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chapter

United States Government Regulations and International Standards Related to Food Analysis

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2.1 INTRODUCTION

Knowledge of government regulations relevant to the chemical analysis of foods is extremely important to persons working in the food industry. Federal laws and regulations reinforce the efforts of the food industry to provide wholesome foods, to inform consumers about the nutritional composition of foods, and to eliminate economic frauds. In some cases, they dictate what ingredients a food must contain, what must be tested, and the procedures used to analyze foods for safety factors and quality attributes. This chapter describes the US federal regulations related to the composition of foods. The reader is referred to references (1–4) for comprehensive coverage of US food laws and regulations. Many of the regulations referred to in this chapter are published in the various titles of the ***Code of Federal Regulations*** (CFR) (5). This chapter also includes information about food standards and safety practices established by international organizations. Internet addresses are given at the end of this chapter for many of the government agencies, organizations, and documents discussed.

2.2 US FEDERAL REGULATIONS AFFECTING FOOD COMPOSITION

2.2.1 US Food and Drug Administration

The **Food and Drug Administration** (FDA) is a government agency within the **Department of Health and Human Services** (DHHS). The FDA is responsible for regulating, among other things, the safety of foods, cosmetics, drugs, medical devices, biologicals, and radiological products. It acts under laws passed by the US Congress to monitor the affected industries and ensure the consumer of the safety of such products. A comprehensive collection of federal laws, guidelines, and regulations relevant to foods and drugs has been published by the Food and Drug Law Institute (1,2).

2.2.1.1 Legislative History

2.2.1.1.1 Federal Food, Drug, and Cosmetic Act of 1938 The **Federal Food, Drug, and Cosmetic** (FD&C) **Act of 1938** was intended to assure consumers that foods are safe and wholesome, produced under sanitary conditions, and packaged and labeled truthfully. This law, which broadened the scope of the Food and Drug Act of 1906, further defined and set regulations on adulterated and misbranded foods. The FDA was given power to seize illegal products and to imprison and fine violators. An important part of the 1938 Act relevant to food analysis is the section that authorizes food definitions and standards of identity, as further described below.

2.2.1.1.2 Amendments and Additions to the 1938 FD&C Act The 1938 FD&C Act has been amended several times to increase its power. The Miller Pesticide Amendment was added in 1954 to specify the acceptable amount of pesticide residues on fresh fruits, vegetables, and other raw agricultural products when they enter the marketplace. This Amendment, then under the authority of the FDA, is now administered by the **Environmental Protection Agency** (EPA).

The **Food Additives Amendment** enacted in 1958 was designed to protect the health of consumers by requiring a food additive to be proven safe before addition to a food and to permit the food industry to use food additives that are safe at the intended level of use. The highly controversial **Delaney Clause**, attached as a rider to this amendment, prohibits the FDA from setting any tolerance level as a food additive for substances known to be carcinogenic.

The **Color Additives Amendment** of 1960 defines color additives, sets rules for both certified and uncertified colors, provides for the approval of color additives that must be certified or are exempt from certification, and empowers the FDA to list color additives for specific uses and set quantity limitations. Similar to the Food Additives Amendment, the Color Additives Amendment contains a Delaney Clause.

The **Nutrition Labeling and Education Act** of 1990 (NLEA), described further in Chap. 3, made nutrition labeling mandatory on most food products under FDA jurisdiction and established definitions for health and nutrient claims. The NLEA emphasized the relationship between diet and health and provided consumers a means to choose foods based on complete and truthful label information.

The **Dietary Supplement Health and Education Act** (1994) (DSHEA) changed the definition and regulations for dietary supplements from those in the FD&C Act and in acts relevant to dietary supplements passed prior to 1994. The DSHEA defined supplements as "dietary ingredients" (defined in specific but broad terms), set criteria to regulate claims and labeling, and established government agencies to handle regulation. Classified now as "dietary ingredients" rather than by the previously used term "food additives," dietary supplements are not subject to the Delaney Clause of the FD&C Act. Regulations for dietary supplements permit claims not allowed for traditional foods. Control and regulation of dietary supplements have been separated from those for traditional foods.

The **Food Quality Protection Act** (1996) amended both the FD&C Act and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as further described in Sect. 2.2.5.1.

2.2.1.1.3 Other FDA Regulations The FDA has developed many administrative rules, guidelines, and action levels, in addition to the regulations described above, to implement the FD&C Act of 1938. Most of them are published in Title 21 of the CFR. They include the **Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food** (GMP) regulations (21 CFR 110), regulations regarding **food labeling** (21 CFR 101), **recall policy** (21 CFR 7.40), and **nutritional quality guidelines** (21 CFR 104). The food labeling regulations include nutritional labeling requirements and guidelines and specific requirements for nutrient content, health claims, and descriptive claims (discussed in Chap. 3).

There has been increased responsibility placed on the food industry and different regulatory agencies to better ensure the safe handling of foods eaten by consumers. Both FDA and USDA have placed considerable emphasis on GMP regulations and on **Hazard Analysis Critical Control Point** (HACCP) systems in an effort to improve food safety and quality programs. HACCP is an important component of an interagency initiative to reduce the incidence of food-borne illness, and it includes the FDA, USDA, EPA, **Centers for Disease Control** (CDC), and state/local regulatory agencies (6).

The **GMP regulations**, legally based on the FD&C Act, but not established as a proposed rule until 1969, are designed to prevent adulterated food in the marketplace (7, 8). The GMP regulations define requirements for acceptable sanitary operation in food plants and include the following relevant to food processing:

1. General provisions that define and interpret the detailed regulations
2. Requirements and expectations for maintaining grounds, buildings, and facilities
3. Requirements and expectations for design, construction, and maintenance of equipment
4. Requirements for production and process controls
5. Defect action levels (DALs) for natural and unavoidable defects

In addition to general GMPs (21 CFR 110), specific GMPs exist for thermally processed low-acid canned foods (21 CFR 113), acidified foods (21 CFR 114), and bottled drinking water (21 CFR 129).

HACCP is an internationally recognized systematic approach that is used to prevent and/or control microbial, chemical, and physical hazards within the food supply. The "farm to the fork" approach was originally designed to be used by the food processing industry to produce zero defect (no hazard) food for astronauts to consume on space flights (9). Within the past few decades, the overall approach has expanded to be used as the most effective method of hazard risk reduction and control in all areas of the food flow, including production, agriculture, distribution, manufacturing, and retail food establishments. Both FDA and USDA have adopted the HACCP concept as part of the overall inspection programs. The HACCP approach begins with a description of the food being produced. A flow diagram of the process is developed to further describe the process used. For each step in the process flow, the HACCP program approach is based on seven principles identified below:

1. Determine potential microbial, chemical, and physical hazards in each step of the process flow.
2. Identify critical control points in the process.
3. Establish control limits for each critical control point.
4. Establish procedures to monitor control points.
5. Establish corrective actions when limits of control point are exceeded.
6. Establish appropriate system of record keeping.
7. Establish program to verify and validate efficacy of program.

While HACCP-based principles are used for many different foods and many different food processes, from a regulatory standpoint, HACCP is only required for the meat and poultry industry (9 CFR Part 417), the seafood industry (21 CFR Part 123), and juice industry (21 CFR Part 120).

2.2.1.2 Food Definitions and Standards

The food definitions and standards established by the FDA are published in 21 CFR 100-169 and include standards of identity, quality, and fill. The **standards of identity**, which have been set for a wide variety of food products, are most relevant to the chemical analysis of foods because they specifically establish which ingredients a food must contain. They limit the amount of water permitted in certain products. The minimum levels for expensive ingredients are often set, and maximum levels for inexpensive ingredients are sometimes set. The kind and amount of certain vitamins and minerals that must be present in foods labeled "enriched" are specified. The standards of identity for some foods include a list of optional ingredients. The standard of identity for sour cream (21 CFR 131.160) is given in Fig. 2-1. Table 2-1 summarizes

§131.160 Sour cream.

(a) **Description.** Sour cream results from the souring, by lactic acid producing bacteria, of pasteurized cream. Sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) **Optional ingredients.**

(1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.
(2) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.
(3) Rennet.
(4) Safe and suitable nutritive sweeteners.
(5) Salt.
(6) Flavoring ingredients, with or without safe and suitable coloring, as follows:
(i) Fruit and fruit juice (including concentrated fruit and fruit juice).
(ii) Safe and suitable natural and artificial food flavoring.

(c) **Methods of analysis.** Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_location.html

(1) Milkfat content - "Fat-Official Final Action," section 16.172.
(2) Titratable acidity - "Acidity-Official Final Action," section 16.023.

(d) **Nomenclature.** The name of the food is "Sour cream" or alternatively "Cultured sour cream". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in ğ101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) **Label declaration.** Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. [42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

2-1 figure Standard of identity for sour cream. [From 21 CFR 131.160 (2009).]

the standards of identity relevant to food analysis for a number of other foods. Note that the standard of identity often includes the recommended analytical method for determining chemical composition.

Although standards of quality and fill are less related to the chemical analysis of foods than are standards of identity, they are important for economic and quality control considerations. **Standards of quality**, established by the FDA for some canned fruits and vegetables, set minimum standards and specifications for factors such as color, tenderness, weight of units in the container, and freedom from defects. The **standards of fill** established for some canned fruits and vegetables, tomato products, and seafood state how full a container must be to avoid consumer deception.

2.2.1.3 Inspection and Enforcement

The FDA has the broadest regulatory authority over most foods (generally, all foods other than meat, poultry, eggs; water supplies; imported foods). However, the FDA shares responsibilities with other regulatory agencies for certain foods, as described in later sections of this chapter. The FDA has responsibility for enforcing the 1938 FD&C Act as amended, which prohibits adulteration and misbranding of food products. Relevant to food analysis and for FDA-regulated foods, the FDA inspects food processing facilities for compliance with GMP regulations and for any mandatory HACCP inspection programs. The FDA monitors appropriate foods for composition and characteristics relevant to the standards of identity, standards of quality, standards of fill, nutrition labeling, and other labeling regulations. It regulates color additives and the use of food additives for all foods.

The FDA, together with other federal agencies described in this chapter and with state and local governments, works to help ensure the quality and safety of food in the USA. Some specific examples of how FDA interacts with other agencies regarding the safety and analysis of foods follow. Working with the National Marine Fisheries Service to ensure seafood safety, the FDA sets and enforces allowable levels of contaminants and pathogenic microorganisms in seafood. The FDA has jurisdiction over some alcoholic beverages and cooking wines and handles questions

2-1 table **Selected Chemical Composition Requirements of Some Foods with Standards of Identity**

Section in 21 CFR[a]	Food Product	Requirement	AOAC Method[b] Number in 13th Edn.	AOAC Method[b] Number in 18th Edn.	AOAC Method[b] Name/Description
131.110	Milk	Milk solids nonfat $\geq 8\frac{1}{4}\%$	16.032	990.19	Total solids, by forced air oven after steam table
		Milkfat $\geq 3\frac{1}{4}\%$	16.059	905.02	Roese-Gottlieb
		Vitamin A (if added) $\geq 2,000$ IU[c]/qt[d]			
		Vitamin D (if added) – 400 IU[c]/qt[d]	43.195–43.208	936.14	Bioassay line test with rats
133.113	Cheddar cheese	Milkfat $\geq 50\%$ by wt. of solids	16.255 and calculation	933.05	Digest with HCl, Roese-Gottlieb
		Moisture $\leq 39\%$ by wt.	16.233	926.08	Vacuum oven
		Phosphatase level $\leq 3\,\mu$g phenol equivalent/0.25 g[e]	16.275–16.277	946.03–946.03C	Residual phosphatase
137.165	Enriched flour	Moisture $\leq 15\%$	14.002, 14.003	925.09, 925.09B	Vacuum oven
		Ascorbic acid ≤ 200 ppm (if added as dough conditioner)			
		Ash[f] $\leq 0.35 + (1/20$ of the percent of protein, calculated on dwb[g])	14.006	923.03	Dry ashing
		(Protein)	2.057	955.04C	Kjeldahl, for nitrate-free samples
		Thiamine, 2.9 mg/lb Riboflavin, 1.8 mg/lb Niacin, 24 mg/lb Iron, 20 mg/lb Calcium (if added), 960 mg/lb Folic acid 0.7 mg/lb			
146.185	Pineapple juice	Soluble solids $\geq 10.5^\circ$Brix[h]	31.009	932.14A	Hydrometer
		Total acidity ≤ 1.35 g/100 ml (as anhydrous citric acid)			Titration with NaOH[i]
		Brix/acid ratio ≥ 12			Calculated[j]
		Insoluble solids $\geq 5\%$ and $\leq 30\%$			Calculated from volume of sediment[k]
163.113	Cocoa	Cocoa fat $\leq 22\%$ and $\geq 10\%$		963.15	Petroleum ether extraction with Soxhlet unit
164.150	Peanut butter	Fat $\leq 55\%$	27.006(a)	948.22	Ether extraction with Soxhlet unit

[a] *CFR*, Code of Federal Regulations (2009).
[b] *Official Methods of Analysis* of AOAC International.
[c] IU, International units.
[d] Within limits of good manufacturing practice.
[e] If pasteurized dairy ingredients are used.
[f] Excluding ash resulting from any added iron or salts of iron or calcium or wheat germ.
[g] dwb, moisture-free or dry weight basis.
[h] Exclusive of added sugars, without added water. As determined by refractometer at 20°C uncorrected for acidity and read as °Brix on International Sucrose Scales. Exception stated for juice from concentrate.
[i] Detailed titration method given in 21 CFR, 145.180 (b)(2)(ix).
[j] Calculated from °Brix and total acidity values, as described in 21 CFR 146.185 (b)(2)(ii).
[k] Detailed method given in 21 CFR 146.185 (b)(2)(iv).

of deleterious substances in alcoholic beverages. Regulations on tolerance levels of pesticide residues in foods and agricultural commodities set by the EPA are enforced by the FDA. Imported food products regulated by the FDA are subject to inspection upon entry through US Customs, and products must comply with US laws and regulations. The FDA works with individual states and the United States Department of Agriculture (USDA) to ensure the safety and wholesomeness of dairy products. Also, the FDA has regulatory power over shellfish sanitation for products shipped interstate.

When violations of the FD&C Act are discovered by the FDA through periodic inspections of facilities and products and through analysis of samples, the FDA can use warning letters, seizures, injunctions, or recalls, depending on the circumstances. The FDA cannot file criminal charges, but rather recommends to the Justice Department that court action be taken that might result in fines or imprisonment of offenders. Details of these enforcement activities of the FDA are given in references (1–4).

2.2.2 US Department of Agriculture

The USDA administers several federal statutes relevant to food standards, composition, and analysis. These include standards of identity for meat products, grade standards, and inspection programs. Some programs for fresh and processed food commodities are mandatory and others are voluntary.

2.2.2.1 Standards of Identity for Meat Products

Standards of identity have been established by the **Food Safety Inspection Service** (FSIS) of the USDA for many meat products (9 CFR 319). These commonly specify percentages of meat, fat, and water. Analyses are to be conducted using an AOAC method, if available.

2.2.2.2 Grade Standards

Grade standards developed for many foods by the USDA classify products in a range from substandard to excellent in quality. While most grade standards are not mandatory requirements (but they are mandatory for certain grains), they are widely used, voluntarily, by food processors and distributors as an aid in wholesale trading, because the quality of a product affects its price. Such grade standards often are used as quality control tools. Consumers are familiar generally with grade standards for beef, butter, and eggs, but buyers for the retail market utilize grade standards for a wide variety of foods. Major users of standards include institutions such as schools, hospitals, restaurants, prisons, and the Department of Defense (see also Sect. 2.5).

The USDA has issued grade standards for more than 300 food products under authority of the Agricultural Marketing Act of 1946 and related statutes. Standards for grades are not required to be stated on the label, but if they are stated, the product must comply with the specifications of the declared grade. Official USDA grading services are provided, for a fee, to pickers, processors, distributors, and others who seek official certification of the grades of their products.

While complete information regarding the standards was published previously in the CFR, currently only some standards are published in the CFR because they are USDA Agricultural Marketing Service (AMS) Administrative Orders. All grade standards are available as pamphlets from USDA and also are accessible on the Internet.

Grade standards, issued by the AMS of the USDA for agricultural products and by the Department of Commerce for fishery products, must not be confused with standards of quality set by the FDA or standards of identity set by the FDA or FSIS of the USDA, as discussed previously. Grade standards exist for many types of meats, poultry, dairy products, fruits, vegetables, and grains, along with eggs, domestic rabbits, certain preserves, dry beans, rice, and peas. Additional information about grade standards for dairy products is given in Sect. 2.3, but examples of grade standards for several other types of foods follow here.

Standards for grades of processed fruits and vegetables often include factors such as color, texture or consistency, defects, size and shape, tenderness, maturity, flavor, and a variety of chemical characteristics. Sampling procedures and methods of analysis are commonly given. As an example, the quality and analytical factors that determine the grade standards of frozen concentrated orange juice (10) are given in Table 2-2.

2-2 table **USDA Standards for Grades Determinants of Frozen Concentrated Orange Juice**

Quality	*Analytical*
Appearance	Concentrate
Reconstitution	Brix
Color	Brix/acid ratio
Defects	Reconstituted Juice
Flavor	Brix
	Soluble orange solids
	Recoverable oil

Grades for various grains (e.g., wheat, corn, soybeans, oats) are determined by factors such as test weight per bushel and percentages of heat-damaged kernels, broken kernels, and foreign material. Also, a grade limit is set commonly for moisture content. Grade standards for rice, beans, peas, and lentils are determined commonly by factors such as defects, presence of foreign material, and insect infestation, and sometimes moisture content is specified.

2.2.2.3 Inspection Programs

The USDA administers some programs on inspection and certification that are mandatory, and some inspection programs are voluntary. Comprehensive inspection manuals specific to various types of foods have been developed to assist inspectors and industry personnel in interpreting and utilizing the regulations. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, the FSIS of the USDA inspects all meat, poultry, and egg products in interstate commerce (9 CFR 200-End). This includes a review of foreign inspection systems and packing plants that export meat and poultry to the USA. Imported products are reinspected at ports of entry. HACCP is a major component of FSIS rules for all slaughter and processing plants, to improve safety of meat and poultry. A program within the **Grain Inspection, Packers and Stockyard Administration** (GIPSA) of the USDA administers the mandatory requirements of the US Grain Standards Act (7 CFR 800). Regulations to enforce this act provide for a national inspection system for grain and mandatory official grade standards of numerous types of grain. Another program of the USDA standardizes, grades, and inspects fruits and vegetables under various voluntary programs. The inspection programs rely heavily on the HACCP concept.

2.2.3 US Department of Commerce

2.2.3.1 Seafood Inspection Service

The **National Oceanic and Atmospheric Administration's** (NOAA) **National Marine Fisheries Service** (NMFS), a division of the **United States Department of Commerce** (USDC), provides a seafood inspection service. The USDC Seafood Inspection Program ensures the safety and quality of seafoods consumed in the USA and certified for export through **voluntary grading, standardization, and inspection programs**, as described in 50 CFR 260. The inspection programs rely heavily on the HACCP concept. USDC Handbook 25 is a comprehensive manual on these subjects entitled *Fishery Products Inspection Manual* (11). The US Standards for Grades of Fishery Products (50 CFR 261) are intended to help the fishing industry maintain and improve quality and to thereby increase consumer confidence in seafoods. Standards are based on attributes such as color, size, texture, flavor, odor, workmanship defects, and consistency.

2.2.3.2 Interaction with FDA and EPA

The FDA and the EPA work with the NMFS for the assurance of seafood safety. The FDA, under the FD&C Act, is responsible for ensuring that seafood shipped or received in interstate commerce is safe, wholesome, and not misbranded or deceptively packaged. The FDA has primary authority in setting and enforcing allowable levels of contaminants and pathogenic microorganisms in seafood. The EPA assists the FDA in identifying the range of chemical contaminants that pose a human health risk and are most likely to accumulate in seafood. A tolerance of 2.0 parts per million (ppm) for total polychlorinated biphenyls (PCBs) (21 CFR 109.30) is the only formal tolerance specified by the FDA to mitigate human health impacts in seafood. However, the EPA has established tolerances for certain pesticide residues, and the FDA has established guidance levels for the toxic elements arsenic, cadmium, chromium, lead, nickel, and methyl mercury (12).

2.2.4 US Bureau of Alcohol, Tobacco, Firearms and Explosives

2.2.4.1 Regulatory Responsibility for Alcoholic Beverages

Beer, wines, liquors, and other alcoholic beverages are termed "food" according to the FD&C Act of 1938. However, regulatory control over their quality, standards, manufacture, and other related aspects is specified by the **Federal Alcohol Administration Act**, which is enforced by the **Alcohol and Tobacco Tax and Trade Bureau** (TTB) of the **US Department of Treasury**. Issues regarding the composition and labeling of most alcoholic beverages are handled by the Bureau. However, the FDA has jurisdiction over certain other alcoholic beverages and cooking wines. The FDA also deals with questions of sanitation, filth, and the presence of deleterious substances in alcoholic beverages.

2.2.4.2 Standards and Composition of Beer, Wine, and Distilled Beverage Spirits

Information related to **definitions, standards of identity**, and certain **labeling requirements** for beer, wine, and distilled beverage spirits is given in 27 CFR 1-30. Standards of identity for these types of beverages

stipulate the need for analyses such as percent alcohol by volume, total solids content, volatile acidity, and calculated acidity. For example, the fruit juice used for the production of wine is often specified by its °Brix and total solids content. The maximum volatile acidity (calculated as acetic acid and exclusive of sulfur dioxide) for grape wine must not be more than 0.14 g/100 ml (20°C) for natural red wine and 0.12 g/100 ml for other grape wines (27 CFR 4.21). The percent alcohol by volume is often used as a criterion for class or type designation of alcoholic beverages. For example, dessert wine is grape wine with an alcoholic content in excess of 14% but not in excess of 24% by volume, while table wines have an alcoholic content not in excess of 14% alcohol by volume (27 CFR 4.21). No product with less than 0.5% alcohol by volume is permitted to be labeled "beer," "lager beer," "lager," "ale," "porter," "stout," or any other class or type designation normally used for malt beverages with higher alcoholic content (27 CFR 7.24).

2.2.5 US Environmental Protection Agency

The EPA was established as an independent agency in 1970 through a reorganization plan to consolidate certain federal government environmental activities. The EPA regulatory activities most relevant to this book are control of pesticide residues in foods, drinking water safety, and the composition of effluent from food processing plants.

2.2.5.1 Pesticide Registration and Tolerance Levels

Pesticides are chemicals intended to protect our food supply by controlling harmful insects, diseases, rodents, weeds, bacteria, and other pests. However, most pesticide chemicals can have harmful effects on people, animals, and the environment if they are improperly used. The three federal laws relevant to protection of food from pesticide residues are certain provisions of the Federal FD&C Act, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and the **Food Quality Protection Act** of 1996. FIFRA, supplemented by the FD&C Act, authorizes a comprehensive program to regulate the manufacturing, distribution, and use of pesticides, along with a research effort to determine the effects of pesticides.

The Food Quality Protection Act amends both the FD&C Act and FIFRA, to take pesticides out of the section of the FD&C Act that includes the Delaney Clause. This was done by changing the definition of a "food additive" to exclude pesticides. This redefinition leaves the Delaney Clause greatly reduced in scope and less relevant.

The EPA registers approved pesticides and sets tolerances for pesticide residues (see also Chap. 18, Sect. 18.3). The EPA is authorized to establish an **allowable limit** or **tolerance** for any detectable pesticide residues that might remain in or on a harvested food or feed crop. The **tolerance level** is often many times less than the level expected to produce undesirable health effects in humans or animals. Tolerances are established based on factors that include registration data, consumption pattern, age groups, mode of action, chemistry of the compound, toxicological data, plant and animal physiology, efficacy data, and risk assessment. While the EPA establishes the tolerance levels, the FDA enforces the regulations by collecting and analyzing food samples, mostly agricultural commodities. Livestock and poultry samples are collected and analyzed by the USDA. Pesticide residue levels that exceed the established tolerances are considered in violation of the FD&C Act.

The Food Quality Protection Act of 1996 requires an explicit determination that tolerances are safe for children and have consideration of children's special sensitivity and exposure to pesticide chemicals. It includes an additional safety factor of up to tenfold, if necessary, to account for uncertainty in data relative to children. The 1996 law requires that all existing tolerances be reviewed within 10 years to make sure they meet the requirements of new health-based safety standards established by law.

Regulations regarding pesticide tolerances in foods are given in 40 CFR 180, which specifies general categories of products and specific commodities with tolerances or exemptions, and in some cases which part of the agricultural product is to be examined. Products covered include a wide variety of both plants (e.g., fruits, vegetables, grains, legumes, nuts) and animals (e.g., poultry, cattle, hogs, goats, sheep, horses, eggs, milk). Unless otherwise noted, the specific tolerances established for the pesticide chemical apply to residues resulting from their application prior to harvest or slaughter. Tolerances are expressed in terms of parts by weight of the pesticide chemical per one million parts by weight of the product (i.e., ppm). Tolerance levels for selected pesticides and insecticides permitted in foods as food additives are given in Table 2-3.

The analytical methods to be used for determining whether pesticide residues are in compliance with the tolerance established are identified among the methods contained or referenced in the *Pesticide Analytical Manual* (13) maintained by and available from the FDA. The methods must be sensitive and reliable at and above the tolerance level. Pesticides are generally detected and quantitated by gas chromatographic or high-performance liquid chromatographic methods (see Chaps. 18, 28, and 29).

2-3 table **Tolerance for Selected Insecticides (I), Fungicides (F), and Herbicides (H) Classified as Food Additives Permitted in Foods for Human Consumption**

Section	*Food Additive*	*Chemical Classification*	*Food*	*Tolerance*[a]
180.294	Benomyl (F)	Carbamate	Apples	7
			Cattle, meat	0.1
			Milk	0.1
			Grapes	10
			Raisins	50
			Strawberry	5
			Tomato products, conc.	50
180.342	Chloropyrifos[b](I)	Organophosphate	Apples	0.01
			Cattle, meat	0.05
			Corn oil	0.25
			Strawberry	0.2
180.435	Deltamethrin (I)	Pyrethroid	Cattle, meat	0.02
			Tomatoes	0.02
			Tomato products, conc.	1.0
180.292	Picloram (H)	Chloropyridine–carboxylic acid	Cattle, meat	0.02
			Milk	0.05
			Corn oil	2.5
			Wheat, grain	0.5

Adapted from 40 CFR 180 (2009).
[a]Parts per million.
[b]Also known as Dursban™ and Lorsban™.

2.2.5.2 Drinking Water Standards and Contaminants

The EPA administers the **Safe Drinking Water Act** of 1974, which is to provide for the safety of drinking water supplies in the USA and to enforce national drinking water standards. The EPA has identified potential contaminants of concern and established their maximum acceptable levels in drinking water. The EPA has primary responsibility to establish the standards, while the states enforce them and otherwise supervise public water supply systems and sources of drinking water. **Primary and secondary drinking water regulations** (40 CFR 141 and 143, respectively) have been established. Recently, concerns have been expressed regarding the special standardization of water used in the manufacturing of foods and beverages.

Maximum contaminant levels (MCL) for primary drinking water are set for certain **inorganic** and **organic chemicals**, **turbidity**, **certain types of radioactivity**, and **microorganisms**. Sampling procedures and analytical methods for the analysis of chemical contaminants are specified, with common reference to *Standard Methods for the Examination of Water and Wastewater* (14) published by the American Public Health Association; *Methods of Chemical Analysis of Water and Wastes* (15), published by the EPA; and *Annual Book of ASTM Standards* (16), published by the American Society for Testing Materials (ASTM). Methods commonly specified for the analysis of inorganic contaminants in water include atomic absorption (direct aspiration or furnace technique), inductively coupled plasma (see Chap. 24), ion chromatography (see Chap. 28), and ion selective electrode (see Chap. 12).

2.2.5.3 Effluent Composition from Food Processing Plants

In administering the **Federal Water Pollution and Control Act**, the EPA has developed effluent guidelines and standards that cover various types of food processing plants. Regulations prescribe effluent limitation guidelines for existing sources, standards of performance for new sources, and pretreatment standards for new and existing sources. Point sources of discharge of pollution are required to comply with these regulations, where applicable. Regulations are prescribed for specific foods under the appropriate point source category: dairy products processing (40 CFR 405), grain mills (40 CFR 406), canned and preserved fruits and vegetables processing (40 CFR 407), canned and preserved seafood processing (40 CFR 408), sugar processing (40 CFR 409), and meat and poultry products (40 CFR 432). **Effluent characteristics** commonly prescribed for food processing plants are **biochemical oxygen demand** (BOD) (see Chap. 20), **total soluble solids** (TSS) (see Chap. 6), and **pH** (see Chap. 13), as

2-4 table **Effluent Limitations for Plants Processing Natural and Processed Cheese**

	Effluent Characteristics					
	Metric Units[a]			*English Units*[b]		
Effluent Limitations	*BOD 5*[c]	*TSS*[d]	*pH*	*BOD 5*	*TSS*	*pH*
Processing more than 100,000 lb/day of milk equivalent						
Maximum for any 1 day	0.716	1.088	([e])	0.073	0.109	([e])
Average of daily values for 30 consecutive days shall not exceed	0.290	0.435	([e])	0.029	0.044	([e])
Processing less than 100,000 lb/day of milk equivalent						
Maximum for any 1 day	0.976	1.462	([e])	0.098	0.146	([e])
Average of daily values for 30 consecutive days shall not exceed	0.488	0.731	([e])	0.049	0.073	([e])

Adapted from 40 CFR 405.62 (2009).
[a]Kilograms per 1000 kg of BOD 5 input.
[b]Pounds per 100 lbs of BOD 5 input.
[c]BOD 5 refers to biochemical oxygen demand measurement after 5 days of incubation.
[d]TSS refers to total soluble solids.
[e]Within the range 6.0–9.0.

shown in Table 2-4 for effluent from a plant that makes natural and processed cheese. The test procedures for measurement of effluent characteristics are prescribed in 40 CFR 136.

2.2.6 US Customs Service

Over 100 countries export food, beverages, and related edible products to the USA. The **United States Customs Service** (USCS) assumes the central role in ensuring that imported products are taxed properly, safe for human consumption, and not economically deceptive. The USCS receives assistance from the FDA and USDA as it assumes these responsibilities. The major regulations promulgated by the USCS are given in Title 19 of the CFR.

2.2.6.1 Harmonized Tariff Schedule of the US

All goods imported into the United States are subject to duty or duty-free entry according to their classification under applicable items in the **Harmonized Tariff Schedule of the United States** (TSUSA). The US tariff system has official tariff schedules for over 400 edible items exported into the USA (17). The TSUSA specifies the food product in detail and gives the general rate of duty applicable to that product coming from most countries and any special higher or lower rates of duty for certain other countries.

2.2.6.2 Food Composition and the TSUSA

The **rate of duty** for certain food products is determined by their chemical composition. For example, the rate of duty on some dairy products is determined in part by the fat content. The tariff for some syrups is determined by the fructose content, for some chocolate products by the sugar or butterfat content, for butter substitutes by the butterfat content, and for some wines by their alcohol content (percent by volume).

2.2.7 US Federal Trade Commission

The **Federal Trade Commission** (FTC) is the most influential of the federal agencies that have authority over various aspects of advertising and sales promotion practices for foods in the USA. The major role of the FTC is to keep business and trade competition free and fair.

2.2.7.1 Enforcement Authority

The **Federal Trade Commission Act** of 1914 authorizes the FTC to protect both the consumer and the business person from anticompetitive behavior and unfair or deceptive business and trade practices. The FTC periodically issues industry guides and trade regulations and rules that tell businesses what they can and cannot do. These issuances are supplemented with advisory opinions given to corporations and individuals upon request. The FTC not only has guidance and preventive functions but is also authorized to issue complaints or shutdown orders and sue for civil penalties for violation of trade regulation rules. The **Bureau of Consumer Protection** is one of the FTC bureaus that enforce and develop trade regulation rules.

2.2.7.2 Food Labels, Food Composition, and Deceptive Advertising

While the **Fair Packaging and Labeling Act** of 1966 is administered by the FTC, that agency does not have specific authority over the packaging and labeling of foods. The FTC and FDA have agreed upon responsibilities: The FTC has primary authority over advertising of foods and the FDA has primary authority over labeling of foods.

Grading, standards of identity, and labeling of foods regulated by several federal agencies as described previously have eliminated many potential problems in the advertising of foods. Such federal regulations and voluntary programs have reduced the scope of advertising and other forms of product differentiation. Misleading, deceptive advertising is less likely to be an issue and is more easily controlled. For example, foods such as ice cream, mayonnaise, and peanut butter have standards of identity that set minimum ingredient standards. If these standards are not met, the food must be given a different generic designation (e.g., salad dressing instead of mayonnaise) or be labeled "imitation." Grading, standards, and labeling of food aid consumers in making price–quality comparisons. Once again, analyses of chemical composition play an important role in developing and setting these grades, standards, and labels. In many cases in which the FTC intervenes, data from a chemical analysis become central evidence for all parties involved.

2.3 REGULATIONS AND RECOMMENDATIONS FOR MILK

The safety and quality of milk and dairy products in the USA are the responsibility of both federal (FDA and USDA) and state agencies. The FDA has regulatory authority over the dairy industry interstate commerce, while the USDA involvement with the dairy industry is voluntary and service oriented. Each state has its own regulatory office for the dairy industry within that state. The various regulations for milk involve several types of chemical analyses.

2.3.1 FDA Responsibilities

The FDA has responsibility under the FD&C Act, the Public Health Service Act, and the Import Milk Act to assure consumers that the US milk supply and imported dairy products are safe, wholesome, and not economically deceptive. Processors of both Grade A and Grade B milk are required under FDA regulations to take remedial action when conditions exist that could jeopardize the safety and wholesomeness of milk and dairy products being handled. As described in Sect. 2.2.1.2, the FDA also promulgates standards of identity and labeling, quality, and fill-of-container requirements for milk and dairy products moving in interstate commerce.

For **Grade A milk and dairy products**, each state shares with the FDA the responsibility of ensuring safety, wholesomeness, and economic integrity. This is done through a **Memorandum of Understanding with the National Conference on Interstate Milk Shipments**, which comprises all 50 states. In cooperation with the states and the dairy industry, the FDA has also developed for state adoption model regulations regarding sanitation and quality aspects of producing and handling Grade A milk. These regulations are contained in the ***Grade A Pasteurized Milk Ordinance*** (PMO) (18), which all states have adopted as minimum requirements.

The standards for Grade A pasteurized milk and milk products and bulk-shipped heat-treated milk products under the PMO are given in Table 2-5. The PMO specifies that "all sampling procedures, including the use of approved in-line samples, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis* of the *AOAC INTERNATIONAL (OMA)*" (18–20).

The FDA monitors state programs for compliance with the PMO and trains state inspectors. To facilitate movement of Grade A milk in interstate commerce,

2-5 table **Pasteurized Milk Ordinance Standards for Grade A Pasteurized Milk and Milk Products and Bulk-Shipped Heat-Treated Milk Products**

Criteria	*Requirement*
Temperature	Cooled to 7°C (45°F) or less and maintained thereat
Bacterial limits[a]	20,000 per ml
Coliform[b]	Not to exceed 10 per ml. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml
Phosphatase[b]	Less than 350 milliunits/L for fluid products and other milk products by the Fluorometer or Charm ALP or equivalent
Drugs[c]	No positive results on drug residue detection methods

Adapted from (18).
[a]Not applicable to acidified or cultured products.
[b]Not applicable to bulk-shipped heat-treated milk products.
[c]Reference to specific laboratory techniques.

a federal-state certification program exists: the **Interstate Milk Shippers** (IMS) **Program**. This program is maintained by the **National Conference on Interstate Milk Shipments**, which is a voluntary organization that includes representatives from each state, the FDA, the USDA, and the dairy industry. In this program, the producers of Grade A pasteurized milk are required to pass inspections and be rated by cooperating state agencies, based on PMO sanitary standards, requirements, and procedures. The ratings appear in the *IMS List* (21), which is published by the FDA, and made available to state authorities and milk buyers to ensure the safety of milk shipped from other states.

2.3.2 USDA Responsibilities

Under authority of the Agricultural Marketing Act of 1946, the **Dairy Quality Program** of the USDA offers **voluntary grading services** for manufactured or processed dairy products (7 CFR 58). If USDA inspection of a dairy manufacturing plant shows that good sanitation practices are being followed to meet the requirements in the *General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service* (22), the plant qualifies for the USDA services of grading, sampling, testing, and certification of its products. A product such as nonfat dry milk is graded based on flavor, physical appearance, and various laboratory analyses (Table 2-6).

As with the USDA voluntary grading programs for other foods described in Sect. 2.2.2.2, the USDA has no regulatory authority regarding dairy plant inspections and cannot require changes in plant operations. The USDA, under an arrangement with the FDA, assists states in establishing safety and quality regulations for manufacturing-grade milk. Much as described previously for the FDA with Grade A milk, the USDA has developed model regulations for state adoption regarding the quality and sanitation aspects of producing and handling manufacturing-grade milk. These regulations are given in the *Milk for Manufacturing Purposes and Its Production and Processing, Recommended Requirements* (23). The states that have **Grade B milk** have essentially adopted these model regulations.

2-6 table **US Standards for Grades of Nonfat Dry Milk (Spray Process)**

Laboratory Tests[a]	*US Extra Grade*	*US Standard Grade*
Bacterial estimate, standard plate count per gram	10,000	75,000
Milkfat content (%)	1.25	1.50
Moisture content (%)	4.0	5.0
Scorched particle content (mg)	15.0	22.5
Solubility index (ml)	1.2	2.0
US High-heat	2.0	2.5
Titratable acidity (lactic acid) (%)	0.15	0.17

US Standards: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName_STELDEV3004466.
[a]All values are maximum allowed.

2.3.3 State Responsibilities

As described previously, individual states have enacted safety and quality regulations for Grade A and manufacturing-grade milk that are essentially identical to those in the PMO and the USDA Recommended Requirements, respectively. The department of health or agriculture in each state normally is responsible for enforcing these regulations. The states also establish their own standards of identity and labeling requirements for milk and dairy products, which are generally similar to the federal requirements.

2.4 REGULATIONS AND RECOMMENDATIONS FOR SHELLFISH

Shellfish include fresh or frozen oysters, clams, and mussels. They may transmit intestinal diseases such as typhoid fever or act as carriers of natural or chemical toxins. This makes it very important that they be obtained from unpolluted waters and handled and processed in a sanitary manner.

2.4.1 State and Federal Shellfish Sanitation Programs

The growing, handling, and processing of shellfish must comply not only with the general requirements of the FD&C Act but also with the requirements of state health agencies cooperating in the **National Shellfish Sanitation Program** (NSSP), a federal, state, industry voluntary cooperative program, administered by the FDA (24). The FDA has no regulatory power over shellfish sanitation unless the product is shipped interstate. However, the Public Health Service Act authorizes the FDA to make recommendations and to cooperate with state and local authorities to ensure the safety and wholesomeness of shellfish. Under special agreement, certain other countries are in the NSSP and are subject to the same sanitary controls as required in the USA. Through the NSSP, state health personnel continually inspect and survey bacteriological conditions in shellfish-growing areas. Any contaminated location is supervised or patrolled so that shellfish cannot be harvested from the area. State inspectors check harvesting boats and shucking plants

before issuing approval **certificates**, which serve as operating licenses. The certification number of the approved plant is placed on each shellfish package shipped.

2.4.2 Natural and Environmental Toxic Substances in Shellfish

A major concern is the ability of shellfish to concentrate radioactive material, insecticides, and other chemicals from their environment. Thus, one aspect of the NSSP is to ensure that shellfish-growing areas are free from sewage pollution and toxic industrial waste. **Pesticide residues** in shellfish are usually quantitated by gas chromatographic techniques, and **heavy metals** such as mercury are commonly quantitated by atomic absorption spectroscopy (e.g., AOAC Method 977.15). Another safety problem with regard to shellfish is the control of **natural toxins**, which is a separate issue from sanitation. The naturally occurring toxins are produced by planktonic organisms, and testing is conducted using a variety of assays. Control of this toxicity is achieved by a careful survey followed by prohibition of harvesting from locations inhabited by toxic shellfish.

2.5 VOLUNTARY FEDERAL RECOMMENDATIONS AFFECTING FOOD COMPOSITION

2.5.1 Food Specifications, Food Purchase, and Government Agencies

Large amounts of food products are purchased by federal agencies for use in domestic (e.g., school lunch) and foreign programs, prisons, veterans' hospitals, the armed forces, and other organizations. Specifications or descriptions developed for many food products are used by federal agencies in procurement of foods, to ensure the safety and quality of the product specified. Such specifications or descriptions often include information that requires assurance of chemical composition. These specifications include the following:

1. Federal Specifications
2. Commercial Item Descriptions (CIDs)
3. Purchase Product Description (PPD)
4. USDA Specifications
5. Commodity Specifications
6. Department of Defense Specifications

Various CIDs, PPDs, Federal Specifications, or USDA Specifications are used by the USDA to purchase meat products for programs such as school lunches. For example, the CID for canned tuna (25) specifies salt/sodium levels and the required method of analysis. The Institutional Meat Purchase Specification (a USDA specification) for frozen ground pork (26) and frozen ground beef products (27) states maximum allowable fat contents.

Commodity Specifications for various poultry and dairy products have been issued by the USDA. For example, the Commodity Specification for dried egg mix (28) specifies that the vegetable oil in the product must meet specifications for the following, as determined by American Oil Chemists' Society (AOCS) test methods: free fatty acid value, peroxide value, linolenic acid, moisture and volatile matter, iodine value, and Lovibond color values (see Chap. 14 for some of these tests). The Commodity Specifications issued by USDA for various dairy products also include compositional requirements. For example, the milk fat content, pH, and moisture and fat contents of pasteurized process American cheese (29) and mozzarella cheese (30) are specified.

The Defense Personnel Support Center of the Defense Logistics Agency, Department of Defense, utilizes a variety of specifications, standards, and notes in the purchase of food for the military. For example, they use CIDs for syrup (specifies Brix, ash content, and color) (31), instant tea (specifies moisture and sugar contents, and titratable acidity) (32), and peanut butter (specifies salt and aflatoxin contents) (33).

2.5.2 National Conference on Weights and Measures: State Food Packaging Regulations

Consumers assume that the weighing scale for a food product is accurate and that a package of flour, sugar, meat, or ice cream contains the amount claimed on the label. While this assumption is usually correct, city or county offices responsible for weights and measures need to police any unfair practices. Leadership in this area is provided by the **National Conference on Weights and Measures** (NCWM), which was established by the **National Institute of Standards and Technology** (NIST) (formerly the National Bureau of Standards) (part of the US Department of Commerce). The NCWM has no regulatory power, but it develops many technical, legal, and general recommendations in the field of weights and measures administration and technology. The NCWM is a membership organization comprising state and local weights and measures regulatory officers, other officials of federal, state, and local governments, and representatives of manufacturers, industry, business, and consumer organizations.

The NIST Handbook 133, *Checking the Net Contents of Packaged Goods* (34), gives model state **packaging and labeling regulations** that have been adopted by

a majority of states. The Handbook specifies that the average quantity of contents of packages must at least equal the labeling quantity, with the variation between the individual package net contents and the labeled quantity not too "unreasonably large." Variations are permitted within the bounds of GMPs and are due to gain or loss of moisture (within the bounds of good distribution practice). For certain products (e.g., flour, pasta, rice), this requires careful monitoring of moisture content and control of storage conditions by the manufacturer.

2.6 INTERNATIONAL STANDARDS AND POLICIES

With the need to compete in the worldwide market, employees of food companies must be aware that allowed food ingredients, names of food ingredients, required and allowed label information, and standards for foods and food ingredients differ between countries (35). For example, colorings and preservatives allowed in foods differ widely between countries, and nutritional labeling is not universally required. To develop foods for, and market foods in, a global economy, one must seek such information from international organizations and from organizations in specific regions and countries.

2.6.1 Codex Alimentarius

The **Codex Alimentarius Commission** (Codex Alimentarius is Latin for "code concerned with nourishment") was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), to develop international standards and safety practices for foods and agricultural products (35, 36). The standards, published in the *Codex Alimentarius*, are intended to protect consumers' health, ensure fair business practices in food trade, and facilitate international trade of foods (36).

The *Codex Alimentarius* is published in 13 volumes: one on general requirements (includes labeling, food additives, contaminants, irradiated foods, import/export inspection, and food hygiene), nine on standards and codes of practice compiled on a commodity basis, two on residues of pesticides and veterinary drugs in foods, and one on methods of analysis and sampling (Table 2-7). Codex has efforts to validate and harmonize methods of food safety analysis among countries and regions, to help maintain the smooth flow of international commerce, and ensure appropriate decisions on food exports and imports. Codex has adopted the HACCP concept as the preferred means to ensure the safety of perishable foods and is determining how HACCP will be implemented in *Codex Alimentarius*.

2-7 table **Content of the Codex Alimentarius (38)**

Volume	*Subject*
1A	General requirements
1B	General requirements (food hygiene)
2A	Pesticide residues in foods (general text)
2B	Pesticide residues in foods (maximum residue limits)
3	Residues in veterinary drugs in foods
4	Foods for special dietary uses
5A	Processed and quick-frozen fruits and vegetables
5B	Fresh fruits and vegetables
6	Fruit juices
7	Cereals, pulses (legumes) and derived products and vegetable proteins
8	Fats and oils and related products
9	Fish and fishery products
10	Meat and meat products, soups, and broths
11	Sugars, cocoa products and chocolate, and miscellaneous Products
12	Milk and milk products
13	Methods of analysis and sampling

Codex has strengthened its commitment to base food standards on strong science, rather than on social or cultural factors, economics, or trade policies. The setting of international standards on food quality by Codex has been a high priority in world trade to minimize "nontariff" trade barriers. International trade of food and raw agricultural products has increased due to reduced economic trade restrictions and tariffs imposed, but food standards set in the past by some countries created nontariff trade barriers. Food standards developed by Codex are intended to overcome the misuse of standards by a country, when the standards do more to protect products in a country from the competition of imports than to protect the health of consumers.

Decisions at the 1994 Uruguay Round of the **General Agreement on Tariffs and Trade** (GATT) strengthened the role of Codex as the principal standard-setting group internationally for the quality and safety of foods. The USA is among the 156 countries that are members of Codex. The USA recognizes treaty obligations related to Codex that have arisen from GATT. As a result, representatives of the FDA, USDA, and EPA (the three US federal agencies that participate in Codex) developed in 1995 a strategic plan for Codex that included greater US acceptance of Codex standards. In the USA, there is increased participation of nongovernmental organizations [e.g., Grocery Manufacturers Association (GMA)] in the Codex process, with many food companies working through these organizations.

2.6.2 ISO Standards

In addition to food standards and policies established by the Codex Alimentarius Commission, the **International Organization for Standardization** (ISO) has the 9000 series of standards on quality management and quality performance (37–39). The intent of the quality management standards is to establish a quality system, maintain product integrity, and satisfy customers. ISO 9001:2000 focuses on a process approach to quality management. Companies can elect to become registered only in the relevant parts of the ISO standards. Some manufacturers and retailers require food industry suppliers to be ISO certified. Relevant to food analysis, ISO standards include sampling procedures and food standards.

2.6.3 Other Standards

Other international, regional, and country-specific organizations publish standards relevant to food composition and analysis. For example, the **Saudi Arabian Standards Organization** (SASO) publishes standards documents (e.g., labeling, testing methods) important in the Middle East (except Israel), and the **European Commission** sets standards for foods and food additives for countries in the European Economic Community (EEC). In the USA, the Food Ingredients Expert Committee, which operates as part of the US Pharmacopeia, sets standards for the identification and purity of food additives and chemicals, published as the **Food Chemicals Codex** (FCC) (40). For example, a company may specify in the purchase of a specific food ingredient that it be "FCC grade." Countries other than the USA adopt FCC standards (e.g., Australia, Canada). At an international level, the **Joint FAO/WHO Expert Committee on Food Additives** (JECFA) sets standards for purity of food additives (41). The Codex Alimentarius Commission is encouraged to utilize the standards established by JECFA. Standards established by FCC and JECFA are used by many countries as they develop their own standards.

2.7 SUMMARY

Various kinds of standards set for certain food products by federal agencies make it possible to get essentially the same food product whenever and wherever purchased in the USA. The standards of identity set by the FDA and USDA define what certain food products must consist of. The USDA and NMFS of the Department of Commerce have specified grade standards to define attributes for certain foods. Grading programs are voluntary, while inspection programs may be either voluntary or mandatory, depending on the specific food product.

While the FDA has broadest regulatory authority over most foods, responsibility is shared with other regulatory agencies for certain foods. The USDA has significant responsibilities for meat and poultry, the NOAA and the NMFS for seafood, and the ATF for alcoholic beverages. The FDA, the USDA, state agencies, and the dairy industry work together to ensure the safety, quality, and economic integrity of milk and milk products. The FDA, the EPA, and state agencies work together in the NSSP to ensure the safety and wholesomeness of shellfish. The EPA shares responsibility with the FDA for control of pesticide residues in foods and has responsibility for drinking water safety and the composition of effluent from food processing plants. The Customs Service receives assistance from the FDA and USDA in its role to ensure the safety and economic integrity of imported foods. The FTC works with the FDA to prevent deceptive advertising of food products, as affected by food composition and labels. The NCWM, under the NIST within the Department of Commerce, has developed model packaging and labeling regulations related to weights and measures of food packages.

The chemical composition of foods is often an important factor in determining the quality, grade, and price of a food. Government agencies that purchase foods for special programs often rely on detailed specifications that include information on food composition.

International organizations have developed food standards and safety practices to protect consumers, ensure fair business practices, and facilitate international trade. The Codex Alimentarius Commission is the major international standard-setting group for food safety and quality. The International Organization for Standardization has a series of standards that focus on documentation of procedures, with some relevant to food analysis. Certain regional and country-specific organizations also publish standards related to food composition and analysis.

2.8 STUDY QUESTIONS

1. Define the abbreviations FDA, USDA, and EPA, and give two examples for each of what they do or regulate relevant to food analysis.
2. Differentiate "standards of identity," "standards of quality," and "grade standards" with regard to what they are and which federal agency establishes and regulates them.
3. Government regulations regarding the composition of foods often state the official or standard method by which the food is to be analyzed. Give the full name of three

organizations that publish commonly referenced sources of such methods.

4. For each type of product listed below, identify the governmental agency (or agencies) that has regulatory or other responsibility for quality assurance. Specify the general nature of that responsibility and, if given, the specific types of analyses that would be associated with that responsibility.
   (a) Frozen fish sticks
   (b) Contaminants in drinking water
   (c) Dessert wine
   (d) Grade A milk
   (e) Frozen oysters
   (f) Imported chocolate products
   (g) Residual pesticide on wheat grain
   (h) Corned beef
5. Food products purchased by federal agencies often have specifications that include requirements for chemical composition. Give the names of four such specifications.
6. You are developing a food product that will be marketed in another country. What factors will you consider as you decide what ingredients to use and what information to include on the food label? What resources should you use as you make these decisions?
7. Upon completing your college degree, you are employed by a major US food company that processes fruits and vegetables.
   (a) Where, specifically, would you look to find if a standard of identity exists for each of your processed products? What kind of information does such a standard include?
   (b) What US governmental agency sets the standards of identity for such products?
   (c) What are the minimum standards called that are set for some fruit and vegetable products?
   (d) What governmental agency sets the grade standards that you may want to use as a quality control tool and in marketing your products?
   (e) You are concerned about pesticide tolerances for the fruits and vegetables you process. What governmental agency sets those tolerances?
   (f) What governmental agency enforces the pesticide tolerances?
   (g) For nutrition labeling purposes for your products, you want to check on official methods of analysis. Where, specifically, should you look?
   (h) You want to check the detailed rules on nutrition labeling that would apply to your products. Where, specifically, would you look to find those rules?
   (i) You are considering marketing some of your products internationally. What resource could you check to determine if there are international standards and safety practices specified for those products?
   (j) You understand that a quality assurance inspection service, based on "HACCP," is being offered to the fruit and vegetable industry. What does "HACCP" stand for, and what is its intent?

2.9 ACKNOWLEDGMENTS

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2.11 RELEVANT INTERNET ADDRESSES

American Public Health Association – http://www.apha.org/
American Society of Testing Materials – http://www.astm.org/
AOAC International – http://www.aoac.org/
Bureau of Alcohol, Tobacco, Firearms, and Explosives – http://www.atf.gov/
Centers for Disease Control and Prevention – http://www.cdc.gov/
Code of Federal Regulations – http://www.access.gpo.gov/nara/cfr/cfr-table-search.html
Codex Alimentarius Commission – http://www.codexalimentarius.net/web/index_en.jsp
Department of Commerce – http://www.doc.gov/
- National Institute of Standards and Technology – http://www.nist.gov/
  - National Conference on Weights and Measures – http://ts.nist.gov/WeightsAndMeasures/
- National Oceanic and Atmospheric Administration – http://www.noaa.gov/
- National Marine Fisheries Service – http://www.nmfs.noaa.gov/

Environmental Protection Agency – http://www.epa.gov/
Federal Trade Commission – http://www.ftc.gov/
Food Chemicals Codex – http://www.usp.org/fcc/
Food and Drug Administration – http://www.fda.gov/
- Center for Food Safety and Applied Nutrition – http://vm.cfsan.fda.gov/list.html
  - Food Labeling and Nutrition – http://vm.cfsan.fda.gov/label.html
  - Food Safety Team – http://www.fda.gov/opacom/backgrounders/foodteam.html
  - Hazard Analysis Critical Control Point – http://vm.cfsan.fda.gov/~lrd/haccp.html
  - Milk Safety References – http://vm.cfsan.fda.gov/~ear/prime.html
  - Pesticides, Metals, Chemical Contaminants and Natural Toxins – http://www.cfsan.fda.gov/~lrd/pestadd.html
  - Seafood Information and Resources – http://vm.cfsan.fda.gov/seafood1.html

International Organization for Standardization – http://www.iso.ch/
National Shellfish Sanitation Program – http://vm.cfsan.fda.gov/~ear/nsspman.html
US Customs and Border Protection – http://www.customs.gov/; http://www.usitc.gov/tata/hts/bychapter/index.htm
US Department of Agriculture – http://www.usda.gov/
- Agricultural Marketing Service – http://www.ams.usda.gov/
  - Quality Standards – http://www.ams.usda.gov/standards/
  - Laboratory Testing Program – http://www.ams.usda.gov/labserv.htm
- Food Safety and Inspection Service – http://www.fsis.usda.gov/
  - HACCP/Pathogen Reduction – http://www.fsis.usda.gov/oa/haccp.imhaccp.htm
- Grain Inspection, Packers, and Stockyards Administration – http://www.usda.gov/gipsa
- Nutrient Database for Standard Reference – http://www.ars.usda.gov/ba/bhnrc/ndl