.

**OTHER USEFUL PUBLICATIONS**

**Food Chemical News; Food**  [http://www.foodchemicalnews.com/](http://www.foodchemicalnews.com/)

A weekly publication providing details of the latest developments in legislation, FDA activity, food safety, court decisions and other aspects of food law. It is invaluable in keeping up to date on a weekly basis on current developments in food law and regulations.

**The Almanac of the Canning, Freezing, Preserving Industries**  

This is a collection of important law and regulations for food processors, including FD&CA, standards of identity and packaging regulations. It is a useful compilation of materials of interest to food processors.


This is a scholarly journal published six times a year by the Food Drug Law Institute, that contains in depth articles by experts on various aspects of food, drug and cosmetic law.


This a scholarly journal published twice a year by the University of Arkansas Law School

**Useful worldwide web sites**

IFTTechnology, Food Law Division:  [http://connect.ift.org/groups/home/51](http://connect.ift.org/groups/home/51)
Codex Alimentarius (international food law): [http://www.codexalimentarius.net/](http://www.codexalimentarius.net/)

References


Question

1. Should there be only one food regulation agency? What are the advantages and disadvantages of having more than one agency regulating the food industry? Read the Food Technology articles relating to this chapter.
FOOD AND DRUG ADMINISTRATION
CODE OF FEDERAL REGULATIONS

21 CFR

PART:

100  General
101  Food labeling
102  Common or usual name for nonstandardized foods
103  Quality standards for foods with no identity standards
104  Nutritional quality guidelines for foods
105  Foods for special dietary use
108  Emergency permit control
109  Unavoidable contaminants in food and food-packaging material
110  Current good manufacturing practice in manufacturing, processing, packaging, or holding human food
113  Thermally processed low-acid foods packaged in hermetically sealed containers
118  Cacao products and confectionery
122  Smoked and smoke-flavored fish
123  Frozen raw breaded shrimp
129  Processing and bottling of bottled drinking water
130  Food standards: general
131  Milk and cream
133  Cheeses and related cheese products
135  Frozen desserts
136  Bakery products
137  Cereal flours and related products
139  Macaroni and noodle products
145  Canned fruits
146  Canned fruit juices
150  Fruit butters, jellies, preserves, and related products
152  Fruit pies
155  Canned vegetables
156  Vegetable juices
158  Frozen vegetables
160  Eggs and Egg products
161  Fish and shellfish
163  Cacao products
164  Tree nut and peanut products
165  Nonalcoholic beverages
166  Margarine
168  Sweeteners and table sirups
169  Food dressings and flavorings
Food additives
Food additives petitions
Food additives permitted for direct addition to food for human consumption
Secondary direct food additives permitted in food for human consumption
Indirect food additives, general
Indirect food additives - adhesive coatings and components
Indirect food additives - paper and paperboard components
Indirect food additives - polymers
Indirect food additives - adjuvants, production aids, and sanitizers
Irradiation in the production, processing and handling of food
Food additives permitted in food on an interim basis or in contact with food pending additional study
Prior-sanctioned food ingredients
Substances generally recognized as safe
Direct food substances affirmed as generally recognized as safe
Indirect food substances affirmed as generally recognized as safe
Substances prohibited from use in human food
Tolerances for pesticides in food administered by the Environmental Protection Agency
Seafood inspection program

*Full text of this part, transferred from former Part 121, was set out under Part 123 in the tenth recodification document published in the Federal Register of March 28, 1975 (40 FR 14156). Part 123 was subsequently transferred to Part 193 by publication in the Federal Register of June 28, 1976 (41 FR 26565).
The FFD&CA is updated annually. Some amendments are quite substantial. Important additions are:

Section I - Short title: The Short Title is the description of the law and is listed in the United States Code.

Section II – Definitions:

Section 321

"For the purpose of this Act -" The purpose is to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics and for other purposes.

The definition of words and terms is very important to understanding the Act. However, in some instances a definition is not clear and may be left open to interpretation.

a) State and Territory is defined to describe the area in which the Act is operative.

b) Interstate commerce is defined because FDA has authority only where food is involved in interstate commerce.

(Section 301a) In order to show that a violation has occurred, the FDA must prove that the food was in interstate commerce.

However, if a buyer acquires goods out of state, for personal use, and takes them home, he has not been involved in interstate commerce, unless he informs the seller that he will be crossing state lines with the goods. Importation from abroad is also included in the definition of interstate commerce.

c) The Department is the U.S. Department of Health and Human Services because the FDA is
part of this organization.

d) The 'Secretary' is the Secretary of the U.S. Department of Health and Human Services.

e) The FDA may prosecute a company or the individual at the head of the company, or any responsible person within the company.

f) In addition to edible material, the term 'food' extends to raw products which may or may not need processing before they are fit to eat. Furthermore, a 'food' need not have nutritive value e.g. flavors, colors and water (3). Foods may be combined to form a new food e.g. flour, eggs (3) Non-edible, but essential, components of a food are also regarded as 'food' (3).

g) 'Drugs' are; A. Articles recognized officially as drugs. B. Articles used for drug purposes. C. Articles, other than food, intended to affect structure or function of the body. D. Component of a drug. A food or dietary supplement making a dietary claim is not a drug if the product is labeled according to labeling regulations.

k) A label is a display on the immediate container.

m) Labeling includes the label.

and any other information or publicity which accompanies the product (2) e.g. handbills and posters in a store that are with the product.

n) Advertising is distinguished from labeling in that it does not accompany the product.

Misbranding is said to occur if labeling or advertising is misleading or fails to reveal the facts or consequences of using a product e.g. a product described as an olive oil blend which is mainly soy oil. Misbranding will be discussed in more detail in a later chapter.

q) Pesticides (1) defined under FIFRA, and includes active and inert ingredients. Pesticides are excluded from the definition of a food additive. (2) pesticide residue, means residue on a raw agricultural commodity or processed food of a pesticide chemical or a breakdown product of a pesticide. (3) The EPA may except a substance from the above definition if, (A) the presence of a substance is not due to the use of pesticides in the production, processing or transport of a raw agricultural commodity and, (B) and the EPA decide it is better regulated by alternative provisions of the FFD&CA, other than a pesticide.
r) **Raw agricultural commodities** are unprocessed goods and includes produce which has had the outer leaves removed or waxed. If preservation or processing has occurred, they are no longer termed raw agricultural commodities.

s) **Food additives** become a component of the food or otherwise change the food. Section 402 (a) (2) (c) of the Act says that a food is adulterated if it contains a food additive which is unsafe according to Section 409. A food additive is a substance which is not Generally Recognized As Safe (GRAS) or prior sanctioned but may be regulated by a Food Additive Petition. Pesticides, dietary supplements and color additives are not classified as food additives, but radiation treatments are.

t) **Color additives** are used only for imparting color. Color additives are unsafe unless they are regulated by FDA.

u) **Safe** relates to man or animals.

ff) **Dietary Supplement** 1. Defined as a product other than tobacco intended to supplement the diet and containing one or more of the following (A) a vitamin (B) a mineral (C) herb or other botanical (D) amino acid (E) something used to increase dietary intake (F) concentrate, metabolite, constituent, extract or combination of any of the ingredients described above. 2. A. (i) It is a product to be digested as a vitamin or mineral (ii) or for special dietary use. B. It is not represented as conventional food. C. It is labeled as a dietary supplement. D. It can be previously used as a dietary supplement. This was added by the 1994 Dietary Supplement and Health Education Act.

gg) **Processed food** defined as any food, other than a raw agricultural commodity, and includes raw agricultural commodities that have been canned, cooked, dehydrated or milled. This was added by the Food Quality Protection Act 1996.

hh) The term "**Administrator**" means Administrator of the EPA, and is used with respect to pesticide regulation. This definition was added following The Food Quality Protection Act 1996.
Case Studies

1. a) A roadside market in Arkansas sells blueberries. A customer buys some of the product for consumption within the state. If he finds the product to be adulterated, does he have recourse under FFD&CA? An Oklahoma resident buys the same product and takes them home. Does he have a case to complain under FFD&CA?

b) A Missouri resident receives a gift of the fruit from the grower, and on returning home, discovers severe insect infestation. Is he protected by the FFD&CA?

2. a) Which of the following are food a) eggshells? b) Candles on a birthday cake? c) Green or raw coffee beans? d) popsicle stick? e) vitamin supplement?

b) A Missouri resident receives a gift of the fruit from the grower, and on returning home, discovers severe insect infestation. Is he protected by the FFD&CA?

3. If a food item is used as a "drug", it is classified as the latter and is more strictly regulated.

a) Is prune juice a food or a drug? b) Are high fiber breakfast cereals food or drugs? c) Is a dietary supplement a food, drug or neither?

4. Starch blockers are obtained from beans and are incorporated into food to inhibit carbohydrate digestion. Are starch blockers a food or a drug?

5. a) Should vitamin tablets be regulated as a foods or drugs?

b) Vitamin A is a red substance. What legal definitions could be appropriate.

6. Toys and trinkets were sometimes mixed with candy in gumball machines (US v. Candy Containing Trinkets 95 F. Supp 490) Are these non-edible items food?

7. Read US v. 500 bags........Green Coffee 97 F. Supp 790. What are the main issues involved in this case? What was the outcome?

8. It was claimed in an advertising campaign that New Zealand mussels would help prevent blood clots and maintain elasticity of the arteries (U.S. v. Articles of Drug, Neptone 568 F. Supp. 1182). What are the legal problems associated with such a promotion.
CHAPTER 4
PROHIBITED ACTS AND PENALTIES

The FFD&CA is primarily concerned with protection of the consumer. This is done through prohibiting adulteration and misbranding in interstate commerce. However, penalties can be imposed for other infringements as well.

One of the following prohibited acts must be established before an individual or corporation can be prosecuted.

PROHIBITED ACTS:

Section 331(a) describes in broad terms that adulterated or misbranded goods are not permitted in interstate commerce. It is illegal to introduce, or deliver for introduction, an adulterated or misbranded food into interstate commerce. Also, a violation has occurred if:

1. Defective goods are sold under contract. This is true whether or not the goods were shipped as long as the purchaser accepts the goods (U.S. vs Seven Barrels 141 F.2d 767), or

2. If a seller knows that the buyer will take the defective goods out of the state. This is ‘delivery for introduction.’

Section 301(a) is directed primarily against the manufacturer.

Section 331(b) dictates against adulteration or misbranding while in interstate commerce. This would include transportation or while being held for sale in warehouses or stores.

Section 331(c) forbids receipt of defective goods. Very few prosecutions occur under this section because the receiver is usually without responsibility for any prior misbranding or adulteration. However, Sec. 301(c)(1) closes this loophole in the law. However, it is necessary to show intent to violate the law.

Section 331(d) refers to violation of laws regarding an emergency permit control and new drugs.

Section 331(e) pertains to requests of records of interstate commerce which are asked for during factory inspections by the FDA.

Section 331(f), FDA inspectors must be allowed to enter a food manufacturing plant when it is operating.
Section 331(g) dictates against the manufacture of adulterated or misbranded food.

Section 331(h) Food guaranties are often given by suppliers and processors to assure buyers of food legality. A false guaranty is subject to prosecution under Sec. 301(h). However, someone receiving a false guaranty, in good faith believing it to be true, is not subject to prosecution.

21 CFR 7.12. Guaranty: each person signing the document is considered to have given the guaranty

Section 331(i) Misrepresentation.

Section 331(j) Trade secrets.

Section 331(k) enables prosecution if the food is adulterated or misbranded or the doing any other act while held for sale. This section gives the FDA power to penalize people who misbrand, adulterate or otherwise violate a product which is held for sale after crossing the state line.

Section 331(a) (b), (k) (m) (n) (o) are used most frequently by FDA in quoting violations.

"A simple summary in respect to foods would state that a person:

- Cannot introduce an adulterated or misbranded food into interstate commerce.
- Cannot receive an adulterated product or misbranded food in interstate commerce.
- Cannot manufacture an adulterated or misbranded food within a United States Territory.
- Cannot adulterate or misbrand a food by changing labeling, or otherwise, while it is in interstate commerce.
- Cannot introduce a food produced under an emergency permit into interstate commerce unless the permit authorizes it.
- Cannot refuse entry for inspection.
- Cannot refuse copying of records of interstate shipments.
- Cannot give a guarantee that a food conforms to the act when it is known to be in violation.
- Cannot forge official markings on food.
- Cannot reveal or use trade secrets.
- Cannot sell colored oleomargarine except in conformance with the act."
- Cannot use an official report or analysis in labeling or advertising food."

from - Food Law Handbook, Schultz

**INJUNCTION PROCEEDINGS:**

Section 332 gives District courts the right to issue injunctions (civil action) restraining violations of Sec. 301. Paragraphs (h), (i) and (j) are not covered by injunction proceedings. An injunction is a court order which prohibits or requires certain action. The FDA brings injunction actions when evidence suggests there has been past violations or likely to be more in the future and it is important that a certain activity be stopped rapidly.

An injunction has advantages over seizure actions or criminal prosecutions:

1. Criminal cases are long and require much time for preparation.
2. Seizure actions prevent shipment of goods, but may not stop questionable practices.

**PENALTIES**

When a possible violation is revealed, the FDA initiates an investigation. If a violation is confirmed, they will take measures depending on the nature of the violation. For minor offenses, only a warning may be necessary, but for major violations, the case may go as far as the Supreme Court. Before any violation is reported to the Office of the Attorney General of the United States for criminal proceedings, the offender is given opportunity to answer the charges and express their view.

**Section 333**

a) First conviction, up to a year in jail or fined $1,000 or both.

b) Second conviction, up to 3 years in jail or fined up to $10,000 or both. Person receiving goods in good faith are not prosecuted. However, the Criminal Fines Enforcement Act, enacted in 1984, increases the fines which can be imposed under the FFD&CA to as much as $500,000.

**SEIZURE:**

Section 334 gives the FDA authority to petition for seizure. The courts can then give the FDA permission to seize adulterated or misbranded goods. A seizure action is against the goods, not against an individual or company. The FDA has come to realize that this is an inefficient means of making industry comply with
the Act. However, it is an effective way to remove large quantities of food from circulation.

Section 335 gives the persons subject to prosecution notice of the action taken and the opportunity to present their case.

REPORT OF MINOR VIOLATIONS:

Section 336 enables the FDA to provide only Warning Letter to offenders for a minor violation. This is often the best way to bring about compliance with the law without resorting to more expensive or time consuming measures.

Section 337 states all enforcement of the Act by the FDA are in the name of the United States and allows subpoenas to be issued to ensure that the necessary witnesses attend court.

State enforcement: This section is amended by Sec.4 NL&EA 1990 by allowing state courts some provision in enforcing federal labeling requirements. The state must give FDA 30 days notice before taking action. If FDA informs the state that federal enforcement action is being taken the state may not act for 90 days. The state may then not act if the FDA is taking action. A state may intervene in some court proceedings.

Exercises:

1. Fred Smith buys 1,000 cases of tomatoes from 'Supercanners,' in Texas. He stores them in his warehouse in Arkansas. After he sold 10%, the FDA inspector arrives and samples the cans and finds substantial microbial contamination. A consumer in Arkansas reports the label on a can to be damaged and informs the FDA. Supercanners state that the labels were in good condition when they left the factory.
   a) Take the position of the FDA. What violations could you cite?
   b) What defense could you make on behalf of Fred Smith?
   c) What other information would you like to have in preparing these cases?

2. A spice supplier in Ohio sells spices to a food processor in the same state. The processor sells and ships it's products to ten states. If the spices are included in these products, is the spice supplier involved in interstate commerce?
3. Read 230 Boxes ...of Fish v. U.S. 168 F.2d. 361.
   a) What are the main facts of the case?
   b) What are the legal issues involved?
   c) How was the final decision made?

4. Read U.S. v. Cassaro 443 F.2d 153 and describe the main facts of the case and issues involved.

5. Read Barnes et al. v. U.S. 142 F.2d. 648. This states the points of law on which the decision was made? Could you produce a case to reverse the decision?
CHAPTER 5
DEFINITIONS AND STANDARDS FOR FOOD

Section 341
The FDA has the authority to promulgate (i.e. publish) regulations defining a particular food. In addition to ensuring unsafe food does not reach the marketplace, food law is also involved in describing and discriminating between safe foods. Food standards have been produced to fulfill that requirement. According to the FFD&CA, Section 341, "Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container."

Thus, a food standard consists of:

1. A definition and standard of identity.
2. A standard of quality.
3. A standard of fill.

1. Definition and Standard of Identity
This includes a statement of the name of the product, the ingredients that it must contain, packaging, processing and a label statement relative to ingredients, class, size characteristics, and style of the product.

2. Standard of Quality
The standard is a minimum level of quality below which a product must be maintained. This description puts limits on the amounts of blemished or defective product that can be included. Testing procedures are often included.

3. The Standard of Fill
This defines the minimum weight or volume of product a container must hold.

There are certain exceptions and allowances:

i) With certain exceptions, there is no standard for fresh and dried fruit and vegetables. Butter
also has no standard.

ii) Allowances are made on the basis of characteristics of variety.

iii) Certain optional ingredients are permitted.

**Purposes of Food Standards**

Food standards are useful for people involved at various levels in food production, processing and consumption.

Producers can use the information in selecting varieties to be grown to meet classes and grades of particular products. Furthermore, the food industry uses such specifications for purchasing raw materials and in maintaining uniformity of products expected by consumers. Marketing uses standards to describe what is being bought and sold. Standards of specific foods are found in the Code of Federal Regulations.

Before any standard for a food can be declared, the Secretary must publish a proposal in the FR that a new standard of identity is intended and give notice of a hearing to enable interested persons to present their views - "Notice and Comment". This is in accordance with Sec.3 71(e) of the Act and Sec 8 of the NL&EA. After the hearing, all relevant information is assessed. The standard is proposed and each detail must be supported by substantial evidence. Evidence for omissions of ingredients, suggested during the hearings, must be presented, also.

Prior to NL&EA 1990 cumbersome formal rulemaking was necessary to establish a new standard. Formal rulemaking continues to be required for revision and revocation of standards of identity for the following products:

1) Dairy products, 2) cheese and related products, 3) frozen desserts, 4) maple syrup. New standards may be adopted through "Notice and Comment" rulemaking (See Chapter 9 for details of the Notice and Comment Process).
Example Tomato juice:

**Standard of Identity**

(1) Definition

(2) Labeling

**Standard of Quality**

(1) Quality

(2) Methodology

**Standard Fill of Container**

The conformation to standards is ensured by adequate quality control facilities.
ISSUES

The objective of food standards is to create product uniformity. Until 1972, a food which did not conform to a standard had to be labeled ‘imitation’ if a standard existed. In the early 1970's, an enriched macaroni with fortified protein was produced for the school meals program. Although the macaroni did not conform to the standard, it was allowed to be sold, as long as the description of the product was included on the label, i.e. ‘fortified with protein.’ Similarly, a tomato juice manufacturer produced a non-standard product with added Vitamin C. The FDA approved the product as long as ‘with added Vitamin C’ appeared on the label.

This open minded attitude on behalf of the FDA in modifying foods, relative to their standards, was threatened when a high calcium orange juice awaited approval. The FDA was concerned that high calcium juice may constitute a health risk.

A New York farmer asked the FDA if ‘goat’s milk yogurt’ was lawful. He was informed that it would be approved if the words 'goats milk' appeared before the name 'yogurt.'

The principle that the FDA seems to be applying is that the name of a standardized food can be used on a non-standard product if a qualifying statement appears in letters of equal size and prominence with the standard name. However, there is still interest in producing standards of identity. Recently an Advanced Notice of Proposed Rulemaking appeared in the FR to produce a standard of identity for frozen yogurt.

The basic issue being raised is: how relevant are food standards in an era of engineered foods? It is being debated that standards may not be needed if labeling requirements are adhered to.

EXERCISES

1. “Food standards are a barrier to innovation and creativity in the food industry”. Discuss.

2. “Without food standards consumers are not protected from inferior or potentially harmful products” Discuss.

3. Describe the facts and issues relating to “standards of identity” and “imitation foods” as shown by
   a) U.S. v. 62 Cases...of Jam 87 F. Supp 735
   b) U.S. v. 651 Cases..of Chocolate Chil-Zert 114 F. Supp. 430.
CHAPTER 6
ADULTERATED FOODS

Section 342

Adulteration is the reducing of purity or quality of an article by adding foreign or inferior material. The Food Drug and Cosmetic Act (FDCA) uses a number of criteria, any one of which can be used to establish a case of adulteration.

SECTION 342(a)

Sec. 342(a)1 "...bears or contains poisonous or deleterious substance."

However, if the substances present are not a health risk and were not added, adulteration has not occurred (see flow diagram).

Sec. 342(a)(2)(A) - Adulterated if “bears or contains any added substance which is poisonous or deleterious and is unsafe within meaning of Sec. 406 – except”:

i. pesticide in or on a raw agricultural commodity (Sec. 408)
ii. food additive (Sec. 348)
iii. color additive (Sec. 706)
iv. new animal drug (Sec. 512)

Sec. 346 - Tolerances for Poisonous Ingredients in Food

Any poisonous or deleterious substance added to any food except where such substance is required in production or cannot be avoided by GMP shall be deemed to be unsafe with respect to 402(a)(2)(A), but if required or cannot be avoided, the secretary shall promulgate regulations limiting quantity there of for protection of public health. If exceed limits, then violation of 402(a)(2)(A). If such regulation is in effect, then not a violation of 402(a)(1).

If a substance is added rather than a naturally occurring toxic, it is more strictly regulated (see flow diagram).

Sec. 342(a)(2)(B) - Added pesticide chemicals unsafe according to Sec. 346a.

Tolerances for pesticides are established by the EPA. It is necessary to demonstrate that the
pesticide is "required or unavoidable" (Sec. 346a) in the production of a wholesome and economical food supply. Furthermore, an expert advisory panel reviews each pesticide chemical. Tolerances are found in 40 C.F.R. Part 180.

Sec. 346a (Amended by the Food Quality Act 1996) - Tolerances for Pesticide Chemicals

346(a) – REQUIREMENTS FOR TOLERANCE OR EXEMPTION

(1) GENERAL RULE: A pesticide residue is unsafe unless:

(A) levels are within existing tolerances

(B) the pesticide is exempted from tolerance requirements.

(2) PROCESSED FOODS:

(A) A processed food is not adulterated, even if it contains a pesticide, if the pesticide was applied to the raw agricultural commodity according to tolerance requirements; and good manufacturing processes have been used to remove pesticide residues; providing the levels in the processed food is no greater than that allowed on the raw agricultural commodity.

(B) The residue of a pesticide that is exempt from tolerances on a processed food does not render the food adulterated, if the pesticide was applied to the agricultural commodity.

(3) RESIDUES OF DEGRADATION PRODUCTS:

Pesticide residue breakdown products in a food does not render the food adulterated If: (A) the risk of the product is no greater than the risk of the pesticide. OR (B)(i) the combination of pesticide and breakdown products do not exceed the published tolerance level. OR (ii) the pesticide is exempt from tolerances.

(4) EFFECT OF TOLERANCES ON EXEMPTIONS

Foods bearing pesticides for which tolerances or exemptions exist are not adulterated within the context of 342(a)(1).

346 (b-m) Outlines the authority of the EPA to regulate pesticide tolerances or exempt a pesticide from tolerances which are enforced by the FDA. These regulations apply to both food produced in the US and imported foods. Changes in tolerances will be published in the Federal Register.
Sec. 342(a)(2)(C) Unsafe food additive is adulteration within the meaning of Sec 409 (Food Additive Amendment) except when an approved pesticide in processed food is not above the level in the raw agricultural commodity, and as much is removed as possible by GMP.

21 CFR Part 193 - Tolerances for Legal Pesticides Administered by EPA and allowed as Food Additives

21 CFR Part 561 - Animal Feeds/Pet Foods - tolerances for pesticides

Sec. 342(a)3 Filthy, putrid or decomposed or otherwise unfit for food. It is not necessary to show that the food is a health risk. The food may only appear offensive in order for a violation to have occurred. Furthermore, it is irrelevant that the food may have been prepared in sanitary conditions.

The terms in 'whole or part' suggest that any defect, however small, constitutes a violation. However, in practice, when raising plants and animals, it is impossible to get 100% defect-free products because on picking or slaughter decomposition commences. The FDA recognizes this and issues Defect Action Levels (DAL) ([http://vm.cfsan.fda.gov/~dms/dalbook.html](http://vm.cfsan.fda.gov/~dms/dalbook.html)). DALs represent levels at or above which the FDA will take action. Because DALs represent higher than average defects, industry should not consider them a minimum standard of acceptability.

DALs for cornmeal are typical.

i) An average of one or more insect per 50g.

ii) An average of 25 insect parts per 50g.

iii) An average of one rodent hair per 25g.

iv) An average of one rodent excreta pellet per 50g.

DALs can be used for prosecution, but are not a prerequisite.

Action levels for other products are based on mold counts, maggots, bacteria count, etc.

In the past, the FDA has tried to prosecute on the basis of finding a few microscopic particles in food. In such cases, the court declares the case "de minimus non curat lex". This means the law does not concern itself with minor details. In this case, minor levels of contamination.
An Decision Flow Chart of Sections 402(a)(1), (2) and Section 406 of the Federal Food, Drug and Cosmetic Act

START

Consider whether article is adulterated under 402(a)(3-7) 407(b),(d) & (e) or 412

Is it, or does it bear or contain a pesticide, food or color additive or new animal drug?

No

Is an article of food involved?

Yes

Does it bear or contain a poisonous or deleterious substance?

Yes

Is the substance added?

No

Is the food ordinarily injurious to health?

Yes

Not Adulterated

No

Is the use in accordance with the rules?

No

Reconsider Classification

Yes

Is the added substance a pesticide chemical in or on a raw agricultural commodity or color additive or a new animal drug?

No

Adulterated

Is the substance required or unavoidable?

No

Is the substance really as poisonous or deleterious as it appears in the article?

Yes

Not Adulterated

No

May the substance render the food injurious?

No

Not Adulterated

Yes

Is there an action level or tolerance under Sec. 406?

No

YES (tolerance)

Adulterated

NO (tolerance)

Is there an action level or tolerance exceeded?

NO

Adulterated

Yes

(406)

Not Adulterated

Not subject to regulatory action
Sec. 342(a)4  Prepared, packed or held under insanitary conditions. This is an unusual section because it concerns itself with the condition of the premises, rather than the quality of food. Signs of rodent or insect activity would constitute an offense irrespective of the quality of the food. Furthermore, it is probably the most violated section of the law.

In order to avoid violation, the processor is advised to follow the Good Manufacturing Practices (GMP). GMP regulations provide guidelines for manufacturers, processors, packers and warehouse managers.

Sec. 342(a)5  Animal died otherwise than slaughter i.e. disease or stress prior to slaughter.

Sec. 342(a)6  Container render contents injurious to health.

Sec. 342(a)7  Intentionally subject to radiation.

SECTION 342b

This section is concerned with economic adulteration of food. Economic adulteration is consumer deception.

Section 342(b)1  Valuable constituent omitted.

Section 342(b)2  Substance substituted.

Sections (1) and (2) can be used when a standard of identity exists for a product and a particular food is shown to be substandard. It has been decided that a cat food labeled as containing 11% protein, but containing less than 11% could not be considered adulterated since there was no standard of identity for cat food (U.S. vs Fabro, Inc.)

The dairy industry has vigorously maintained that milk and dairy substitutes be labeled as such to avoid economic adulteration of dairy products with non-milk alternatives.

Sec. 342(b)3  Damage or inferiority concealed.

Sec. 342(b)4  Substance added . . . increase bulk . . . reduce quality . . . appear greater value.

In cases where (3) and (4) have been quoted, the use of colorants to make the product more desirable has occurred. For example, the identity of mineral oil, which was sold as popcorn oil, was concealed by use of dyes (U.S. vs 36 drums of Pop' n Oil). Economic adulteration is closely related
to misbranding. However, misbranding can be corrected by labeling changes, while economic adulteration cannot.

342(c) Food is adulterated if it contains an unsafe color additive.

342(d) Confectionary

342(e) Definition of adulterated butter or margarine

342(f) (1) Adulterated dietary supplements – if contains ingredient

   (A) if significant risk of injury (i) under recommended use, or (ii) ordinary conditions of use, or
   (B) inadequate information to provide reasonable assurances, or
   (C) The Secretary declares a significant hazard, or
   (D) Adulterated under 342(a)(1) under recommended use

342 (g) (1) Dietary supplement 'prepared, packed held' under non-GMP conditions

   (2) GMPs for dietary supplements may be prescribed similar to food GMPs

342 (h) Imported food is adulterated if it has previously been denied access into USA

342 (i) Unsanitary transport

2002 BIOTERRORISM ACT

Includes provisions to protect the US food supply from acts of bioterrorism or intentional adulteration. The FDA has published a proposed rule in February 3rd 2003 (68 Fed. Reg. 5,378) that will require the registration of domestic and foreign food facilities to determine the cause and source of a potential attack and provide rapid communications. Domestic facilities must register whether or not they are in interstate commerce. Exemptions are, foreign facilities whose product undergoes further processing outside the USA, farms, retail facilities, non-profit facilities serving food directly to consumers, restaurants, exclusively USDA regulated facilities, fishing vessels involved in processing.

**Exercise:** Case Studies

1. U.S. vs 1232 Cases American Beauty Brand Oysters 43 F. Supp. 749. It was proposed that certain oysters "contains shell fragments, many of them small enough to be swallowed . . . and inflict injury." Every effort was made in processing to remove as much shell fragments as
possible with the machinery available. It was impossible to remove all fragments.

a) Produce a case in favor of the FDA citing appropriate violation(s).

b) Produce a case in favor of the processor. Is there any precedent for marketing a product of this type?

2. U.S. vs Lexington Mill and Elevator Company 232 U.S. 399. It was alleged that flour had been treated by the Alsop process to bleach the flour. Nitrogen peroxide was generated by this process. It was claimed to be an adulterant and health risk. Is this process illegal?

3. Why is it not adulteration to add butter to margarine, as currently practiced?


Coffee which was imported from Brazil and stored in a warehouse in New Orleans had been damaged by water from a storm. The product molded to some extent and was deemed adulterated by FDA under Section 402(a)(3) of the FD&C Act. The company holding the product had made an effort to dry the product and repackage it. The District Court initially found that the beans were OK, and that they were not injurious to health nor grossly contaminated. The Court of Appeal's finding was that the District Court had made a misinterpretation of Section 342(a)(3). This Section states "if it consists in whole or in part of any filthy, putrid or decomposed substance or if it is otherwise unfit for food." The District Court interpreted this as one entire statement. The Court of Appeals and others held that the statements were actually "independent and complimentary" of each other so that a food could contain filth, but not necessarily be unfit for consumption and still be adulterated. In this case, part of the government's evidence consisted of unpublished filth levels concerning mold in coffee beans. They stated that the percentage of tested samples of this product was roughly 5% greater than the tolerance level that they used. The claimant had no actual notice of the tolerance levels as it had not been published up until that date. The U.S. District Court of Appeals returned the case back to the District Court for a correct reading of the statutes at hand and to determine whether or not the coffee was adulterated. The Court of Appeals also stated that in the future claimants are entitled to know allowable tolerances. In 1972, FDA was
requested under the Freedom of Information Act to make public all of its filth guidelines.


The product in question was butter contaminated with certain insect and rodent parts. The defendants were charged with introducing adulterated foods into interstate commerce. The judge interpreted Section 402(a)(3) of the FD&C Act that the food was not, by virtue of its containing filth, necessarily unfit for human consumption. He raised questions concerning FDA's tolerance levels for filth. At this time they were not stated or published. FDA had published comments pertaining to the fact that few foods are totally free of unavoidable filth or defects. The amount of material that was found to be adulterating this product was to be an overall ratio of 3 particles of insect fragments per pound of butter. Since no standard of filth for butter had been established or published, the judge found that the defendants were not guilty. Therefore, no criminal action was warranted since the levels of filth had not been published.

6. LONGER CASES: **Flemming v. Florida Citrus Exchange** 358 U.S. 153  
**U.S. v. Coca Cola** 241 U.S. 265. Outline the legal principles involved in these cases.
Regulation of food labeling is necessary to:

a. Avoid deception due to misleading information
b. Enable the public to make an informed judgment of a product.

Food Labeling

USDA regulation of labeling -- USDA regulates labeling of meat, poultry, egg products, and fruit and vegetables. Unlike the FDA, USDA must approve all labels prior to use. However, the regulatory requirements of the FDA and USDA are similar.

The law relating to misbranding is found in Section 403 of the Act, but the Fair Packaging and Labeling Act 1966 (FPLA) and the Nutrition Labeling and Education Act 1990 (NL&EA), describes additional labeling laws and regulations. These acts will be referred to in this chapter to clarify Section 403. Two labeling terms used in the FPLA are defined below as they are used extensively in this chapter.

Principal display panel (PDP) of a package -- This is the part of the label (package) that is displayed in a retail store. It should be large enough to display all necessary information clearly without obscuring any vignette or label design.

Information panel of a package -- This is the label to the immediate right of the PDP when facing the package. Letters and numbers on the PDP and IP should be no smaller than one-sixteenth of an inch.

SECTION 343

Sec. 343(a)

(1) Labeling false or misleading. This section is broad in its scope and covers any aspect of questionable labeling. This includes:

i) A food made from two ingredients when the label implies only one, e.g. oil blend.
ii) Misleading vignettes, pictures or designs.
iii) Misuse of the word "natural." Natural shall be used to refer to minimal processing and preservation.
These are only examples to illustrate the wide area of application of the clause.

(2) Misleading advertising is also regulated.

Sec. 343(b)

Sale under another name. Foods shall be named according to the standard of identity, if possible. If no standard is available, a common name may be used.

Sec. 343(c)

Imitation. Imitation products should be clearly labeled as such. Examples of these would be: 1) Analog cheeses, prepared using vegetable oils and 2) Salisbury steak style, textured vegetable protein prepared from soy protein. The use of the words "analog" and "style" imply imitation.

Sec. 343(d) - Container found, or made to be misleading -- If a food is packed in a manner so as to give consumers the impression that they are buying more product than is actually the case, it is misbranded. If a larger package is used for a good reason (e.g. protection) the product is legal.

Sec 343(e)

(1) Name and place of business -- The package should state the manufacturer, packer and distributor. According to the FPLA, this may be placed on the information panel (IP).

(2) Statement of contents -- The FPLA states that the net contents must appear in the lower 30% of the principal display panel (PDP) if the PDP exceeds 5 sq. inches. Liquids are expressed in volume and solids in weight. Statements regarding the product must be conspicuous, legible and separate from other printing on the panel. This is to enable the consumer to readily obtain the information regarding a product before purchasing.

Sec. 343(f) - Conspicuousness of any word, statement or other information. It is important that required information is easily seen and read. Statements should be at least equally conspicuous on vignettes, designs or trade marks on the packaging.

Sec. 343(g) - Comply with definitions and standards of identity --

(1) A food must be consistent with the definition and standard of identity of that product.

(2) The label must bear the name of the defined food. Optional ingredients must also be listed.

(a) Complete information of ingredients should be supplied of standardized foods and is also encouraged for foods in the absence of legal authority.

(b) Label declaration of all optional ingredients to be enforced.

(c) Declaration of mandatory ingredients on the label of a standardized food is not required.

Sec. 343(h) Representation with regard to quality or fill of container

1. Comply with minimum standard of quality -- If a food has a standard of quality and the product is below that standard, it is misbranded, unless a statement on the label declares that it is substandard.

2. Comply with minimum standard of fill -- If a food container contains less product than prescribed by the standard of fill, it is misbranded, unless there is a label statement declaring the product to be substandard.

See Number of Servings 21 CFR 101.8 Food labeling: number of servings.

(a) If a label states the number of servings, it should also state the net quantity.

QUANTITY DECLARATION

(b) All nutrient quantities declared in relation to a usual serving.

Sec. 343(i) Non-defined products

1. If there are no standards for a product, the manufacturer should put the most common name for the food on the label.

2. When non-defined foods are made from two or more ingredients, each ingredient should be listed by its common name. Spices, flavorings and colorings need not be named specifically, but can be described as 'spices,' 'flavorings,' and 'colorings.' If it is difficult for certain products to comply with these requirements, changes in labeling will be considered, on a case-to-case basis, by the Secretary. According to the FPLA, ingredients must be listed in order of prominence e.g. potato chips -- 'potatoes, salt, oil and preservatives.' This should be on the PDP or IP.
FFD&CA Sec. 343(i) is amended by **NL&EA 1990 Sec. 7** The total percentage of fruit or vegetable juice in beverage products must be disclosed. This information should be displayed prominently on the IP (Effective 11/8/91).

**Sec. 343(j) - Special dietary use** -- If a food makes dietary claims, the label must report information of vitamin, mineral and other dietary properties on the label as evidence of the claim. This is important in labeling of low sodium foods, hypo-allergenic foods, infant foods and weight control foods. When labeling a product in any of these categories, the appropriate regulations must be observed. *See Food for Special Dietary Use 21 CFR 105.3.*

**Sec. 343(k) - Artificial color, color additives and chemical preservatives** -- If these are present, they must be named on the label. This does not apply to butter, cheese or ice cream, which are standardized foods.

**Sec. 343(l) - Pesticide chemicals** -- Raw agricultural commodities containing pesticides should declare the presence of that substance, by its common or usual name on the shipping container. However, if the commodity has been removed from its container, the presence of a pesticide does not need to be stated. Nevertheless, if retail labeling states that no pesticide is present when this is not true, the statement is 'false and misleading.'

**Sec 343(m) Color additives** - Conforms to packaging and labeling requirements under Sec. 379(e)

**Sec. 343(n) - Childproof packaging of poisonous substances** -- Non-food items.

**Sec. 343(o)(p) - Saccharin** -- Products containing saccharin must have a label stating conspicuously that "use of this product may be hazardous to your health."

**Nutritional Labeling and Education Act (NL&EA) 1990**

The NLE&A amends the FFD&CA. Sec 343(q) and (r) were added to the FFD&CA by the NL&EA 1990.

The most important changes are:

1. Mandatory nutritional labeling for nearly all foods, including fresh produce and seafood.
2. Federal regulation of nutrient content and health claims.
3. National uniformity of most food labeling.

**Sec. 343 (q) Mandatory nutritional labeling:** added by **Sec. 2 NL&EA 1990.** Label must have the
following nutritional information:

1. serving size
2. number of servings per container
3. Amount of the following nutrients provided by each serving:
   * Total calories
   * Total calories from total fat
   * Total fat
   * Saturated fat
   * Cholesterol
   * Sodium
   * Total carbohydrates
   * Complex carbohydrates
   * Sugars
   * Dietary fiber
   * Total protein

Any nutrient required before 1990 must also be on the label. In addition, food sold in bulk containers must have the necessary nutrition information available where the food is offered for sale.

The FDA must issue proposed regulations to implement the NL&EA within one year and final regulations must be published within two years of the enactment of the 1990 Act. The final regulations will be operative 6 months after publication. If final regulations fail to be published on time the proposed regulations will become effective. Except for fresh produce and seafood the requirement of the Act will be effective 30 months after publication.

**Nutritional labeling of fresh produce and seafood**

Voluntary guidelines:

FDA must obtain public comment and produce voluntary guidelines for food retailers on the 20 most popular vegetables, 20 most popular fruit and 20 most popular varieties of seafood. The lists may vary in different regions of the country.
Mandatory requirements:

If retailers do not comply with the voluntary guidelines FDA must propose mandatory regulations for
the nutrition labeling of fresh produce and seafood 30 months after the Act's enactment. Final regulations
must be published 6 months after the proposals, or the proposed regulations become effective.

**Exemptions:** Small retailers with annual gross sales of $500,000, or less, or annual gross food sales of
$50,000, or less, are exempt from nutritional labeling requirements. The following food products are also
exempt:

* Restaurant and carry out foods
* Infant formulas
* Medical foods
* Foods intended for further processing or labeling or re-packing
* Food in small packages if not labeled with any nutritional information.
* Foods that contain insignificant amounts of all nutrients required on the label e.g. coffee and tea, if no
  nutritional claims are made.
* Foods distributed to restaurants and food service institutions

FDA must provide consumer education on the availability and importance of nutritional information.

**Sec. 343 (r) Nutrient content claims and health claims:** added by Sec. 3 NL&EA 1990.

**NUTRIENT CLAIMS:**

A nutrient content claim is a statement "characterizing" the level of a nutrient which should be
declared on the label. These claims must only be made using terms defined by the FDA. FDA is required
to define the following terms:

* "Free" "Low" "Light" or "Lite" "Reduced" "Less" and "High "*

All claims must be accompanied by a statement, "see ________ for nutritional information". The
panel where this information is located should be stated in the blank.

1. **Claims regarding the absence of a nutrient:** A claim about the absence of a nutrient can
only be made if the nutrient is normally present. However, FDA can permit claims if the
information would
be useful and the statement reveals that the nutrient is not usually present. e.g. ______ a
naturally fat free product.

2. **Cholesterol content claims**: There are limits on claims for food that contain amounts of fat or
saturated fat that would increase the risk of disease in the general population. For these
foods, a cholesterol content claim can be made only if:

(a) FDA adopts a regulation that the level of cholesterol in a food is substantially less than is
normally present, or

(b) FDA adopts a regulation that cholesterol is not usually present in the food and a
statement to that effect would be in the interest of the consumer.

Any permissible cholesterol claim must be next to the cholesterol content statement.

In July 1990 FDA published a tentative rule on cholesterol claims which prohibited
cholesterol content claims if fat content is above a certain level. In contrast, The Act asks FDA
to consider claims if accompanied by the food's fat content.

3. **Saturated fat claim**: Any saturated fat claim relating to a food containing cholesterol must be
accompanied by a prominent disclosures of the level of cholesterol next to the claim.

4. **Dietary fiber claims**: A food cannot claim to be "high" in dietary fiber unless: (a) it is "low" in
total fat, as defined by FDA or (b) The total fat content is stated next to the dietary fiber claim.

**HEALTH CLAIMS:**

A health claim is any claim that "characterizes the relationship of any nutrient required on the label
to a disease or health related condition. Health claims may only be made in accordance with FDA
regulations". In considering claims FDA may consider the relative contribution of a food to the diet.
Hence, claims regarding snack foods are less likely to be considered favorably than claims for basic food
with the same level of a particular nutrient.

**NLEA & DSHEA Authorized Health Claims**

Health claims are used on labels that characterize a relationship between a food, a food component,
dietary ingredient, or dietary supplement and risk of a disease (for example, "diets high in calcium may
reduce the risk of osteoporosis") if the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on scientific literature reviews.

* Calcium and osteoporosis
* Dietary fiber and cancer
* Lipids and Cardiovascular disease
* Lipids and cancer
* Sodium and hypertension
* Dietary fiber and cardiovascular disease

**Health Claims Based on Authoritative Statements**

The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides another way to use a health claim on foods. FDAMA allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement" from a scientific body of the U.S. Government or the National Academy of Sciences.

**Qualified Health Claim**

The use of qualified health claims is allowed when there is developing evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Both conventional foods and dietary supplements may use qualified health claims.

- Selenium and cancer
  
  "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."

- Antioxidant vitamins and cancer
  
  "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not..."
Omega 3 fatty acids and coronary heart disease

“Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.”

Omega 3 fatty acids rich foods must be low in cholesterol and saturated fat before such a claim can be made.

- Olive oil

“Limited and but not conclusive evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to mono-unsaturated fat in the olive oil. To achieve this possible benefit, olive oil is to replace similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product [Name of food] contains [x] grams of olive oil.”

Foods making this claim do not have to comply with a low fat, low saturated fat requirement, as applied to omega 3 fatty acid claims. However, foods with this claim with high saturated fat must direct consumers to consult the nutritional information panel with regard to saturated fat content and be relatively low in cholesterol.

FDA is not allowed to require pre-market approval of claims. (In February 1990, FDA re-proposed regulations on health messages very similar to those described in the NL&EA).

Exemptions: Health claim requirements do not apply to infant formulas, medical foods and restaurant food.

FDA must propose regulations within 12 months and adopt final regulations within 24 months. If no final regulations are adopted after 24 months the proposed regulations should be regarded as final.

STRUCTURE/FUNCTION CLAIM

Structure/function claims been on conventional foods and dietary supplement labels. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a
nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient.

There is some provision for state courts to enforce the food labeling requirements of the FFD&CA (Sec 4 NL&EA).

NATIONAL UNIFORMITY AND EXEMPTIONS: (Sec. 343A FFD&CA and Sec. 6 NL&EA)

This represents an important extension of FDA's authority. Previously, FDA had no statement on pre-emption and national uniformity of labeling. Existing standards of identity were adopted as national standards for the purpose of the NL&EA one year after enactment.

* Imitation labeling requirements (FFD&CA 343(c))
* Identification of manufacturer, packer and distributor (FFD&CA 403(e)(1))
* Net contents declaration (FFD&CA 343(e)(2))
* Listing of food ingredients (FFD&CA 343(i)(2))

A requirement of the NL&EA 1990 is that uniform national standards concerning nutrient labeling, nutrient content (403(q)) and health claims (343(r)) were introduced 30 months after enactment.

The NL&EA requires the FDA to commission a study to determine if the following provisions of the FFD&CA, and related state and federal laws, are being adequately enforced:

* Misrepresentation of food names (FFD&CA 343(b))
* Deceptive packaging (FFD&CA 343(d))
* Prominence of label statements (FFD&CA 343(f))
* Standards of quality and standards of fill (FFD&CA 343(h))
* Common or usual names (FFD&CA 343(i)(1))
* Declaration of artificial colors and preservatives (FFD&CA 343(k))

The study must be complete within 6 months of the enactment of the NL&EA and published 3 months
later. Final conclusions must be published 24 months after enactment of NL&EA. If FDA concludes that any provision is inadequately implemented it must publish proposed revisions of the relevant regulations within 24 months of the enactment of the NL&EA.

The NL&EA allows states and local authorities to petition FDA for exemptions from national uniformity.

Section 9 of NL&EA affirms the traditional authority of FDA and USDA with respect to regulation of food labeling.

1997 Food and Drug Administration Modernization Act (FDAMA): Before FDAMA the only health or nutrient claims that could be used were those for which FDA had published regulations. The FDAMA now allows the use of claims that are based on “current published authoritative statements from certain federal scientific bodies”. This was done to speed the process whereby the scientific basis of claims was established. Notification of the use of a new claim should be submitted to FDA for approval. The FDA will respond to the notification within 120 days and may accept or refuse the use of the claim. If the claim is refused it can be amended and resubmitted.

2004 Food Allergen Labeling and Consumer Act ('Food Allergen Act')
The Act requires that food labels show clearly the 8 most common allergenic substances: milk, eggs fish, shell fish, tree nuts, peanuts, wheat and soy beans, if present in the food. The label should include the word “contains” followed by the name of any of the allergens present. The food ingredient labels listing the contents should be in a print, size and format than is easier to read than was previously required. Food manufacturers are required to avoid cross contamination of food ingredients. HHS is required to perform allergen research over an extended period. FDA will continue to have authority to regulate the safety of bioengineered protein products and The Center for Disease Control will keep a record of food allergy related deaths.
EXERCISES -- CASE STUDIES

1. Kordel v. U.S. 335 U.S. 345 - Kordel marketed his own health food products. Pamphlets were sent to the public by vendors describing the benefits of the product. Some pamphlets were displayed where Kordel's products were sold. It was claimed that the literature contained false information and the case was brought to court. Produce a case for the prosecution.

2. U.S. v. Ninety-Five Barrels of . . . Apple Cider Vinegar 265 U.S. 438 Ninety-five barrels of vinegar were seized. Each barrel was labeled:

"Douglas Packing Company Excelsior Brand Apple Cider Vinegar Made From Selected Apples Reduced to 4 Percentum Rochester, N.Y."

The vinegar was, in fact, prepared from dried or evaporated apples.

a. Prepare a case on behalf of the FDA for the prosecution citing appropriate violation.

b. Produce a defense on behalf of the cider company.

4. Sunshine Packing Corporation shipped in interstate commerce frozen strawberries labeled as:

"Quick Frozen Sunshine Brand Sliced Strawberries - New Weight 14 oz. - This one pound package serves 4." What is the nature of the violation, if any?

5. On the following pages are two labels from cans of "Carnation milk". One of the labels is from the product as sold in the U.S.A. while the other is marketed in Britain.

a. What are the features of the U.S. label that ensure that it conforms to labeling regulations?

b. Would the British label be acceptable in the USA? Give reasons for your answers.

c. Does the PDP for "Jaffa Cakes" conform to labeling U.S. requirements?

6. Analyze the following cases:


c. Weeks ... v. U.S. 245 U.S. 618
What is the problem with this nutritional label?
1. FOOD ADDITIVES

According to FFD and CA, a food is adulterated if it contains an 'added' ingredient "which may render the food injurious to health." Before 1958, the FDA had to prove that such an added substance was harmful. The Food Additive Amendment of 1958 and the Color Additive Amendment of 1960 were important changes in food law. The burden of proving the safety of an additive was moved to the manufacturer who had to supply pre-market data to satisfy the FDA that a particular new additive was "safe" or had a "reasonable" certainty of no harm.

Food Additive Amendment 1958 (Sec. 348)

Food Additives are defined in Sec. 321(s).

Sec. 348(a) An additive is an adulterant unless,
1) It is exempt due to its use for research purposes, or
2) Regulations exist for its use. "Unless a substance is 'GRAS' or 'prior sanctioned,' a substance added to a food is a food additive and may only be used in conjunction with a regulation authorizing its use" -- Dubeck and Eldred, Practical Food Law. This assumes that the substance is not one of another group of excluded substances which is regulated separately, i.e., pesticide in or on a raw agricultural commodity, color additive, or animal drug, which are all regulated separately.

Three ways a substance can be approved for use in foods are:

i. Achieve GRAS status

ii. By prior sanction

iii. Approval of a Food Additive Petition (Sec. 408b)

3) Food contact substance

1. GRAS (Generally Recognized As Safe) Status

GRAS substances are excluded from the food additive definition. To be GRAS, certain
requirements must be met.

a. Prove safety of the substance by review of the scientific knowledge with supporting expert witnesses, OR

b. For substances in use before 1958, recognition of safety may be based on experience of long-term use.

Typical GRAS substances include common spices, sodium bicarbonate, citric acid, gums and monoglycerides.

On becoming GRAS, the substance is still open to scrutiny and may be removed from the GRAS list at a later date. In 1969, cyclamate sweeteners were removed from the GRAS list and banned when new experimental evidence was available. Since then, the GRAS list was reviewed for health risks whereupon saccharin was banned in 1977.

2. Prior Sanction 21 CFR 170.3 (1)

Before the Food Additives Amendment of 1958, manufacturers made inquiries to FDA and USDA regarding the acceptability of adding certain substances to foods. 'Prior sanctioned' substances are those approved following an informal inquiry before 1958. These substances are excluded from the food additive definition. However, the company must have proof of 'prior sanction' and use the substance only in the approved manner.

3. Food Additive Petition 348(b)

If a substance is a food additive, according to Sec. 321(s), in order to authorize its use a Food Additive Petition (FAP) can be filed as described in Sec. 348(b). The petition shall include:

a. Chemical identity

b. Conditions of proposed use and intended labeling

c. Data on quantity of additive needed to produce the desired effect

d. Methods of analysis

e. Reports of safety investigations

f. Details of manufacture of the additive
348(c) Action on the Petition

If approved, the Secretary will produce regulations on how the additive is to be used. Three main factors are considered in considering a food additive (Sec. 348(c)(5)).

a. Probable consumption of the additive
b. Cumulative effects of the additive
c. Safety factors which experts consider would be necessary

The Delaney Clause 348(c)(3)A

Because of concern about the carcinogens being used in food, Sec. 409(c)(3)(A) was added to the food additive amendment. This is called the Delaney Clause "...That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives to induce cancer in man or animal..." The clause implies that there is zero tolerance for any carcinogen in food. A problem arises because as analytical methods have become more sensitive, carcinogens have been found in micro quantities in nearly all foods. As a result, zero tolerance is no longer practical. The FDA now interprets the Delaney Clause in terms of 'quantitative risk assessment,' i.e. the probability of a risk to health.

DES Proviso

Diethylstilbestrol (DES) is a growth promoter used in cattle and was reported to cause cancer in some animals. Concern was expressed regarding residues of DES in meat. This contradicted the 'anticancer clause.' However, the Drug amendment of 1962 modified the hard line prohibition of carcinogens so that Sec. 409(c)(3)(A) reads: "...except that this proviso shall not apply with respect to use of substances as an ingredient of food for animals...if i). additive not adversely affect the animals, ii). no residue of additive will be found."

348 (d) Regulation issued on Secretary’s Initiative

The Secretary can publish a proposed regulation. 30 days after publication the Secretary can establish a regulation based on the proposal.

348 (e) Publication and effective date of orders
Secretary may inactivate a published regulation if hearing is sought with respect to part of the regulation.

348 (f) Objections and public hearings

Any person adversely affected by a proposal can file objections within 30 days of publication.

348 (g) Judicial review

Any person adversely affected can file in the US Court of Appeals.

348 (h) Expedited review of Food Additive Petitions

The 1997 FDA Modernization Act (FDAMA) allows industry to notify FDA 120 days prior to the use of unregulated “food contact substance”. The notification should include the identity and intended use of the substance and valid scientific evidence support the technical claims. The substance can be used after 120 days, if the Secretary does not determine that substance is unsafe during that time.

The expedited food additive petition process provides the food industry with the incentive to develop and implement additives with anti-microbial action that will decrease the incidents of food-borne disease.

Issues

GRAS status was revoked on sulfiting agents, but the FDA has published rules and regulations on the use of sulfites and the labeling of products with sulfites (21 CFR Part 182). Sulfiting agents cannot be used on fruits and vegetables that are served or sold raw. 10 ppm is the maximum concentration of sulfites to be used without a declaration on the label. If sulfites are present at a level of less than 10 ppm, and have a technical effect, they should be declared on the label, also.

The 1997 FDMA is changing the regulation of food additives away from the responsibility of the food industry having to spend much time and money to proof that an additive is safe, to the FDA having to proof within 120 days that a new additive is not safe.

COLOR ADDITIVES - Section 706

The FFD and CA of 1938 regulated only coal tar color additives as this was the only color additive at that time that was considered harmful. The Color Additive Amendment of 1960 gave the FDA authority over all color additives in foods. A pretesting and safety procedure similar to that adopted by the Food Additive Amendment.
According to Sec. 201(t), a color additive is a dye which, when applied to food, imparts a color and has no other designated function. The term "color" includes black, white, and gray, but excludes pesticides or other agricultural chemicals.

Under the 1960 Color Additive Amendment, Sec. 379, a color additive is not considered safe unless regulations are issued declaring it is safe. It may be restricted to some particular use. In order for manufacturers to use a certain color additive, they must file a Color Additive Petition with the FDA. Approval will be given only if a color additive is shown to be 1) safe, 2) not deceptive, and 3) not carcinogenic, Sec. 379(b)(5)(B). If approved, it is placed on a list of approved colors.

A color additive can be disapproved if new scientific evidence becomes available.

At the time the Color Amendment was passed, a "provisional listing" of colors already on the market was published. An original 30 month period was given for these colors to acquire permanent listing. Since then, there has been an extension for 25 years, during which the FDA has acquired the authority to make further extensions.

Issues

FD&C Yellow No. 6 obtained permanent listing for general use. This resulted from a petition filed by the Cosmetic Toiletry and Fragrance Association, and others. The color is now removed from the provisional list of color additives.

Dietary Supplements – 1994 DSHEA

In the mid-1990’s, and later, antioxidants and alternative medicine were widely ingested as a result of the popularity of herbal extracts and phytochemicals that were being marketed. The 1994 Dietary Supplement Health and Education Act created a definition of dietary supplements (See chapter 3). Ingredients in dietary supplements are not subject to regulation governing regular food additives. In contrast to the historically lengthy approval process for drugs and food additives, food supplements can be marketed without a formal FDA approval process or rigorous scientific evidence to show safety or efficacy. However, information should be provided to FDA to support any labeling claim. In order to establish food supplement safety, the company must notify FDA with 75 days of marketing a new ingredient that the product “will reasonably be expected to be safe” and does not pose a “significant or unreasonable risk of
illness or injury”. The manufacturer must be responsible for the safety of the product but FDA bears the burden of proof in showing that the product is unsafe or mislabeled. State and local governments can have more rigorous regulations if they wish. There have been several recalls over recent years, including the herb ephedra, which was responsible for a number of deaths.

Dietary supplements are food products and must be labeled as “dietary supplements” and be in the form of pills, capsules, tablets or gelcaps, etc. Specific labeling information must be presented, including list all dietary ingredients, daily values of each serving, statement of identity (contents), net quantity, ingredient list in descending order by weight and name and address of manufacturer, packer or distributor.

Four label health claims, as defined under the NLEA, can be made but must meet the same criteria as in foods. For example, 1. calcium-osteoporosis; 2. folate-neural tube birth defects; 3. soluble fiber-coronary heart disease and 4. sugar alcohols-dental caries.

Structure/function label claims can be made but FDA must be notified within 30 days of marketing the product and substantiate the claim is true and not misleading. However, the claim must not imply that a supplement can be used to “treat, diagnose, cure or prevent a disease”. A disclaimer must be on the label;

“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease”. Read: Food Technology 53:87-96 (1999).

EXERCISE:

1. Distinguish between a food, food additive, color additive and dietary supplement.
2. Is potato in a beef stew a food additive or food?
3. Analyze the legal principles in the following cases:
   b. Fmali Herb v. . Heckler 715 F.2d 1385
   c. Monsanto v. Kennedy 613 F.2d 947
4. Do dietary supplements pose health problems as well as reported benefits? Should they be more heavily regulated?
Chapter VII of the FFD&CA provides FDA, through the HHS, with the authority to promulgate (i.e. publish) regulations, conduct hearings and administrative procedures to enforce the FD&CA.

Sec. 371 -375 describes how the regulations relating to adulteration and misbranding are enforced. Sec 371 and related material will be discussed in this chapter. Chapter 10 will discuss Sec 372-375 that relates to the factory inspection.

**Sec. 371 - Promulgate regulations and conduct hearings**

Sec. 371 (a) - This section gives the HHS Secretary the right to promulgate (publish) and enforce food law and regulations.

Sec. 371 (b) – Authority is given to the Secretary of the Treasury and Secretary of HHS to prescribe regulations regarding Sec. 801, which relates to the regulation of imported food. Imported food must meet the same quality standards as domestic products. In practice, FDA works with USDA and U.S. Customs in preventing the importation of adulterated or misbranded food.

Sec 371 (c) - The Secretary, or someone designated by HHS i.e. FDA, can conduct hearings when necessary.

371 (d) - Enforcement of definitions and standards of identity is described in.

371 (e) - Food law and regulations can be changed or repealed by the Secretary, but he must allow interested persons to present their views. These views will be taken into account, prior to amendments.

This is done through the 'Notice and Comment' rule making process.

**“Notice and Comment” Process:**

1. **Advanced Notice of Proposed Rulemaking** (ANPR) – Sometimes the intent a promulgate will be announced in the Federal Register as an Advanced Notice of Proposed Rulemaking, before publishing the Proposed Rule. This is a means of obtaining information from the public, various political lobbies, and industry before a Proposed Rule is drafted. The need for the new regulation is outlined followed by the questions for which the agency is seeking input. This announcement
provides early notification of regulatory activity and allows input from a variety of sources into development of a new Proposed Rule.

2. **Proposed Rule** (PR) - A *Proposed Rule* is published in the Federal Register. The reason for the proposed new regulation explained and draft of the legislation is presented. Comments are invited to be submitted within a specified time frame, often 30 days, and this feedback is considered before a final ruling is made. Interested parties may include food industries and consumer groups. A contact person is listed who can provide additional information. Public meetings may be held where individuals can express their views in person.

3. **Comments** – Comments received in response to an ANPR or PR are vital in developing new legislation. The most useful responses are those that are a clear reasoned arguments either supporting or objecting to the new proposed regulation. Objections should include alternative approaches. The law requires that each comment is responded to although, in the opinion of the FDA, the validity of opinions expressed vary greatly. Thus, adequately responding to all the comments may take much time e.g. the proposed rules for the regulations for NLEA Act attracted 38,000 comments.

4. **Final Rule** – If after consideration of all the Comments a final rule is published in the Federal Register, it will then be added to the Code of Federal Regulations. Alternatively, the *Proposed Rule* may never be published if it is seen to be unnecessary, or harmful. The time between the publication of *Proposed Rule* and that of the *Final Rule* varies greatly and can be years but is typically only months after the deadline for submitting comments. These Final Rules are regulations which can be repealed (removed) or modified by further Notice and Comment.

**Enforcement:**

If the FDA believes that a violation has occurred, there are two broad categories of responses it can make. These are judicial and non-judicial actions. Judicial actions involve the law courts whereas non-judicial does not.

**Non-Judicial Actions:**

1. Warning Letters
2. Recalls
3. Publicity

1. Warning Letters

Sec 374 FFD&CA provides FDA with the means of providing a written notice to a food company of the need to take action to correct an infringement of the law. The letter is issued within 15 days of observing a violation and requires a response within 15 of being issued. It is vital that a company responds promptly to such a letter to describe what has been done to correct the situation. If it is inevitable that a problem may take more than 15 days to be corrected, an acknowledgement of the problem, and the plan to remedy the situation should be described. If warning letters are not taken seriously FDA can take more serious action, such as injunction or seizures, without notice. Warning letters, and the response letters sent to FDA, are public documents. Therefore, should be dealt with timely fashion and the response letter drafted carefully.

The main reasons for sending a warning letter are:

a) If the FDA believe that the problem will be acted on quickly
b) If the violation is clear and obvious
c) If the violation is serious enough that other more aggressive enforcement will occur if the matter is not quickly dealt with

Events causing the Warning Letter to be sent would be:

a) Pesticide or chemical contamination in the absence of a tolerance or action level.
b) Low acid canning violations
c) Infant formula, medical foods and dietary supplement violations
d) Labeling violations
e) Food and color additive violations

Warning Letters are a fast, cost effective way of enforcement.

2. Recalls

Recalls are the removal of a defective product from the market place. They are the most rapid and effective means of removing product from the stores. Recalls are voluntary, although the FDA may strongly suggest a recall as an alternative to a law suite. However, recalls can be initiated without FDA involvement. Under these circumstances, the FDA should be informed prior to the recall, as a courtesy.
Recalls are classified as follows:

Class I - Serious adverse health consequences due to the product.

Class II - The defective product may cause temporary or medically reversible effects

Class III - Product not likely to cause ill health

A Class I recall is due to possible fatal consequences while a Class II recall is to avoid temporary illness. A Class III recall may occur due to contamination or 'filth' in the food which poses no health risk. In addition, there are other product retrieval systems which are distinct from recalls.

Market Withdrawal -- This is withdrawal of a legal product from the marketplace for purely technical or minor reasons. For example, the product may not meet the company's unusually high specifications, but it is safe and legal.

Stock Recovery -- This is the retrieval of a violative product while it is in the company's control. The product may be stored in warehouses or waiting to be shipped. This differs from a recall where the food is in the marketplace.

Recalls are the largest single category of FDA enforcement. Guidelines on how to conduct recalls are in the Code of Federal Regulations.

Every company should take effective preventive measures, such as:

1) Adequate quality control operation

2) A written contingency plan for handling recalls

3. Publicity

Two main categories of publicity can be used by the FDA: mandatory and discretionary. Section 375(a) obliges the Secretary to publish the results of all legal judgements and court decisions. This is mandatory publicity which is published monthly in the FDA Consumer and every week in the FDA Enforcement Report. This publicity is usually not controversial.

Section 375(b) allows the FDA to publish discretionary publicity. This is to allow public warning where there is "imminent danger to health or gross deception of the consumer." The FDA can collect information from its reports for use in publicity.

"FDA issues publicity for the following purposes:
1. To warn against the use of the marketed products that may be hazardous;
2. To warn against gross economic deception;
3. To encourage public comment on proposed regulations or actions, and other public participation in FDA activities;
4. To report to the public on adjudicated court proceedings;
5. To present to the public FDA's views on matters of public interest; and
6. To report on studies and investigations that may form the basis for an FDA regulatory action.

Each of these activities is used by FDA as a means of implementing its overall policies and enforcement programs." -- From Practical Food Law by Dubeck and Eldred.

**Judicial Actions**

The three main types of judicial actions were discussed briefly in Chapter 4, they are:

1. Criminal prosecution
2. Injunction
3. Seizure

1. **Criminal Prosecution**

A person can be subject to criminal prosecution if a prohibited act described under Section 301 is committed. The use of the word "causing" in this section has been interpreted broadly to include even the president of the company, although he may have no knowledge of the violation. However, because of his position of responsibility, he is liable for criminal prosecution. This precedent was set by the case U.S. v. Park (421 U.S. 658). It was further expanded by the case, U.S. v. Dotterweich (320 U.S. 277). Persons having authority have a duty not only to seek out and correct violations but to also to prevent them and ensure that no adulterated products are in interstate trade.

Dotterweich, the president of Buffalo Pharmaceutical Company was tried for shipping adulterated drugs in inter-state commerce despite having no prior knowledge of the occurrence. Nevertheless he was convicted and served a prison sentence.

While such penalties may seem severe, they are used as an effective tool securing regulation.

2. **Injunctions**
As described in Chapter 4, an injunction is a court order requiring the stopping of certain actions which constitute a violation. This is used as an effective means of quickly ending prohibited acts. An injunction can be issued even if unlawful activity has ceased. In these circumstances, an injunction is granted if it is thought that there is a likelihood of the offense being repeated.

3. Seizures

Seizures are an action against the goods, removing them while being held for sale in interstate commerce. They differ from recalls in being a legal action supervised by FDA.

Section 304(c) allows the obtaining of samples of the seized goods for analysis by interested parties to compare with FDA findings. It is possible to contest a seizure if there is reason to believe that FDA sampling is inadequate. When goods are seized, there are three lines of action for a company to follow:

1) to allow the goods to go; 2) if it is economically viable and the government allows, food can be relabeled or reconditioned; 3) to protest the charges in court. Depending on the outcome of the case, the second option may be a possibility following a trial.

EXERCISE

1. **U.S. v. ...Black Raspberry Puree** 63 F.2d 1322.

Under what circumstances can a condemned food be sold?
CHAPTER 10

EXAMINATIONS AND INVESTIGATIONS

A FDA may arrive unannounced to conduct a factory inspection. Therefore, preparation is vital and a plan must be in place on how the inspection and inspection will be dealt with and who will be involved.

Educating key employees as to the regulations governing the inspection is of paramount importance to avoid mishandling situations.

The Act

Sec. 372 describes the FDA's rights and responsibilities when carrying out examinations and investigations.

Sec. 372 - Examinations and Investigations

a) The Secretary is authorized to conduct examinations and investigations necessary for the enforcement of the Act.

b) If in the carrying out of such investigations a sample is taken for analysis, a portion of this must be given to the alleged offender for their own analysis, if requested.

c) FDA has the right to make factory inspections.

Sec. 373 - Records of Interstate Shipments -- This paragraph gives FDA the right to request access to records of interstate shipments. Technically, this request should be in writing, but it usually is verbal.

Sec. 374 - Factory Inspection -- The factory inspection is the most useful means FDA has to ensure enforcement of the Act. Certain rules apply in conducting an inspection that are described below.

Sec. 374(a) -- When the FDA inspector presents his credentials and a written notice of inspection, he is entitled to:

A. **Enter** a plant or vehicle which is involved in interstate commerce at a reasonable time.

   Reasonable time implies when the processing operation is usually running.

B. **Inspect** at 'reasonable times' within 'reasonable limits.' The inspection should be completed promptly. Usually in one or two days at the most. These limits exclude the possibility of stripping
down machinery essential to an operation without good cause and making similar unreasonable requests.

Sec. 374(b) -- Before leaving the plant the inspector must leave a report of any violations of Sec. 402(a)(3) and (4).

Sec. 374(c) -- If any samples are taken from the premises by the FDA inspector, he should leave a receipt with the persons concerned.

Because the inspection is important to both FDA and the industry, the inspection will be discussed in more detail.

Outline of Factory Inspections

There are three main types of factory inspection:

1. **Comprehensive:** This is general inspection and is a thorough examination scheduled periodically by FDA which is unannounced.

2. **Abbreviated:** This inspection centers on areas which have been of FDA concern and may initiate a comprehensive inspection. The areas are critical for the company to be in compliance with current regulations.

3. **Directed:** These inspections are called when a food safety problem arises as a result of a consumer complaint or receiving information by other means. Specific areas are covered and may be followed by a recall or a comprehensive inspection.

Opening Conference

The inspector may appear at the plant unannounced and prior to the inspection a short conference takes place to allow the inspector to:

a. Present his credentials

b. Give notice of the inspection

The inspection can be delayed by requesting a warrant, but this is no more than a delaying tactic and may only give the inspector the impression that there is something wrong with the operation. However, it may provide enough time to correct a problem.
Personnel Accompanying the Inspector

The choice of employees accompanying the inspector is important. It has been suggested that two people escort the inspector, one engaging in conversation while the other takes notes. The people should be friendly and competent and not given to providing unnecessary or unsolicited information. They should distinguish information they are obliged to give from information that is discretionary. This is important because FDA inspectors will ask for access to records which they are not legally entitled to. Such inquiries can be dealt with by asking FDA to make a written request.

FDA Samples

Conditions of FDA sampling have been described in 372(b) and 374(c). Persons accompanying the inspector should observe the sampling technique to ensure a representative sample is taken. Method of sampling may be crucial if samples are used in a court case. In addition, the company should take its own samples before and after the FDA sampling.

FDA Record Review

The inspector will ask to see records of interstate shipments. The FDA has no authority to see business records i.e. accounting and sales, unless the premises are subject to low acid and acidified food regulations or infant formula regulations. Refusal to provide such information will constitute a violation under Sec. 404, "Emergency Permit Control".

The Inspector will ask to see other records, on a voluntary basis, without informing the company representative of their right to refuse such requests. Information of this type includes production records, sampling and testing records, maintenance records and formulations. It is at the company's discretion whether or not this information is provided.

Signatures

Technically, the FDA cannot insist on obtaining signatures of company representatives. However, two documents are usually presented by the FDA for signatures.

1. Interstate shipping declaration -- If signed, the inspector will probably not inspect interstate shipping records. The company can insist on a written request before revealing interstate shipment records (Sec. 374).
2. Receipts for payment of samples -- Should large samples be taken, the company representative may be asked to sign a receipt for payment of the samples.

Final Conference

Prior to this discussion, any recommendations that can be implemented in the inspector's presence should be done.

During the conference the inspector will discuss his findings which will include:

1. Improvement in conditions and practices
2. Any significant violations (Sec. 374 (b))
3. Consumer complaint letters
4. Presentation of an "Inspection Observations Report" (Sec. 374 (b)).

After the Inspection

An Establishment Inspection Report (EIR) is prepared by the inspector for the FDA. This includes observations, discussions, and the results of tests on samples. The FDA can follow-up their findings with either judicial or non-judicial remedies if necessary.

Practical Issues

A plan and policy on factory inspection must be developed and known to employees. Issues to be addressed are:

1. Who will receive the Notice of Inspection and review the credentials of the inspector. Employees should be listed in order of priority?
2. Who will accompany the FDA official during the inspection?
3. Who will receive document requests?
4. Who needs to be informed that an inspection is underway?
5. Policies must be developed on the use of i) cameras and tape recorders; ii) employee interviews by FDA; ii) collection of duplicate samples after FDA sampling.

Current Issues

There continues to be concern regarding the use of cameras during the inspection. Inspectors are instructed by the FDA to carry cameras, with consent of the company. Industry is concerned that
photographs could exaggerate the appearance of a situation or reveal trade secrets. Use of a camera would then be outside 'reasonable limits' (Sec. 374(a) B) and constitute 'unreasonable search and seizure' as described by the fourth amendment.

While there is no definitive legal decision as yet, courts have admitted photographic evidence. The latest case is Dow Chemicals v. U.S., 106 S.Ct.1819. The Supreme Court upheld the right of EPA to take aerial photographs as part of the inspection.

A lesser issue is the use of tape recorders during inspections. The FDA instructs that tape recorders be used only in unusual situations.

2002 Bioterrorism Act has produced new regulations enhancing inspections, especially at ports and develop food safety and security strategies.

SEC. 302. PROTECTION AGAINST ADULTERATION OF FOOD. (see adulteration notes)

Useful websites:
Compliance Policy Guides Manual:

EXERCISE:

Following a warrantless inspection, extensive rodent activity was reported. This was documented by photographs. The company did not object to the use of a camera. In the court case, the photographic evidence was presented. A criminal prosecution was sought by the FDA.

a. What defense could you use to suppress the use of photographic evidence?
b. What could the company have done to avoid the photographs being taken?
c. How would you argue the case for the prosecution?
d. What does this case teach you about preparing for a factory inspection?
REFERENCES


Davis, D.R. 1987. Statutes and Regulations Pertaining to Food and Food Products.


