Government Regulation of the Food Supply and Labeling

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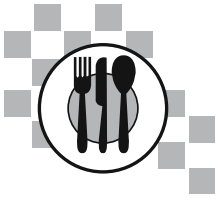

Introduction

Consumers want the assurance that they have a sure, safe, and sanitary food supply. They want deceptive claims and fraudulence to be nonissues for them to face in everyday life. Therefore, for centuries, governments throughout the world have regulated the food supply. Federal, state, and local government, their regulation, enforcement, as well as the educational materials they offer, assist in providing a safe food supply. The intent of this chapter is to view government regulation of the food supply and labeling. However, a safe and sound food supply is still dependent, not alone on a government agency or program yet also upon the individual!

All the way through this food science textbook, the role of government has been addressed. One of the major regulatory agencies protecting the food supply is the *Food and Drug Administration* (*FDA*). Their basic purpose is to protect the public from foodborne illness. The FDA regulations known as "Good Manufacturing Practices" or GMPs are in operation at food plants. Of course, maintaining plant sanitation and food safety (see Chap. 19) are ongoing duties of the food processing plant's own personnel—hopefully well trained and motivated!

The FDA's Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) is the main law that regulates the food supply in the United States. They are responsible for public health encompassing safety, specific safe drugs, and cosmetics as well as biological products and medical devices. It ensures the safety of all food except for meat, poultry, and some egg products.

The FDA Code of Federal Regulations (CFR) is cited several times in this chapter, with the hope of better portraying and understanding the government ruling on an issue.

Interstate transport of food, food packaging, and labeling are regulated, and grading standards and ordinances that specify sanitation for the food environment are enforced. *Intrastate* transport is regulated by each *state*'*s* Department of Agriculture that may adopt their own, more strict regulations than the federal.

Another federal regulatory agency with influence and enforcement over the food supply is the *United States Department of Agriculture* (*USDA*). This agency has responsibility for inspecting animal products, including meat, poultry, and eggs; processing plants for meat and poultry; as well as voluntary grading.

The two federal agencies, FDA and USDA, despite friction at times, work together to maintain food safety and consumer health. It may be

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proactive or reactive responses that are necessary for the well-being of the US citizens.

Of course, in addition to the government's regulation of the food supply, *industry* and *consumers* must be vigilant and play their part in assuring a safe food supply! Food safety is still dependent upon the individual!

Additionally, general labeling, nutrition labeling, health claims, food allergen labeling, and labeling for foodservice are discussed in this chapter.

The Food and Drug Administration

The FDA is a public health agency. The agency regulates approximately 25 % of every dollar spent annually by American consumers—over $1 trillion worth of products (FDA)—and does so at a taxpayer cost of just dollars per individual. The FDA inspects food—to assure that it is safe and wholesome, it also inspects cosmetics, medicines and medical devices, radiation-emitting devices (such as microwave ovens), animal feed, and drugs.

Biological products often represent the cutting edge of medical science and research. Also known as biologics, these products replicate natural substances such as enzymes, antibodies, or hormones in our bodies.

Biological products can be composed of sugars, proteins, or nucleic acids, or a combination of these substances. They may also be living entities, such as cells and tissues. Biologics are made from a variety of natural resources—human, animal, and microorganism—and may be produced by biotechnology methods.—FDA

Today, the FDA regulates $1 trillion worth of products a year. It ensures the safety of all food *except for meat, poultry and some egg products*; ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and tissues for transplantation), medical devices, and animal drugs and feed; and makes sure that cosmetics and medical and consumer products that emit radiation do no harm. (FDA)

FDA Federal Food, Drug, and Cosmetic Act: 1938

"The Food and Drugs Act of 1906 was the first of more than 200 laws that constitute one of the world's most comprehensive and effective networks of public health and consumer protections. The Federal *Food, Drug, and Cosmetic Act of 1938* officially passed after a legally marketed toxic elixir killed 107 people, including many children. The FD&C Act completely overhauled the public health system. Among other provisions, the law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections." (FDA)

Since the origin of this law, there have been numerous amendments. This law replaced the 1906 Federal Food and Drug Act, or "Pure Food Law," and is assigned to regulate many packaged or processed food products. The regulation includes the necessity for adequate and truthful labels if the food is subject to import or interstate commerce. Additionally, a federal Code of Regulations was written to cover specific rules for the food industry.

The FDA has several thousand researchers, inspectors, and legal staff in approximately 150 cities throughout federal, regional, and local offices in the United States, including scientists (over 2,000), chemists (approximately 900), and microbiologists (approximately 300). Agents of the FDA may work with public affairs or small business as well as any laboratory personnel. They interpret law and monitor the manufacture, import, transport, and storage of products both prior to and following sale on the market. Products are examined for construction integrity, and labels must be truthful.

Among the varied activities of federal FDA agents includes advising state and local agencies in general duties and prevention of disasters. The FDA has both a regulatory arm of enforcement

and cooperative programs of partnership with industry. The latter, for example, helps train employees in preventing foodborne illness. Despite budgetary constraints and a transition of the FDA to a Hazard Analysis Critical Control Point (HACCP) focus, the role of this government agency remains to protect the public.

Voluntary correction of public health problems is necessary, although when warranted, *legal sanctions* may be brought to bear against manufacturers or distributors. Recalls of faulty products are generally the fastest and most effective way to protect the public from unsafe products on the market.

Amendments to the Food, Drug, and Cosmetic Act

Several major amendments to the Food, Drug, and Cosmetic Act that were introduced and became the US law include the following:

- *1954 Pesticide Chemical Amendment*: The use of pesticides is subject to FDA approval. Raw agriculture products are prohibited from containing pesticide residues above a certain level.
- *1958 Food Additives Amendment*: With this amendment, the burden of proof for usefulness and harmlessness of an additive was shifted to industry. Exempt from this proof were Generally Recognized as Safe (GRAS) substances already in common use with no proof of cancer (see section "GRAS Substances" below).
- The *Delaney Clause* (1966) of the Food Additives Amendment states that an additive *cannot* be used if it leads to cancer in man or animals or if the carcinogen is detectable by any appropriate test.

In recent years, a much-debated question on the necessity of the Delaney Clause has arisen. For example, what *is* an appropriate test to determine the level of a food additive that induces cancer? Finer detection of minute amounts of agents responsible for cancer has become available. Thus, the question is: At what level is the presence of a carcinogen indicative of the need to remove that item from the food supply? There is *no* food item that is, or can be, totally safe at any level of ingestion. (Simply consuming too much *water* has landed people in the hospital!) The future will offer more debate and regulation of this matter.

- *1960 Color Additives Amendment*: The use of food colors is subject to FDA approval.
- *1966 Fair Packaging and Labeling Act* requires all consumer products in interstate commerce to contain accurate information on the package, facilitating better control of misinformation. Consumers benefit in that they can use the label information on packages, in making purchasing and value comparisons.
- *1990 Nutrition Labeling and Education Act* (NLEA) was passed by Congress, and the FDA then wrote regulations for compliance covering extensive labeling changes, including mandatory nutrition labels, uniform use of product health claims, and uniform serving sizes.

This was an attempt to protect the consumer against misinformation and fraud. New "nutrition facts" labels appeared on food products in May of 1994.

GRAS Substances

GRAS substances, according to the General Provisions of the CFR, Title 21 (21CFR582), Sec. 582.1, are discussed as follows:

"It is impractical to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use."

Standards for Interstate Transport of Food

The FDA has mandatory standards, identified in the following:

Standard of Identity. The FDA describes food and lists both required and optional ingredients

that are included in manufacture. Examples of products that follow a Standard of Identity included foods such as mayonnaise, white bread, and jelly.

When initially introduced as law, a food product followed a Standard of Identity in its manufacture, and many required and optional ingredients were *not* listed on labels, as it was understood that the consumer was familiar with ingredients that composed basic foods. In time, however, it became apparent that this familiarity with foods was not widespread! As a result, after 1967, *optional* ingredients of foods were *required* to be included on labels, even if the product followed the Standard of Identity. A standard was continually reviewed and revised as new additives are approved for food use.

Currently, manufacturers are *required* to state *all* ingredients on the product label, including required and optional ingredients. This change to the complete identification of food ingredients benefits consumers who are unfamiliar with food ingredients that make up a food, as well as those with food allergies or intolerances.

Standards of Minimum Quality. The FDA states the minimum quality standards for specific characteristics in a food, such as color, defects, and tenderness. (Color, tenderness, blemishes, clarity of liquid, and product size are some of the criteria used at the wholesale and retail level for evaluation.) A food must state "below standard in quality" if the minimum level of a particular quality descriptor is not obtained.

For example, we see processors of canned vegetables and fruits follow this standard. Substandard does not signify safety hazards.

Standard of Fill of Container. This FDA standard ensures that the headspace/void volume of packaged food offered for sale does not interfere with the *weight* of the product as stated on the label. It assures that the product offers the correct weight even if the package is only partially full! For example, packages of cereal, crackers, and potato chips may not appear full due to extra air space in the package that is needed to prevent food breakage, yet, this fact is taken into account, and the food is sold by the *weight*, *not* by the *volume*. Food products packed in a liquid medium, such as canned fruits or vegetables, must contain the stated weight of the product.

Adulterated and Misbranded Food

Adulterated and misbranded foods are defined as follows:

Adulterated food may *not* be offered for sale. According to the FDA, a food is adulterated if it:

- Is poisonous or harmful to health at detrimental concentrations
- Contains filth or is decomposed
- Contains a food or coloring agent that is not approved or certified
- Was prepared or packed under unsanitary conditions, making it contaminated
- Is derived from a diseased animal
- Contains any excessive levels of residue
- Was subject to radiation, other than where permitted
- Has any valuable constituent omitted
- Substitutes a specified ingredient with an unspecified ingredient
- Is damaged or conceals defects
- Is increased in bulk weight or reduced in its strength, making it appear better than it is

According to the FDA, a food is *misbranded* if it:

- Is labeled falsely or misleadingly
- Is offered for sale under the name of another food
- Is an imitation of another food, without stating "imitation" on the label
- Is packaged (formed or filled) so as to be misleading
- Fails to list the name and address of the manufacturer, packer, and distributor and a statement of net contents on the label

- Fails to declare the common name of the product and the names of each ingredient or has label information that is not legible and easily understood
- Is represented as a food for which there is a Standard of Identity but the food does not conform with an accurate statement of quantity or ingredients
- Is represented to conform to a quality standard or to a fill of container and does not conform
- Is represented with a nutritional claim or for special dietary use but the label fails to provide information concerning dietary properties of the food, as required by law
- Lacks proper nutrition labeling

Food Safety Modernization Act (FSMA) Proposed 1/2013

" . . .The rules follow extensive outreach by the FDA to the produce industry, the consumer community, other government agencies and the international community. Since January 2011, FDA staff have toured farms and facilities nationwide and participated in hundreds of meetings and presentations with global regulatory partners, industry stakeholders, consumer groups, farmers, state and local officials, and the research community.

"The FDA Food Safety Modernization Act is a common sense law that shifts the food safety focus from reactive to preventive," said Health and Human Services Secretary Kathleen Sebelius. "With the support of industry, consumer groups, and the bipartisan leadership in Congress, we are establishing a science-based, flexible system to better prevent foodborne illness and protect American families." . . .

See *Food Safety Modernization Act*. The focus of legislation changed from *responding* to a problem to its *prevention*.

In the FSMA through the FDA, two new rules were proposed. One requires HACCP, risk-based preventive controls and plans for correcting any domestic food problem that arise. "The second rule proposes science- and risk-based standards for the safe production and harvesting of produce on farms" (Kuntz 2013) (see more on this law in Chap. 19).

The FDA also enforces *the Public Health Service Act* to maintain sanitary standards at retail foodservice establishments and in milk processing and shellfish operations. The FDA monitors food for safety and wholesomeness on interstate carriers such as planes and trains. As well, the FDA has a Seafood HACCP (program, which is aimed at controlling pathogens and foodborne illness from seafood).

If the FDA determines that a product poses a serious risk to public health, the FDA inspectors will submit Form 482c *Notice of Inspection-Request for Records* in order to conduct an emergency food contamination inspection. The FDA is allowed to obtain needed records, and the form must be submitted in writing to the owner, operator, or agent in charge of the company.

Maintaining business, protecting profits, as well as learning how to recover from disasters are duties of the food plant. Each of these goals must be protected. As mentioned in a recent article *Building your plant's ark*, "Noah may have been among the first to plan for impending natural disaster. Don't let him be the last" (Stier 2006).

Developing an emergency plan is "more than putting words on paper. Map out how your plant will react to a variety of disasters: hurricanes,

earthquakes, tornados, fires, chemical spills/leaks, terrorism or other potential problems. At the very least, you need an evacuation plan to get workers to a safe location" (Stier 2006).

The United States Department of Agriculture (USDA)

The USDA is another major government agency regulating and with enforcement powers, the food supply in the United States. At the helm is the Secretary of Agriculture, and it is a full federal government department. It is responsible for inspection of meat, poultry, agricultural products, including milk, eggs, fruit, and vegetables, and also meat and poultry processing plants. The USDA also has involvement in the protection of the United State's natural resources and environment.

While the ***inspection service***, including bacterial counts, is *mandatory*, the ***grading service*** is *voluntary* and is paid for by the manufacturer, marketer, or packer. Accommodations such as a desk, telephone, and parking space should be made available for the USDA inspector who is routinely or regularly present at a plant to assure safe food handling and plant sanitation. Of course, it needs to be stressed once more—food safety is still dependent upon the individual!

The USDA, or the individual State Departments of Agriculture (states may exceed, however, at least *meet* federal standards), inspects meat and stamps it with an abbreviation of "Inspected and Passed," containing a number that identifies the plant from which it came. Every *carcass*, although not every *cut* of meat, requires this stamp (made using nontoxic vegetable dye) as proof of sanitary quality and wholesomeness. The stamp is required for shipment in interstate commerce. The label stating ***wholesome*** indicates that no signs of illness were found, *not* that the meat is free from pathogenic microorganisms.

The Federal Meat Inspection Act of 1906, Federal Poultry Products Inspection Act of 1957, and the Wholesome Poultry Products Act of 1968 are enforced by the *Food Safety and Inspection Service* (*FSIS*) of the USDA. The inspection, labeling, and handling of poultry and poultry products are similar to the meat inspection process. Processed poultry products do not undergo a mandatory inspection.

The FSIS conducts activities such as the following to ensure the *safety* of meat and poultry products consumed in the United States:

- The USDA inspectors and veterinarians conduct slaughter inspection of all carcasses at meat and poultry slaughtering plants for disease and other abnormalities and sample for the presence of chemical residues.
- The USDA conducts processing inspection for sanitation and cleanliness, labeling, and packing at facilities where meat and poultry is cut up, boned, cured, and canned.
- Scientific testing in support of inspection operations is performed by USDA/FSIS laboratory services to identify the presence of pathogens, residues, additives, diseases, and foreign matters in meat and poultry.
- Inspection systems in countries exporting meat and poultry products to the United States are reviewed by the USDA as part of the import–export inspection system.
- The USDA is placing increased emphasis on pathogen reduction and HACCP in the entire meat and poultry production chain. This involves developing new methods for rapid detection of pathogenic microorganisms, new production, and inspection practices to reduce bacterial contamination and educating consumers on safe food-handling practices.
- The USDA's Meat and Poultry Hotline is a toll-free service where consumers, educators, researchers, and the media can speak with experts in the field of food safety.

The USDA also has a Food and Nutrition Service (FNS).

The USDA FNS administers the food and nutrition assistance programs in the U.S. Department of Agriculture. FNS provides children and needy families with better access to food and a more healthful diet through its programs and nutrition education efforts.

Program and Service Highlights includes:

- Women, Infant, and Children (WIC) Program—The FNS administers several programs that provide healthy food to children including the National School Lunch Program, the School Breakfast Program, the Child and Adult Care Food Program, the Summer Food Service Program, the Fresh Fruit and Vegetable Program, and the Special Milk Program. Administered by state agencies, each of these programs helps fight hunger and obesity by reimbursing organizations such as schools, child care centers, and after-school programs for providing healthy meals to children.
- Supplemental Nutrition Assistance Program—SNAP offers nutrition assistance to millions of eligible, low-income individuals and families and provides economic benefits to communities. SNAP is the largest program in the domestic hunger safety net. The FNS works with state agencies, nutrition educators, and neighborhood and faith-based organizations to ensure that those eligible for nutrition assistance can make informed decisions about applying for the program and can access benefits. FNS also works with state partners and the retail community to improve program administration and ensure program the integrity.
- School Meals—The FNS administers several programs that provide healthy food to children including the National School Lunch Program, the School Breakfast Program, the Child and Adult Care Food Program, the Summer Food Service Program, the Fresh Fruit and Vegetable Program, and the Special Milk Program. Administered by state agencies, each of these programs helps fight hunger and obesity by reimbursing organizations such as schools, child care centers, and after-school programs for providing healthy meals to children.
- Food Distribution Programs—The FNS Food Distribution Programs' mission is to strengthen the nation's nutrition safety net by providing food and nutrition assistance to school children and families and support American agriculture by distributing high-quality, 100 % American-grown USDA Foods.
- Disaster Assistance—Nothing is more important than providing food when people find themselves suddenly, and often critically, in need following a storm, earthquake, flood, or other disaster emergency. The USDA makes sure that people have enough to eat.
- Child and Adult Care Food Program—CACFP plays a vital role in improving the quality of day care for children and elderly adults by making care more affordable for many low-income families.

Through CACFP, more than 3.3 million children and 120,000 adults receive nutritious meals and snacks each day as part of the day care they receive.

- Summer Food Service Program—During the school year, many children receive free and reduced-price breakfast and lunch through the School Breakfast and National School Lunch Programs. What happens when school lets out? Hunger is one of the most severe roadblocks to the learning process. Lack of nutrition during the summer months may set up a cycle for poor performance once school begins again. Hunger also may make children more prone to illness and other health issues. The Summer Food Service Program is designed to fill that nutrition gap and make sure children can get the nutritious meals they need.
- Farmers' Market Nutrition Programs—The WIC Farmers' Market Nutrition Program (FMNP) is associated with

the Special Supplemental Nutrition Program for Women, Infants and Children, popularly known as WIC. The WIC Program provides supplemental foods, health care referrals, and nutrition education at no cost to low-income pregnant, breastfeeding, and non-breastfeeding postpartum women and to infants and children up to 5 years of age, who are found to be at nutritional risk.

The WIC FMNP was established by Congress in 1992, to provide fresh, unprepared, locally grown fruits and vegetables to WIC participants and to expand the awareness, use of, and sales at farmers' markets. Women, infants (over 4 months old), and children that have been certified to receive WIC program benefits or who are on a waiting list for WIC certification are eligible to participate in the WIC FMNP. State agencies may serve some or all of these categories. A variety of fresh, nutritious, unprepared, locally grown fruits, vegetables, and herbs may be purchased with FMNP coupons. State agencies can limit sales to specific foods grown within state borders to encourage FMNP recipients to support the farmers in their own states.

- Nutrition Education—NS provides children and adults of all ages with nutrition education materials on how to improve their diets and their lives.—USDA

There are many USDA programs. In order to face the complex nutrition issue in the twenty-first century, there may be a need for researchers, policymakers, and both private and public sector organizations to define and implement a strategy for action agenda.

Presently, there are many nutrition programs, as mentioned, such as the Food Stamp Program and Special Supplemental Nutrition Program for Women, Infants, and Children. There are also Dietary Guidelines, NLEA, etc., the "building blocks" over the past few decades, yet they do not represent a national nutrition policy (Crockett et al. 2002).

The most recent USDA Food Code is discussed in the chapter on Food Safety (Chap. 19).

The USDA's FSIS has a Food Biosecurity Action Team (F-BAT). Its intent is to protect agriculture and the food supply, ensure employee safety, have adequate capacity and security at agency laboratories, ensure that essential USDA functions can continue, and be able to pass on necessary information (to employees, consumers, industry, the media, Congress, and other agencies) in a single, consistent message (USDA).

The USDA Undersecretary for Food Safety formed the F-BAT to coordinate and facilitate all activities pertaining to biosecurity, countering terrorism, and emergency preparedness with FSIS. F-BAT also serves as FSIS' voice with other governmental agencies and internal and external constituents on biosecurity issues (USDA).

Unfortunately the FSIS has managed many recalls of food products. However, they have decided that during food recalls, distribution lists, which are usually confidential, may be made available to state and federal agencies. Such lists would not be subject to public disclosure.

See

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule.

[Federal Register Volume 78, Number 11 (2013)] [www.gpo.gov]

State and Local Health Departments

As previously mentioned, the *federal* agencies (FDA, USDA) regulate interstate food supplies, and it is the task of *state* agencies, such as state FDAs and state Agriculture Departments, to regulate *intra*state food supplies. In some states, the State Health Department has complete authority over all food operations, whereas in other states, county or city health departments adopt their own specific foodservice regulations.

Additional Agencies Regulating the Food Supply

The Federal Trade Commission (FTC) protects against unfair and deceptive advertising practices of products, including food.

The National Marine Fisheries Service (NMFS) of the Commerce Department is responsible for voluntary grading of seafood.

The Occupational Health and Safety Administration (OSHA) regulates health hazards in the workplace (such as food manufacture, processing, or retail foodservice) and determines compliance with regulations.

The Environmental Protection Agency (EPA) sets environmental standards. This agency regulates air and water pollution by plants, toxic substances, pesticides, and the use of radiation.

Education and Training

Education and training on the part of the government and industry is significant in regulating the food supply. Each segment/person must be properly trained and motivated to do their part in maintaining a safe food supply and seeing that they adhere to proper labeling. The public should do their part in adhering to proven government safety and labeling strategies (see Chap. 19).

General Labeling

General labeling requires that complete information about food must be supplied on food packages. It must include the following:

- Name of product; name and place of business
- Net weight—ounces (oz.), or pounds and ounces
- Ingredients—listed by weight in descending order on ingredients list of label (not Nutrition Facts portion)
- Company name and address
- Product date if applicable to product
- Open date labeling—voluntary types able to be read by the consumer
- Expiration date—deadline for recommended eating (i.e., yeast)
- "Best if used by" date—date for optimum quality, QA, or freshness
- Pack date—date food was packaged
- Pull date—last day sold as fresh (i.e., milk, ice cream, deli)
- Code date—read only by manufacturer
- Nutrition information—"Nutrition Facts" on nearly all labels
- Nutrient content claims substantiated
- Health claims used only as allowed
- Other information
  - Religious symbols—such as Kosher (if applicable)
  - Safe handling instructions—such as on meats
  - Special warning labels—alcohol, aspartame that may affect select consumers
  - Product code (UPC)—bar code

Labeling Basics (Reported Concisely Herein by a Labeling Company)

"Labeling regulations exist to ensure that consumers know what they are buying. Improperly labeled products may be deemed misbranded or adulterated and subject to regulatory agency action. Avoid receiving an FDA warning letter or cyber letter and other costly labeling errors by ensuring that your labels are compliant with FDA & FTC regulations. FDALabels.com helps you with all your labeling needs.

Every product sold in the United States must include the following information on the label:

- Statement of identity or standard product name (What is it?)
- Net quantity of contents statement (How much is in the package?)
- Component/Ingredient statement (What is it made of?)
- Signature line or name and place of business of the US manufacturer, packer or distributor (Who made it and who should be contacted if something goes wrong?)

In addition, each type of FDA-regulated product has other distinct labeling requirements:

Functional Foods—Food and functional food products sold in the United States are subject to FDA labeling regulations found in the CFR. In addition to the requirements that labels include a statement of identity; net quantity of contents statement, ingredient list and signature line, food labels must also include a Nutrition Facts Box and allergen statement.

"The contents of the Nutrition Facts Box must comply with thresholds of declaration and rounding rules outlined in 21 CFR 101.9. FDA regulations allow for the use of calculated values to declare the levels of calories, fat, trans fat, protein, carbohydrates, sodium, cholesterol and other nutrients. Food products that meet specific guidelines may be labeled with nutrient content claims and certain health claims."

"Food products containing meat or poultry are regulated by the USDA. While the labeling regulations for these products mirror the requirements for foods regulated by FDA, USDA labels must be submitted to the USDA Food Safety and Information Service for review prior to use. Organic labeling is also administered by the USDA and subject to prior certification."—*FDALabels.com—a site providing product development and regulatory affairs consultation for FDA and USDA regulated products*

"The U.S. Federal Food, Drug and Cosmetic Act (FFDCA) defines food 'labeling' as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. The term 'accompanying' is interpreted liberally to mean more than physical association with the food product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instructions, websites, etc.

The Nutrition Labeling and Education Act (NLEA), which amended the FFDCA requires most foods to bear specific nutrition and ingredient labeling and requires food, beverage, and dietary supplement labels that bear nutrient content claims and certain health messages to comply with specific requirements. Furthermore, the Dietary Supplement Health and Education Act (DSHEA) amended the FFDCA, in part, by defining "dietary supplements," adding specific labeling requirements for dietary supplements, and providing for optional labeling statements."

http://www.registrarcorp.com/fda-food/labeling/regulations.jsp?lang = en

Radio Frequency Identification Tags

Radio Frequency Identification (RFID) tags appear on many food product labels. A number of consumer packaged goods, retail operations, transportation, defense, and pharmaceuticals use RFID. A number of retailers require it of their suppliers. It is more than an inventory or packaging/labeling technology (Higgons 2006). It assists manufactures and users track packaged food throughout the supply chain. For example, benefits of RFID may include better consumer safety and security and improved operating efficiencies for packaging, manufacturing, distribution, and sales.

Since it may be required of various vendors delivering to suppliers, training in its benefits and uses may assist users/potential users of the technology. Training can help hardware and software providers, and both the public and private sectors, as well as educators and researchers.

Nutrition Labeling

Food products intended for human consumption are subject to mandatory ***nutrition labeling***, regulated by the FDA. As a result of the Nutrition Labeling and Education Act of 1990 (NLEA), there are regulations that specify information food processors must include on their labels, including "Nutrition Facts." The purpose of the NLEA is the following:

- Assist consumers in selecting foods that can lead to a healthier diet
- Eliminate consumer confusion
- Encourage production innovation by the food industry

NLEA regulations became effective in 1994, and approximately 595,000 food products had to meet these regulations, according to the FDA and USDA.

Consumers benefit from the educational component of the labeling law, as the information on labels is easy to read and may be useful in planning healthful diets. The label provides consumers with consistency under mandatory "Nutrition Facts" which appears on most products offered for sale in the United States. Voluntary information for cuts of meat, raw fish, and the 20 most commonly eaten fruits and vegetables may appear on package bags, brochures, or posters at the point of sale. Labeling values for produce and fish have been revised since initially required and further revisions will be proposed every 4 years.

The FDA has set 139 reference serving sizes for use on "Nutrition Facts" labels that more closely approximate amounts consumers actually eat than previous labeling. The serving size indicates values, such as the number of ounces in a beverage or the ounces and number of cookies or crackers per serving; the nutrient content of a food is based on this reference-serving size and stated on the label. In packaged food, a food is still labeled as a *single serving* if the amount of food is greater than 50 % and less than 200 % of the designated single-serving size. Also see the following website: http://vm.cfsan.fda.gov/~lrd/cf101-12.html.

Portion sizes are thus designated by the FDA. (See choosemyplate.gov) View Food Gallery) to see photos of actual foods and portion sizes. Depending on personal intake, the individual nutrient consumption may be more or less than that FDA "one serving." Of course that is acceptable as long as the person who desires to either limit or attain certain nutrients realistically knows what constitutes that "one serving"! In example, a serving of ice cream is one scoop, not one bowlful! Thus calories, fat, cholesterol, and so forth are calculated accordingly. ("Portion distortion" is what is sometimes referred to as a person's mistaken idea of what equals an actual portion!)

With the passage of the NLEA, the FDA set regulations stating that a food label must express nutrient information in terms of recommended daily intake, in grams (or milligrams) or as a percentage, thus the "% Daily Values" or "DV." It shows how a serving of the food fits into a total day's diet.

Two sets of values were included in the establishment of Daily Values. One is the Reference Daily Intakes (RDI), which is based on former "U.S. RDA" (derived from 1968 RDA) labeling values. The second is Daily Reference Values (DRV) for nutrients, such as fat, sodium, cholesterol, and total carbohydrates including dietary fiber and sugars, which do not have an RDA yet have a significant health impact. The DV reference values are based on a 2,000- or 2,500-calorie diet, and consumers ingesting more or less calories should adjust numbers accordingly.

Numerous values are provided on nutrition labels. For example, the total calories and calories from fat, the total fat, and the saturated fat (perhaps monounsaturated and polyunsaturated fat if the processor wants to include these) and trans fat are stated. Cholesterol and sodium are stated in milligrams. The total carbohydrate, sugar, and dietary fiber are also reported on Nutrition Facts. Protein is expressed as a quantity that takes into account the completeness of amino acids (complete = having all essential amino acids in the needed amount). Food processors have the option of reporting protein as a %DV on a label, and, if they do, they must determine the quality of the protein to ascertain which Daily Value of protein to use as a comparison.

As mentioned earlier, consumers may be attempting to limit or attain specific quantities of certain nutrients in their diet. For example, a consumer may desire to limit fat or cholesterol, or they may want to increase their intake of vitamins and minerals commonly needed in the United States, such as vitamins A and C, calcium, and iron. A nutrition label can help the consumer know what nutrients are in food.

Examples of terms allowed on food labels appear in Table 20.1. Terms are consistent among products, and manufacturers and food processors must abide by these definitions on their product labels. Yet, when merchandising a product through the various forms of advertisement, there exists no FDA regulation of terms.

The label information intended to assist consumers in making informed food choices, and it did not come cheaply to food processors. The product analyses, as well as label redesign and printing costs, were incurred. In a survey conducted by the National Food Processors Association, it was estimated that well over $1 billion would be spent by the food industry as it implemented NLEA in an 18-month period.

Methods of analyses for nutrition labeling are available to food processors from the AOAC International and the Food Chemicals Codex (FCC). "Whole food" and "ingredient" databases assisted in providing the necessary nutrient information for labels.

In a land of plenty, with an increasing concern of managing personal weight, the USDA has released the 2005 Dietary Guidelines for Americans. They include the following: the USDA and Health and Human Services (HHS) publication emphasizes both lifestyle and dietary measures for health. Food Technology reports: "So, the news for the food sector is to continue to improve processes and formulations where appropriate, and help consumers avoid foodborne illness and excess, while keeping excitement at the table" (Katz 2000). Other nations have adopted similar dietary guidelines for their population.

Dietary Guidelines for Americans

"Dietary Guidelines for Americans is published jointly every 5 years by the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA). The Guidelines provide authoritative advice for people two years and older about how good dietary habits can promote health and reduce risk for major chronic diseases." (USDA)

Current recommendations are found in www.healthierus.gov/dietaryguidelines:

- Integrate better eating habits into your life.
- Integrate better activity habits into your life.
- Set realistic goals.
- Take small steps to meet them.

Table 20.1 Some examples of terms allowed on food labels

General descriptive terms
• *Free—negligible amount of the nutrient*
• Good source of—between 10 and 19 % of the Daily Value of the nutrient
• Healthy—low-fat, saturated fat, cholesterol, and sodium food with at least 10 % of the Daily Value for vitamins A and C, protein, iron, calcium, or fiber
• Low—not meeting Daily Values with frequent consumption
• High—20 % or more of the Daily Values for a nutrient per serving
• Light or lite—one-third fewer calories, or one-half the fat of the comparison food
• More—at least 10 % more of the Daily Value than a comparison food
• Less—at least 25 % or less of a nutrient than the comparison food
Energy/calories
• *Free—fewer than 5 cal per serving*
• Low calorie—40 cal or less per serving
• Reduced calorie—at least 25 % fewer calories per serving than a comparison food
• Light—one-third less calories than the comparison food
Fat and cholesterol
• *Fat*
• *Fat-free—less than 0.5-g fat per serving*
• Low fat—3 g or less fat per serving
• Percent (%) fat-free—only if low fat or fat-free, calories based on 100-g portions
• Less fat—25 % or less fat than a comparison food
• Light—50 % less fat than a comparison food
Saturated fat
• *Saturated fat-free—less than 0.5 g of saturated fat and trans-fatty acid per serving*
• Low saturated fat—1 g or less saturated fat per serving
• Less saturated fat—25 % or less saturated fat than a comparison food
Cholesterol
• *Cholesterol-free—less than 2-mg cholesterol and 2 g or less saturated fat per serving*
• Low cholesterol—20 mg or less cholesterol and 2 g or less saturated fat per serving
• Less cholesterol—25 % or less cholesterol than a comparison food, and 2 g or less saturated fat per serving
• Extra lean—less than 5 g of fat, 2-g saturated fat, and 95-mg cholesterol per serving and per 100 g of meat, poultry, and seafood
• Lean—less than 10-g fat, 4.5-g saturated fat, and 95 mg of cholesterol per serving and per 100 g of meat, poultry, and seafood
Carbohydrates: *fiber and sugar*
• High fiber—5 g or more fiber per serving, with 3 g or less of fat per serving (low fat) unless a higher level of fat is specified
• Sugar-free—less than 0.5-g sugar per serving
Sodium
• *Sodium-free—less than 5-mg sodium per serving*
• Low sodium—140 mg or less per serving
• Light—50 % less sodium, in a low-calorie or low-fat food
• Very low sodium—35 mg or less per serving

Health Claims (More in Appendices)

In order to make the approved health claims (Table 20.2), a food must contain no more than 20 % of the Daily Value for total fat, saturated fat, cholesterol, or sodium, and the food must naturally contain at least 10 % of the Daily Value for either vitamins A and C, protein, fiber, calcium, or iron.

Table 20.2 Examples of approved model health claims used on food labels

• Calcium and lower risk of osteoporosis
• Sodium and a greater risk of hypertension (high blood pressure)
• Saturated fat and cholesterol and a greater risk of coronary heart disease (CHD)
• Dietary fat and a greater risk of cancer
• Fiber-containing grain products, fruits, and vegetables and a reduced risk of cancer
• Fruits, vegetables, and grain products that contain fiber (particularly soluble fiber) and a reduced risk of CHD
• Fruits and vegetables and a reduced risk of cancer
• Folate and reduced risk of neural tube defect
• Sugar alcohols and reduced risk of tooth decay
• Soluble fiber from whole oats and psyllium seed husk and reduced risk of CHD
• Soy protein and reduced risk of CHD
• Whole grains and reduced risk of CHD and certain cancers
• Plant sterol and plant stanol esters and reduced risk of CHD
• Potassium and reduced risk of high blood pressure and stroke

Examples of approved health claims appear in Table 20.2. Currently, the FDA is considering greater flexibility in the use of health claims on foods; yet, other claims outside of these may not be used on food products. Health claims for dietary supplements are being constructed (http://www.cfsan.fda.gov).

Labeling for Food Allergens

Food product legislation for more simple wording and common sense labeling is supported by the Food Allergy Initiative (FAI), the Food Allergy and Anaphylaxis Network, and the Center for Science in the Public Interest (CSPI). It has been suggested that perhaps labels should just say "wheat" or say "milk products." This is in part due to food allergies. Additional information on food allergens is found in the chapter on food safety.

Allergen food labeling is required after or adjacent to the ingredients list if a food may/does contain allergens. **The Food Allergen Labeling and Consumer Protection Act of 2004** (**FALCPA**) requires that food manufacturer identify foods that contain the presence of protein derived from crustacean shellfish, eggs, fish, milk, peanuts, soybeans, tree nuts, or wheat. Use of any ingredients that may contain protein from these eight major allergens must be clearly stated for the consumer.

> Immediately after or adjacent to the list of ingredients, put the word "Contains" followed by the name of the food for each of the major food allergens present in the food's ingredients.
>
> For example:
>
> **Contains Wheat, Milk, Egg, and Soy**—USDA

See FARE—Food Allergy Research & Education, Inc. (http://www.foodallergy.org\).

See Chap. 19 on Food Safety; also see Food Safety Research Information Office (FSRIO) National Agricultural Library (NAL)—Frequently Asked Questions—Regulations, Standards, and Guidelines:

http://fsrio.nal.usda.gov/faq-page/regulations-standards-and-guidelines

Labeling for Foodservice

The inclusion of material in this labeling for foodservice chapter section is intended to clarify labeling requirements of food served for immediate consumption. While this section addresses the *menu*, and *not labels* on packaged foods, it may be of less concern to the food scientist. Yet foods eaten at a foodservice operation represent a

significant portion of the buying public's consumption and therefore deserve attention.

The FDA encourages foodservice operations to provide nutrition and health claims to consumers, and further regulations may be forthcoming. Yet, nutrition analysis testing and Nutrition Facts labeling are *not* required of food service.

Any nutrient content or health claims appearing on menus must be substantiated by the foodservice operation, either verbally or in written form, to consumers who request such information. Claims must meet established FDA criteria—specified in the CFR, a reliable cookbook or computer software program may be used as a reference, and preparation methods must support the claim, or the menu item must be removed from the menu.

The CFR (21CFR101) specifies the following with regard to labeling for foodservice: "A nutrient claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the (same) requirements of this section…"

Menu-related obstacles to nutrition labeling include menu variations, use of daily specials, limited page space, and loss of flexibility. There are also *personnel-related* obstacles, for instance, difficulty in training employees and a shortage of time.

Today there are information options. Nutrition expertise and labeling assistance could be provided to companies by dietitians as many restaurants already provide.

The National Center for Nutrition and Dietetics of the Academy of Nutrition and Dietetics has a *hotline number* (800-366-1655) that offers messages and personally answers consumer questions about food labeling (The National Center for Nutrition and Dietetics of the Academy of Nutrition and Dietetics, Chicago, IL).

Supermarket Savvy Information and Resource Service® (order@supermarketsavvy.com) is an example of a *service* that provides new product information. A newsletter is included as one part of its service. It is written for the health professional and designed to provide information about new products (especially the healthier ones) so that the health professional can answer his/her clients' questions about new foods and guide his/her clients to better food choices in the supermarket and health/natural foods store (McDonald. Information and resource service).

Conclusion

Concluding this issue is difficult to do! Perhaps this chapter cannot close! However, suffice it to say that government regulation, industrial compliance, and consumer education are all means of ensuring a safe food supply to consumers. Food safety is still dependent upon the individual! We need to then act on what we know.

The FDA is a public health agency that regulates food, cosmetics, medicines, medical devices, and radiation-emitting products, such as microwave ovens. The Food, Drug, and Cosmetic Act of 1938 and its amendments were introduced to regulate the processing of many products subject to interstate commerce or import. Food inspections are the responsibility of the FDA, with meat product inspection regulated by the USDA. Food packaging and labeling is regulated by the FDA and USDA for their respective products. The USDA administers the FSIS and numerous food programs.

The NLEA is an attempt to protect the consumer against fraud and misinformation. Labeling terms, "Nutrition Facts," and health claims are regulated by the FDA. The purpose of the NLEA is to assist consumers in selecting foods that can lead to a healthier diet, eliminate confusion, and encourage production innovation by the food industry. With greater knowledge of nutrients, nutrient interactions, and promotion of health, greater health benefits may be provided with the formulation of new food products.

Additionally, general labeling, nutrition labeling, health claims, food allergen labeling, and labeling for foodservice were discussed in this chapter.

Of course, in addition to the government's regulation of the food supply, *industry plants*

and *consumers* must be vigilant and play their part in assuring a safe food supply!

Extra: Food Security and an Emergency Plan

In the aftermath of the September 11, 2001 terrorist attacks on the United States, the FDA has urged industry to take necessary steps to ensure better food security. For example, farms, processors, grocery stores and restaurants can better protect the nation's food supply by requiring criminal background checks of all workers, and closely checking all food and water sources. New guidelines were issued by the FDA, and addressed by the ADA. (FDA, ADA)

Bioterrorism Preparedness and Response Act of 2002 ("The Bioterrorism Act")

The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002. (http://www.fda.gov/oc/bioterrorism/bioact.html)

Notes

CULINARY ALERT!

Glossary

Daily Value (%DV) Two sets of values used on nutrition labels, including Reference Daily Intakes (RDI), based on former US RDAs and Daily Reference Values (DRV) of nutrients that do not have an RDA but have a significant health impact.

Generally Recognized As Safe (GRAS) Substances (food ingredients) generally recognized as safe for their intended use.

Grading Service Conducted as a voluntary service of the USDA, paid for by packers.

Health Claims Describe an association between a nutrient or food substance and disease or health-related condition.

Inspection Service Of the USDA or state Department of Agriculture inspects and stamps inspected meat with a circle containing the abbreviations for "inspected and passed."

Nutrition Labeling For the purpose of assisting consumers in selecting foods that can lead to a healthier diet, to eliminate consumer confusion, and to encourage production innovation by the food industry. Labeling expresses nutrients in terms of Reference Daily Intakes (RDI) and Daily Reference Values (DRV), both comprising the Daily Values.

Standard of Fill of Container FDA standard that the volume of packaged food offered for sale does not interfere with the weight of the product as stated on the label.

Standard of Identity FDA list of required and optional ingredients that are included in manufacture.

Standards of Minimum Quality FDA minimum quality standards for specific food characteristics–color, etc.

Wholesome The carcass and viscera of the animal were examined, and no signs of illness were indicated, and conditions met sanitary standards.

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USDA ChooseMyPlate.gov