2 chapter

US Government Regulations and International Standards Related to Food Analysis

S.Suzanne Nielsen
Department of Food Science,
Purdue University,
West Lafayette, IN 47907-2009, USA
e-mail: nielsens@purdue.edu

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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 Refs. [1–4] for a 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. Nutrition labeling regulations are not covered in this chapter, but Chap. 3 is devoted to this topic, as it is related to food analysis.

2.2 US FEDERAL REGULATIONS AFFECTING FOOD COMPOSITION

2.2.1 US Food and Drug Administration (FDA)

The 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, biologics, tobacco, and radiation-emitting 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*

Since the original Food and Drug Act of 1906, various acts, amendments, and regulations have been put in place to regulate foods. Table 2.1 summarizes these acts, amendments, and regulations with food analysis implications. The FDA implements and enforces the **Federal Food, Drug, and Cosmetic (FD&C) Act** of 1938 as amended. Select aspects of this and other regulations are further described in the subsections that follow.

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. As an example, the standard of identity for sour cream (21 CFR 131.160) is given in Fig. 2.1. Table 2.2 summarizes 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 generally 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 FDA has also set a standard of quality for bottled water, which includes set allowable levels for the following: coliform, turbidity, color, odor, radium-226 and radium-228 activity, beta particle and photon radioactivity, and more than 70 chemical contaminants [21 CFR 165.110(b)]. The FDA has established **standards of fill** for some canned fruits and vegetables, tomato products, and seafood, stating 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, egg products; water supplies). However, the FDA shares responsibilities with other regulatory agencies for certain foods, as described in later sections of this chapter. Table 2.3 summarizes the food

2.1 table Food and Drug Administration acts, amendments, and regulations with food analysis implications

Act, amendment, or regulation (year)	*Intent*	*Food analysis relevance*
Federal Food, Drug, and Cosmetic Act (FD&C) (1938)	Intended to assure consumers that foods are safe, wholesome, produced under sanitary conditions, and packaged and labeled truthfully. Prohibits adulteration and misbranding of foods	Authorizes food definitions and standards of identify, many of which require testing food composition
Food Additive Amendment (1958)	Designed to protect the health of consumers by requiring a food additive to be proven safe before addition to a food, and used at only a safe level in foods. Delaney Clause (rider to amendment) prohibits FDA from setting any tolerance as a food additive for substances known to be a carcinogen	Requires testing food additives (type, amount, safety)
Color Additive Amendment (1960)	Defined color additives. Set rules for both certified and uncertified colors. Provides for approval of color additives. Allows for listing color additives for specific uses and sets quantity limitations. Contains Delaney Clause (see above)	Requires testing food additives (type, amount, safety)
Current Good Manufacturing Practices (cGMP) (1969) (21 CRS 110 – general; specific GMPs also exist for certain foods)	Designed to prevent adulterated foods in the marketplace	Requires testing for adulterants (including extraneous matter)
Hazard Analysis Critical Control Point (HACCP): 21 CFR Part 123 – seafood; 21 CRS Part 120 – juice; 9 CFR Part 417 – meat and poultry) (Refs. [6–9])	Intended to improve food safety and quality	Requires testing for microbial, chemical, and physical hazards
Nutrition Labeling and Education Act (NLEA) (1990)	Made nutrition labeling mandatory on most food products under FDA jurisdiction. Established definitions for health and nutrient claims	Requires testing for food composition (specific components and their levels)
Dietary Supplement Health and Education Act (DSHEA)(1994)	Defined supplements as "dietary ingredients," set criteria to regulate claims and labeling, and established government agencies to handle regulation. Changed the definition and regulations for dietary supplements, so no longer considered a food	Eliminated testing of dietary supplements as required when defined as a food
Food Safety Modernization Act (FSMA) (2011)	Aims to ensure the food supply is safe by shifting the focus from responding to contamination to preventing it	Requires testing for hazards and preventive controls, including physical and chemical hazards, food allergens, sanitation controls, and supply chain controls
Food Labeling: Revision of the Nutrition and Supplement Facts Label (2016)	Updated information on label to help consumers maintain health dietary practices	Changes the nutrients tested and reported on label

analysis-related scope of responsibility of the FDA, compared to and often in cooperation with other federal agencies, to ensure the quality and safety of foods in the USA. Table 2.4 summarizes which federal agency has responsibility for ensuring the quality and safety of specific types of foods.

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, administrative detention, suspension of registration, seizures, injunctions, or recalls, depending on the circumstances. The

§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 §101.22 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 (2015)]

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 Refs. [1–4].

2.2.2 US Department of Agriculture (USDA)

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 whole-

2.2 table Selected chemical composition requirements of some foods with standards of identity

Section in 21 CFR[a]	*Food product*	*Requirement*	*Number in 13th Edn.*	*AOAC method*[b] *Number in 18th Edn.*	*Name/description*
131.110	Milk	Milk solids nonfat ≥8 1/4%	16.032	990.19	Total solids, by forced air oven after steam table
		Milk fat ≥3 1/4%	16.059	905.02	Roese-Gottlieb
		Vitamin A (if added) ≥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	Milk fat ≥50% by wt. of solids	16.255 and calculation	933.05	Digest with HCl, Roese-Gottlieb
		Moisture ≤39% by wt.	16.233	926.08	Vacuum oven
		Phosphatase level ≤3 µg phenol equivalent/0.25 g[e]	16.275–16.277	946.03–946.03C	Residual phosphatase
137.165	Enriched flour	Moisture ≤15%	14.002, 14.003	925.09, 925.09B	Vacuum oven
		Ascorbic acid ≤200 ppm (if added as dough conditioner)			
		Ash[f] ≤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 ≥10.5°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 ≥5 and ≤30%			Calculated from volume of sediment[k]
163.113	Cocoa	Cocoa fat ≤22% and ≥10%		963.15	Petroleum ether extraction with Soxhlet unit
164.150	Peanut butter	Fat ≤55%	27.006(a)	948.22	Ether extraction with Soxhlet unit

[a]*CFR* Code of Federal Regulations (2015)
[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)

2.3 table

Food analysis-related scope of responsibility for federal agencies

US Food and Drug Administration (FDA)	*US Department of Agriculture (USDA)*	*US Dept. Commerce, National Oceanic and Atmospheric Administration – National Marine Fisheries Service (NOAA-NMFS)*	*US Dept. Justice, Alcohol and Tobacco Tax and Trade Bureau (TTB)*	*US Environmental Protection Agency (EPA)*	*US Customs and Border Protection (CBP)*	*US Federal Trade Commission (FTC)*
Standards of identity (most foods, except meats) Standards of quality (canned fruits and vegetables) Standards of fill (select foods) Nutrition labeling (all foods but meats) (see Chap. 3 for details) Standards for some alcoholic beverages and cooking wines Enforces tolerances set on pesticides (note: tolerances set by EPA) For seafood, works with NMFS to ensure safety; Sets and enforces allowable levels of contaminants and pathogenic microorganisms in seafood For shellfish, through National Shellfish Sanitation Program (NSSP) (part of FDA): sanitation for products shipped interstate; Ensures shellfish-growing areas are free of sewage pollution and toxic industrial waste For imported foods, works with US Customs Service For dairy products, works with USDA and States for safety and wholesomeness Food additives (all foods) Color additives (all foods) Inspects food processing facilities for compliance with cGMP regulations and mandatory HACCP inspection programs	Standards of identity for meat products Grade standards (voluntary; for many foods) Inspection programs (meats, poultry, eggs, grains) For select imported products, works with CBP	Grading, standardization and inspection program for seafood (works with FDA and EPA)	Standards and labeling of most alcoholic beverages	Sets tolerances for pesticide residues (note: tolerance enforced by FDA) Sets standards for drinking water and allowed levels of contaminants Sets standards and guidelines for effluent from food processing plants	Ensure imported products are taxed properly, are safe for human consumption, and are not economically deceptive (works with FDA)	Authority over advertizing and sales promotion practices for foods

2.4 table Federal agencies with quality and safety responsibility for specific foods

Water	*Dairy products*	*Meats and meat products*	*Seafood*	*Shellfish*	*Alcoholic beverages*	*Fruits and vegetables*	*Harvested food or feed crops: pesticide residues*	*Infant formula*
EPA (drinking; effluent) FDA (bottled)	FDA USDA States	USDA	Dept. Commerce: NOAA-NMFS FDA EPA	FDA: NSSP	Dept. Treasury: TTB (most products) FDA (select products)	FDA	EPA (sets tolerances) FDA (enforces tolerances)	FDA

sale 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 2.5.

2.5 table USDA standards for grade 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, the 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. Hazard Analysis Critical Control Point (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 **US 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. 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 Between FDA and Environmental Protection Agency*

The FDA and the Environmental Protection Agency (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 level for methyl mercury [11].

2.2.4 US Alcohol and Tobacco Tax and Trade Bureau

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 wine (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 (EPA)

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.

2.6 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]
180.103	Captan (F)	Phthalimide	Apples	25
			Cattle, meat	0.2
			Milk	0.1
			Grapes	25
			Peach	15
			Strawberry	20
			Sunflower, seed	0.05
180.342	Chlorpyrifos[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 (2016)
[a]Parts per million
[b]Also known as Dursban™ and Lorsban™

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 (1) certain provisions of the FD&C Act, (2) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and (3) 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. 32, Sect. 32.3). The EPA is authorized to register approved pesticides and to establish an **allowable limit** or **tolerance level** for any detectable pesticide residues that might remain in or on a harvested food or feed crop (see Chap. 31, Sect. 31.3). 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.

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. Unless otherwise noted, the specific tolerances established for the pesticide chemical apply to residues resulting from their application prior to harvest or slaughter. Tolerance levels for selected pesticides and insecticides permitted in foods as food additives are given in Table 2.6.

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* [12] 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. 13, 14, and 30).

2.7 table Effluent limitations for plants processing natural and processed cheese

Effluent limitations	Effluent characteristics					
	Metric units[a]			English units[b]		
	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]
Avg 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]
Avg 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 (2016)
[a]Kilograms per 1,000 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

2.2.5.2 *Drinking Water Standards and Contaminants*

While the FDA regulates bottled water with a standard of identify, a detailed standard of quality, and specific current Good Manufacturing Practices (cGMP) regulations, the EPA regulates drinking (i.e., tap) water. 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. 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* [13] published by the American Public Health Association; *Methods of Chemical Analysis of Water and Wastes* [14], published by the EPA; and *Annual Book of ASTM Standards* [15], 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. 9), ion chromatography (see Chap. 13), and ion-selective electrode (see Chap. 21).

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. 28), **total soluble solids** (TSS) (see Chap. 15), and **pH** (see Chap. 22), as shown in Table 2.7 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 and Border Protection (CBP)

Over 100 countries export food, beverages, and related edible products to the USA. The CBP assumes the

central role in ensuring that imported products are taxed properly, safe for human consumption, and not economically deceptive. The CBP receives assistance from the FDA and USDA as it assumes these responsibilities. The major regulations promulgated by the CBP are given in Title 19 of the CFR.

All goods imported into the USA 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 [16]. 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.

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 (FTC)

The 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 shut down 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: FTC has primary authority over advertising of foods, and 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. As described in Sect. 2.2.1.2, the FDA 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 is comprised of all 50 states. In cooperation with the states and the dairy industry, the FDA has also developed for state adoption model

2.8 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 US Department of Health and Human Services, Public Health Service, Food and Drug Administration [17]
[a]Not applicable to acidified or cultured products
[b]Not applicable to bulk-shipped heat-treated milk products
[c]Reference to specific laboratory techniques

2.9 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
Milk fat content, percent	1.25	1.50
Moisture content, percent	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), percent	0.15	0.17

http://www.ams.usda.gov/sites/default/files/media/Nonfat_Dry_Milk_%28Spray_Process%29_Standard%5B1%5D.pdf
[a]All values are maximum allowed

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) [17], 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 Tables 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, and 2.8. 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.

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* [20], 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 2.9).

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 [21] for state adoption regarding the quality and sanitation aspects of producing and handling manufacturing grade milk.

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.

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 [22]. 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. 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.

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 inductively coupled plasma-mass spectrometry (ICP-MS) (Chap. 9, Sect. 9.6). 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 SPECIFICATIONS FOR FOODS PURCHASED BY 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, in addition to specified microbial quality. Many such documents are referred to as a **commercial item description** (CID). These specifications, with specific examples for foods and their content, are given in Table 2.10.

2.10 table Specifications for foods purchased by government agencies

Specification type	*Example product*	*Example content of specification*
Commercial item description (CID)	Canned tuna [23]	Salt/sodium content, methylmercury, and histamine, with specified methods of analysis
Federal specification	Macaroni and cheese mix CID [24]	Fat and sodium contents and viscosity, with specified methods of analysis (AOAC International)
	Beans, precooked, dehydrated CID [25]	Moisture, fat, cholesterol, and sodium contents, with specified methods of analysis (AOAC International)
Department of Defense specification	Syrup CID [26]	Brix, ash content, color
	Instant tea mix CID [27]	Moisture and sugar contents, titratable acidity
	Nut butters CID [28]	Salt content, aflatoxin content
Commodity specification	Dried egg mix [29]	Vegetable oil composition/characteristics: free fatty acid value, peroxide value, linolenic acid, moisture, volatile matter, iodine value, Lovibond color, by specified methods of analysis (American Oil Chemists' Society)
	American cheese [30] and mozzarella cheese [31]	pH, milk fat, and moisture contents
USDA specification (e.g., Institutional Meat Purchase Specification)	Sausage products [32]	Fat content

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. 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 [33]. 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.

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 2.11). Codex has efforts to validate and harmonize methods of food safety analysis among countries and regions, help maintain the smooth flow of international commerce, and ensure appropriate decisions on food exports and imports. 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.

2.6.2 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) [34]. 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 [35]. 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.

2.11 table Content of the Codex Alimentarius [33]

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 misc. products
12	Milk and milk products
13	Methods of analysis and sampling

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 the 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 TTB 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 CBP 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 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. 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. 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? (See Chap. 3)
   (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?

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