SUBCHAPTER A—GENERAL

PART 1—GENERAL ENFORCEMENT REGULATIONS

Subpart A—General Provisions

Subpart B—General Labeling Requirements

Subpart C [Reserved]

Subpart D—Electronic Import Entries

Subpart E—Imports and Exports

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

GENERAL PROVISIONS

PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

ADDITIONAL PROVISIONS

Subpart I—Prior Notice of Imported Food

GENERAL PROVISIONS

REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

CONSEQUENCES

Subpart N [Reserved]

Subpart O—Sanitary Transportation of Human and Animal Food

Subpart S—Additional Traceability Records for Certain Foods

AUTHORITY: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

SOURCE: 42 FR 15553, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 1.1 General.

(a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.

(c) The definition of *package* in § 1.20 and of *principal display panel* in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.7(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.7(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 101.7(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.7(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in § 501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements part of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

[42 FR 15553, Mar. 22, 1977, as amended at 58 FR 17085, Apr. 1, 1993; 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013; 81 FR 59131, Aug. 29, 2016]

§ 1.3 Definitions.

(a) *Labeling* includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) *Label* means any display of written, printed, or graphic matter on the immediate container of any article, or

any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

§ 1.4 Authority citations.

(a) For each part of its regulations, the Food and Drug Administration includes a centralized citation of all of the statutory provisions that provide authority for any regulation that is included in that part.

(b) The agency may rely on any one or more of the authorities that are listed for a particular part in implementing or enforcing any section in that part.

(c) All citations of authority in this chapter will list the applicable sections in the organic statute if the statute is the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Fair Packaging and Labeling Act. References to an act or a section thereof include references to amendments to that act or section. These citations will also list the corresponding United States Code (U.S.C.) sections. For example, a citation to section 701 of the Federal Food, Drug, and Cosmetic Act would be listed: Sec. 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371).

(d) If the organic statute is one other than those specified in paragraph (c) of this section, the citations of authority in this chapter generally will list only the applicable U.S.C. sections. For example, a citation to section 552 of the Administrative Procedure Act would be listed: 5 U.S.C. 552. The agency may, where it determines that such measures are in the interest of clarity and public understanding, list the applicable sections in the organic statute and the corresponding U.S.C. section in the same manner set out in paragraph (c) of this section. References to an act or a section thereof include references to amendments to that act or section.

(e) Where there is no U.S.C. provision, the agency will include a citation to the U.S. Statutes at Large. Citations to the U.S. Statutes at Large will refer to volume and page.

(f) The authority citations will include a citation to executive delegations (i.e., Executive Orders), if any, necessary to link the statutory authority to the agency.

[54 FR 39630, Sept. 27, 1989]

Subpart B—General Labeling Requirements

§ 1.20 Presence of mandatory label information.

In the regulations specified in § 1.1(c) of this chapter, the term *package* means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231–233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234–236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251–256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257–257i).

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or

container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of §101.7(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

[42 FR 15553, Mar. 22, 1977, as amended at 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013; 81 FR 59131, Aug. 29, 2016]

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, cosmetic, or tobacco product shall be deemed to be misleading if it fails to reveal facts that are:

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or

(2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

(b) Affirmative disclosure of material facts pursuant to paragraph (a) of this section may be required, among other appropriate regulatory procedures, by

(1) Regulations in this chapter promulgated pursuant to section 701(a) of the act; or

(2) Direct court enforcement action.

(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, cosmetics, or tobacco products under the Federal Food, Drug, and Cosmetic Act.

(2) Permit a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness as defined in sections 505(d) and 512(d) of the act.

[42 FR 15553, Mar. 22, 1977, as amended at 77 FR 5176, Feb. 2, 2012]

§ 1.23 Procedures for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this part 1, the term *act* means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 1.24 Exemptions from required label statements.

The following exemptions are granted from label statements required by this part:

(a) *Foods.* (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in this part if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(2) Random food packages, as defined in §101.7(j) of this chapter, bearing labels declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration, and placement requirements of §101.7 of this chapter if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by this paragraph (a)(2) except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in this part.

(4) Individually wrapped pieces of *penny candy* and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

(5)(i) Soft drinks packaged in bottles shall be exempt from the placement requirements for the statement of identity prescribed by §101.3 (a) and (d) of this chapter if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multiunit retail package, the multiunit retail package shall be exempt from the statement of identity declaration requirements prescribed by §101.3 of this chapter if the statement of identity on the unit container is not obscured by the multiunit retail package.

(ii) A multiunit retail package for soft drinks shall be exempt from the declaration regarding name and place of business required by §101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with §101.5 of this chapter. The declaration required by §101.5 of this chapter may appear on the top or side of the closure of bottled soft drinks if the statement is conspicuous and easily legible.

(iii) Soft drinks packaged in bottles which display other required label information only on the closure shall be exempt from the placement requirements for the declaration of contents prescribed by §101.7(f) of this chapter if the required content declaration is blown, formed, or molded into the surface of the bottle in close proximity to the closure.

(iv) Where a trademark on a soft drink package also serves as, or is, a statement of identity, the use of such trademark on the package in lines not parallel to the base on which the package rests shall be exempted from the requirement of §101.3(d) of this chapter that the statement be in lines parallel to the base so long as there is also at least one statement of identity in lines generally parallel to the base.

(v) A multiunit retail package for soft drinks in cans shall be exempt from the declaration regarding name and place of business required by §101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on

the unit containers complies with §101.5 of this chapter. The declaration required by §101.5 of this chapter may appear on the top of soft drinks in cans if the statement is conspicuous and easily legible, provided that when the declaration is embossed, it shall appear in type size at least one-eighth inch in height, or if it is printed, the type size shall not be less than one-sixteenth inch in height. The declaration may follow the curvature of the lid of the can and shall not be removed or obscured by the tab which opens the can.

(6)(i) Ice cream, french ice cream, ice milk, fruit sherbets, water ices, quiescently frozen confections (with or without dairy ingredients), special dietary frozen desserts, and products made in semblance of the foregoing, when measured by and packaged in ½-liquid pint and ½-gallon measure-containers, as defined in the ''Measure Container Code of National Bureau of Standards Handbook 44,'' Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 ''Measure-Containers,'' which is incorporated by reference, are exempt from the requirements of §101.7(b)(2) of this chapter to the extent that net contents of 8–fluid ounces and 64–fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or 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_locations.html*.

(ii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in 1–liquid pint, 1–liquid quart, and ½-gallon measure-containers, as defined in the ''Measure Container Code of National Bureau of Standards Handbook 44,'' Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 ''Measure-Containers,'' which is incorporated by reference, are exempt from the dual net-contents declaration requirement of §101.7 of this chapter. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or 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_locations.html*.

(iii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in ½-liquid pint, 1–liquid pint, 1–liquid quart, ½-gallon, and 1–gallon measured-containers, as defined in the ''Measure Container Code of National Bureau of Standards Handbook 44,'' Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 ''Measure-Containers,'' which is incorporated by reference, are exempt from the requirement of §101.7(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or 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_locations.html*.

(7)(i) Milk, cream, light cream, coffee or table cream, whipping cream, light whipping cream, heavy or heavy whipping cream, sour or cultured sour cream, half-and-half, sour or cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk and milk products, skim or skimmed milk, vitamin D milk and milk products, fortified milk and milk products, homogenized milk, flavored milk and milk products, buttermilk, cultured buttermilk, cultured milk or cultured whole buttermilk, low-fat milk (0.5 to 2.0 percent butterfat), and acidified milk and milk products, when packaged in containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of

§ 101.7(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively.

(ii) The products listed in paragraph (a)(7)(i) of this section, when packaged in glass or plastic containers of ½-pint, 1–pint, 1–quart, ½-gallon, and 1–gallon capacities are exempt from the placement requirement of § 101.7(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel, provided that other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(iii) The products listed in paragraph (a)(7)(i) of this section, when packaged in containers of 1–pint, 1–quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.7(j) of this chapter.

(8) Wheat flour products, as defined by §§ 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200, and 137.205 of this chapter, packaged:

(i) In conventional 2–, 5–, 10–, 25–, 50–, and 100–pound packages are exempt from the placement requirement of § 101.7(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label; and

(ii) In conventional 2–pound packages are exempt from the dual net-contents declaration requirement of § 101.107 of this chapter provided the quantity of contents is expressed in pounds.

(9)(i) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs and designed to permit the division of such carton by the retail customer at the place of purchase into two portions of one-half dozen eggs each are exempt from the labeling requirements of this part with respect to each portion of such divided carton if the carton, when undivided, is in conformance with the labeling requirements of this part.

(ii) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs are exempt from the placement requirements for the declaration of contents prescribed by § 101.7(f) of this chapter if the required content declaration is otherwise placed on the principal display panel of such carton and if, in the case of such cartons designed to permit division by retail customers into two portions of one-half dozen eggs each, the required content declaration is placed on the principal display panel in such a manner that the context of the content declaration is destroyed upon division of the carton.

(10) Butter as defined in 42 Stat. 1500 (excluding whipped butter):

(i) In 8–ounce and in 1–pound packages is exempt from the requirements of § 101.7(f) of this chapter that the net contents declaration be placed within the bottom 30 percent of the area of the principal display panel;

(ii) In 1–pound packages is exempt from the requirements of § 101.7(j)(1) of this chapter that such declaration be in terms of ounces and pounds, to permit declaration of ''1–pound'' or ''one pound''; and

(iii) In 4–ounce, 8–ounce, and 1–pound packages with continuous label copy wrapping is exempt from the requirements of §§ 101.3 and 101.7(f) of this chapter that the statement of identity and net contents declaration appear in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided that such statement and declaration are not so positioned on the label as to be misleading or difficult to read as the package is customarily displayed at retail.

(11) Margarine as defined in § 166.110 of this chapter and imitations thereof in 1–pound rectangular packages, except for packages containing whipped or soft margarine or packages that contain more than four sticks, are exempt from the requirement of § 101.7(f) of this chapter that the declaration of the net quantity of contents appear within the bottom 30 percent of the principal display panel and from the requirement of § 101.7(j)(1) of this chapter that such declaration be expressed both in ounces and in pounds to permit declaration of ''1-pound'' or ''one

pound,'' provided an accurate statement of net weight appears conspicuously on the principal display panel of the package.

(12) Corn flour and related products, as they are defined by §§137.211, 137.215, and §§137.230 through 137.290 of this chapter, packaged in conventional 5–, 10–, 25–, 50–, and 100–pound bags are exempt from the placement requirement of §101.7(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label.

(13)(i) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass or plastic containers of ½-pint, 1–pint, 1–quart, ½-gallon, and 1–gallon capacities are exempt from the placement requirement of §101.7(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel: *Provided*, That other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(ii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 1–pint, 1–quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of §101.7(j) of this chapter.

(iii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of §101.7(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint (or half pint) and ½ gallon (or half gallon), respectively.

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement ''This Unit Not Labeled For Retail Sale'' in type size not less than one-sixteenth of an inch in height. The word ''Individual'' may be used in lieu of or immediately preceding the word ''Retail'' in the statement.

(b) *Drugs.* Liquid over-the-counter veterinary preparations intended for injection shall be exempt from the declaration of net quantity of contents in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof as required by §201.62 (b), (i), and (j) of this chapter, and from the dual declaration requirements of §201.62(i) of this chapter, if such declaration of net quantity of contents is expressed in terms of the liter and milliliter, or cubic centimeter, with the volume expressed at 68 °F (20 °C).

(c) *Cosmetics.* Cosmetics in packages containing less than one-fourth ounce avoirdupois or one-eighth fluid ounce shall be exempt from compliance with the requirements of section 602(b)(2) of the Federal Food, Drug, and Cosmetic Act and section 4(a)(2) of the Fair Packaging and Labeling Act:

(1) When such cosmetics are affixed to a display card labeled in conformance with all labeling requirements of this part; or

(2) When such cosmetics are sold at retail as part of a cosmetic package consisting of an inner and outer container and the inner container is not for separate retail sale and the outer container is labeled in conformance

with all labeling requirements of this part.

[42 FR 15553, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 47 FR 32421, July 27, 1982; 49 FR 13339, Apr. 4, 1984; 54 FR 9033, Mar. 3, 1989; 58 FR 2174, Jan. 6, 1993; 61 FR 14478, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 81 FR 49895, July 29, 2016; 81 FR 59131, Aug. 29, 2016; 85 FR 72906, Nov. 16, 2020]

Subpart C [Reserved]

Subpart D—Electronic Import Entries

SOURCE: 81 FR 85870, Nov. 29, 2016, unless otherwise noted.

§ 1.70 Scope.

This subpart specifies the data elements that are required by the Food and Drug Administration (FDA) to be included in an electronic import entry submitted in the Automated Commercial Environment (ACE) system or any other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange (EDI) system, which contains an article that is being imported or offered for import into the United States and that is regulated by FDA.

§ 1.71 Definitions.

For purposes of subpart D:

ACE filer means the person who is authorized to submit an electronic import entry for an FDA-regulated product in the Automated Commercial Environment or any other CBP-authorized EDI system.

Acidified food means acidified food, as defined in § 114.3(b) of this chapter, and subject to the requirements in parts 108 and 114 of this chapter.

Automated Commercial Environment or *ACE* means the automated and electronic system for processing commercial importations that is operated by U.S. Customs and Border Protection in accordance with the National Customs Automation Program established in Subtitle B of Title VI—Customs Modernization, in the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (Customs Modernization Act), or any other CBP-authorized EDI system.

Biological product means a biological product as defined in section 351(i)(1) of the Public Health Service Act.

Cosmetic means a cosmetic as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act.

CBP or U.S. Customs and Border Protection means the Federal Agency that is primarily responsible for maintaining the integrity of the borders and ports of entry of the United States.

Drug means those articles meeting the definition of a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

FDA or Agency means the U.S. Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act.

Food contact substance means any substance, as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

HCT/Ps means human cells, tissues, or cellular or tissue-based products, as defined in § 1271.3(d) of this chapter.

Low-acid canned food means a thermally processed low-acid food (as defined in § 113.3(n) of this chapter) in a hermetically sealed container (as defined in § 113.3(j) of this chapter), and subject to the requirements in parts 108 and 113 of this chapter.

Medical device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in humans.

Radiation-emitting electronic product means an electronic product as defined in section 531 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act.

Veterinary device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in animals.

[81 FR 85870, Nov. 29, 2016, as amended at 87 FR 62984, Oct. 18, 2022]

§ 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

General. When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, veterinary devices, radiation-emitting electronic products, cosmetics, and tobacco products.

(a) *Product identifying information* for the article that is being imported or offered for import. This consists of:

(1) *FDA Country of Production,* which is the country where the article was last manufactured, processed, or grown (including harvested, or collected and readied for shipment to the United States). The FDA Country of Production for an article that has undergone any manufacturing or processing is the country where that activity occurred provided that the manufacturing or processing had more than a minor, negligible, or insignificant effect on the article.

(2) *The Complete FDA Product Code,* which must be consistent with the invoice description of the product.

(3) *The Full Intended Use Code.*

(b) *Importer of record contact information,* which is the telephone and email address of the importer of record.

[81 FR 85870, Nov. 29, 2016, as amended at 87 FR 62984, Oct. 18, 2022]

§ 1.73 Food.

(a) *Food contact substances.* An ACE filer must submit the information specified in § 1.72 at the time of filing entry in ACE for food that is a food contact substance.

(b) *Low-acid canned food.* For an article of food that is a low-acid canned food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

(c) *Acidified food.* For an article of food that is an acidified food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

§ 1.74 Human drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for drugs, including biological products and eligible prescription drugs as defined in § 251.2 of this chapter that are imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) For a drug intended for human use that is not an eligible prescription drug covered under paragraph (b) of this section:

(1) *Registration and listing.* The Drug Registration Number and the Drug Listing Number of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry filing in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the human drug article being imported or offered for import.

(2) *Drug application number.* For a drug intended for human use that is the subject of an approved application

under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved biologics license application, the number of the applicable application.

(3) *Investigational new drug application number*. For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(b) For an eligible prescription drug as defined in §251.2 of this chapter that is imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act:

(1) *Registration and listing*. The Drug Registration Number and the Drug Listing Number. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the unique facility identifier submitted by the Foreign Seller registrant under §251.9 of this chapter in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number that the Importer will use when relabeling the eligible prescription drug as required in §251.13 of this chapter.

(2) *Drug application number*. The number of the new drug application or abbreviated new drug application for the counterpart FDA-approved drug.

(3) *Lot or control number*. The lot or control number assigned by the manufacturer of the eligible prescription drug.

(4) *FDA Quantity*. FDA Quantity, which is the quantity of each eligible prescription drug in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units.

(5) *Pre-Import Request number*. The Pre-Import Request number assigned by FDA.

[85 FR 62125, Oct. 1, 2020, as mended at 86 FR 17060, Apr. 1, 2021]

§1.75 Animal drugs and veterinary devices.

(a) *Animal drugs*. In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(1) *Registration and listing*. For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE at the time of entry is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(2) *New animal drug application number*. For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(3) *Veterinary minor species index file number*. For a drug intended for use in animals that is the subject of an Index listing under section 572 of the Federal

Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(4) *Investigational new animal drug file number.* For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug file under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

(b) *Veterinary devices.* An ACE filer must submit the data specified in §1.72 at the time of filing entry in ACE for veterinary devices.

[87 FR 62984, Oct. 18, 2022]

§ 1.76 Medical devices.

In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE for medical devices regulated by the FDA Center for Devices and Radiological Health.

(a) *Registration and listing.* For a medical device, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(b) *Investigational devices.* For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(c) *Premarket number.* For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

(e) *Lead wire/patient cable.* For electrode lead wires and patient cables intended for use with a medical device, an Affirmation of Compliance with the applicable performance standard under §898.12 of this chapter.

(f) *Impact resistant lens.* For impact resistant lenses in eyeglasses and sunglasses, an Affirmation of Compliance with the applicable requirements of §801.410 of this chapter.

(g) *Convenience kit.* If applicable for a medical device, an Affirmation of Compliance that the article imported or offered for import is a convenience kit or part of a convenience kit.

§ 1.77 Radiation-emitting electronic products.

In addition to the data required to be submitted in §1.72, an ACE filer must submit all of the declarations required in Form FDA 2877 electronically in ACE at the time of filing entry for products subject to the standards under parts 1020–1050 of this chapter.

§ 1.78 Biological products, HCT/Ps, and related drugs and medical devices.

In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE for biological products, HCT/Ps, and related drugs and medical devices regulated by

the FDA Center for Biologics Evaluation and Research.

(a) *Product name* which identifies the article being imported or offered for import by the name commonly associated with that article including the established name, trade name, brand name, proper name, or product description if the article does not have an established name, trade name, brand name, or proper name.

(b) *HCT/P registration and affirmation.* (1) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter that is manufactured by an establishment that is required to be registered under part 1271 of this chapter, the HCT/P Registration Number; and

(2) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter, an Affirmation of Compliance with the applicable requirements of part 1271 of this chapter.

(c) *Licensed biological products.* For a biological product that is the subject of an approved biologics license application under section 351 of the Public Health Service Act, the Submission Tracking Number of the biologics license application and/or the Biologics License Number.

(d) *Drug registration.* For a drug intended for human use, the Drug Registration Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register the drug under part 207 or part 607 of this chapter as applicable. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.

(e) *Drug application number.* For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or the abbreviated new drug application.

(f) *Investigational new drug application number.* For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(g) *Medical device registration and listing.* For a medical device subject to the registration and listing procedures contained in part 807 of this chapter, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(h) *Investigational devices.* For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(i) *Medical device premarket number.* For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those

medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(j) *Medical device component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

[81 FR 85870, Nov. 29, 2016, as mended at 86 FR 17060, Apr. 1, 2021]

§ 1.79 Tobacco products.

In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE.

(a) *Brand name* of an article that is a tobacco product that is being imported or offered for import. If the article does not have a specific brand name, the ACE filer must submit a commercial name for the brand name. This data element is not applicable to those products solely intended either for further manufacturing or as investigational tobacco products.

(b) [Reserved]

§ 1.80 Cosmetics.

An ACE filer must submit the data specified in §1.72 at the time of filing entry in ACE.

§ 1.81 Rejection of entry filing.

FDA may reject an entry filing for failure to provide complete and accurate information that is required pursuant to this subpart.

Subpart E—Imports and Exports

§ 1.83 Definitions.

For the purposes of regulations prescribed under section 801(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the ''importer of record.''

(b) The term *division director* means the director of the division of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the division as he or she may designate to act on his or her behalf in administering and enforcing the provisions of section 801(a), (b), and (c).

[42 FR 15553, Mar. 22, 1977, as amended at 81 FR 85872, Nov. 29, 2016; 85 FR 50781, Aug. 18, 2020]

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the division director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the division director or U.S. Customs and Border Protection of the results of examination of the sample.

[85 FR 50781, Aug. 18, 2020]

§ 1.91 Payment for samples.

The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration division where the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in §1.95.

[42 FR 15553, Mar. 22, 1977, as amended at 85 FR 50781, Aug. 18, 2020]

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug that may be subject to destruction under section

801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the division director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

[80 FR 55242, Sept. 15, 2015, as amended at 81 FR 85873, Nov. 29, 2016; 85 FR 50781, Aug. 18, 2020]

§ 1.95 Application for authorization to relabel and recondition.

Application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

[42 FR 15553, Mar. 22, 1977, as amended at 85 FR 50781, Aug. 18, 2020]

§ 1.96 Granting of authorization to relabel and recondition.

(a) When authorization of a proposal under §1.95 is granted by the division director, the applicant shall be notified of authorization, in writing, which may include:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or U.S. Customs and Border Protection, as appropriate;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the division director may grant such additional time as he or she deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the division director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond with U.S. Customs and Border Protection and obtained a new authorization from the Food and Drug Administration division director. Any authorization granted under this section shall supersede and nullify any previously

granted authorization with respect to the article.

[42 FR 15553, Mar. 22, 1977, as amended at 54 FR 9033, Mar. 3, 1989; 85 FR 50781, Aug. 18, 2020]

§ 1.97 Bonds.

(a) The bond requirements under section 801(b) of the Federal Food, Drug, and Cosmetic Act may be satisfied by the owner or consignee executing, on the appropriate U.S. Customs and Border Protection form, a single-transaction or continuous bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of U.S. Customs and Border Protection and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with U.S. Customs and Border Protection.

(b) U.S. Customs and Border Protection may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if U.S. Customs and Border Protection receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but U.S. Customs and Border Protection shall not act under this regulation unless the Food and Drug Administration division director is in full agreement with the action.

[85 FR 50782, Aug. 18, 2020]

§ 1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801(b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his or her home station, as provided by law.

(c) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 267 percent of the hourly rate of regular pay of a grade GS–11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(d) The charge for the service of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 267 percent of the hourly rate of regular pay of a grade GS–12/4 employee. The rate per hour equal to 267 percent of the equivalent hourly rate of regular pay of the supervising officer (GS–11/4) and the analyst (GS–12/4) is computed as follows:

TABLE 1 TO PARAGRAPH (d)

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
10 legal public holidays—New Year's Day, Birthday of Martin Luther King, Jr., Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	80
Annual leave—26 d	208
Sick leave—13 d	104
Total	392

TABLE 1 TO PARAGRAPH (d)—Continued

	Hours
Net number of working hours	1,688
Gross number of working hours in 52 40-hr weeks	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½ pct. of annual rate of pay of employee	176
Equivalent annual working hours	2,256
Support required to equal to 1 person-year	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation	4,512

Note: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours 4,512/1,688 = 267 pct.

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

[42 FR 15553, Mar. 22, 1977, as amended at 85 FR 50782, Aug. 18, 2020]

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, cosmetics, and tobacco products exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.* Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, except that records pertaining to the export of foods and cosmetics under section 801(e)(1) of the act shall be kept for 3 years after the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications: The records must contain sufficient information to match the foreign purchaser's specifications to a particular export;

(2) Records demonstrating that the product does not conflict with the laws of the importing country: This may consist of either a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export: This may consist of copies of any labels or labeling statements, such as ''For export only,'' that are placed on the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials.

(c) *Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of*

the Public Health Service Act. In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biological product under section 351(h) of the Public Health Service Act shall maintain, for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records demonstrating that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Records demonstrating the distribution of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product and other records demonstrating that the exported partially processed biological product is intended for further manufacture into a final dosage form outside the United States; this may include a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biological products, and devices exported under section 802 of the act*. (1) Persons exporting a human drug, biological product, or device under section 802 of the act, other than a drug, biological product, or device for investigational use exported under section 802(c) of the act, or a drug, biological product, or device exported in anticipation of marketing authorization under section 802(d) of the act, shall provide written notification to FDA. The notification shall identify:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002.

(ii) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research—Office of Drug Security, Integrity and Response, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(iii) For devices—DRP2: Division of Establishment Support, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1423, Silver Spring, MD 20993.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act*. (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the product's lot or control number or, if the

product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

[66 FR 65447, Dec. 19, 2001, as amended at 69 FR 48774, Aug. 11, 2004; 70 FR 14980, Mar. 24, 2005; 74 FR 13112, Mar. 26, 2009; 75 FR 20914, Apr. 22, 2010; 77 FR 5176, Feb. 2, 2012; 80 FR 18090, Apr. 3, 2015; 85 FR 50782, Aug. 18, 2020]

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

SOURCE: 68 FR 58960, Oct. 10, 2003, unless otherwise noted.

GENERAL PROVISIONS

§ 1.225 Who must register under this subpart?

(a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in § 1.226.

(b) If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.

(c) If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

§ 1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

(a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;

(b) Farms;

(c) Retail food establishments;

(d) Restaurants;

(e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, ''processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

§ 1.227 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility,

traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term ''farm'' includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(*1*) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(*1*) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(*2*) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(*3*) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in

section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ''consumers'' does not include businesses. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. A ''retail food establishment'' also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, ''farm-operated business'' means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

[80 FR 56141, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2016; 81 FR 45950, July 14, 2016]

PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

§ 1.230 When must you register or renew your registration?

(a) *Registration.* You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States. You may authorize an individual to register the facility on your behalf.

(b) *Registration renewal.* You must submit a registration renewal containing the information required under §1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. You may authorize an individual to renew a facility's registration on your behalf. If the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration renewal, and identifies by name, address, and telephone number, the individual who authorized submission of the registration renewal. In addition, the registration renewal must also identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under §1.245. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option). Each electronic registration renewal must include the name of the individual submitting the renewal.

(c) *Abbreviated registration renewal process.* If you do not have any changes to the information required under §1.232 since you submitted the preceding registration, registration renewal, or update for your facility, you may use the abbreviated registration renewal process. If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under §1.232 since you submitted the preceding registration, registration renewal or update, and you must certify that the information submitted is

truthful and accurate. Each abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option). Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under §1.245. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA.

[81 FR 45950, July 14, 2016]

§ 1.231 How and where do you register or renew your registration?

(a) *Electronic registration and registration renewal.* (1) To register or renew a registration electronically, you must go to *http://www.fda.gov/furls*, which is available for registration 24 hours a day, 7 days a week. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under §1.245.

(3) After you submit your electronic registration, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's UFI as part of your electronic registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(4) For electronic registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to electronic registration renewals, after completion of the electronic registration renewal, FDA will provide an electronic confirmation of the registration renewal. For electronic registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide an electronic confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(5) For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you

update information about your U.S. agent as part of your electronic registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in §1.234.

(7) You will be considered registered once FDA electronically sends you your confirmation and registration number.

(b) *Registration or registration renewal by mail or fax.* Beginning January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted you a waiver under §1.245, you may register or renew a registration by mail or by fax.

(1) You must register or renew a registration (including abbreviated registration renewals) using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301–436–2804.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.

(5) After you submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to registration renewals, after you submit your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(6) For registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration by mail or fax, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to registration renewals, after completion of the registration renewal by mail or fax, FDA will provide a confirmation of the registration renewal. For registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(7) For a foreign facility, after you submit your registration by mail or fax, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to registration renewals, after you complete your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update information about your U.S. agent as part of your registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(8) FDA will mail or fax you a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the Agency (*i.e.*, by mail or fax).

(9) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(10) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Fees.* No registration fee is required.

(d) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

[81 FR 45950, July 14, 2016]

§ 1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

(1) The name, full address, and phone number of the facility;

(2) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;

(3) The preferred mailing address, if different from that of the facility;

(4) The name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(5) All trade names the facility uses;

(6) The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under § 1.245;

(7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;

(8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:

(i) Ambient human food storage warehouse/holding facility;

(ii) Refrigerated human food warehouse/holding facility;

(iii) Frozen human food warehouse/holding facility;

(iv) Interstate conveyance caterer/catering point;

(v) Contract sterilizer;

(vi) Labeler/relabeler;

(vii) Manufacturer/processor;

(viii) Acidified food processor;

(ix) Low-acid food processor;

(x) Farm mixed-type facility;

(xi) Packer/repacker;

(xii) Salvage operator (reconditioner);

(xiii) Animal food warehouse/holding facility;

(xiv) Other activity.

(9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by

the Federal Food, Drug, and Cosmetic Act;

(10) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA has granted a waiver under §1.245. Each registration must include the name of the individual submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address.

[81 FR 45951, July 14, 2016]

§ 1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit.

[81 FR 45952, July 14, 2016]

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* You must update a facility's registration within 60 calendar days of any change to any of the information previously submitted under §1.232 (e.g., change of operator, agent in charge, or U.S. agent), except a change of the owner. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under §1.245.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in §1.235 within 60 calendar days of the change and the new owner must submit a new registration for the facility as specified in §1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at *http://www.fda.gov/furls.*

(2) After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the electronic update, FDA will verify that the individual

identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.

(4) Your registration will be considered updated once FDA sends you your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted you a waiver under §1.245, you may update your facility's registration by mail or by fax.

(1) You must update your registration using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the Agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible updates into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax). After you submit your update by mail or fax, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide a confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration update by mail or fax, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the registration update until that individual confirms that he or she authorized the update.

(7) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(8) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

[81 FR 45952, July 14, 2016]

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* You must cancel a registration within 60 calendar days of the reason for cancellation (e.g., your facility ceases operations, ceases providing food for consumption in the United States, or is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and email address (if available) of the individual submitting the cancellation;

(5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under §1.245; and

(6) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at *http://www.fda.gov/furls.*

(2) Once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation.

(3) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(4) Your registration will be considered cancelled once FDA sends you your cancellation confirmation.

(d) *Cancellation by mail or fax.* Beginning January 4, 2020, you must cancel your registration electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted a waiver under §1.245, you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the Agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax).

(6) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system. FDA will send you your cancellation confirmation.

[81 FR 45952, July 14, 2016]

ADDITIONAL PROVISIONS

§ 1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§ 1.241 What are the consequences of failing to register, update, renew, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.

(c) FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

(d) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

[81 FR 45953, July 14, 2016]

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

§ 1.245 Waiver request.

Under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d), beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such

requirement. Under §1.232(a)(6), you must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement. In addition, under §§1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740.

[81 FR 45953, July 14, 2016]

Subpart I—Prior Notice of Imported Food

SOURCE: 73 FR 66402, Nov. 7, 2008, unless otherwise noted.

GENERAL PROVISIONS

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed.

(4) *FDA Country of Production* means: (i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(6) *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.

(7) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(8) *International mail* means foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

(9) *Manufacturer* means the last facility, as that word is defined in §1.227, that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

(10) *No longer in its natural state* means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.

(11) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

(12) *Port of entry*, in section 801(m) and (l) of the act (21 U.S.C. 381(m) and (l)), means the port of entry as defined in 19 CFR 101.1.

(13) *Registration number* means the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part.

(14) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States.

(15) *United States* means the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(16) *You* means the person submitting the prior notice, i.e., the submitter or the transmitter, if any.

[73 FR 66402, Nov. 7, 2008, as amended at 80 FR 56143, Sept. 17, 2015]

§ 1.277 What is the scope of this subpart?

(a) This subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

(b) Notwithstanding paragraph (a) of this section, this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*);

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and

(7) Articles of food subject to Article 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

§ 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by international mail:

(1) If prior notice is submitted via the Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

(2) If prior notice is submitted via the FDA Prior Notice System Interface (FDA PNSI), you may not submit prior notice more than 15-calendar days before the anticipated date of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration (e.g., CN22 or CN23 or U.S. equivalent) that accompanies the package.

(f) A copy of the confirmation, including the PN Confirmation Number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to U.S. Customs and Border Protection (CBP) or FDA upon arrival.

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

§ 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. You must submit all prior notice information in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including the items listed in the previous sentence, must be submitted using the Latin (Roman) alphabet. Unless paragraph (c) of this section applies, you must submit prior notice through:

(1) The U.S. Customs and Border Protection (CBP) Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS); or

(2) The FDA PNSI at *https://www.access.fda.gov/*. You must submit prior notice through the FDA Prior Notice System Interface (FDA PNSI) for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACE/ITDS.

(b) If a customhouse broker's or self-filer's system is not working or if the ABI/ACE/ITDS interface is not working, prior notice must be submitted through the FDA PNSI.

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at *https://www.access.fda.gov*—see log-in page. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017; 85 FR 50782, Aug. 18, 2020]

§ 1.281 What information must be in a prior notice?

(a) *General.* For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in paragraphs (a)(1) through (18) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type;

(4) The U.S. Customs and Border Protection (CBP) entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide

the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(10) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival;

(iii) The anticipated time of that arrival; and

(iv) Notwithstanding paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section, if the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the owner's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Planned shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable. This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may by submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying

an individual when entering the United States; and

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual.

(18) Any country to which the article has been refused entry.

(b) *Articles arriving by international mail.* For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in paragraphs (b)(1) through (12) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by §113.60(c) of this chapter; acidified foods, by §114.80(b) of this chapter; and infant formula, §106.90 of this chapter;

(5) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(9) The country from which the article is shipped (i.e., mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(12) Any country to which the article has been refused entry.

(c) *Refused articles.* If the article of food has been refused under section 801(m)(1) of the act and under this subpart, you must submit the information for the article that is required in paragraphs (c)(1) through (19) of this section. However, if the refusal is based on §1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to resubmit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACE/ITDS. If the refusal is based on §1.283(a)(1)(ii), you should cancel the previous submission per §1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her

business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type;

(4) The CBP entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by §113.60(c) of this chapter; acidified foods, by §114.80(b) of this chapter; and infant formula, by §106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(10) The country from which the article is shipped;

(11) Arrival information about the article of food being imported or offered for import, as follows:

(i) The port of arrival; and

(ii) The date on which the article of food arrived at the port of arrival.

(iii) Notwithstanding paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section, if the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner, if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a

registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The SCAC or IATA code of the carrier which carried the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable; however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States; and

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

(19) Any country to which the article has been refused entry.

[73 FR 66402, Nov. 7, 2008, as amended at 76 FR 25545, May 5, 2011; 82 FR 15629, Mar. 30, 2017]

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a), except the information required in:

(i) Section 1.281(a)(5)(iii) (quantity),

(ii) Section 1.281(a)(11) (anticipated arrival information), or

(iii) Section 1.281(a)(17) (planned shipment information), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PNSI, you should cancel the prior notice via the FDA PNSI.

(c) If you submitted the prior notice via ABI/ACE/ITDS, you should cancel the prior notice via ACE by requesting that CBP cancel the entry.

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

CONSEQUENCES

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice.* If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless U.S. Customs and Border Protection (CBP) concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice.* If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act. If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice.* If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food.* (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(ii) Refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at that port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(3) *Segregation of refused foods.* If an article of food that is refused is part of a shipment that contains articles of food that have not been placed under hold or other merchandise not subject to this subpart, the refused article of food may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs.* Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal.* An article of food that has been refused under paragraph (a) of this section may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under paragraph (a) of this section is exported, the prior notice should be cancelled within 5-business days of exportation.

(6) *No post-refusal submission or request for review.* If an article of food is refused under section 801(m)(1) of the act

and no prior notice is submitted or resubmitted, no request for FDA review is submitted in accordance with paragraph (d) of this section, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(b) *Food carried by or otherwise accompanying an individual.* If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the prior notice (PN) confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual does not arrange to have the food held at the port or exported, FDA or CBP may destroy the article of food.

(c) *Post-Refusal prior notice submissions.* (1) If an article of food is refused under paragraph (a)(1)(i) of this section (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§1.280 and 1.281(c).

(2) If an article of food is refused under paragraph (a)(1)(ii) of this section (inaccurate prior notice) and the food is not exported, the prior notice should be canceled in accordance with §1.282 and you must resubmit prior notice in accordance with §§1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in §1.279.

(d) *FDA review after refusal.* (1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under §1.277, or whether the information submitted in a prior notice is complete and accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5-calendar days of the refusal. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under §1.277 or that the prior notice submission is complete and accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) *International mail.* If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the act and there is a return address, the parcel may be returned to sender marked ''No Prior Notice—FDA Refused.'' If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food

is no longer refused admission under section 801(m)(1) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or other designated secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions.* A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 801(m)(1) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m) of the act, including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under sections 301 and 303 of the act (21 U.S.C. 331 and 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

(a) *Consequences.* If an article of food from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H of this part is imported or offered for import into the United States, the food is subject to being held under section 801(l) of the act (21 U.S.C. 381(l)).

(b) *Hold.* Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food has been placed under hold under section 801(l) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food.* (1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) of the act must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at the port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(d) *Segregation of held foods.* If an article of food that has been placed under

hold under section 801(l) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs.* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after hold.* An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No registration or request for review.* If an article of food is placed under hold under section 801(l) of the act and no registration number or request for FDA review is submitted in accordance with paragraph (j) of this section or export has not occurred in accordance with paragraph (f) of this section, the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(h) *Food carried by or otherwise accompanying an individual.* If an article of food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) *Post-hold submissions.* (1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(2) The FDA Division of Food Defense Targeting must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by fax or e-mail. The contact information for these delivery methods is listed at *http://www.fda.gov*—see Prior Notice. The notification should include the applicable CBP entry identifier.

(3) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(j) *FDA review after hold.* (1) If an article of food has been placed under hold under section 801(l) of the act, a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5-calendar days of the hold. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415 of the act, it will notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) *International mail.* If an article of food that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is placed under hold under section 801(l) of the act and there

is a return address, the parcel may be returned to sender marked ''No Registration—No Admission Permitted.'' If the article is under hold and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender marked ''No Registration—No Admission Permitted'' or, if there is no return address, destroy the parcel, at FDA expense.

(l) *Prohibitions on delivery and transfer.* Notwithstanding section 801(b) of the act, while an article of food is under hold under section 801(l) of the act, it may not be delivered to the importer, owner, or ultimate consignee. If an article of food is no longer subject to hold under section 801(l) of the act, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

Subpart J—Establishment, Maintenance, and Availability of Records

SOURCE: 69 FR 71651, Dec. 9, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in §1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in §1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, ''processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in §1.345 to establish and maintain

records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Farm means:

(1) *Primary production farm.* A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of

crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term ''farm'' includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(*1*) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(*1*) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(*2*) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(*3*) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of,

and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging (when used as a noun) means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

[69 FR 71651, Dec. 9, 2004, as amended at 80 FR 56143, Sept. 17, 2015; 81 FR 3715, Jan. 22, 2016]

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE PREVIOUS SOURCES OF FOOD

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE SUBSEQUENT RECIPIENTS OF FOOD

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

REQUIREMENTS FOR TRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;
(5) Description of freight;
(6) Route of movement and name of each carrier participating in the transportation; and
(7) Transfer points through which shipment moved; or
(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:
(1) Date received;
(2) Received from;
(3) Consigned to;
(4) Destination;
(5) State of;
(6) County of;
(7) Route;
(8) Delivering carrier;
(9) Car initial;
(10) Car no;
(11) Trailer initials/number;
(12) Container initials/number;
(13) No. packages; and
(14) Description of articles; or
(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:
(1) Shipper's name and address;
(2) Consignee's name and address;
(3) Customs reference/status;
(4) Airport of departure and destination;
(5) First carrier; and
(6) Description of goods; or
(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in §1.352(a), (b), (c), or (d). The agreement must contain the following elements:
(1) Effective date;
(2) Printed names and signatures of authorized officials;
(3) Description of the records to be established and/or maintained;
(4) Provision for the records to be maintained in compliance with §1.360, if the agreement provides for maintenance of records;
(5) Provision for the records to be available to FDA as required by §1.361, if the agreement provides for maintenance of records;
(6) Acknowledgement that the nontransporter assumes legal responsibility under §1.363 for establishing and/or maintaining the records as required by this subpart; and
(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

GENERAL REQUIREMENTS

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.
(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.
(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.
(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.
(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

[77 FR 10662, Feb. 23, 2012]

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

[80 FR 56144, Sept. 17, 2015

COMPLIANCE DATES

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is

determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2006, for small businesses employing fewer that 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

[69 FR 71651, Dec. 9, 2004, as amended at 70 FR 8727, Feb. 23, 2005]

Subpart K—Administrative Detention of Food for Human or Animal Consumption

SOURCE: 69 FR 31701, June 4, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA Division Director in whose division the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

[76 FR 25541, May 5, 2011]

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10-calendar day detention period at the time the detention order is issued, or at any time within the 20-calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with §1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order under §1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under §1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under §1.393 is a prohibited act under section 301 of the act (21 U.S.C. 331).

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act (21 U.S.C. 334(h)), it may not be delivered to any of its importers, owners, or consignees. This section does not preclude movement at FDA's direction of imported food to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under §1.384 or the detention period expires under §1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

(2) To move the detained article of food to a secure facility under the terms of a detention order,

(3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for modification of the detention order in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting modification of a detention order for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

(e) If FDA approves a request for modification of a detention order, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained

article, you must immediately notify in writing the authorized FDA representative who approved the modification of the detention order that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax, e-mail, or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under §1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative who approves the modification of a detention order under this section.

(g) The transfer of an article of food in violation of a detention order issued under §1.393 is a prohibited act under section 301 of the act.

§1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under §1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the DOJ of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How Does FDA Order a Detention?

§1.391 Who approves a detention order?

An authorized FDA representative must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has reason to believe that such article of food is adulterated or misbranded.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381(c);

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, email address, fax number, and the name of the FDA Division Director in whose division the detained article of food is located;

(13) A statement indicating the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing; and

(14) The name and the title of the authorized FDA representative who approved the detention order.

[69 FR 31701, June 4, 2004, as amended at 76 FR 25541, May 5, 2011; 85 FR 16550, Mar. 24, 2020]

WHAT IS THE APPEAL PROCESS FOR A DETENTION ORDER?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA Division Director in whose division the detained article of food is located, at the mailing address, email address, or fax number identified in the detention order according to the following applicable timeframes:

(1) *Perishable food:* If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) *Nonperishable food:* If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not

filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(b) A request for a hearing under this section must be addressed to the FDA Division Director in whose division the article of food involved is located;

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart;

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart;

(e) Section 1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information;

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart;

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 calendar day, as appropriate;

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

(j) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart,

the administrative record of the hearing specified in §§16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under §10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

[69 FR 31701, June 4, 2004, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16550, Mar. 24, 2020]

§ 1.404 Who serves as the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16550, Mar. 24, 2020]

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under §1.403(h), the presiding officer must issue a final decision within the 5-calendar day period after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-calendar day period, the detention order is deemed terminated.

(b) If you appeal the detention order, but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under §1.384 or the detention period expires under §1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under §1.384.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security (''classified information''), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

Subpart L—Foreign Supplier Verification Programs for Food Importers

SOURCE: 80 FR 74340, Nov. 27, 2015, unless otherwise noted.

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in

keeping with good public health practice.

Audit means the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm means farm as defined in § 1.227.

Farm mixed-type facility means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Good compliance standing with a foreign food safety authority means that the foreign supplier—

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting applies to applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by §1.506(e)(1)(i) or §1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer means:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee).

You means a person who is subject to some or all of the requirements in this subpart.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.501 To what foods do the requirements in this subpart apply?

(a) *General.* Except as specified otherwise in this section, the requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) *Exemptions for juice and seafood—*(1) *Importers of certain juice and seafood products.* This subpart does not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under §120.14 or §123.12 of this chapter, respectively.

(2) *Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter.* This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) *Exemption for food imported for research or evaluation.* This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public;

(2) Is labeled with the statement ''Food for research or evaluation use'';

(3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) *Exemption for food imported for personal consumption.* This subpart does not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(e) *Exemption for alcoholic beverages.* (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with §117.5(i) of this chapter.

(f) *Inapplicability to food that is transshipped or imported for processing and export.* This subpart does not apply to food:

(1) That is transshipped through the United States to another country and is not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) *Inapplicability to U.S. food returned.* This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

(h) *Inapplicability to certain meat, poultry, and egg products.* This subpart does not apply with respect to:

(1) Meat food products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(2) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(3) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) *General.* Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) *Low-acid canned foods*—(1) *Importers of low-acid canned foods not subject to further manufacturing or processing.* With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) *Certain importers of raw materials or other ingredients subject to part 113 of this chapter.* With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

(a) *Qualified individual.* A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

(b) *Qualified auditor.* A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical expertise obtained

through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

§ 1.504 What hazard analysis must I conduct?

(a) *Requirement for a hazard analysis.* Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and

(iii) Physical hazards (such as stones, glass, and metal fragments).

(2) Your analysis must include known or reasonably foreseeable hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of natural toxins).

(d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) *Hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable that is ''covered produce'' as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological

hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) *No hazards requiring a control.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under §1.505 and you are not required to conduct foreign supplier verification activities under §1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is ''covered produce'' as defined in §112.3 of this chapter.

§1.505 What evaluation for foreign supplier approval and verification must I conduct?

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with §1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

(A) The foreign supplier's procedures, processes, and practices related to the safety of the food;

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) *Reevaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under §1.506 or §1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent

actions you take in accordance with paragraph (c)(1).

(d) *Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) *Inapplicability to certain circumstances.* You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under §1.506 if one of the circumstances described in §1.507 applies to your importation of a food and you are in compliance with that section.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) *Use of approved foreign suppliers.* (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under §1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) *Requirement of supplier verification.* The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) *Determination of appropriate foreign supplier verification activities*—(1)(i) *General.* Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (*e.g.*, when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (e)(1)(i) of this section;

(B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

(2) *Verification activities for certain serious hazards.* When a hazard in a food will be controlled by the foreign supplier and is one for which there is a

reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities listed in paragraph (d)(1)(ii) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with paragraph (c) of this section, based on the determination made under §1.505.

(3) *Reliance on a determination by another entity*. You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) *Performance of foreign supplier verification activities*—(1) *Verification activities*. Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

(i) *Onsite audit of the foreign supplier*. (A) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(D) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(*1*) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(*2*) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(ii) *Sampling and testing of the food*. You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on

which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(iii) *Review of the foreign supplier's relevant food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* (A) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(2) *Reliance upon performance of activities by other entities.* (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with §1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with §1.510(b).

(4) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of this section, and payment must not be related to the results of the activity.

§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

(a) *Circumstances.* You are not required to conduct an evaluation of a food and foreign supplier under §1.505 or supplier verification activities under §1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (*e.g.*, raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food

is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard;

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(*1*) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507); or

(*2*) Obtain a similar written assurance from the entity's customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) *Written assurances.* Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) *Provision of assurances.* The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 1.508 What corrective actions must I take under my FSVP?

(a) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under §1.506 or §1.511(c), a reevaluation of the risks posed by the food and the foreign

supplier's performance conducted under §1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under §1.506 or §1.511(c) or a reevaluation conducted under §1.505(c) or (d), that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(c) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§1.509 How must the importer be identified at entry?

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of ''importer'' in §1.500.

§1.510 How must I maintain records of my FSVP?

(a) *General requirements for records.* (1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(2) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(3) All records must be legible and stored to prevent deterioration or loss.

(b) *Record availability.* (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) *Record retention.* (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after their use is discontinued (*e.g.*, because you no longer import a particular food, you no longer use a particular foreign supplier, you

have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) *Use of existing records.* (1) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

§ 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?

(a) *Importers subject to certain requirements in the dietary supplement current good manufacturing practice regulation.* If you are required to establish specifications under §111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§111.73 and 111.75 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§1.503 and 1.509, but you are not required to comply with the requirements in §1.502, §§1.504 through 1.508, or §1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) *Importers whose customer is subject to certain requirements in the dietary supplement current good manufacturing practice regulation.* If your customer is required to establish specifications under §111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, your customer is in compliance with the requirements of §§111.73 and 111.75 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§1.503, 1.509, and 1.510, but you are not required to comply with the requirements in §1.502 or §§1.504 through 1.508.

(c) *Other importers of dietary supplements*—(1) *General.* If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the evaluation conducted under §1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before

importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) *Determination of appropriate foreign supplier verification activities*—(i) *General.* Except as provided in paragraph (c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under §1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;

(B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) *Reliance upon determination by other entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with §1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) *Performance of foreign supplier verification activities.* (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) *Onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(*1*) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(*2*) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(*3*) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(*4*) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(*5*) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(*i*) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(*ii*) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(B) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(C) *Review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) *Other appropriate activity.* (*1*) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(*2*) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(*1*) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(ii) *Reliance upon performance of activities by other entities.* (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with §1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with §1.510(b).

(iv) *Independence of qualified individuals conducting verification activities.*

There must not be any financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?

(a) *Eligibility*. This section applies only if:

(1) You are a very small importer; or

(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) *Applicable requirements*—(1) *Documentation of eligibility*—(i) *Very small importer status*. (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) *Small foreign supplier status*. If you are a importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(2) *Additional requirements*. If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

(3) *Foreign supplier verification activities*. (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent

to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with §112.4(a) of this chapter, or in accordance with §§112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the shell eggs and at least every 2 years thereafter, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(4) *Corrective actions.* You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with the assurance provided in accordance with §1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) *Records*—(i) *General requirements for records.* (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(B) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(C) All records must be legible and stored to prevent deterioration or loss.

(ii) *Availability.* (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) *Record retention.* (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records

that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (*e.g.*, because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer.

(iv) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(v) *Use of existing records.* (A) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(vi) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) *Requirements for importers of food from certain small foreign suppliers.* The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) *Evaluation of foreign supplier compliance history*—(i) *Initial evaluation.* Except as specified in paragraph (c)(1)(iii) of this section, in approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in §1.505(a)(1)(iii)(A) and (C).

(ii) *Reevaluation of foreign supplier compliance history.* (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) *Review of another entity's evaluation or reevaluation of foreign supplier compliance history.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the

evaluation or reevaluation was conducted by a qualified individual.

(2) *Approval of foreign supplier.* You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

(a) *General.* (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§1.504 through 1.508. You would still be required to comply with the requirements in §§1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(b) *Conditions and requirements.* (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph (b)(2).

§ 1.514 What are some consequences of failing to comply with the requirements of this subpart?

(a) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with §1.500.

(b) *Prohibited act.* The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

Subpart M—Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

SOURCE: 80 FR 74650, Nov. 27, 2015, unless otherwise noted.

§ 1.600 What definitions apply to this subpart?

(a) The *FD&C Act* means the Federal Food, Drug, and Cosmetic Act.

(b) Except as otherwise defined in paragraph (c) of this section, the definitions of terms in section 201 of the FD&C Act apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of this subpart.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of this subpart.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Audit means the systematic and functionally independent examination of an eligible entity under this subpart by an accredited third-party certification body or by FDA. An audit conducted under this subpart is not considered an inspection under section 704 of the FD&C Act.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of this part.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food certification means an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

Foreign cooperative means an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and

(ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

Relinquishment means:

(i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and

(ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-

party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

§ 1.601 Who is subject to this subpart?

(a) *Accreditation bodies.* Any accreditation body seeking recognition from FDA to accredit third-party certification bodies to conduct food safety audits and to issue food and facility certifications under this subpart.

(b) *Third-party certification bodies.* Any third-party certification body seeking accreditation from a recognized accreditation body or direct accreditation by FDA for:

(1) Conducting food safety audits; and

(2) Issuing certifications that may be used in satisfying a condition of admissibility of an article of food under section 801(q) of the FD&C Act; or issuing a facility certification for meeting the eligibility requirements for the Voluntary Qualified Importer Program under section 806 of the FD&C Act.

(c) *Eligible entities.* Any eligible entity seeking a food safety audit or a food or facility certification from an accredited third-party certification body under this subpart.

(d) *Limited exemptions from section 801(q) of the FD&C Act*—(1) *Alcoholic beverages.* (i) Any certification required under section 801(q) of the FD&C Act does not apply with respect to alcoholic beverages from an eligible entity that is a facility that meets the following two conditions:

(A) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(B) Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(ii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to food that is not an alcoholic beverage that is received and distributed by a facility described in paragraph (d)(1)(i) of this section, provided such food:

(A) Is received and distributed in prepackaged form that prevents any direct human contact with such food; and

(B) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(iii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to raw materials or other ingredients that are imported for use in alcoholic beverages provided that:

(A) The imported raw materials or other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(B) Such manufacturing/processing, packing, or holding is performed by the importer;

(C) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(D) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i).

(2) *Certain meat, poultry, and egg products.* Any certification required under section 801(q) of the FD&C Act does not apply with respect to:

(i) Meat food products that at the time of importation are subject to the requirements of the United States Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(ii) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(iii) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

RECOGNITION OF ACCREDITATION BODIES UNDER THIS SUBPART

§ 1.610 Who is eligible to seek recognition?

An accreditation body is eligible to seek recognition by FDA if it can demonstrate that it meets the requirements of §§ 1.611 through 1.615. The accreditation body may use documentation of conformance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, supplemented as necessary, in meeting the applicable requirements of this subpart.

§ 1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

§ 1.612 What competency and capacity must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) The resources required to adequately implement its accreditation program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively evaluate the qualifications of third-party certification bodies seeking accreditation and to effectively monitor the performance of accredited third-party certification bodies; and

(2) Adequate financial resources for its operations; and

(b) The capability to meet the applicable assessment and monitoring requirements, the reporting and notification requirements, and the procedures of this subpart, if recognized.

§ 1.613 What protections against conflicts of interest must an accreditation body have to qualify for recognition?

An accreditation body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation

from, or accredited by, such accreditation body; and

(b) The capability to meet the applicable conflict of interest requirements of this subpart, if recognized.

§ 1.614 What quality assurance procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents and its accreditation program, including procedures to:

(1) Identify areas in its accreditation program or performance where deficiencies exist; and

(2) Quickly execute corrective actions that effectively address deficiencies when identified; and

(b) The capability to meet the applicable quality assurance requirements of this subpart, if recognized.

§ 1.615 What records procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for the period of time necessary to meet its contractual and legal obligations pertaining to this subpart and to provide an adequate basis for evaluating its program and performance; and

(b) The capability to meet the applicable reporting and notification requirements of this subpart, if recognized.

Requirements for Accreditation Bodies That Have Been Recognized Under This Subpart

§ 1.620 How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation?

(a) Prior to accrediting a third-party certification body under this subpart, a recognized accreditation body must perform, at a minimum, the following:

(1) In the case of a foreign government or an agency of a foreign government, such reviews and audits of the government's or agency's food safety programs, systems, and standards as are necessary to determine that it meets the eligibility requirements of § 1.640(b).

(2) In the case of a foreign cooperative or any other third-party seeking accreditation as a third-party certification body, such reviews and audits of the training and qualifications of agents conducting audits for such cooperative or other third party (or in the case of a third-party certification body that is an individual, such individual) and such reviews of internal systems and any other investigation of the cooperative or other third party necessary to determine that it meets the eligibility requirements of § 1.640(c).

(3) In conducting a review and audit under paragraph (a)(1) or (2) of this section, an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the third-party certification body or its agents (or, in the case of a third-party certification body that is an individual, such individual).

(b) A recognized accreditation body must require a third-party certification body, as a condition of accreditation under this subpart, to comply with the reports and notification requirements of §§ 1.652 and 1.656 and to agree to submit to FDA, electronically and in English, any food or facility certifications it issues for purposes of sections 801(q) or 806 of the FD&C Act.

(c) A recognized accreditation body must maintain records on any denial of accreditation (in whole or in part) and on any withdrawal, suspension, or reduction in scope of accreditation of a third-party certification body under this subpart. The records must include the name and contact information for the third-party certification body; the date of the action; the scope of accreditation denied, withdrawn, suspended, or reduced; and the basis for such action.

(d) A recognized accreditation body must notify any third-party certification body of an adverse decision associated with its accreditation under

this subpart, including denial of accreditation or the withdrawal, suspension, or reduction in the scope of its accreditation. The recognized accreditation body must establish and implement written procedures for receiving and addressing appeals from any third-party certification body challenging such an adverse decision and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§1.692 and 1.693, and include requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not participated in the accreditation decision or be subordinate to a person who has participated in the accreditation decision to investigate and decide appeals;

(3) Advise third-party certification bodies of the final decisions on their appeals; and

(4) Maintain records under §1.625 of appeals, final decisions on appeals, and the bases for such decisions.

§ 1.621 How must a recognized accreditation body monitor the performance of third-party certification bodies it accredited?

(a) A recognized accreditation body must annually conduct a comprehensive assessment of the performance of each third-party certification body it accredited under this subpart by reviewing the accredited third-party certification body's self-assessments (including information on compliance with the conflict of interest requirements of §§1.643 and 1.657); its regulatory audit reports and notifications submitted to FDA under §1.656; and any other information reasonably available to the recognized accreditation body regarding the compliance history of eligible entities the accredited third-party certification body certified under this subpart; or that is otherwise relevant to a determination whether the accredited third-party certification body is in compliance with this subpart.

(b) No later than 1 year after the initial date of accreditation of the third-party certification body and every 2 years thereafter for duration of its accreditation under this subpart, a recognized accreditation body must conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents) (or, in the case of a third-party certification body that is an individual, such individual) accredited under this subpart and must visit the accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters). The recognized accreditation body will consider the results of such observations and visits in the annual assessment of the accredited third-party certification body required by paragraph (a) of this section.

§ 1.622 How must a recognized accreditation body monitor its own performance?

(a) A recognized accreditation body must annually, and as required under §1.664(g), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in accreditation activities and the degree of consistency in conducting accreditation activities;

(2) The compliance of the recognized accreditation body and its officers, employees, and other agents involved in accreditation activities, with the conflict of interest requirements of §1.624; and

(3) If requested by FDA, any other aspects of its performance relevant to a determination whether the recognized accreditation body is in compliance with this subpart.

(b) As a means to evaluate the recognized accreditation body's performance, the self-assessment must include onsite observation of regulatory audits of a representative sample of third-party certification bodies it accredited under this subpart. In meeting this requirement, the recognized accreditation body may use the results of onsite observations performed under §1.621(b).

(c) Based on the evaluations conducted under paragraphs (a) and (b) of this section, the recognized accreditation body must:

(1) Identify any area(s) where deficiencies exist;

(2) Quickly implement corrective action(s) that effectively address those deficiencies; and

(3) Establish and maintain records of any such corrective action(s) under § 1.625.

(d) The recognized accreditation body must prepare, and as required by § 1.623(b) submit, a written report of the results of its self-assessment that includes the following elements. Documentation of conformance to ISO/IEC 17011:2004 may be used, supplemented as necessary, in meeting the requirements of this paragraph.

(1) A description of any corrective actions taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the recognized accreditation body, and its officers, employees, and other agents involved in accreditation activities, complied with the conflict of interest requirements in § 1.624; and

(3) A statement attesting to the extent to which the recognized accreditation body complied with applicable requirements of this subpart.

§ 1.623 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *Reporting results of assessments of accredited third-party certification body performance.* A recognized accreditation body must submit to FDA electronically, in English, a report of the results of any assessment conducted under § 1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited third-party certification body to conduct food safety audits under this subpart.

(b) *Reporting results of recognized accreditation body self-assessments.* A recognized accreditation body must submit to FDA electronically, in English:

(1) A report of the results of an annual self-assessment required under § 1.622, no later than 45 days after completing such self-assessment; and

(2) For a recognized accreditation body subject to § 1.664(g)(1), a report of such self-assessment to FDA within 60 days of the third-party certification body's withdrawal. A recognized accreditation body may use a report prepared for conformance to ISO/IEC 17011:2004, supplemented as necessary, in meeting the requirements this section.

(c) *Immediate notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, immediately upon:

(1) Granting (including expanding the scope of) accreditation to a third-party certification body under this subpart, and include:

(i) The name, address, telephone number, and email address of the accredited third-party certification body;

(ii) The name of one or more officers of the accredited third-party certification body;

(iii) A list of the accredited third-party certification body's audit agents; and

(iv) The scope of accreditation, the date on which it was granted, and its expiration date.

(2) Withdrawing, suspending, or reducing the scope of an accreditation under this subpart, and include:

(i) The basis for such action; and

(ii) Any additional changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(3) Determining that a third-party certification body it accredited failed to comply with § 1.653 in issuing a food or facility certification under this subpart, and include:

(i) The basis for such determination; and

(ii) Any changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(d) *Other notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, within 30 days after:

(1) Denying accreditation (in whole or in part) under this subpart and include:

(i) The name, address, telephone number, and email address of the third-party certification body;

(ii) The name of one or more officers of the third-party certification body;

(iii) The scope of accreditation requested; and

(iv) The scope and basis for such denial.

(2) Making any significant change that would affect the manner in which it complies with the applicable requirements of this subpart and include:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.624 How must a recognized accreditation body protect against conflicts of interest?

(a) A recognized accreditation body must implement a written program to protect against conflicts of interest between the recognized accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such recognized accreditation body, including the following:

(1) Ensuring that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control the third-party certification body (or any affiliate, parent, or subsidiary); and

(2) Prohibiting officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or item of value from the third-party certification body.

(3) The items specified in paragraph (a)(2) of this section do not include:

(i) Money representing payment of fees for accreditation services and reimbursement of direct costs associated with an onsite assessment of the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an assessment and on the premises where the assessment is conducted, if necessary to facilitate the efficient conduct of the assessment.

(b) A recognized accreditation body may accept the payment of fees for accreditation services and the reimbursement of direct costs associated with assessment of a certification body only after the date on which the report of such assessment was completed or the date of which the accreditation was issued, whichever comes later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities will be considered the financial interests of such officers, employees, and other agents involved in accreditation activities.

(d) A recognized accreditation body must maintain on its Web site an up-to-date list of the third-party certification bodies it accredited under this subpart and must identify the duration and scope of each accreditation and the date(s) on which the accredited third-party certification body paid any fee or reimbursement associated with such accreditation. If the accreditation of a certification body is suspended, withdrawn, or reduced in scope, this list must also include the date of suspension, withdrawal, or reduction in scope and maintain that information for the duration of accreditation or until the suspension is lifted, the certification body is reaccredited, or the scope of accreditation is reinstated, whichever comes first.

§ 1.625 What records requirements must an accreditation body that has been recognized meet?

(a) An accreditation body that has been recognized must maintain electronically for 5 years records created while it is recognized (including documents and data) demonstrating its compliance with this subpart, including records relating to:

(1) Applications for accreditation and renewal of accreditation under § 1.660;

(2) Decisions to grant, deny, suspend, withdraw, or expand or reduce the scope of an accreditation;

(3) Challenges to adverse accreditation decisions under § 1.620(c);

(4) Its monitoring of accredited third-party certification bodies under § 1.621;

(5) Self-assessments and corrective actions under § 1.622;

(6) Regulatory audit reports, including any supporting information, that an accredited third-party certification body may have submitted;

(7) Any reports or notifications to FDA under § 1.623, including any supporting information; and

(8) Records of fee payments and reimbursement of direct costs.

(b) An accreditation body that has been recognized must make records required by paragraph (a) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accreditation body or at a reasonably accessible location. If the records required by paragraph (a) of this section are requested by FDA electronically, the records must be submitted to FDA electronically not later than 10 business days after the date of the request. Additionally, if the requested records are maintained in a language other than English, the accreditation body must electronically submit an English translation within a reasonable time.

(c) An accreditation body that has been recognized must not prevent or interfere with FDA's access to its accredited third-party certification bodies and the accredited third-party certification body records required by § 1.658.

PROCEDURES FOR RECOGNITION OF ACCREDITATION BODIES UNDER THIS SUBPART

§ 1.630 How do I apply to FDA for recognition or renewal of recognition?

(a) *Applicant for recognition.* An accreditation body seeking recognition must submit an application demonstrating that it meets the eligibility requirements in § 1.610.

(b) *Applicant for renewal of recognition.* An accreditation body seeking renewal of its accreditation must submit a renewal application demonstrating that it continues to meet the requirements of this subpart.

(c) *Submission.* Recognition and renewal applications and any documents provided as part of the application process must be submitted electronically, in English. An applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during onsite assessments of the applicant by FDA.

(d) *Signature.* Recognition and renewal applications must be signed in the manner designated by FDA, by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.631 How will FDA review my application for recognition or renewal of recognition and what happens once FDA decides on my application?

(a) *Review of recognition or renewal application.* FDA will examine an accreditation body's recognition or renewal application for completeness and notify the applicant of any deficiencies. FDA will review an accreditation body's recognition or renewal application on a first in, first out basis according to the date on which the completed application was submitted; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of recognition or renewal.* FDA will evaluate any completed recognition or renewal application to determine whether the applicant meets the applicable requirements of this subpart. Such evaluation may include an onsite assessment of the accreditation body. FDA will notify the applicant, in writing, regarding whether the application has been approved or denied. FDA may make such notification electronically. If FDA does not reach a final decision on a renewal application before an accreditation body's recognition terminates by expiration, FDA may extend such recognition for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Issuance of recognition.* FDA will notify an applicant that its recognition or renewal application has been approved through issuance of recognition that will list any limitations associated with the recognition.

(d) *Issuance of denial of recognition or renewal application.* FDA will notify an applicant that its recognition or renewal application has been denied

through issuance of a denial of recognition or denial of a renewal application that will state the basis for such denial and provide the procedures for requesting reconsideration of the application under §1.691.

(e) *Notice of records custodian after denial of an application for renewal of recognition.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by §1.625(a) and make them available to FDA as required by §1.625(b). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by §1.625(a) will be located.

(f) *Effect of denial of an application for renewal of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the denial of a recognition renewal to any third-party certification bodies accredited by the accreditation body whose renewal application was denied. The third-party certification body's accreditation will remain in effect so long as the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of the denial of recognition renewal, conducts a self-assessment under §1.655 and reports the results of the self-assessment to FDA under §1.656(b); and

(ii) No later than 1 year after issuance of the notice of denial of recognition renewal or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under §1.664(c).

(g) *Effect of denial of an application for renewal of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of a denial of the renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in the voluntary qualified importer program (VQIP).

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide notice on the Web site described in §1.690 of the date of issuance of a denial of a renewal application and will describe the basis for the denial.

§ 1.632 What is the duration of recognition?

FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition.

§ 1.633 How will FDA monitor recognized accreditation bodies?

(a) FDA will evaluate the performance of each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment must occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. FDA may conduct additional assessments of a recognized accreditation body at any time.

(b) An FDA assessment of a recognized accreditation body may include onsite assessments of a representative sample of third-party certification bodies the recognized accreditation body accredited and onsite audits of a representative sample of eligible entities certified by such third-party certification bodies under this subpart. These may be conducted at any time and, as FDA determines necessary or appropriate, may occur without the recognized accreditation body or, in the case of an audit of an eligible entity, the accredited third-party certification body present.

§ 1.634 When will FDA revoke recognition?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body found not to be in compliance with the requirements of this subpart, including for any one or more of the following:

(1) Refusal by the accreditation body to allow FDA to access records required by § 1.625, or to conduct an assessment or investigation of the accreditation body or of a third-party certification body it accredited to ensure the accreditation body's continued compliance with the requirements of this subpart.

(2) Failure to take timely and necessary corrective action when:

(i) The accreditation of a third-party certification body it accredited is withdrawn by FDA under § 1.664(a);

(ii) A significant deficiency is identified through self-assessment under § 1.622, monitoring under § 1.621, or self-assessment by one or more of its accredited third-party certification bodies under § 1.655; or

(iii) Directed to do so by FDA to ensure compliance with this subpart.

(3) A determination by FDA that the accreditation body has committed fraud or has submitted material false statements to the Agency.

(4) A determination by FDA that there is otherwise good cause for revocation, including:

(i) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(ii) Failure to adequately support one or more decisions to grant accreditation under this subpart.

(iii) Failure to pay the annual user fee within 90 days of the payment due date, as specified in § 1.725(b)(3).

(b) *Records request associated with revocation.* To assist in determining whether revocation is warranted under paragraph (a) of this section, FDA may request records of the accreditation body required by § 1.625 or the records, required by § 1.658, of one or more of the third-party certification bodies it accredited under this subpart.

(c) *Issuance of revocation of recognition.* (1) FDA will notify an accreditation body that its recognition has been revoked through issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under § 1.693 on the revocation, and the procedures for requesting reinstatement of recognition under § 1.636.

(2) Within 10 business days of the date of issuance of the revocation, the accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain the records and make them available to FDA as required by § 1.625. The contact information for the custodian must provide, at a minimum, an email address and the physical address where the records will be located.

(d) *Effect of revocation of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the revocation of recognition to any accredited third-party certification body accredited by the accreditation body whose recognition was revoked. The third-party certification body's accreditation will remain in effect if the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of revocation, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after issuance of the notice of the revocation, or the original date of expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(e) *Effect of revocation of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of the revocation of recognition will remain in effect until the certificate terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse

to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(f) *Public notice of revocation of recognition.* FDA will provide notice on the Web site described in §1.690 of the issuance of the revocation of recognition of an accreditation body and will describe the basis for revocation.

[80 FR 74650, Nov. 27, 2015, as amended at 81 FR 90193, Dec. 14, 2016]

§ 1.635 What if I want to voluntarily relinquish recognition or do not want to renew recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* A recognized accreditation body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing recognition or before allowing recognition to expire without seeking renewal. The recognized accreditation body must provide the name and contact information of the custodian who will maintain the records required under §1.625(a) after the date of relinquishment or the date recognition expires, as applicable, and make them available to FDA as required by §1.625(b). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by §1.625(a) will be located.

(b) *Notice to accredited third-party certification bodies of intent to relinquish or not to renew recognition.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the recognized accreditation body must notify any currently accredited third-party certification body that it intends to relinquish recognition or to allow its recognition to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under §1.625.

(c)(1) *Effect of voluntary relinquishment or expiration of recognition on third-party certification bodies.* The accreditation of a third-party certification body issued prior to the relinquishment or expiration of its accreditation body's recognition will remain in effect, so long as the third-party certification body:

(i) No later than 60 days after the date of relinquishment or the date of expiration of the recognition, conducts a self-assessment under §1.655 and reports the results of the self-assessment to FDA under §1.656(b); and

(ii) No later than 1 year after the date of relinquishment or the date of expiration of recognition, or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under §1.664(c).

(d) *Effect of voluntary relinquishment or expiration of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to relinquishment or expiration of its recognition will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(e) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the Web site described in §1.690 of the voluntary relinquishment or expiration of recognition of an accreditation body under this subpart.

§ 1.636 How do I request reinstatement of recognition?

(a) *Application following revocation.* An accreditation body that has had its recognition revoked may seek reinstatement by submitting a new application for recognition under §1.630. The accreditation body must submit evidence that the grounds for revocation

have been resolved, including evidence addressing the cause or conditions that were the basis for revocation and identifying measures that have been implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

(b) *Application following relinquishment.* An accreditation body that previously relinquished its recognition under §1.635 may seek recognition by submitting a new application for recognition under §1.630.

ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.640 Who is eligible to seek accreditation?

(a) A foreign government, agency of a foreign government, foreign cooperative, or any other third party may seek accreditation from a recognized accreditation body (or, where direct accreditation is appropriate, FDA) to conduct food safety audits and to issue food and facility certifications to eligible entities under this subpart. An accredited third-party certification body may use documentation of conformance with ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012, supplemented as necessary, in meeting the applicable requirements of this subpart.

(b) A foreign government or an agency of a foreign government is eligible for accreditation if it can demonstrate that its food safety programs, systems, and standards meet the requirements of §§1.641 through 1.645.

(c) A foreign cooperative or other third party is eligible for accreditation if it can demonstrate that the training and qualifications of its agents used to conduct audits (or, in the case of a third-party certification body that is an individual, such individual) and its internal systems and standards meet the requirements of §§1.641 through 1.645.

§ 1.641 What legal authority must a third-party certification body have to qualify for accreditation?

(a) A third-party certification body seeking accreditation from a recognized accreditation body or from FDA must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform such examinations of facilities, their process(es), and food(s) as are necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and conformance with applicable industry standards and practices and to issue certifications where appropriate based on a review of the findings of such examinations. This includes authority to:

(1) Review any relevant records;

(2) Conduct onsite audits of an eligible entity; and

(3) Suspend or withdraw certification for failure to comply with applicable requirements.

(b) A third-party certification body seeking accreditation must demonstrate that it is capable of exerting the authority (as a governmental entity or as legal entity with contractual rights) necessary to meet the applicable requirements of accreditation under this subpart if accredited.

§ 1.642 What competency and capacity must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) The resources necessary to fully implement its certification program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA regulations, conformance with applicable industry standards and practices, and issuance of valid and reliable certifications; and

(2) Adequate financial resources for its operations; and

(b) The competency and capacity to meet the applicable requirements of this subpart, if accredited.

§ 1.643 What protections against conflicts of interest must a third-party certification body have to qualify for accreditation?

A third-party certification body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and clients seeking examinations or certification from, or audited or certified by, such third-party certification body; and

(b) The capability to meet the conflict of interest requirements in §1.657, if accredited.

§1.644 What quality assurance procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities, including procedures to:

(1) Identify deficiencies in its auditing and certification program or performance; and

(2) Quickly execute corrective actions that effectively address any identified deficiencies; and

(b) The capability to meet the quality assurance requirements of §1.655, if accredited.

§1.645 What records procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for evaluating its program and performance; and

(b) Is capable of meeting the reporting, notification, and records requirements of this subpart, if accredited.

REQUIREMENTS FOR THIRD-PARTY CERTIFICATION BODIES THAT HAVE BEEN ACCREDITED UNDER THIS SUBPART

§1.650 How must an accredited third-party certification body ensure its audit agents are competent and objective?

(a) An accredited third-party certification body that uses audit agents to conduct food safety audits must ensure that each such audit agent meets the following requirements with respect to the scope of its accreditation under this subpart. If the accredited third-party certification body is an individual, that individual is also subject to the following requirements, as applicable:

(1) Has relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Has been determined by the accredited third-party certification body, through observations of a representative sample of audits, to be competent to conduct food safety audits under this subpart relevant to the audits they will be assigned to perform;

(3) Has completed annual food safety training that is relevant to activities conducted under this subpart;

(4) Is in compliance with the conflict of interest requirements of §1.657 and has no other conflicts of interest with the eligible entity to be audited that might impair the audit agent's objectivity; and

(5) Agrees to notify its accredited third-party certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health.

(b) In assigning an audit agent to conduct a food safety audit at a particular eligible entity, an accredited third-party certification body must determine that the audit agent is qualified to conduct such audit under the criteria established in paragraph (a) of this section and based on the scope and

purpose of the audit and the type of facility, its process(es), and food.

(c) An accredited third-party certification body cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited third-party certification body demonstrates to FDA, under §1.663, there is insufficient access to audit agents in the country or region where the eligible entity is located. If the accredited third-party certification body is an individual, that individual is also subject to such limitations.

§ 1.651 How must an accredited third-party certification body conduct a food safety audit of an eligible entity?

(a) *Audit planning.* Before beginning to conduct a food safety audit under this subpart, an accredited third-party certification body must:

(1) Require the eligible entity seeking a food safety audit to:

(i) Identify the scope and purpose of the food safety audit, including the facility, process(es), or food to be audited; whether the food safety audit is to be conducted as a consultative or regulatory audit subject to the requirements of this subpart, and if a regulatory audit, the type(s) of certification(s) sought; and

(ii) Provide a 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit; and

(2) Determine whether the requested audit is within its scope of accreditation.

(b) *Authority to audit.* In arranging a food safety audit with an eligible entity under this subpart, an accredited third-party certification body must ensure it has authority, whether contractual or otherwise, to:

(1) Conduct an unannounced audit to determine whether the facility, process(es), and food of the eligible entity (within the scope of the audit) comply with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of such audit;

(3) When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with ISO/IEC 17025:2017 to perform the analysis.

(4) Notify FDA immediately if, at any time during a food safety audit, the accredited third-party certification body (or its audit agent, where applicable) discovers a condition that could cause or contribute to a serious risk to the public health and provide information required by §1.656(c);

(5) Prepare reports of audits conducted under this subpart as follows:

(i) For consultative audits, prepare reports that contain the elements specified in §1.652(a) and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and

(ii) For regulatory audits, prepare reports that contain the elements specified in §1.652(b) and submit them to FDA and to its recognized accreditation body (where applicable) under §1.656(a); and

(6) Allow FDA and the recognized accreditation body that accredited such third-party certification body, if any, to observe any food safety audit conducted under this subpart for purposes of evaluating the accredited third-party certification body's performance under §§1.621 and 1.662 or, where appropriate, the recognized accreditation body's performance under §§1.622 and 1.633.

(c) *Audit protocols.* An accredited third-party certification body (or its audit agent, where applicable) must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation.

(1) With the exception of records review, which may be scheduled, the audit must be conducted without announcement during the 30-day timeframe identified under paragraph

(a)(1)(ii) of this section and must be focused on determining whether the facility, its process(es), and food are in compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices that are within the scope of the audit.

(2) The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph (b)(3) of this section to conduct the analysis. The audit may include any other activities necessary to determine compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices.

(3) The audit must be sufficiently rigorous to allow the accredited third-party certification body to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and for consultative audits, also includes conformance with applicable industry standards and practices, at the time of the audit; and for a regulatory audit, whether the eligible entity, given its food safety system and practices would be likely to remain in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under this subpart. An accredited third-party certification body (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

(4) Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by §1.652 and maintained as a record under §1.658.

[80 FR 74650, Nov. 27, 2015, as amended at 86 FR 68817, Dec. 3, 2021]

§1.652 What must an accredited third-party certification body include in food safety audit reports?

(a) *Consultative audits.* An accredited third-party certification body must prepare a report of a consultative audit not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report under §1.658, subject to FDA access in accordance with the requirements of section 414 of the FD&C Act. A consultative audit report must include:

(1) The identity of the site or location where the consultative audit was conducted, including:

(i) The name, address and the FDA Establishment Identifier of the facility subject to the consultative audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, the FDA Establishment Identifier and unique facility identifier, if designated by FDA, and, where applicable, registration number under subpart H of this part;

(3) The name(s) and telephone number(s) of the person(s) responsible for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations

(4) The dates and scope of the consultative audit;

(5) The process(es) and food(s) observed during such consultative audit; and

(6) Any deficiencies observed that relate to or may influence a determination of compliance with the applicable food safety requirements of the FD&C Act and FDA regulations that require corrective action, the corrective action

plan, and the date on which such corrective actions were completed. Such consultative audit report must be maintained as a record under §1.658 and must be made available to FDA in accordance with section 414 of the FD&C Act.

(b) *Regulatory audits.* An accredited third-party certification body must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to its recognized accreditation body (or, in the case of direct accreditation, only to FDA) and must provide to the eligible entity a report of such regulatory audit that includes the following information:

(1) The identity of the site or location where the regulatory audit was conducted, including:

(i) The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, and, where applicable, registration number under subpart H of this part;

(3) The dates and scope of the regulatory audit;

(4) The process(es) and food(s) observed during such regulatory audit;

(5) The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations;

(6) Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product:

(i) Will cause serious adverse health consequences or death to humans and animals; or

(ii) May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death to humans or animals is remote;

(7) The corrective action plan for addressing each deficiency identified under paragraph (b)(6) of this section, unless corrective action was implemented immediately and verified onsite by the accredited third-party certification body (or its audit agent, where applicable);

(8) Whether any sampling and laboratory analysis (*e.g.*, under a microbiological sampling plan) is performed in or used by the facility; and

(9) Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the 2 years preceding the regulatory audit.

(c) *Submission of regulatory audit report.* An accredited third-party certification body must submit a completed regulatory audit report as required by paragraph (b) of this section, regardless of whether the certification body issued a food or facility certification to the eligible entity.

(d) *Notice and appeals of adverse regulatory audit results.* An accredited third-party certification body must notify an eligible entity of a denial of certification and must establish and implement written procedures for receiving and addressing appeals from eligible entities challenging such adverse regulatory audit results and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§1.692 and 1.693, including requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the accredited third-party certification body, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;

(3) Advise the eligible entity of the final decision on its appeal; and

(4) Maintain records under §1.658 of the appeal, the final decision, and the basis for such decision.

§ 1.653 What must an accredited third-party certification body do when issuing food or facility certifications?

(a) *Basis for issuance of a food or facility certification.* (1) Prior to issuing a food or facility certification to an eligible entity, an accredited third-party certification body (or, where applicable, an audit agent on its behalf) must complete a regulatory audit that meets the requirements of §1.651 and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

(2) If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, an accredited third-party certification body may not issue a food or facility certification to such entity until after the accredited third-party certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies that are the subject of a notification under §1.656(c).

(3) An accredited third-party certification body must consider each observation and the data and other information from a regulatory audit and other activities conducted under §1.651 to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification issued under this subpart.

(4) A single regulatory audit may result in issuance of one or more food or facility certifications under this subpart, provided that the requirements of issuance are met as to each such certification.

(5) Where an accredited third-party certification body uses an audit agent to conduct a regulatory audit of an eligible entity under this subpart, the accredited third-party certification body (and not the audit agent) must make the determination whether to issue a food or facility certification based on the results of such regulatory audit.

(b) *Issuance of a food or facility certification and submission to FDA.* (1) Any food or facility certification issued under this subpart must be submitted to FDA electronically and in English. The accredited third-party certification body may issue a food or facility certification under this subpart for a term of up to 12 months.

(2) A food or facility certification must contain, at a minimum, the following elements:

(i) The name and address of the accredited third-party certification body and the scope and date of its accreditation under this subpart;

(ii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the eligible entity to which the food or facility certification was issued;

(iii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the facility where the regulatory audit was conducted, if different than the eligible entity;

(iv) The scope and date(s) of the regulatory audit and the certification number;

(v) The name of the audit agent(s) (where applicable) conducting the regulatory audit; and

(vi) The scope of the food or facility certification, date of issuance, and date of expiration.

(3) FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines, that such food or facility certification is not valid or reliable because, for example:

(i) The certification is offered in support of the admissibility of a food that was not within the scope of the certification;

(ii) The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation under this subpart; or

(iii) The certification was issued without reliable demonstration that the requirements of paragraph (a) of this section were met.

§ 1.654 When must an accredited third-party certification body monitor an eligible entity that it has issued a food or facility certification?

If an accredited third-party certification body has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited third-party certification body must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited third-party certification body must immediately notify FDA, under § 1.656(d), if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The accredited third-party certification body must maintain records of such monitoring under § 1.658.

§ 1.655 How must an accredited third-party certification body monitor its own performance?

(a) An accredited third-party certification body must annually, upon FDA request made for cause, or as required under § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in auditing and certification activities, including the performance of audit agents in examining facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations;

(2) The degree of consistency among its officers, employees, or other agents involved in auditing and certification activities, including evaluating whether its audit agents interpreted audit protocols in a consistent manner;

(3) The compliance of the accredited third-party certification body and its officers, employees, and other agents involved in auditing and certification activities, with the conflict of interest requirements of § 1.657;

(4) Actions taken in response to the results of any assessments conducted by FDA or, where applicable, the recognized accreditation body under § 1.621; and

(5) As requested by FDA, any other aspects of its performance relevant to a determination of whether the accredited third-party certification body is in compliance with this subpart.

(b) As a means to assess its performance, the accredited third-party certification body may evaluate the compliance of one or more of eligible entities to which a food or facility certification was issued under this subpart.

(c) Based on the assessments and evaluations conducted under paragraphs (a) and (b) of this section, the accredited third-party certification body must:

(1) Identify any deficiencies in complying with the requirements of this subpart;

(2) Quickly implement corrective action(s) that effectively address the identified deficiencies; and

(3) Under § 1.658, establish and maintain records of such corrective action(s).

(d) The accredited third-party certification body must prepare a written report of the results of its self-assessment that includes:

(1) A description of any corrective action(s) taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the accredited third-party certification body, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements in § 1.657; and

(3) A statement attesting to the extent to which the accredited third-party certification body complied with the applicable requirements of this subpart.

(e) An accredited third-party certification body may use a report, supplemented as necessary, on its conformance to ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012 in meeting the requirements of this section.

§ 1.656 What reports and notifications must an accredited third-party certification body submit?

(a) *Reporting results of regulatory audits.* An accredited third-party certification body must submit a regulatory audit report, as described in § 1.652(b), electronically, in English, to FDA and to the recognized accreditation body that granted its accreditation (where applicable), no later than 45 days after completing such audit.

(b) *Reporting results of accredited third-party certification body self-assessments.* An accredited third-party certification body must submit the report of its annual self-assessment required by § 1.655 electronically to its recognized accreditation body (or, in the case of direct accreditation, electronically and in English, to FDA), within 45 days of the anniversary date of its accreditation under this subpart. For an accredited third-party certification body subject to an FDA request for cause, or § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits under this subpart.

(c) *Notification to FDA of a serious risk to public health.* An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

(1) The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number under subpart H of this part;

(2) The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility under subpart H of this part; and

(3) The condition for which notification is submitted.

(d) *Immediate notification to FDA of withdrawal or suspension of a food or facility certification.* An accredited third-party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

(e) *Notification to its recognized accreditation body or an eligible entity.* (1) After notifying FDA under paragraph (c) of this section, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify the recognized accreditation body that granted its accreditation, except for third-party certification bodies directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA.

(2) An accredited third-party certification body must notify its recognized accreditation body (or, in the case of direct accreditation, FDA) electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements of this subpart and must include with such notification the following information:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.657 How must an accredited third-party certification body protect against conflicts of interest?

(a) An accredited third-party certification body must implement a written program to protect against conflicts of interest between the accredited third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and an eligible entity seeking a food safety audit or food or facility certification from, or audited or certified by, such accredited third-party

certification body, including the following:

(1) Ensuring that the accredited third-party certification body and its officers, employees, or other agents involved in auditing and certification activities do not own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity;

(2) Ensuring that the accredited third-party certification body and, its officers, employees, or other agents involved in auditing and certification activities are not owned, managed, or controlled by any person that owns or operates an eligible entity to be certified;

(3) Ensuring that an audit agent of the accredited third-party certification body does not own, operate, have a financial interest in, manage, or otherwise control an eligible entity or any affiliate, parent, or subsidiary of the entity that is subject to a consultative or regulatory audit by the audit agent; and

(4) Prohibiting an accredited third-party certification body's officer, employee, or other agent involved in auditing and certification activities from accepting any money, gift, gratuity, or other item of value from the eligible entity to be audited or certified under this subpart.

(5) The items specified in paragraph (a)(4) of this section do not include:

(i) Money representing payment of fees for auditing and certification services and reimbursement of direct costs associated with an onsite audit by the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an audit and on the premises where the audit is conducted, if necessary to facilitate the efficient conduct of the audit.

(b) An accredited third-party certification body may accept the payment of fees for auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity only after the date on which the report of such audit was completed or the date a food or facility certification was issued, whichever is later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of accredited third-party certification body's officers, employees, and other agents involved in auditing and certification activities will be considered the financial interests of such officers, employees, and other agents involved in auditing and certification activities.

(d) An accredited third-party certification body must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications under this subpart. For each such eligible entity, the Web site also must identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification.

§ 1.658 What records requirements must a third-party certification body that has been accredited meet?

(a) A third-party certification body that has been accredited must maintain electronically for 4 years records created during its period of accreditation (including documents and data) that document compliance with this subpart, including:

(1) Any audit report and other documents resulting from a consultative audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit;

(2) Any request for a regulatory audit from an eligible entity;

(3) Any audit report and other documents resulting from a regulatory audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit, and, when sampling and analysis is conducted, laboratory testing records and results from a laboratory that is accredited in

accordance with §1.651(b)(3), and documentation demonstrating such laboratory is accredited in accordance with §1.651(b)(3);

(4) Any notification submitted by an audit agent to the accredited third-party certification body in accordance with §1.650(a)(5);

(5) Any challenge to an adverse regulatory audit decision and the disposition of the challenge;

(6) Any monitoring it conducted of an eligible entity to which food or facility certification was issued;

(7) Its self-assessments and corrective actions taken to address any deficiencies identified during a self-assessment; and

(8) Significant changes to its auditing or certification program that might affect compliance with this subpart.

(b) An accredited third-party certification body must make the records of a consultative audit required by paragraph (a)(1) of this section available to FDA in accordance with section 414 of the FD&C Act.

(c) An accredited third-party certification body must make the records required by paragraphs (a)(2) through (8) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accredited third-party certification body or at a reasonably accessible location. If such records are requested by FDA electronically, the records must be submitted electronically not later than 10 business days after the date of the request. Additionally, if the records are maintained in a language other than English, an accredited third-party certification body must electronically submit an English translation within a reasonable time.

PROCEDURES FOR ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.660 Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body and what happens once the recognized accreditation body decides on my application?

(a) *Submission of accreditation or renewal application to a recognized accreditation body.* A third-party certification body seeking accreditation must submit its request for accreditation or renewal of accreditation by a recognized accreditation body identified on the Web site described in §1.690.

(b) *Notice of records custodian after denial of application for renewal of accreditation.* An applicant whose renewal application was denied by a recognized accreditation body must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of accreditation or denial of the renewal application, of the name and contact information of the custodian who will maintain the records required by §1.658(a) and make them available to FDA as required by §1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by §1.658(a) will be located.

(c) *Effect of denial of an application for renewal of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application l will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of denial of an application for renewal of accreditation.* FDA will provide notice on the Web site described in §1.690 of the date of issuance of a denial of renewal of accreditation of a third-party certification body that had previous been accredited.

§ 1.661 What is the duration of accreditation by a recognized accreditation body?

A recognized accreditation body may grant accreditation to a third-party certification body under this subpart for a period not to exceed 4 years.

§ 1.662 How will FDA monitor accredited third-party certification bodies?

(a) FDA will periodically evaluate the performance of each accredited third-party certification body to determine whether the accredited third-party certification body continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the accredited third-party certification body that, if not corrected, would warrant withdrawal of its accreditation under §1.664. FDA will evaluate each directly accredited third-party certification body annually. For a third-party certification body accredited by a recognized accreditation body, FDA will evaluate an accredited third-party certification body not later than 3 years after the date of accreditation for a 4-year term of accreditation, or by no later than the mid-term point for accreditation granted for less than 4 years. FDA may conduct additional performance assessments of an accredited third-party certification body at any time.

(b) In evaluating the performance of an accredited third-party certification body under paragraph (a) of this section, FDA may review any one or more of the following:

(1) Regulatory audit reports and food and facility certifications;

(2) The accredited third-party certification body's self-assessments under §1.655;

(3) Reports of assessments by a recognized accreditation body under §1.621;

(4) Documents and other information relevant to a determination of the accredited third-party certification body's compliance with the applicable requirements of this subpart; and

(5) Information obtained by FDA, including during inspections, audits, onsite observations, or investigations, of one or more eligible entities to which a food or facility certification was issued by such accredited third-party certification body.

(c) FDA may conduct its evaluation of an accredited third-party certification body through a site visit to an accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters), through onsite observation of an accredited third party certification body's performance during a food safety audit of an eligible entity, or through document review.

§ 1.663 How do I request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits?

(a) An accredited third-party certification body may submit a request to FDA to waive the requirements of §1.650(c) preventing an audit agent from conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months. The accredited third-party certification body seeking a waiver or waiver extension must demonstrate there is insufficient access to audit agents and any third-party certification bodies that are comprised of an individual in the country or region where the eligible entity is located.

(b) Requests for a waiver or waiver extension and all documents provided in support of the request must be submitted to FDA electronically, in English. The requestor must provide such translation and interpretation services as are needed by FDA to process the request.

(c) The request must be signed by the requestor or by any individual authorized to act on behalf of the requestor for purposes of seeking such waiver or waiver extension.

(d) FDA will review requests for waivers and waiver extensions on a first in, first out basis according to the date on which the completed submission is received; however, FDA may prioritize the review of specific requests to meet the needs of the program. FDA will evaluate any completed waiver request to determine whether the criteria for waiver have been met.

(e) FDA will notify the requestor whether the request for a waiver or waiver extension is approved or denied.

(f) If FDA approves the request, issuance of the waiver will state the duration of the waiver and list any limitations associated with it. If FDA denies the request, the issuance of a denial of a waiver request will state the basis for denial and will provide the address and procedures for requesting reconsideration of the request under §1.691.

(g) Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in §1.650(c) has elapsed.

§1.664 When would FDA withdraw accreditation?

(a) *Mandatory withdrawal.* FDA will withdraw accreditation from a third-party certification body:

(1) Except as provided in paragraph (b) of this section, if the food or facility certified under this subpart is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(2) Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this subpart; or

(3) Following its refusal to allow FDA to access records under §1.658 or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this subpart.

(4) If payment of the third-party certification body's annual fee is not received within 90 days of the payment due date, as specified in §1.725(c)(3).

(b) *Exception.* FDA may waive mandatory withdrawal under paragraph (a)(1) of this section, if FDA:

(1) Conducts an investigation of the material facts related to the outbreak of human or animal illness;

(2) Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

(3) Determines that the accredited third-party certification body satisfied the requirements for issuance of certification under this subpart.

(c) *Discretionary withdrawal.* FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked under §1.634, if FDA determines there is good cause for withdrawal, including:

(1) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(2) Performance that calls into question the validity or reliability of its food safety audits or certifications.

(d) *Records access.* FDA may request records of the accredited third-party certification body under §1.658 and, where applicable, may request records under §1.625 of an accreditation body that has been recognized under §1.625, when considering withdrawal under paragraph (a)(1), (a)(2), or (c) of this section.

(e) *Notice to the third-party certification body of withdrawal of accreditation.* (1) FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing under §1.693 on the withdrawal, and the procedures for requesting reaccreditation under §1.666.

(2) Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by §1.658, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(f) *Effect of withdrawal of accreditation on eligible entities.* A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to

consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(g) *Effect of withdrawal of accreditation on recognized accreditation bodies.* (1) FDA will notify a recognized accreditation body if the accreditation of a third-party certification body it accredited is withdrawn by FDA. Such accreditation body's recognition will remain in effect if, no later than 60 days after withdrawal, the accreditation body conducts a self-assessment under § 1.622 and reports the results of the self-assessment to FDA as required by § 1.623(b).

(2) FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under § 1.634.

(h) *Public notice of withdrawal accreditation.* FDA will provide notice on the Web site described in § 1.690 of its withdrawal of accreditation of a third-party certification body and provide a description of the basis for withdrawal.

[80 FR 74650, Nov. 27, 2015, as amended at 81 FR 90193, Dec. 14, 2016]

§ 1.665 What if I want to voluntarily relinquish accreditation or do not want to renew accreditation?

(a) *Notice to FDA of intent to relinquish or not to renew accreditation.* A third-party certification body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required under § 1.658(a) after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(b) *Notice to recognized accreditation body and eligible entities of intent to relinquish or not to renew accreditation.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the certification body must notify its recognized accreditation body and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625(a).

(c) *Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of voluntary relinquishment or expiration of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of accreditation of a certification body under this subpart.

§ 1.666 How do I request reaccreditation?

(a) *Application following withdrawal.* FDA will reinstate the accreditation of a third-party certification body for which it has withdrawn accreditation:

(1) If, in the case of direct accreditation, FDA determines, based on evidence presented by the third-party certification body, that the third-party certification body satisfies the applicable requirements of this subpart and adequate grounds for withdrawal no longer exist; or

(2) In the case of a third-party certification body accredited by an accreditation body for which recognition has been revoked under § 1.634:

(i) If the third-party certification body becomes accredited by another recognized accreditation body or by

FDA through direct accreditation no later than 1 year after withdrawal of accreditation, or the original date of the expiration of accreditation, whichever comes first; or

(ii) Under such conditions as FDA may impose in withdrawing accreditation.

(b) *Application following voluntary relinquishment.* A third-party certification body that previously relinquished its accreditation under §1.665 may seek accreditation by submitting a new application for accreditation under §1.660 or, where applicable, §1.670.

ADDITIONAL PROCEDURES FOR DIRECT ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§1.670 How do I apply to FDA for direct accreditation or renewal of direct accreditation?

(a) *Eligibility.* (1) FDA will accept applications from third-party certification bodies for direct accreditation or renewal of direct accreditation only if FDA determines that it has not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing the accredited third-party audits and certification program. Such FDA determination may apply, as appropriate, to specific types of third-party certification bodies, types of expertise, or geographic location; or through identification by FDA of any requirements of section 808 of the FD&C Act not otherwise met by previously recognized accreditation bodies. FDA will only accept applications for direct accreditation and renewal applications that are within the scope of the determination.

(2) FDA may revoke or modify a determination under paragraph (a)(1) of this section if FDA subsequently identifies and recognizes an accreditation body that affects such determination.

(3) FDA will provide notice on the Web site described in §1.690 of a determination under paragraph (a)(1) of this section and of a revocation or modification of the determination under paragraph (a)(1) of this section, as described in paragraph (a)(2) of this section.

(b) *Application for direct accreditation or renewal of direct accreditation.* (1) A third-party certification body seeking direct accreditation or renewal of direct accreditation must submit an application to FDA, demonstrating that it is within the scope of the determination issued under paragraph (a)(1) of this section, and it meets the eligibility requirements of §1.640.

(2) Applications and all documents provided as part of the application process must be submitted electronically, in English. An applicant must provide such translation and interpretation services as are needed by FDA to process the application, including during an onsite audit of the applicant.

(3) The application must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking or renewing direct accreditation.

§1.671 How will FDA review my application for direct accreditation or renewal of direct accreditation and what happens once FDA decides on my application?

(a) *Review of a direct accreditation or renewal application.* FDA will examine a third-party certification body's direct accreditation or renewal application for completeness and notify the applicant of any deficiencies. FDA will review applications for direct accreditation and for renewal of direct accreditation on a first in, first out basis according to the date the completed submission is received; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of a direct accreditation or renewal application.* FDA will evaluate any completed application to determine whether the applicant meets the requirements for direct accreditation under this subpart. If FDA does not reach a final decision on a renewal application before the expiration of the direct accreditation, FDA may extend the duration of such direct accreditation for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Notice of approval or denial.* FDA will notify the applicant that its direct accreditation or renewal application

has been approved through issuance of or denied.

(d) *Issuance of direct accreditation.* If an application has been approved, the issuance of the direct accreditation that will list any limitations associated with the accreditation.

(e) *Issuance of denial of direct accreditation.* If FDA issues a denial of direct accreditation or denial of a renewal application, the issuance of the denial of direct accreditation will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(f) *Notice of records custodian after denial of application for renewal of direct accreditation.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(b) will be located.

(g) *Effect of denial of renewal of direct accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(h) *Public notice of denial of renewal of direct accreditation.* FDA will provide notice on the Web site described in § 1.690 of the issuance of a denial of renewal application for direct accreditation under this subpart.

§ 1.672 What is the duration of direct accreditation?

FDA will grant direct accreditation of a third-party certification body for a period not to exceed 4 years.

Requirements for Eligible Entities Under This Subpart

§ 1.680 How and when will FDA monitor eligible entities?

FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited third-party certification body under this subpart. Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present. An FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

§ 1.681 How frequently must eligible entities be recertified?

An eligible entity seeking recertification of a food or facility certification under this subpart must apply for recertification prior to the expiration of its certification. For certifications used in meeting the requirements of section 801(q) or 806 of the FD&C Act, FDA may require an eligible entity to apply for recertification at any time FDA determines appropriate under such section.

General Requirements of This Subpart

§ 1.690 How will FDA make information about recognized accreditation bodies and accredited third-party certification bodies available to the public?

FDA will place on its Web site a registry of recognized accreditation bodies and accredited third-party certification bodies, including the name, contact information, and scope and duration of recognition or accreditation. The registry may provide information on third-party certification bodies accredited by recognized accreditation bodies through links to the Web sites

of such recognized accreditation bodies. FDA will also place on its Web site a list of accreditation bodies for which it has denied renewal of recognition, for which FDA has revoked recognition, and that have relinquished their recognition or have allowed their recognition to expire. FDA will also place in its Web site a list of certification bodies whose renewal of accreditation has been denied, for which FDA has withdrawn accreditation, and that have relinquished their accreditations or have allowed their accreditations to expire. FDA will place on its Web site determinations under §1.670(a)(1) and modifications of such determinations under §1.670(a)(2).

§1.691 How do I request reconsideration of a denial by FDA of an application or a waiver request?

(a) An accreditation body may seek reconsideration of the denial of an application for recognition, renewal of recognition, or reinstatement of recognition no later than 10 business days after the date of the issuance of such denial.

(b) A third-party certification body may seek reconsideration of the denial of an application for direct accreditation, renewal of direct accreditation, reaccreditation of directly accredited third-party certification body, a request for a waiver of the conflict of interest requirement in §1.650(b), or a waiver extension no later than 10 business days after the date of the issuance of such denial.

(c) A request to reconsider an application or waiver request under paragraph (a) or (b) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for reconsideration. The request must be submitted electronically in English and must comply with the procedures described in the notice.

(d) After completing its review and evaluation of the request for reconsideration, FDA will notify the requestor through the issuance of the recognition, direct accreditation, or waiver upon reconsideration or through the issuance of a denial of the application or waiver request under paragraph (a) or (b) of this section upon reconsideration.

§1.692 How do I request internal agency review of a denial of an application or waiver request upon reconsideration?

(a) No later than 10 business days after the date of issuance of a denial of an application or waiver request upon reconsideration under §1.691, the requestor may seek internal agency review of such denial under §10.75(c)(1) of this chapter.

(b) The request for internal agency review under paragraph (a) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for internal review. The request must be submitted electronically in English to the address specified in the denial upon reconsideration and must comply with procedures it describes.

(c) Under §10.75(d) of this chapter, internal agency review of such denial must be based on the information in the administrative file, which will include any supporting information submitted under §1.691(c).

(d) After completing the review and evaluation of the administrative file, FDA will notify the requestor of its decision to overturn the denial and grant the application or waiver request through issuance of an application or waiver request upon reconsideration or to affirm the denial of the application or waiver request upon reconsideration through issuance of a denial of an application or waiver request upon reconsideration.

(e) Issuance by FDA of a denial of an application or waiver request upon reconsideration constitutes final agency action under 5 U.S.C. 702.

§1.693 How do I request a regulatory hearing on a revocation of recognition or withdrawal of accreditation?

(a) *Request for hearing on revocation.* No later than 10 business days after the date of issuance of a revocation of recognition of an accreditation body under §1.634, an individual authorized to act on the accreditation body's behalf may submit a request for a regulatory hearing on the revocation under part 16 of this chapter. The issuance of

revocation issued under §1.634 will contain all of the elements required by §16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Request for hearing on withdrawal.* No later than 10 business days after the date of issuance of a withdrawal of accreditation of a third-party certification body under §1.664, an individual authorized to act on the third-party certification body's behalf may submit a request for a regulatory hearing on the withdrawal under part 16 of this chapter. The issuance of withdrawal under §1.664 will contain all of the elements required by §16.22 of this chapter and will thereby constitute the notice of opportunity of hearing under part 16 of this chapter.

(c) *Submission of request for regulatory hearing.* The request for a regulatory hearing under paragraph (a) or (b) of this section must be submitted with a written appeal that responds to the basis for the FDA decision, as described in the issuance of revocation or withdrawal, as appropriate, and includes any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the address specified in the notice and must comply with the procedures it describes.

(d) *Effect of submission of request on FDA decision.* The submission of a request for a regulatory hearing under paragraph (a) or (b) of this section will not operate to delay or stay the effect of a decision by FDA to revoke recognition of an accreditation body or to withdraw accreditation of a third-party certification body unless FDA determines that a delay or a stay is in the public interest.

(e) *Presiding officer.* The presiding officer for a regulatory hearing for a revocation or withdrawal under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(f) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing for a revocation or withdrawal under §16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(g) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing for a revocation or withdrawal, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by requestor, the presiding officer, and FDA.

(2) The presiding officer must conduct the regulatory hearing for revocation or withdrawal under part 16 of this chapter, except that, under §16.5(b) of this chapter, such procedures apply only to the extent that the procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 are inapplicable to regulatory hearings under this subpart: §16.22 (Initiation of a regulatory hearing); §16.24(e) (timing) and (f) (contents of notice); §16.40 (Commissioner); §16.60(a) (public process); §16.95(b) (administrative decision and record for decision); and §16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or the withdrawal of accreditation is considered a final agency action under 5 U.S.C. 702.

§1.694 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§1.695 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

REQUIREMENTS FOR USER FEES UNDER THIS SUBPART

SOURCE: Sections 1.700 through 1.725 appear at 81 FR 90193, Dec. 14, 2016, unless otherwise noted.

§ 1.700 Who is subject to a user fee under this subpart?

(a) Accreditation bodies submitting applications or renewal applications for recognition in the third-party certification program;

(b) Recognized accreditation bodies participating in the third-party certification program;

(c) Third-party certification bodies submitting applications or renewal applications for direct accreditation; and

(d) Accredited third-party certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party certification program.

§ 1.705 What user fees are established under this subpart?

(a) The following application fees:

(1) Accreditation bodies applying for recognition are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

(2) Recognized accreditation bodies submitting renewal applications are subject to a renewal application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

(3) Third-party certification bodies applying for direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation.

(4) Accredited third-party certification bodies applying for renewal of direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for direct accreditation.

(b) The following annual fees:

(1) Recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor performance of recognized accreditation bodies under § 1.633.

(2) Third-party certification bodies directly accredited by FDA are subject to an annual fee for the estimated average cost of the work FDA performs to monitor directly accredited third-party certification bodies under § 1.662.

(3) Third-party certification bodies accredited by recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor third-party certification bodies that are accredited by a recognized accreditation body under § 1.662.

§ 1.710 How will FDA notify the public about the fee schedule?

FDA will notify the public of the fee schedule annually. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

§ 1.715 When must a user fee required by this subpart be submitted?

(a) Accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

§ 1.720 Are user fees under this subpart refundable?

User fees accompanying completed applications and annual fees under this subpart are not refundable.

§ 1.725 What are the consequences of not paying a user fee under this subpart on time?

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of

§1.631(a) until the date that FDA receives the application fee. An application for direct accreditation or for renewal of direct accreditation will not be considered complete for the purposes of §1.671(a) until FDA receives the application fee.

(b) A recognized accreditation body that fails to submit its annual user fee within 30 days of the due date will have its recognition suspended.

(1) FDA will notify the accreditation body electronically that its recognition is suspended. FDA will notify the public of the suspension on the Web site described in §1.690.

(2) While an accreditation body's recognition is suspended, the accreditation body will not be able to accredit additional third-party certification bodies. The accreditation of third-party certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications issued by such third-party certification bodies, would remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will revoke the accreditation body's recognition under §1.634(a)(4)(iii), and provide notice of such revocation in accordance with §1.634.

(c) An accredited third-party certification body that fails to submit its annual fee within 30 days of the due date will have its accreditation suspended.

(1) FDA will notify the third-party certification body that its accreditation is suspended, electronically and in English. FDA will notify a recognized accreditation body, electronically and in English, if the accreditation of one if its third-party certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in §1.690.

(2) While a third-party certification body's accreditation is suspended, the third-party certification body will not be able to issue food or facility certifications. A food or facility certification issued by a third-party certification body prior to the suspension of the auditor/certification body accreditation will remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will withdraw the third-party certification body's accreditation under §1.664(a)(4), and provide notice of such withdrawal in accordance with §1.664.

Subpart N [Reserved]

Subpart O—Sanitary Transportation of Human and Animal Food

SOURCE: 81 FR 20166, Apr. 6, 2016, unless otherwise noted.

GENERAL PROVISIONS

§ 1.900 Who is subject to this subpart?

(a) Except for non-covered businesses as defined in §1.904 and as provided for in paragraph (b) of this section, the requirements of this subpart apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food, *e.g.*, in 21 CFR parts 1, 117, 118, 225, 507, and 589.

(b) The requirements of this subpart do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations:

(1) Of food that is transshipped through the United States to another country; or

(2) Of food that is imported for future export, in accordance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act, and that is neither consumed nor distributed in the United States; or

(3) Of food when it is located in food facilities as defined in §1.227 of this chapter, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?

(a) The criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this subpart.

(b) The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act.

§ 1.904 What definitions apply to this subpart?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Animal food means food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Farm has the meaning given in §1.227 of this chapter.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Non-covered business means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

Operating temperature means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, *e.g.*, seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of §1.908(a)(3).

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Receiver means any person who receives food at a point in the United States after transportation, whether or

not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Small business means a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to § 1.900(a) having less than $27,500,000 in annual receipts.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

VEHICLES AND TRANSPORTATION EQUIPMENT

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, *i.e.*, adulterated within the meaning of section 402(a)(1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(c) Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.

TRANSPORTATION OPERATIONS

§ 1.908 What requirements apply to transportation operations?

(a) *General requirements.* (1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, loaders, and receivers engaged in transportation operations. A person may be subject to these requirements in multiple capacities, *e.g.*, the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart. An entity subject to this subpart (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this subpart

to another party subject to this subpart. The written agreement is subject to the records requirements of §1.912(d).

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subpart must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including:

(i) Taking effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.

(ii) Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

(iii) Taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control.

(4) The type of food, *e.g.*, animal feed, pet food, human food, and its production stage, *e.g.*, raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.

(5) Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section. The written procedures are subject to the records requirements of §1.912(e).

(6) If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

(b) *Requirements applicable to shippers engaged in transportation operations.* (1) Unless the shipper takes other measures in accordance with paragraph (b)(3) of this section to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, that will prevent the food from becoming unsafe, the shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. One-time notification shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in §1.912(a).

(2) Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. One-time notification shall be sufficient unless a factor, *e.g.*, the conditions of shipment, changes, necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in §1.912(a).

(3) A shipper must develop and implement written procedures, subject to the records requirements of §1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of §1.912(a).

(4) A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of §1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of §1.912(a).

(5) The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of §1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of §1.912(a) and must include measures equivalent to those specified for carriers under paragraphs (e)(1) through (3) of this section.

(c) *Requirements applicable to loaders engaged in transportation operations.* (1) Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(1) of this section, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.*, it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.

(2) Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(2) of this section, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation.

(d) *Requirements applicable to receivers engaged in transportation operations.* Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, *e.g.*, for off-odors.

(e) *Requirements applicable to carriers engaged in transportation operations.* When the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation, the carrier is responsible for the following functions as applicable per the agreement:

(1) A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

(2) A carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper in accordance with paragraph

(b)(2) of this section. Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper in accordance with paragraph (b)(2) of this section.

(4) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle.

(5) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

(6) A carrier must develop and implement written procedures subject to the records requirements of §1.912(b) that:

(i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by §1.906(b);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (e)(2) of this section, and;

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (e)(4) and (5) of this section.

TRAINING

§1.910 What training requirements apply to carriers engaged in transportation operations?

(a) When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter.

(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of §1.912(c).

RECORDS

§1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

(a) Shippers must retain records:

(1) That demonstrate that they provide specifications and operating temperatures to carriers as required by §1.908(b)(1) and (2) as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

(2) Of written agreements and the written procedures required by §1.908(b)(3), (4), and (5), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(b) Carriers must retain records of the written procedures required by §1.908(e)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(c) Carriers must retain training records required by §1.910(b) for a period of 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.

(d) Any person subject to this subpart must retain any other written agreements assigning tasks in compliance with this subpart for a period of 12 months beyond the termination of the agreements.

(e) Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity in accordance with the provisions of §1.908(a)(5), must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.

(f) Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.

(g) All records required by this subpart must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(h) Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

(i) Except for the written procedures required by §1.908(e)(6)(i), offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by §1.908(e)(6)(i) must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.

(j) All records required by this subpart are subject to the disclosure requirements under part 20 of this chapter.

WAIVERS

§ 1.914 Under what circumstances will we waive a requirement of this subpart?

We will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, when we determine that:

(a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and

(b) The waiver will not be contrary to the public interest.

§ 1.916 When will we consider whether to waive a requirement of this subpart?

We will consider whether to waive a requirement of this subpart on our own initiative or on the petition submitted under §10.30 of this chapter by any person who is subject to the requirements of this subpart with respect to any class of persons, vehicles, food, or nonfood products.

§ 1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?

In addition to the requirements set forth in §10.30 of this chapter, the Statement of Grounds in a petition requesting a waiver must:

(a) Describe with particularity the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement(s) of this subpart to which the waiver would apply; and

(b) Present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to the public interest.

§ 1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?

We will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 1.922 Who will respond to a petition requesting a waiver?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM), or the Director, Office of Compliance, CFSAN, or the Director, Office of Surveillance

and Compliance, CVM, will respond to a petition requesting a waiver.

§ 1.924 What process applies to a petition requesting a waiver?

(a) In general, the procedures set forth in §10.30 of this chapter govern our response to a petition requesting a waiver.

(b) Under §10.30(h)(3) of this chapter, we will publish a notice in the FEDERAL REGISTER, requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.

(c) Under §10.30(e)(3) of this chapter, we will respond to the petitioner in writing.

(1) If we grant the petition, either in whole or in part, we will publish a notice in the FEDERAL REGISTER setting forth any waiver and the reasons for such waiver.

(2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

§ 1.926 Under what circumstances may we deny a petition requesting a waiver?

We may deny a petition requesting a waiver if the petition does not provide the information required under §1.918 (including the requirements of §10.30 of this chapter), or if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or that the waiver could be contrary to the public interest.

§ 1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?

If we, on our own initiative, determine that a waiver is appropriate, we will publish a notice in the FEDERAL REGISTER setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver that we grant become effective?

Any waiver that we grant will become effective on the date that notice of the waiver is published in the FEDERAL REGISTER.

§ 1.932 Under what circumstances may we modify or revoke a waiver?

We may modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest.

§ 1.934 What procedures apply if we determine that a waiver should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.

(2) We will publish a notice of our determination that a waiver should be modified or revoked in the FEDERAL REGISTER. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the FEDERAL REGISTER. The effective date of the decision will be the date of publication of the notice.

Subpart P [Reserved]

Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use

§ 1.980 Administrative detention of drugs.

(a) *General.* This section sets forth the procedures for detention of drugs believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of drugs encountered during inspections that may

be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. Drugs that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of drugs may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act, has reason to believe that a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order must be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined.

(2) If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order must include the following information:

(i) A statement that the drugs identified in the order are detained for the period shown;

(ii) A brief, general statement of the reasons for the detention;

(iii) The location of the drugs;

(iv) A statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative;

(v) Identification of the detained drugs;

(vi) The detention order number;

(vii) The date and hour of the detention order;

(viii) The period of the detention;

(ix) The text of section 304(g) of the Federal Food, Drug, and Cosmetic Act and paragraphs (g)(1) and (g)(2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) *Approval of detention order.* A detention order, before issuance, must be approved by the FDA Division Director in whose division the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained drug.* An FDA representative issuing a detention order under paragraph (d) of this section must label or mark the drugs with official FDA tags that include the following information:

(1) A statement that the drugs are detained by the U.S. Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the drugs must not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order.* (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA Division Director in whose division the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized.

(3) Any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under §16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under §16.80(a) of this chapter;

(ii) A request for a hearing under this section should be addressed to the FDA Division Director;

(iii) The last sentence of §16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section;

(iv) Paragraph (g)(4) of this section, rather than §16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by §16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer must, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer must render a decision on the appeal, affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the drugs continue to be detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA must terminate the detention under paragraph (j) of this section.

(h) *Movement of detained drugs.* (1) Except as provided in this paragraph, no person may move detained drugs within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for the purpose in the preceding sentence, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the drugs;

(ii) To destroy the drugs;

(iii) To bring the drugs into compliance;

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA division office official, of the new location of the detained drugs.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of drugs under this paragraph, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded drugs.* If FDA determines that the detained drugs, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the drugs or the responsible individuals, or both, or request that the drugs be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained drugs are manufactured, processed, packed, or held, must

have, or establish, and maintain adequate records relating to how the detained drugs may have become adulterated or misbranded, records on any distribution of the drugs before and after the detention period, records on the correlation of any in-process detained drugs that are put in final form under paragraph (h) of this section to the completed drugs, records of any changes in, or processing of, the drugs permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph must be provided to FDA on request for review and copying. Any FDA request for access to records required under this paragraph must be made at a reasonable time, must state the reason or purpose for the request, and must identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph must be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the Agency determines that the drugs are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in part 211 of this chapter).

[79 FR 30719, May 29, 2014, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16551, Mar. 24, 2020]

Subpart R—Laboratory Accreditation for Analyses of Foods

SOURCE: 86 FR 68817, Dec. 3, 2021; 87 FR 5660, Feb. 2, 2022, unless otherwise noted.

GENERAL PROVISIONS

§ 1.1101 What documents are incorporated by reference in this subpart

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the source listed elsewhere in this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html*.

(1) ISO/IEC 17011:2017(E), Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second edition, November 2017, IBR approved for §§ 1.1113(a) and (c), 1.1114(b), 1.1120(c), 1.1131(a).

(2) ISO/IEC 17025:2017(E), General requirements for the competence of testing and calibration laboratories, Third edition, November 2017, IBR approved for §§ 1.1120(c), 1.1121(a), 1.1138(a), 1.1139(b) and (c), 1.1141(a), 1.1152(a) and (d), 1.1153(c), and 1.1161(a).

§ 1.1102 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart, unless otherwise specified. For the purposes of this subpart, the following definitions also apply:

Analyst means an individual who analyzes samples.

Corrective action means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.

Directed food laboratory order means an order issued by FDA under § 1.1108 requiring food testing to be conducted under this subpart by or on behalf of an owner or consignee.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food testing and *testing of food* means the analysis of food product samples or environmental samples.

Laboratory accreditation for analyses of foods (LAAF)-accreditation means a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this subpart to conduct food testing under this subpart using one or more methods of analysis.

LAAF-accredited laboratory means a laboratory that a recognized accreditation body has determined meets the applicable requirements of this subpart and has been LAAF-accredited to conduct food testing under this subpart using one or more methods of analysis.

Owner or consignee means any person with an ownership or consignment interest in the food product or environment that is the subject of food testing conducted under § 1.1107(a).

Recognition means a determination by FDA that an accreditation body meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

Representative sample means a sample that accurately, to a statistically acceptable degree, represents the characteristics and qualities of the food product or environment from which the sample was collected.

Sampler means an individual who collects samples.

Sampling firm means an entity that provides sampling services.

Scope of LAAF-accreditation refers to the methods of analysis for which the laboratory is LAAF-accredited.

Street address means the full physical address, including the country. For purposes of this rule, a post office box number alone is insufficient; however, a post office box number may be provided in addition to the street address.

§ 1.1103 Who is subject to this subpart?

(a) *Accreditation bodies.* An accreditation body is subject to this subpart if it has been or is seeking to be recognized by FDA to LAAF-accredit laboratories to conduct food testing under this subpart.

(b) *Laboratories.* A laboratory is subject to this subpart if it has been or is seeking to be LAAF-accredited by a recognized accreditation body to conduct food testing under this subpart.

(c) *Owners and consignees.* An owner or consignee is subject to this subpart if it is required to use a LAAF-accredited laboratory to conduct food testing under this subpart.

General Requirements

§ 1.1107 When must food testing be conducted under this subpart?

(a) Food testing must be conducted under this subpart whenever such testing is conducted by or on behalf of an owner or consignee:

(1) In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in the following provisions:

(i) *Sprouts.* Section 112.146(a), (c), and (d) of this chapter;

(ii) *Shell eggs.* Sections 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e) of this chapter; and

(iii) *Bottled drinking water.* Section 129.35(a)(3)(i) of this chapter (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli*);

(2) As required by FDA in a directed food laboratory order issued under § 1.1108;

(3) To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the Federal Food, Drug, and Cosmetic Act prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section

415(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

(4) In support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act; and

(5) To support removal from an import alert through successful consecutive testing.

(b) When food testing is conducted under paragraph (a) of this section, analysis of samples must be conducted by a laboratory that is LAAF-accredited for the appropriate analytical method by a recognized accreditation body under this subpart.

(c) Food testing conducted on articles of food offered for import into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act pursuant to paragraph (a)(4) or (a)(5) of this section may only be conducted after the articles offered for import have arrived in the United States unless the owner or consignee has written approval from FDA that a sample taken prior to arrival is or would be a representative sample of the article offered for import into the United States.

§ 1.1108 When and how will FDA issue a directed food laboratory order?

(a) FDA may require the owner or consignee to conduct food testing, or to have food testing conducted on their behalf, under this subpart to address an identified or suspected food safety problem, as FDA deems appropriate.

(b) The directed food laboratory order will specify the food product or environment to be tested; whether the food testing may be conducted using a LAAF-accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used.

(c) The directed food laboratory order will contain all the elements required by §16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter. An affected owner or consignee may request a regulatory hearing on a directed food laboratory order pursuant to §1.1174.

§ 1.1109 How will FDA make information about recognized accreditation bodies and LAAF-accredited laboratories available to the public?

FDA will place on its website a publicly available registry listing of:

(a) Recognized accreditation bodies, including for each: the name, contact information, and duration of recognition of the recognized accreditation body;

(b) Accreditation bodies that have a change in recognition, including for each: the name of the accreditation body, the specific change in recognition (*i.e.*, probation, revocation of recognition, denial of renewal of recognition, relinquishment of recognition, or expiration of recognition) and the effective date of the change;

(c) LAAF-accredited laboratories, including for each: the name, contact information, and scope of LAAF-accreditation, and the name and contact information of the recognized accreditation body that has LAAF-accredited the laboratory; and

(d) Laboratories that have a change in LAAF-accreditation, including for each: the name of the laboratory, the specific change in LAAF-accreditation (*i.e.*, suspension, reduction of scope, or withdrawal of LAAF-accreditation by the recognized accreditation body, probation or disqualification by FDA, or relinquishment of LAAF-accreditation), and the effective date of the change.

§ 1.1110 What are the general requirements for submitting information to FDA under this subpart?

(a) All applications, reports, notifications, and records submitted to FDA under this subpart must be submitted electronically and in English unless otherwise specified. If FDA requests inspection or submission of records that are maintained in any language other than English, the recognized accreditation body or LAAF-accredited laboratory must provide an English translation within a reasonable time.

(b) A program applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during any onsite assessments of the applicant by FDA.

FDA RECOGNITION OF ACCREDITATION BODIES

§ 1.1113 What are the eligibility requirements for a recognized accreditation body?

A recognized accreditation body or an accreditation body seeking recognition must meet all of the following requirements:

(a) Demonstrates compliance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101).

(b) Demonstrates that it is a full member of the International Laboratory Accreditation Cooperative (ILAC).

(c) Demonstrates that it is a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017(E) with a scope of ''Testing: ISO/IEC 17025.''

(d) Will comply with all additional requirements for recognized accreditation bodies under this subpart while recognized.

§ 1.1114 How does an accreditation body apply to FDA for recognition or renewal of recognition?

(a) *Application for recognition or renewal of recognition.* An accreditation body seeking initial recognition or renewal of recognition must submit an application to FDA demonstrating that it meets the eligibility requirements in § 1.1113.

(b) *Documentation of conformance with requirements.* The accreditation body must submit documentation of conformance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101) and separate documentation of ILAC membership and ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017(E) with a scope of ''Testing: ISO/IEC 17025,'' in meeting the requirements of § 1.1113(a) through (c). The accreditation body also must submit documentation of its compliance with § 1.1113(d).

(c) *Signature.* An application for recognition or renewal of recognition must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.1115 How will FDA evaluate applications for recognition and renewal of recognition?

(a) *Review of application for recognition or renewal of recognition.* FDA will review an accreditation body's application for recognition or renewal of recognition for completeness and notify the applicant of any insufficiencies. FDA generally will review accreditation body applications for recognition or renewal of recognition in the order in which completed applications are received; however, FDA may prioritize the review of specific applications to meet program needs.

(b) *Evaluation of application for recognition or renewal of recognition.* FDA will evaluate a complete application for recognition or renewal of recognition to determine whether the applicant meets the requirements for recognition. Such evaluation may include an onsite evaluation of the accreditation body. If FDA does not reach a final decision on an application for renewal of recognition before an accreditation body's recognition expires, FDA may extend the existing term of recognition for a specified period of time or until FDA reaches a final decision on the application for renewal of recognition.

(c) *Grant of recognition.* FDA will notify the applicant that its application for recognition or renewal of recognition has been approved and will include any conditions associated with the recognition.

(d) *Duration of recognition.* FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition, except under the circumstances described in paragraph (b) of this section.

(e) *Denial of application for recognition or renewal of recognition.* FDA will notify the applicant that its application for recognition or renewal of recognition has been denied and will state the basis for such denial and describe the procedures for requesting reconsideration of the application under § 1.1171.

(f) *Notice of records custodian after denial of an application for renewal of recognition.* Within 10 business days of the date of FDA's issuance of a denial of an application for renewal of recognition, the applicant must provide the name and contact information of the custodian who will maintain required records and make them available to FDA under §1.1124. The contact information must include an email address for the records custodian and the street address where the records required under §1.1124 will be located.

(g) *FDA notice to LAAF-accredited laboratories.* FDA will promptly notify all laboratories LAAF-accredited by the accreditation body whose application for renewal of recognition was denied, informing them of such denial.

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide public notice on the website described in §1.1109 of the issuance of a denial of an application for renewal of recognition and will include the date of the issuance of such denial.

§ 1.1116 What must a recognized accreditation body do to voluntarily relinquish or not renew its recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* At least 60 calendar days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal, a recognized accreditation body must notify FDA of its intention to leave the program, specifying the date on which the relinquishment or expiration will occur. The recognized accreditation body must provide the name and contact information of the custodian who will maintain and make available to FDA the records required by § 1.1124 after the date of relinquishment or the date recognition expires, as applicable. The contact information must include an email address for the records custodian and the street address where the records required under § 1.1124 will be located.

(b) *Notice to LAAF-accredited laboratories of intent to relinquish or not to renew recognition.* At least 60 calendar days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal, a recognized accreditation body must notify the laboratories it LAAF accredits of its intention to leave the program, specifying the date on which relinquishment or expiration will occur.

(c) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the website described in § 1.1109 of the voluntary relinquishment or expiration of recognition of an accreditation body.

§ 1.1117 How may an accreditation body request reinstatement of recognition?

(a) *Application following revocation of recognition.* An accreditation body that has had its recognition revoked by FDA (as described in §1.1131) may seek reinstatement by submitting a new application for recognition under § 1.1114. The accreditation body must also submit evidence to FDA with its application to demonstrate that the issues resulting in revocation of recognition have been resolved, including evidence addressing the cause or condition of the grounds for revocation of recognition. The evidence also must identify measures that have been implemented to help ensure that such cause or condition is unlikely to recur.

(b) *Application following relinquishment or expiration of recognition.* An accreditation body that previously relinquished its recognition or allowed its recognition to expire (as described in §1.1116) may seek reinstatement by submitting a new application for recognition under § 1.1114.

Requirements for Recognized Accreditation Bodies

§ 1.1119 What are the conflict of interest requirements for a recognized accreditation body?

(a) In addition to meeting the impartiality and conflict of interest requirements of §1.1113(a), a recognized accreditation body must:

(1) Ensure that the recognized accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) does not own or have a financial interest in,

manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it LAAF-accredits, subject to the exceptions in paragraphs (c) and (d) of this section; and

(2) Prohibit, subject to the exceptions in paragraph (e) of this section, officers, employees, or other agents involved in LAAF-accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory the recognized accreditation body LAAF-accredits or assesses for LAAF-accreditation.

(b) The financial interests of any children younger than 18 years of age or a spouse of a recognized accreditation body's officers, employees, and other agents involved in LAAF-accreditation activities are considered the financial interests of such officers, employees, and other agents involved in LAAF-accreditation activities.

(c) An accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) may have an interest in a publicly traded or publicly available investment fund (*e.g.*, a mutual fund), or a widely held pension or similar fund if the accreditation body (and its officers, employees, or other agents involved in LAAF-accreditation activities) neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(d) A recognized accreditation body's agent that is a contract assessor will be permitted to own or have a financial interest in, manage, or otherwise control a LAAF-accredited laboratory if all of the following circumstances apply:

(1) The contract assessor's primary occupation is owning or having a financial interest in, managing, or otherwise controlling a LAAF-accredited laboratory;

(2) The assessor contracts with the recognized accreditation body to provide assessment services on an intermittent or part-time basis;

(3) The contract assessor does not assess the LAAF-accredited laboratory that the assessor owns or has a financial interest in, manages, or otherwise controls; and

(4) The contract assessor and the recognized accreditation body inform any laboratory that the contract assessor may assess or reassess for LAAF-accreditation that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory. The laboratory seeking LAAF-accreditation assessment or reassessment must acknowledge that the contract assessor owns or has a financial interest in, manages, or otherwise controls a LAAF-accredited laboratory and be provided the option to be assessed by a different representative of the recognized accreditation body.

(e) The prohibited items of value specified in paragraph (a)(2) of this section do not include:

(1) Money representing payment of fees for LAAF-accreditation services or reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory; or

(2) Meal of de minimis value provided during the course of an assessment or reassessment and on the premises where the assessment or reassessment is conducted, if necessary for the efficient conduct of the assessment or reassessment.

§ 1.1120 How must a recognized accreditation body assess laboratories seeking LAAF-accreditation and oversee LAAF-accredited laboratories?

(a) A recognized accreditation body must conduct an initial assessment of a laboratory seeking LAAF-accreditation in accordance with the requirements of this subpart, to determine whether the laboratory meets the requirements of § 1.1138.

(b) Subject to the exception in paragraph (c) of this section, the initial assessment must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(c) If, within the previous 2 years, the recognized accreditation body conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017(E) (incorporated by reference, see § 1.1101) to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017(E) (incorporated

by reference, see §1.1101), then the initial assessment under this section:

(1) May be conducted remotely, and

(2) Need only address whether the laboratory meets the requirements of §1.1138(a)(2) and (3) and (b).

(d) A recognized accreditation body must oversee the performance of a laboratory it LAAF-accredits in accordance with the requirements of §1.1113(a), except as otherwise provided by this subpart, to determine whether the LAAF-accredited laboratory continues to meet the applicable requirements of this subpart.

(e) A recognized accreditation body must conduct a reassessment of a LAAF-accredited laboratory in accordance with this subpart at least every 2 years. Such reassessment must be conducted onsite, although certain reassessment activities may be conducted remotely if it will not aid in the reassessment to conduct the activities onsite.

(f) If the recognized accreditation body conducted the initial assessment of the LAAF-accredited laboratory remotely in accordance with paragraph (c) of this section, the recognized accreditation body must conduct its first reassessment of the LAAF-accredited laboratory no later than 2 years after the recognized accreditation body last conducted an onsite assessment of the laboratory.

(g) The reassessment at the end of the LAAF-accredited laboratory's ISO/IEC 17025:2017-accreditation cycle, which the recognized accreditation body must conduct in accordance with this subpart, must be conducted onsite, although certain reassessment activities may be conducted remotely if it will not aid the reassessment to conduct them onsite.

(h) Any assessments or reassessments conducted by a recognized accreditation body in addition to the assessments or reassessments referred to in paragraphs (a), (e), and (g) of this section may be conducted remotely if it will not aid the assessment or reassessment to conduct it onsite.

§ 1.1121 When must a recognized accreditation body require corrective action, suspend a LAAF-accredited laboratory, or reduce the scope of or withdraw the LAAF-accreditation of a laboratory?

(a) *Corrective action.* A recognized accreditation body may require corrective action using the procedures described by ISO/IEC 17025:2017(E) (incorporated by reference, see §1.1101) section 8.7 to address any deficiencies identified while assessing and overseeing a LAAF-accredited laboratory.

(1) The recognized accreditation body must notify the LAAF-accredited laboratory of all deficiencies requiring corrective action and will either specify a deadline to implement corrective action or will require the LAAF-accredited laboratory to submit a corrective action plan and timeframe for implementation to the recognized accreditation body for approval.

(2) The LAAF-accredited laboratory must implement appropriate corrective action under ISO/IEC 17025:2017(E) section 8.7, and submit the results of the corrective action to the recognized accreditation body.

(3) The recognized accreditation body will review the corrective action and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(b) *Suspension.* If a recognized accreditation body determines that a laboratory it LAAF-accredits has not effectively implemented corrective action or otherwise fails to address deficiencies identified, the recognized accreditation body may temporarily suspend the LAAF-accredited laboratory for one or more LAAF-accredited methods, and require corrective action under paragraph (a) of this section.

(1) The recognized accreditation body must notify the LAAF-accredited laboratory of the grounds for the suspension, the LAAF-accredited methods subject to the suspension, and all deficiencies that must be addressed via the process described in paragraph (a) of this section.

(2) The recognized accreditation body must notify FDA of the suspension under this section in accordance with the requirements of §1.1123(d)(5). FDA

will provide notice of the LAAF-accredited laboratory's suspension on the website described in §1.1109.

(3) The recognized accreditation body will review the corrective action required under paragraph (b) of this section and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(4) A LAAF-accredited laboratory shall remain suspended until it demonstrates to the recognized accreditation body's satisfaction that the LAAF-accredited laboratory has successfully implemented appropriate corrective action.

(5) If the recognized accreditation body determines that a LAAF-accredited laboratory on suspension has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, the recognized accreditation body may reduce the scope of or withdraw the LAAF-accreditation of the laboratory under paragraph (c) of this section.

(c) *Reduction of scope or withdrawal of LAAF-accreditation.* A recognized accreditation body must reduce the scope of or withdraw the LAAF-accreditation of a laboratory it LAAF-accredits when the laboratory substantially fails to comply with this subpart. When only certain methods within the laboratory's scope of LAAF-accreditation are affected by the noncompliance, the recognized accreditation body may reduce the scope of the laboratory's LAAF-accreditation for only those affected methods. If all methods are affected, the recognized accreditation body must withdraw the laboratory's LAAF-accreditation.

(d) *Procedures for reduction of scope or withdrawal of LAAF-accreditation.* (1) The recognized accreditation body must notify the laboratory of any reduction of scope or withdrawal of LAAF-accreditation, including:

(i) The grounds for the reduction of scope or withdrawal of LAAF-accreditation;

(ii) The method(s) to which the reduction of scope applies;

(iii) The procedures for appealing the reduction of scope or withdrawal of LAAF-accreditation as described in §1.1122; and

(iv) The date the reduction of scope or withdrawal of LAAF-accreditation is effective.

(2) The recognized accreditation body must notify FDA of the reduction of scope or withdrawal of LAAF-accreditation under this section in accordance with the requirements in §1.1123(d)(4). FDA will provide notice of the reduction of scope or withdrawal of the laboratory's LAAF-accreditation on the website described in §1.1109.

(e) *Records request associated with suspension, reduction of scope, or withdrawal of LAAF-accreditation.* To assist the recognized accreditation body in determining whether a suspension, reduction of scope, or withdrawal of LAAF-accreditation is warranted under this section, the recognized accreditation body may require the submission of records that the LAAF-accredited laboratory is required to maintain under §1.1154.

(f) *Consequences of suspension, reduction of scope, or withdrawal of LAAF-accreditation.* (1) A LAAF-accredited laboratory may not conduct food testing under this subpart using suspended methods.

(2) If the recognized accreditation body withdraws the laboratory's LAAF-accreditation, the laboratory is immediately ineligible to conduct any food testing under this subpart. If the recognized accreditation body reduces the laboratory's scope of LAAF-accreditation, the laboratory is immediately ineligible to use the methods to which the reduction of scope applies to conduct food testing under this subpart.

§1.1122 What procedures must a recognized accreditation body provide for appeals of decisions to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation?

A recognized accreditation body must consider a laboratory's appeal regarding a decision to suspend, reduce the scope of, withdraw, or deny LAAF-accreditation in accordance with the requirements of §1.1113(a). Appeals must be reviewed and decided by a competent person(s) free from bias or prejudice who has not participated in the LAAF-accreditation decision and is not the subordinate of a person who

participated in the LAAF-accreditation decision. For the purposes of appeals, the competent person(s) may be external to the recognized accreditation body.

§ 1.1123 What reports, notifications, and documentation must a recognized accreditation body submit to FDA?

(a) *General requirements.* All reports and notifications required by this section must include:

(1) The name, street address, telephone number, and email address of the recognized accreditation body associated with the report or notification, and the name of an appropriate point of contact for the recognized accreditation body, and

(2) If the report or notification concerns a LAAF-accredited laboratory, the name, street address, telephone number, and email address of the LAAF-accredited laboratory, and the name of an appropriate point of contact for the LAAF-accredited laboratory.

(b) *Internal audit reports.* A recognized accreditation body must submit to FDA a report of the results of the internal audit conducted pursuant to § 1.1125 within 45 calendar days of completing the audit. The audit report must include:

(1) A description of the internal audit conducted;

(2) A description of any identified deficiencies;

(3) A description of any corrective action taken or planned, including the timeline for such corrective action; and

(4) A statement disclosing the extent to which the internal audit was conducted by personnel different from those who perform the activity or activities that were audited.

(c) *Changes affecting recognition.* A recognized accreditation body must notify FDA within 48 hours when the recognized accreditation body is aware of a change that would affect the recognition of such accreditation body, and the notification must include:

(1) A description of the change, and

(2) If the change is one made by the recognized accreditation body, an explanation of the purpose of the change.

(d) *Changes in LAAF-accreditation.* A recognized accreditation body must notify FDA and submit a certificate reflecting the scope of accreditation within 48 hours when any of the following occur:

(1) The recognized accreditation body grants or extends LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation requested by the laboratory,

(ii) The scope of LAAF-accreditation granted, and

(iii) The effective date of the grant or extension;

(2) The recognized accreditation body denies LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation requested by the laboratory,

(ii) The scope of LAAF-accreditation denied, and

(iii) The grounds for the denial;

(3) The recognized accreditation body receives notice that a laboratory it LAAF-accredits intends to relinquish its LAAF-accreditation and the laboratory has not provided notice to FDA 60 calendar days prior to relinquishment as required under § 1.1140. The recognized accreditation body's notification must include:

(i) The scope of LAAF-accreditation to which the relinquishment applies, as applicable, and

(ii) The effective date of the relinquishment;

(4) The recognized accreditation body reduces the scope of or withdraws the LAAF-accreditation of a laboratory, and the notification must include:

(i) The scope of LAAF-accreditation to which the reduction applies,

(ii) The grounds for the reduction of scope or withdrawal, and

(iii) The effective date of the reduction of scope or withdrawal;

(5) The recognized accreditation body suspends or lifts the suspension of a LAAF-accredited laboratory, and the notification must include:

(i) The scope of LAAF-accreditation to which the suspension applies,

(ii) The grounds for the suspension or for lifting the suspension, and

(iii) The effective date of the suspension or date the suspension is lifted.

(e) *Laboratory fraud.* A recognized accreditation body must notify FDA within 48 hours if the recognized accreditation body knows that a laboratory it LAAF-accredits has committed fraud or submitted material false statements to FDA, and the notification must include:

(1) A description of the basis for the recognized accreditation body's knowledge of the fraud or material false statements,

(2) A description of the fraud or material false statements, and

(3) The action(s) taken by the recognized accreditation body with respect to such LAAF-accredited laboratory.

§ 1.1124 What are the records requirements for a recognized accreditation body?

(a) In addition to meeting the requirements of § 1.1113(a) related to records, a recognized accreditation body must maintain, for 5 years after the date of creation of the records, records created while it is recognized demonstrating its compliance with this subpart, including records relating to:

(1) Applications for LAAF-accreditation;

(2) Assessments, reassessments, and decisions to grant, extend the scope of, renew, deny, reduce the scope of, or withdraw LAAF-accreditation or to suspend or lift the suspension of a LAAF-accredited laboratory;

(3) Appeals of suspensions, denials, reductions of scope of, and withdrawals of LAAF-accreditation, final decisions on such appeals, and the bases for such final decisions;

(4) Its oversight of laboratories it has LAAF-accredited;

(5) Its oversight of its own performance, including all records related to internal audits, complaints, and corrective actions;

(6) Any reports or notifications required to be submitted to FDA under § 1.1123, including any supporting information;

(7) Records of fee payments and reimbursement of direct costs; and

(8) Any documents demonstrating compliance with the requirements for assessment activities by contract assessors with certain financial interests described in § 1.1119(d).

(b) A recognized accreditation body must make the records it is required to maintain by paragraph (a) of this section available for inspection and copying or for electronic submission upon written request of an authorized officer or employee of FDA. If FDA requests records for inspection and copying, the recognized accreditation body must make such records promptly available at the physical location of the recognized accreditation body or at another reasonably accessible location. If FDA requests electronic submission, the records must be submitted within 10 business days of the request.

(c) A recognized accreditation body must not prevent or interfere with FDA's access to the records the LAAF-accredited laboratories it LAAF-accredits are required to maintain under § 1.1154.

§ 1.1125 What are the internal audit requirements for a recognized accreditation body?

As part of the internal audit a recognized accreditation body is required to conduct pursuant to § 1.1113(a), the recognized accreditation body must audit its compliance with the requirements of § 1.1113(d).

FDA Oversight of Recognized Accreditation Bodies

§ 1.1130 How will FDA oversee recognized accreditation bodies?

(a) FDA will evaluate each recognized accreditation body to determine its compliance with the applicable requirements of this subpart no later than:

(1) Year 4 of a 5-year recognition period; or

(2) The midpoint of a recognition period less than 5 years.

(b) An FDA evaluation of a recognized accreditation body may include review of records, an onsite evaluation of the accreditation body, and onsite reviews of one or more LAAF-accredited laboratories the recognized accreditation body LAAF-accredits, with or without the recognized accreditation body present. Certain evaluation activities may be conducted remotely if it will not aid in the evaluation to conduct them onsite.

(c) FDA may conduct additional evaluations of a recognized accreditation body at any time to determine whether the recognized accreditation body complies with the applicable requirements of this subpart.

§ 1.1131 When will FDA require corrective action, put a recognized accreditation body on probation, or revoke the recognition of an accreditation body?

(a) *Corrective action.* FDA may require corrective action to address any deficiencies identified while evaluating a recognized accreditation body under this subpart.

(1) FDA will notify the recognized accreditation body of all deficiencies requiring corrective action and will either specify a deadline to implement corrective action or will require the recognized accreditation body to submit a corrective action plan and timeframe for implementation to FDA for approval.

(2) The recognized accreditation body must handle FDA's notification as a complaint under ISO/IEC 17011:2017(E) (incorporated by reference, see §1.1101) section 7.12, implement appropriate corrective action under ISO/IEC 17011:2017(E) section 9.5, and submit both the results of the complaint investigation and subsequent corrective action to FDA.

(3) FDA will review the corrective action and will notify the recognized accreditation body whether the corrective action is acceptable.

(b) *Probation.* If FDA determines that a recognized accreditation body has not effectively implemented corrective action or otherwise fails to address deficiencies identified, FDA may put the recognized accreditation body on probation and require corrective action under paragraph (a) of this section.

(1) FDA will notify the recognized accreditation body of the grounds for the probation and all deficiencies requiring corrective action via the process described in paragraph (a) of this section.

(2) FDA will notify all laboratories LAAF-accredited by the recognized accreditation body that the recognized accreditation body is on probation and will provide notice of the probation on the website described in §1.1109.

(3) FDA will review the corrective action and will notify the recognized accreditation body whether the corrective action is acceptable.

(4) A recognized accreditation body shall remain on probation until the recognized accreditation body demonstrates to FDA's satisfaction that it has successfully implemented appropriate corrective action.

(5) If FDA determines that a recognized accreditation body on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, FDA may revoke recognition of the recognized accreditation body under paragraph (c) of this section.

(c) *Revocation of recognition.* FDA will revoke the recognition of an accreditation body if it fails to meet the requirements of this subpart, if FDA determines the accreditation body has committed fraud or submitted material false statements to FDA, or if FDA determines that a recognized accreditation body on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified.

(d) *Revocation of recognition procedures.* (1) FDA will issue a notice of revocation of recognition to the recognized accreditation body that will include the grounds for revocation, the date on which revocation is effective, the procedures for requesting a regulatory hearing on the revocation under §1.1173, and the procedures for requesting reinstatement of recognition under §1.1117.

(2) FDA will notify all laboratories LAAF-accredited by the recognized accreditation body that recognition has been revoked and will provide notice of the revocation of recognition of an accreditation body on the website described in § 1.1109.

(3) Within 10 business days of the date of issuance of revocation, the accreditation body must provide the name and contact information of the custodian who will maintain records and make them available to FDA as required by §1.1124. The contact information must include an email address for the records custodian and the street address where the records required by §1.1124 will be located.

(e) *Effect of probation or revocation of recognition on the accreditation body.* (1) A recognized accreditation body that is put on probation by FDA must continue to oversee laboratories that it has LAAF-accredited under this subpart and may continue to LAAF-accredit laboratories under § 1.1120.

(2) An accreditation body that has had its recognition revoked by FDA may not LAAF-accredit laboratories under this subpart or continue to oversee the laboratories it has previously LAAF-accredited while the accreditation body is not recognized.

[86 FR 68817, Dec. 3, 2021; 87 FR 5660, Feb. 2, 2022]

LAAF-ACCREDITATION OF LABORATORIES

§ 1.1138 What are the eligibility requirements for a LAAF-accredited laboratory?

(a) A laboratory that is LAAF-accredited or seeking LAAF-accreditation must demonstrate it is capable of conducting each method of food testing for which it is or will be LAAF-accredited by meeting all of the following requirements:

(1) For each method, the laboratory is accredited by a recognized accreditation body to ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101).

(2)(i) Except as provided in paragraph (a)(2)(ii) of this section, the laboratory has successfully passed a proficiency test provided by a competent proficiency testing organization within the last 12 months for each method within the scope of LAAF-accreditation.

(ii) If the laboratory determines there is no proficiency testing program available or practicable for a method, it may use a comparison program. A laboratory must request approval from the recognized accreditation body regarding the determination prior to using a comparison program in lieu of an annual proficiency test. The laboratory is required to demonstrate competency through participation in the comparison program.

(iii) A laboratory must submit all proficiency test and comparison program results, regardless of outcome, to the recognized accreditation body within 30 calendar days of receipt.

(3) The laboratory ensures that its procedures for monitoring the validity of the results of testing it conducts under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.

(b) Will comply with all additional requirements for LAAF-accredited laboratories under this subpart while LAAF-accredited.

§ 1.1139 How does a laboratory apply for LAAF-accreditation or extend its scope of LAAF-accreditation?

(a) *Application for LAAF-accreditation.* A laboratory seeking LAAF-accreditation or extension of its scope of LAAF-accreditation must submit its application for LAAF-accreditation to a recognized accreditation body identified on the website described in § 1.1109. The recognized accreditation body will review and assess the application in accordance with the requirements of this subpart. If the laboratory seeking LAAF-accreditation had its LAAF-accreditation withdrawn or one or more methods within its scope of LAAF-accreditation reduced by a recognized accreditation body or has been previously disqualified by FDA, the laboratory must meet the additional requirements specified by § 1.1142(a).

(b) *Documentation of conformance with ISO/IEC 17025:2017(E).* The laboratory may use documentation of conformance with ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101), as applicable and supplemented as necessary, in meeting the applicable requirements of this subpart.

(c) *Duration of accreditation.* If a LAAF-accredited laboratory maintains compliance with all requirements of this subpart, including accreditation to ISO/IEC 17025:2017(E), the laboratory's LAAF-accreditation will not end until reduced in scope, withdrawn, relinquished, or the laboratory is disqualified, under this subpart.

§ 1.1140 What must a LAAF-accredited laboratory do to voluntarily relinquish its LAAF-accreditation?

(a) *Notice to FDA and the recognized accreditation body of intent to relinquish.* A LAAF-accredited laboratory must

notify FDA and its recognized accreditation body at least 60 calendar days before voluntarily relinquishing LAAF-accreditation or any method within the scope of LAAF-accreditation. The notice must include the date on which relinquishment will occur. If the laboratory will relinquish all methods within its scope of LAAF-accreditation, the notification must also include the name and contact information of the custodian who will maintain the records required by §1.1154 after the date of relinquishment. The contact information for the records custodian must include an email address and the street address where the records required by §1.1154 will be located.

(b) *Public notice of voluntary relinquishment of accreditation.* FDA will provide notice on the website described in §1.1109 of the voluntary relinquishment of LAAF-accreditation of a laboratory.

§ 1.1141 What is the effect on a LAAF-accredited laboratory if its recognized accreditation body is no longer recognized by FDA?

If a recognized accreditation body has its application for renewal of recognition denied, relinquishes its recognition or allows its recognition to expire, or has its recognition revoked, any laboratory LAAF-accredited by the accreditation body must take either the actions in paragraph (a) of this section or the action in paragraph (b) of this section no later than 30 calendar days after receiving the notice to the LAAF-accredited laboratory required under §1.1115(g), §1.1116(b), or §1.1131(d)(2):

(a)(1) The LAAF-accredited laboratory must submit to FDA documentation of the LAAF-accredited laboratory's most recent internal audit, required under §1.1154(a)(5), documentation showing compliance with the conflict of interest requirements in §1.1147, and documentation of the most recent proficiency test or comparison program result for each test method within the laboratory's scope of LAAF-accreditation, to show compliance with §1.1138(a)(2); and

(2) The laboratory must become LAAF-accredited by another recognized accreditation body before the laboratory's ISO/IEC 17025:2017(E) (incorporated by reference, see §1.1101) accreditation lapses or not later than 1 year after the LAAF-accredited laboratory receives the applicable notice under §1.1115(g), §1.1116(b), or §1.1131(d)(2), whichever is sooner.

(b) The LAAF-accredited laboratory initiates relinquishment of its LAAF-accreditation under §1.1140, with the relinquishment to occur within 90 calendar days.

§ 1.1142 How does a laboratory request reinstatement of LAAF-accreditation?

(a) *Application following reduction of scope or withdrawal of LAAF-accreditation by a recognized accreditation body or disqualification by FDA.* A laboratory that has had any methods within its scope of LAAF-accreditation reduced or has had its LAAF-accreditation withdrawn by a recognized accreditation body or that has been disqualified by FDA may seek reinstatement of LAAF-accreditation by submitting a new application for LAAF-accreditation to a recognized accreditation body under §1.1139. The laboratory must also:

(1) Notify FDA prior to submitting a new application for LAAF-accreditation to the recognized accreditation body, including in the notification the name of the laboratory, contact information for the laboratory, the name of the recognized accreditation body to which the laboratory will be submitting the application, and the date that the laboratory expects to submit the new application for LAAF-accreditation; and

(2) Demonstrate, to the satisfaction of the recognized accreditation body to which it is submitting the new application, that the grounds for the reduction of scope or withdrawal of LAAF-accreditation or disqualification have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring.

(b) *Application following voluntary relinquishment of LAAF-accreditation.* A laboratory that voluntarily relinquished any methods within the scope of its LAAF-accreditation pursuant to §1.1140, may seek reaccreditation by submitting a new application for

LAAF-accreditation to a recognized accreditation body under § 1.1139.

REQUIREMENTS FOR LAAF-ACCREDITED LABORATORIES

§ 1.1147 What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?

(a) In addition to the impartiality and conflict of interest requirements in § 1.1138(a)(1), a LAAF-accredited laboratory must, subject to the exceptions in paragraph (b) of this section, prohibit the LAAF-accredited laboratory's employees, contractors, and agents involved in food testing under this subpart and related activities from accepting any money, gift, gratuity, or other item of value from the owner or consignee of the food that is being tested or will be tested by the LAAF-accredited laboratory.

(b) The prohibited items of value in paragraph (a) of this section do not include:

(1) Payment of fees for food testing under this subpart and related services;

(2) Reimbursement of direct costs associated with the food testing by the LAAF-accredited laboratory; and

(3) With respect to a LAAF-accredited laboratory that is owned by the owner or consignee of the food that is or will be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

(c) The LAAF-accredited laboratory must require the owner's or consignee's payment to the LAAF-accredited laboratory of fees for food testing services and reimbursement of direct costs associated with food testing to be independent of the outcome of the test results.

§ 1.1149 What oversight standards apply to sampling?

(a) *Documents.* Before analyzing a sample, the LAAF-accredited laboratory must develop (if it collected the sample) or obtain (if another firm collected the sample) the following information to be submitted with test results (see § 1.1152(c)):

(1) Written documentation of the sampler's applicable qualifications by training and experience. A LAAF-accredited laboratory only needs to develop or obtain documentation of a sampler's qualifications the first time that sampler collects a sample for the LAAF-accredited laboratory under this subpart. If a LAAF-accredited laboratory has previously submitted the sampler's qualifications to FDA under § 1.1152(c), the LAAF-accredited laboratory may refer to its previously submitted qualifications.

(2) The written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler and sampling firm and must list factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample; and

(3) A written sample collection report for each sample collected. The written sample collection report must include:

(i) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled);

(ii) The date of the sampling;

(iii) The lot number, size, identity, and quantity of the sample;

(iv) Documentation of sample collection procedures and any sample preparation techniques; and

(v) Documentation of the chain of custody of the sample and of measures taken to ensure the validity of the subsequent analytical testing, including controlling for the representational nature of the sample.

(b) *Potential consequences.* If any of the requirements in paragraph (a) of this section is not met, FDA may consider the analysis of the sample to be invalid.

(c) *Advance notice of sampling.* (1) If FDA determines that sampling conducted may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if FDA determines that the sampling otherwise may have been improper, FDA may require the LAAF-accredited laboratory that analyzed the associated sample, and other LAAF-accredited laboratories that have analyzed samples previously collected by the sampling firm, to obtain from the sampling firm, and submit, or require

the sampling firm to submit, an advance notice of sampling. The advance notice of sampling must be submitted to FDA at least 48 hours before each of the next 10 occasions that the sampling firm will collect a sample that the LAAF-accredited laboratory will analyze under this subpart.

(2) FDA may, as appropriate:

(i) Specify that the requirement applies to samples collected by a particular sampler;

(ii) Specify the type of food product or environment that requires advance notice of sampling under this subpart;

(iii) Determine that an amount of time other than 48 hours in advance is required, from a minimum of 24 hours up to 7 business days in advance;

(iv) Determine that a number of occasions other than 10 is required, from a minimum of 1 occasion to a maximum of 20 occasions;

(v) Notify affected LAAF-accredited laboratories that submission of additional notices of sampling are not required; and

(vi) Notify the owner or consignee that the advance notice applies to sampling for food testing being conducted on their behalf.

(3) The advance notice of sampling must contain:

(i) A unique identification for the advance notice of sampling;

(ii) The name of the LAAF-accredited laboratory that will conduct analysis of the sample;

(iii) The name and street address of the sampling firm that will conduct the sampling;

(iv) A primary contact (name and phone number) for the sampling firm;

(v) The reason why the food product or environment will be sampled;

(vi) The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled;

(vii) As applicable, the U.S. Customs and Border Protection entry and line number;

(viii) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled); and

(ix) The date and approximate time the sampling will begin.

§ 1.1150 What are the requirements for analysis of samples by a LAAF-accredited laboratory?

In addition to the sample analysis requirements of § 1.1138(a):

(a) The analysis must be conducted on either the sample received from the sampling firm or, if appropriate, on a representative sample of the sample received from the sampling firm.

(b) The analyst must:

(1) Be qualified by appropriate education, training, and/or experience to conduct the analysis;

(2) Have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and

(3) Be in compliance with the conflict of interest requirements of §§ 1.1138(a) and 1.1147.

(c) The method used to conduct the food testing must meet the requirements of § 1.1151.

(d) The LAAF-accredited laboratory must document the testing information and test results to the extent necessary to account for all information that is required to be included in a full analytical report (*see* § 1.1152(d)).

§ 1.1151 What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart?

In addition to the requirements of § 1.1138(a), a LAAF-accredited laboratory must meet the following requirements:

(a) The method of analysis used to conduct food testing under this subpart must be:

(1) Fit for purpose;

(2) Within the laboratory's scope of LAAF-accreditation;

(3) Appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and

(4) Appropriately verified by the LAAF-accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.

(b) Food testing must be conducted using the specified method:

(1) Under §1.1107(a)(1), if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribe a test method.

(2) Under §1.1107(a)(2), if the directed food laboratory order prescribes a test method.

(c)(1) A LAAF-accredited laboratory must validate methods in accordance with the requirements of §1.1138(a).

(2) A LAAF-accredited laboratory performing validation of a method under this subpart must record the information required by §1.1138(a) and the supporting analytical data.

(d)(1) Before a LAAF-accredited laboratory conducts food testing under this subpart using a method for a specific intended use for which the method has been validated, but for which the LAAF-accredited laboratory has not previously applied the method under this subpart, the LAAF-accredited laboratory must have verified it can properly perform the method for the specific intended use.

(2) A LAAF-accredited laboratory performing verification of a method under this subpart must record the method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the LAAF-accredited laboratory is able to properly perform the method.

(e) A LAAF-accredited laboratory may submit a written request to FDA requesting permission to use a method outside of its scope of LAAF-accreditation for food testing. FDA may approve the request if both following conditions are satisfied:

(1) A new method or methodology has been developed and validated but no reasonably available laboratory has been LAAF-accredited to perform such method or methodology, and

(2) The use of such method is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

§ 1.1152 What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA?

(a) *General requirements.* (1) All notifications, results, reports, and studies required to be submitted to FDA by a LAAF-accredited laboratory under this subpart must:

(i) Include the name and street address of the LAAF-accredited laboratory;

(ii) Identify a point of contact for the LAAF-accredited laboratory, including email and telephone number, whom FDA may contact with questions or comments;

(iii) Display an identification unique to the test results, report, notification, or study; and

(iv) Be true, accurate, unambiguous, and objective.

(2) The LAAF-accredited laboratory that conducts the analysis of the sample under this subpart is responsible for the submission of all notifications, results, reports, and studies to FDA as required by this section.

(3) If the LAAF-accredited laboratory becomes aware that any aspect of the submitted material is inaccurate, the LAAF-accredited laboratory must immediately inform FDA and submit a corrected version. Such corrections must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017(E) (incorporated by reference, see §1.1101) section 7.8.8.

(4) Any opinions and interpretations in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements in ISO/IEC 17025:2017(E) section 7.8.7 and any statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements of ISO/IEC 17025:2017(E) section 7.8.6.

(b) *Test results.* (1) The LAAF-accredited laboratory must submit the results of all testing required to be conducted under this subpart directly to FDA via the location specified by the website described in §1.1109, unless another location is specified by FDA regarding testing conducted under §1.1107(a)(2) or (3).

(2) The test results must be clear and identify:

(i) The name and street address of the owner or consignee for which the testing was conducted,

(ii) As appropriate, the U.S. Customs and Border Protection entry and line number(s), and

(iii) The associated notifications, reports, and studies required to be submitted with the test results under this subpart.

(c) *Documentation required to be submitted with test results.* The following documentation must be included with each full analytical report (see paragraph (d) of this section) and each abridged analytical report (see §1.1153) submitted to FDA under this subpart:

(1) All sampling plans and sample collection reports related to the food testing conducted as developed or obtained by the LAAF-accredited laboratory in accordance with §1.1149;

(2) Written documentation of the sampler's qualifications or an indication that the sampler's qualifications have been submitted previously, in accordance with §1.1149(a)(1);

(3) For any validation studies required by §1.1151(c)(1), the documentation required by §1.1151(c)(2);

(4) For any verification studies required by §1.1151(d)(1), the documentation required by §1.1151(d)(2);

(5) The justification for any modification to or deviation from the method(s) of analysis used and documentation of the LAAF-accredited laboratory's authorization for the modification or deviation; and

(6) A certification from one or more members of the LAAF-accredited laboratory's management certifying that the test results, notifications, reports, and studies are true and accurate; and that the documentation includes the results of all tests conducted under this subpart. The certification must include the name, title, and signature of any certifiers.

(d) *Full analytical report contents.* In addition to the documentation required to be submitted with all test results (see paragraph (c) of this section), a full analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d);

(2) Documentation of references for the method of analysis used;

(3) Name and signature of the analyst who conducted each analytical step, including any applicable validation and verification steps, and the date each step was performed;

(4) Calculations, presented in a legible and logical manner;

(5) As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and presented in a clear order;

(6) Identification of the source and purity of reference standards used, and, as applicable: Certified reference materials, certified reference cultures traceable to a nationally or internationally recognized type culture collection (including concentration, units, preparation, and storage conditions), and reference standard preparation information (including who prepared the reference standard, date of preparation, expiration date, chemical balance, and solvent used);

(7) A copy of the label from any immediate container sampled, if available, and any additional labeling needed to evaluate the product;

(8) All original compilations of raw data secured in the course of the analysis, including discarded, unused, or reworked data, with the justification for discarding or re-working such data, corresponding supporting data, and quality control results (including the expected result and whether it is acceptable), all identified with unique sample identification, date, and time, associated with the test;

(9) Any other relevant additional supporting information such as the storage location of analyzed samples, appropriate attachments such as instrument printouts, computer generated charts and data sheets, and photocopies or original labels for the product analyzed;

(10) Identification of any software used;

(11) Any certificate of analysis for standards and software; and

(12) The following information about the qualifications of each analyst involved in the analysis conducted under this subpart, if the LAAF-accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly

changed since the LAAF-accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

(i) The analyst's curriculum vitae;

(ii) Training records for the applicable methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider; and

(iii) Any other documentation of the analyst's ability to perform the method properly in the context of the food testing to be conducted, pursuant to §1.1150(b).

(e) *Additional information about nonstandard methods.* If the LAAF-accredited laboratory conducts the analysis using a method that is not published in a reputable international or national standard or that is otherwise not publicly and readily available, upon request by FDA the LAAF-accredited laboratory must submit documentation of the method to FDA.

(f) *Immediate notification of significant changes.* The LAAF-accredited laboratory must notify FDA and the recognized accreditation body that LAAF-accredited the laboratory of changes that affect the LAAF-accreditation of the laboratory within 48 hours, including a detailed description of such changes, and an explanation of how such changes affect the LAAF-accreditation of the laboratory. LAAF-accredited laboratories are not required to notify FDA of changes that a recognized accreditation body must provide to FDA under §1.1123(d).

(g) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA under this section, FDA may consider the related food testing to be invalid.

§ 1.1153 What are the requirements for submitting abridged analytical reports?

(a) *Requesting permission.* A LAAF-accredited laboratory may request permission to submit abridged analytical reports for each major food testing discipline: Biological, chemical, and physical.

(1) FDA will grant permission to submit abridged analytical reports for a single major food testing discipline if all of the following conditions are met:

(i) The LAAF-accredited laboratory is not on suspension or probation for any method within the major food testing discipline that is the subject of its request (see §1.1121(b) or §1.1161(b));

(ii) The LAAF-accredited laboratory has successfully implemented any required corrective action under §1.1121(a) or §1.1161(a); and

(iii) The last five full analytical reports for the major food testing discipline contain no shortcomings that call into question the validity of the test results or repeated administrative errors.

(2) FDA will notify the LAAF-accredited laboratory if permission is granted or denied.

(b) *FDA review of abridged analytical reports.* (1) FDA will review all abridged analytical reports submitted.

(2) FDA will notify the LAAF-accredited laboratory if FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors, will require corrective action under §1.1161(a), and may revoke permission to submit abridged analytical reports for the specific major food testing discipline.

(3) If FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors in abridged analytical reports from a LAAF-accredited laboratory that has previously had its permission to submit abridged analytical reports revoked for any major food testing discipline, FDA may put the LAAF-accredited laboratory on probation for one or more methods under §1.1161(b). Under §1.1162(a), a laboratory on probation for one or more methods may not submit abridged analytical reports for the major food testing disciplines of which the probationary methods are a part.

(4) A LAAF-accredited laboratory that has had permission to submit abridged analytical reports revoked for one or more major food testing disciplines may request permission to submit abridged analytical reports as described in paragraph (a) of this section for each major food testing discipline.

(c) *Contents of abridged analytical reports.* In addition to the documentation required to be submitted with all test

results (see §1.1152(c)), an abridged analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) (incorporated by reference, see §1.1101) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d); and

(2) Quality control results (including the expected result and whether it is acceptable).

(d) *Exceptions.* FDA may require additional documentation or a full analytical report from a LAAF-accredited laboratory permitted to submit abridged analytical reports in the following circumstances:

(1) FDA may require a full analytical report related to an FDA investigation or FDA enforcement proceeding.

(2) Occasionally, for the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program, FDA will require additional documentation or a full analytical report within 72 hours of FDA's request.

(e) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA under paragraph (c) of this section, FDA may consider the related food testing to be invalid.

§ 1.1154 What other records requirements must a LAAF-accredited laboratory meet?

(a) In addition to the records requirements of §1.1138(a), a LAAF-accredited laboratory must maintain, for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart, including:

(1) Documents related to the LAAF-accredited laboratory's grant of LAAF-accreditation (and, if applicable, extensions and reductions of scope of LAAF-accreditation) from its recognized accreditation body, including all required proficiency test and comparison program records for each method within the scope of LAAF-accreditation under §1.1138(a)(2);

(2) Documentation of food testing the LAAF-accredited laboratory conducted under this subpart sufficient to account for all information required by §1.1152(d), in accordance with §1.1150(d);

(3) All documents that the LAAF-accredited laboratory was required to submit to FDA under §§1.1152 and 1.1153, and associated correspondence between the LAAF-accredited laboratory (and its officers, employees, and other agents) and the owner or consignee (and its officers, employees, and other agents) regarding food testing under this subpart;

(4) All requests for food testing from an owner or consignee that would be conducted under this subpart;

(5) Documentation of any internal investigations, internal audits, and corrective action taken to address any problems or deficiencies related to activities under this subpart;

(6) All documentation related to suspension, probation, reduction of scope, or withdrawal of LAAF-accreditation, or laboratory disqualification under this subpart; and

(7) Documentation of changes to its management system or food testing activities that may affect its compliance with this subpart.

(b) Make the records required by paragraph (a) of this section available for inspection and copying or for electronic submission upon written request of an authorized officer or employee of FDA. If FDA requests records for inspection and copying, the laboratory must make such records promptly available at the physical location of the laboratory or at another reasonably accessible location. If the authorized officer or employee of FDA requests electronic submission, the records must be submitted within 10 business days of the request.

(c) Ensure that significant amendments to records described by this section can be tracked to previous and original versions. If such a significant amendment is made, both the original document and amended document must be maintained by the LAAF-accredited laboratory during the time period for which the amended document must be maintained under this subpart. The laboratory must also document the date of amendment, the personnel responsible for the amendment, and a conspicuous indication on the original document stating that the document

has been altered and that a more recent version of the document exists.

FDA OVERSIGHT OF LAAF-ACCREDITED LABORATORIES

§ 1.1159 How will FDA oversee LAAF-accredited laboratories?

(a) FDA may review the performance of LAAF-accredited laboratories at any time to determine whether the LAAF-accredited laboratory continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the LAAF-accredited laboratory that, if not corrected, would warrant corrective action, probation, or disqualification under § 1.1161.

(b) In evaluating the performance of a LAAF-accredited laboratory, FDA may review any of the following:

(1) Records the LAAF-accredited laboratory is required to maintain under this subpart;

(2) Records the recognized accreditation body that LAAF-accredited the laboratory is required to maintain under this subpart;

(3) Information obtained by FDA during a review of the LAAF-accredited laboratory conducted pursuant to paragraph (c) of this section;

(4) Information obtained by FDA during an evaluation of the recognized accreditation body that LAAF-accredits the laboratory;

(5) Analytical reports and test results submitted to FDA; and

(6) Any other information obtained by FDA, including during FDA's inspections or investigations of one or more owners or consignees.

(c) FDA may conduct an onsite review of a LAAF-accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to review the performance of a LAAF-accredited laboratory under this subpart. Certain review activities may be conducted remotely if it will not aid in the review to conduct them onsite.

(d) FDA may report any observations and deficiencies identified during its review of LAAF-accredited laboratory performance under this subpart to the recognized accreditation body.

§ 1.1160 How will FDA review test results and analytical reports?

(a) If FDA finds that any test result, analytical report, related documents, or the associated analysis contains deficiencies or otherwise indicates that any aspect of the food testing is not being conducted in compliance with this subpart, FDA will notify the LAAF-accredited laboratory that submitted the analytical report of any deficiency and may:

(1) Require the laboratory to correct the test result, analytical report, related documents, or the associated analysis;

(2) Revoke permission to submit abridged reports for that major food testing discipline under § 1.1153(b);

(3) Require a corrective action under § 1.1161(a);

(4) Consider the analysis to be invalid; and/or

(5) Notify the owner or consignee of the deficiency.

(b) FDA may report any deficiencies identified during its review of any test results, reports, and related documents under this subpart to the recognized accreditation body that LAAF-accredits the laboratory.

(c) Nothing in this subpart shall be construed to limit the ability of FDA to review and act on information received about food testing, including determining the sufficiency of such information and testing.

§ 1.1161 When will FDA require corrective action, put a LAAF-accredited laboratory on probation, or disqualify a LAAF-accredited laboratory from submitting analytical reports?

(a) *Corrective action.* FDA may require corrective action to address any deficiencies identified while reviewing a LAAF-accredited laboratory's performance under this subpart.

(1) FDA will notify the LAAF-accredited laboratory of all deficiencies requiring corrective action and will either specify a deadline to implement corrective action or will require the LAAF-accredited laboratory to submit a corrective action plan and timeframe for implementation to FDA for approval.

(2) The LAAF-accredited laboratory must handle FDA's notification as a complaint under ISO/IEC 17025:2017(E) (incorporated by reference, see §1.1101) section 7.9, implement appropriate corrective action under ISO/IEC 17025:2017(E) section 8.7, and submit both the results of the complaint investigation and subsequent corrective action to FDA.

(3) FDA will review the corrective action and will notify the LAAF-accredited laboratory whether the corrective action is acceptable.

(b) *Probation.* If FDA determines that a LAAF-accredited laboratory has not effectively implemented corrective action or otherwise fails to address deficiencies identified, FDA may put the LAAF-accredited laboratory on probation for one or more methods and require corrective action under paragraph (a) of this section.

(1) FDA will notify the LAAF-accredited laboratory and its recognized accreditation body of the grounds for the probation, the method(s) covered by the probation, and all deficiencies requiring corrective action via the process described in paragraph (a) of this section.

(2) FDA will provide notice of a LAAF-accredited laboratory's probation on the website described in §1.1109.

(3) FDA will review the corrective action and will notify the LAAF-accredited laboratory and its recognized accreditation body whether the corrective action is acceptable.

(4) A LAAF-accredited laboratory will remain on probation until the LAAF-accredited laboratory demonstrates to FDA's satisfaction that it has successfully implemented appropriate corrective action.

(5) If FDA determines that a LAAF-accredited laboratory on probation has failed to implement appropriate corrective action or otherwise fails to address deficiencies identified, FDA may disqualify the LAAF-accredited laboratory under paragraph (c) of this section.

(c) *Disqualification.* FDA may disqualify a LAAF-accredited laboratory from submitting analytical reports under this subpart for one or more methods for good cause, which may include any of the following reasons:

(1) Deliberate falsification of analytical reports, testing results, or other records submitted to FDA.

(2) Failure of a LAAF-accredited laboratory on probation to effectively implement corrective action or otherwise address identified deficiencies.

(3) Other failure to substantially comply with this subpart where the laboratory's recognized accreditation body has not reduced the scope of or withdrawn LAAF-accreditation of the laboratory.

(d) *Disqualification procedures.* (1) FDA will issue a notice of disqualification to a LAAF-accredited laboratory and its recognized accreditation body, which will include:

(i) The grounds for disqualification;

(ii) The method or methods to which the disqualification applies;

(iii) The date the disqualification will be effective;

(iv) The procedures for requesting a regulatory hearing on the disqualification under §1.1173; and

(v) The procedures for requesting reinstatement after disqualification under §1.1142.

(2) FDA will provide notice of a LAAF-accredited laboratory's disqualification on the website described in §1.1109.

§ 1.1162 What are the consequences if FDA puts a LAAF-accredited laboratory on probation or disqualifies a LAAF-accredited laboratory?

(a) A LAAF-accredited laboratory that FDA has put on probation for one or more methods is permitted to continue to conduct food testing under this subpart; however, a LAAF-accredited laboratory that is on probation for one or more methods is not permitted to submit abridged analytical reports for the major food testing discipline of which the probationary methods are part.

(b) If FDA disqualifies a LAAF-accredited laboratory for all methods within its scope of LAAF-accreditation, the laboratory is immediately ineligible to conduct food testing under this subpart. If FDA disqualifies a LAAF-accredited laboratory for specific methods within the scope of LAAF-accreditation, the laboratory is immediately ineligible to use the methods for which the laboratory has

been disqualified to conduct food testing under this subpart.

(c) With respect to food testing conducted by the laboratory prior to its disqualification, FDA may refuse to consider results and associated reports of food testing conducted under this subpart if the basis for the disqualification of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

(d) Within 10 business days of the date of issuance of disqualification, the laboratory must provide the name and email address of the custodian who will maintain and make available to FDA the records required by §1.1154, and the street address where the records will be located.

(e) Within 10 business days of the date of issuance of a notice of probation or disqualification, the laboratory must notify any owners or consignees for which it is conducting food testing using methods for which it is being placed on probation or disqualified under this subpart, that it is on probation or has been disqualified.

REQUESTING FDA RECONSIDERATION OR REGULATORY HEARINGS OF FDA DECISIONS UNDER THIS SUBPART

§1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?

(a) *Timing of request.* An accreditation body may seek reconsideration of FDA's decision to deny its application for recognition or renewal of recognition under §1.1114, or reinstatement of recognition under §1.1117, no later than 10 business days after the date of the issuance of such denial.

(b) *Submission of request.* The request to reconsider an application under paragraph (a) of this section must be signed by the accreditation body, as appropriate, or by an individual authorized to act on its behalf. The accreditation body must submit the request, together with any supporting information, to FDA in accordance with the procedures described in the notice of denial.

(c) *Notification of FDA's decision.* After completing its review and evaluation of the request for reconsideration and any supporting information submitted pursuant to paragraph (b) of this section, FDA will notify the accreditation body of its decision to grant or deny recognition upon reconsideration.

§1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the accreditation body's recognition or disqualify a LAAF-accredited laboratory?

(a) *Request for hearing.* No later than 10 business days after the date FDA issued a revocation of recognition of an accreditation body pursuant to §1.1131 or disqualification of a LAAF-accredited laboratory under §1.1161, the accreditation body, laboratory, or an individual authorized to act on the accreditation body's or laboratory's behalf, may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the revocation or disqualification. The notice of revocation issued under §1.1131 or notice of disqualification issued under §1.1161, as applicable, will contain all the elements required by §16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing under this subpart must be submitted with a written appeal that responds to the bases for the FDA decision described in the written notice of revocation or disqualification, together with any supporting information. The request, appeal, and supporting information must be submitted to FDA in accordance with the procedures described in the notice of revocation or disqualification.

(c) *Effect of submitting a request for a regulatory hearing on an FDA decision.* The submission of a request for a regulatory hearing under this subpart will not operate to delay or stay the effect of a decision by FDA to revoke the recognition of an accreditation body or disqualify the LAAF-accredited laboratory unless FDA determines that delay or a stay is in the public interest.

(d) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a

request for a regulatory hearing is submitted to FDA.

(e) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to §16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(f) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the accreditation body or laboratory, and the presiding officer and FDA.

(2) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to §16.5(b) of this chapter, the procedures for a regulatory hearing apply only to the extent that such procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: The requirements of §16.22 (Initiation of regulatory hearing); §16.24(e) (timing) and (f) (contents of notice); §16.40 (Commissioner); §16.60(a) (public process); §16.95(b) (administrative decision and record for decision); and §16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or laboratory disqualification is considered a final agency action under 5 U.S.C. 702.

§1.1174 How does an owner or consignee request a regulatory hearing on a directed food laboratory order?

(a) *Request for hearing.* No later than 3 business days after FDA has issued the directed food laboratory order, an owner or consignee may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the directed food laboratory order. The directed food laboratory order will contain all of the elements required by §16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing must be submitted with a written appeal that responds to the bases, as appropriate, for FDA's determinations described in the directed food laboratory order, together with any supporting information. The request, appeal, and supporting information must be submitted in accordance with the procedures described in the directed food laboratory order.

(c) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(d) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to §16.26(a) of this chapter.

(e) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, such hearing will be held within 2 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the requestor and the presiding officer and FDA.

(2) The presiding officer may require that a hearing conducted under this subpart be completed within 1 business day, as appropriate.

(3) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to §16.5(b) of this chapter, the procedures for a regulatory hearing described in part 16 of this chapter apply only to the extent that such procedures are supplementary and not in conflict with the procedures specified for the conduct of regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: §16.22 (Initiation of regulatory hearing); §16.24(e) (timing) and (f) (contents of notice); §16.40 (Commissioner); §16.60(a) (public process); §16.95(b) (administrative decision and record for decision); and §16.119 (Reconsideration and stay of action).

(4) A decision by the presiding officer to affirm the directed food laboratory order is considered a final agency action under 5 U.S.C. 702.

ELECTRONIC RECORDS AND PUBLIC DISCLOSURE REQUIREMENTS

§ 1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 1.1200 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

Subpart S—Additional Traceability Records for Certain Foods

SOURCE: 87 FR 71077, Nov. 21, 2022, unless otherwise noted.

GENERAL PROVISIONS

§ 1.1300 Who is subject to this subpart?

Except as otherwise specified in this subpart, the requirements in this subpart apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act (Food Traceability List). FDA will publish the Food Traceability List on its website, *www.fda.gov.*, in accordance with section 204(d)(2)(B) of the FDA Food Safety Modernization Act.

§ 1.1305 What foods and persons are exempt from this subpart?

(a) *Exemptions for certain small producers.* (1) *Certain produce farms.* (i) This subpart does not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter,

(ii) This subpart does not apply to produce farms when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(2) *Certain shell egg producers.* This subpart does not apply to shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm.

(3) *Certain other producers of raw agricultural commodities.* This subpart does not apply to producers of raw agricultural commodities other than produce or shell eggs (*e.g.*, aquaculture operations) when the average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of the raw agricultural commodities they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(b) *Exemption for farms when food is sold or donated directly to consumers.* This subpart does not apply to a farm with respect to food produced on the farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.

(c) *Inapplicability to certain food produced and packaged on a farm.* This subpart does not apply to food produced and packaged on a farm, provided that:

(1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(2) The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. FDA will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm.

(d) *Exemptions and partial exemptions for foods that receive certain types of processing*. This subpart does not apply to the following foods that receive certain types of processing:

(1) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in §112.2(b) of this chapter are met for the produce;

(2) Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in §118.3 of this chapter) in accordance with §118.1(a)(2) of this chapter;

(3) Food that you subject to a kill step, provided that you maintain records containing:

(i) The information specified in §1.1345 for your receipt of the food to which you apply the kill step (unless you have entered into a written agreement concerning your application of a kill step to the food in accordance with paragraph (d)(6) of this section); and

(ii) A record of your application of the kill step;

(4) Food that you change such that the food is no longer on the Food Traceability List, provided that you maintain records containing the information specified in §1.1345 for your receipt of the food you change;

(5) Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the Food Traceability List;

(6) Food that will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List, provided that:

(i) There is a written agreement between the shipper of the food and the receiver stating that the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or

(ii) There is a written agreement between the shipper of the food and the receiver stating that an entity in the supply chain subsequent to the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List and that the receiver will only ship the food to another entity that agrees, in writing, it will:

(A) Apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or

(B) Enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the Food Traceability List.

(iii) A written agreement entered into in accordance with paragraph (d)(6)(i) or (ii) of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and

(iv) A written agreement entered into in accordance with paragraph (d)(6)(i) or (ii) must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years.

(e) *Exemption for produce that is rarely consumed raw*. This subpart does not apply to produce that is listed as rarely consumed raw in §112.2(a)(1) of this chapter.

(f) *Exemption for raw bivalve molluscan shellfish*. This subpart does not apply to raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program, subject to the requirements of

part 123, subpart C, and §1240.60 of this chapter, or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish.

(g) *Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the U.S. Department of Agriculture (USDA).* This subpart does not apply to persons who manufacture, process, pack, or hold food on the Food Traceability List during or after the time when the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(h) *Partial exemption for commingled raw agricultural commodities.* (1) Except as specified in paragraph (h)(3) of this section, this subpart does not apply to commingled raw agricultural commodities (which, as defined in §1.1310, do not include types of fruits and vegetables to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply).

(2) Except as specified in paragraph (h)(3) of this section, this subpart does not apply to a raw agricultural commodity that will become a commingled raw agricultural commodity, provided that:

(i) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that the receiver will include the commodity as part of a commingled raw agricultural commodity; or

(ii) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that an entity in the supply chain subsequent to the receiver will include the commodity as part of a commingled raw agricultural commodity and that the receiver will only ship the raw agricultural commodity to another entity that agrees, in writing, it will either:

(A) Include the raw agricultural commodity as part of a commingled raw agricultural commodity; or

(B) Enter into a similar written agreement with a subsequent receiver stating that the raw agricultural commodity will become part of a commingled raw agricultural commodity;

(iii) A written agreement entered into in accordance with paragraph (h)(2)(i) or (ii) of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and

(iv) A written agreement entered into in accordance with paragraph (h)(2)(i) or (ii) must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years;

(3) With respect to a commingled raw agricultural commodity that qualifies for either of the exemptions set forth in paragraphs (h)(1) and (2) of this section, if a person who manufactures, processes, packs, or holds such commodity is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable raw agricultural commodity, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such food in accordance with §§1.337 and 1.345. Such records must be maintained for 2 years.

(i) *Exemption for small retail food establishments and small restaurants.* This subpart does not apply to retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(j) *Partial exemption for retail food establishments and restaurants purchasing directly from a farm.* (1) Except as specified in paragraph (j)(2) of this section, this subpart does not apply to a retail food establishment or restaurant with respect to a food that is produced on a farm (including food produced and packaged on the farm) and both sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm.

(2) When a retail food establishment or restaurant purchases a food directly

from a farm in accordance with paragraph (j)(1) of this section, the retail food establishment or restaurant must maintain a record documenting the name and address of the farm that was the source of the food. The retail food establishment or restaurant must maintain such a record for 180 days.

(k) *Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant.* (1) Except as specified in paragraph (k)(2) of this section, this subpart does not apply to either entity when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice (*e.g.*, not pursuant to a contractual agreement to purchase food from the seller).

(2) When a retail food establishment or restaurant purchases a food on the Food Traceability List from another retail food establishment or restaurant in accordance with paragraph (k)(1) of this section, the retail food establishment or restaurant that makes the purchase must maintain a record (*e.g.*, a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase.

(l) *Partial exemption for farm to school and farm to institution programs.* (1) Except as specified in paragraph (l)(2) of this section, this subpart does not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution.

(2) When a school or institution conducting a farm to school or farm to institution program obtains a food from a farm in accordance with paragraph (l)(1) of this section, the school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food. The school food authority or relevant food procurement entity must maintain such record for 180 days.

(m) *Partial exemption for owners, operators, or agents in charge of fishing vessels.* (1) Except as specified in paragraph (m)(2) of this section, with respect to a food that is obtained from a fishing vessel, this subpart does not apply to the owner, operator, or agent in charge of the fishing vessel, and this subpart also does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.

(2) With respect to any person who receives the partial exemption set forth in paragraph (m)(1) of this section, if such person is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

(n) *Exemption for transporters.* This subpart does not apply to transporters of food.

(o) *Exemption for nonprofit food establishments.* This subpart does not apply to nonprofit food establishments.

(p) *Exemption for persons who manufacture, process, pack, or hold food for personal consumption.* This subpart does not apply to persons who manufacture, process, pack, or hold food for personal consumption.

(q) *Exemption for certain persons who hold food on behalf of individual consumers.* This subpart does not apply to persons who hold food on behalf of specific individual consumers, provided that these persons:

(1) Are not parties to the transaction involving the food they hold; and

(2) Are not in the business of distributing food.

(r) *Exemption for food for research or evaluation.* This subpart does not apply to food for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public; and

(2) Is accompanied by the statement ''Food for research or evaluation use.''

§ 1.1310 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, the following definitions apply to words and phrases as they are used in this subpart:

Commingled raw agricultural commodity means any commodity that is combined or mixed after harvesting but before processing, except that the term ''commingled raw agricultural commodity'' does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply. For the purpose of this definition, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is ''combined or mixed'' only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Also, for the purpose of this definition, the term ''processing'' means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

Cooling means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Critical tracking event means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

Farm means farm as defined in § 1.328. For producers of shell eggs, ''farm'' means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3 of this chapter.

First land-based receiver means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)).

Food Traceability List means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act. The term ''Food Traceability List'' includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (*e.g.*, fresh) in which it appears on the list.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from

the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Initial packing means packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.

Key data element means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.

Kill step means lethality processing that significantly minimizes pathogens in a food.

Location description means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes an individual, partnership, corporation, and association.

Point of contact means an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.

Produce means produce as defined in § 112.3 of this chapter.

Product description means a description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.

Raw agricultural commodity means ''raw agricultural commodity'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving means an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (*e.g.*, by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.

Reference document number means the identification number assigned to a specific reference document.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ''consumers'' does not include businesses. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. A ''retail food establishment'' also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their

crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, ''farm-operated business'' means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Shipping means an event in a food's supply chain in which a food is arranged for transport (*e.g.*, by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Traceability lot means a batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability lot code source means the place where a food was assigned a traceability lot code.

Traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

Transformation means an event in a food's supply chain that involves manufacturing/processing a food or changing a food (*e.g.*, by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event (*e.g.*, harvesting, cooling).

Transporter means a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air.

You means a person subject to this subpart under § 1.1300.

Traceability Plan

§ 1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

(a) If you are subject to the requirements in this subpart, you must establish and maintain a traceability plan containing the following information:

(1) A description of the procedures you use to maintain the records you are required to keep under this subpart, including the format and location of these records.

(2) A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;

(3) A description of how you assign traceability lot codes to foods on the Food Traceability List in accordance with § 1.1320, if applicable;

(4) A statement identifying a point of contact for questions regarding your traceability plan and records; and

(5) If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.

(i) Except as specified in paragraph (a)(5)(ii) of this section, the farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.

(ii) For aquaculture farms, the farm map must show the location and name of each container (*e.g.*, pond, pool, tank, cage) in which you raise seafood on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each container.

(b) You must update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you are in compliance with the requirements of this subpart. You must retain your previous traceability plan for 2 years after you update the plan.

§ 1.1320 When must I assign traceability lot codes to foods on the Food Traceability List?

(a) You must assign a traceability lot code when you do any of the following: Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel; perform the first land-based receiving of a food obtained from a fishing vessel; or transform a food.

(b) Except as otherwise specified in this subpart, you must not establish a new traceability lot code when you conduct other activities (*e.g.*, shipping) for a food on the Food Traceability List.

RECORDS OF CRITICAL TRACKING EVENTS

§ 1.1325 What records must I keep and provide when I harvest or cool a raw agricultural commodity on the Food Traceability List?

(a) *Harvesting.* (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must maintain records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(ii) The commodity and, if applicable, variety of the food;

(iii) The quantity and unit of measure of the food (*e.g.*, 75 bins, 200 pounds);

(iv) The location description for the farm where the food was harvested;

(v) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;

(vi) For aquacultured food, the name of the container (*e.g.*, pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;

(vii) The date of harvesting; and

(viii) The reference document type and reference document number.

(2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must provide (in electronic, paper, or other written form) your business name, phone number, and the information in paragraphs (a)(1)(i) through (vii) of this section to the initial packer of the raw agricultural commodity you harvest, either directly or through the supply chain.

(b) *Cooling before initial packing.* (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must maintain records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(ii) The commodity and, if applicable, variety of the food;

(iii) The quantity and unit of measure of the food (*e.g.*, 75 bins, 200 pounds);

(iv) The location description for where you cooled the food;

(v) The date of cooling;

(vi) The location description for the farm where the food was harvested; and

(vii) The reference document type and reference document number.

(2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must provide (in electronic, paper, or other written form) the information in paragraphs (b)(1)(i) through (vi) of this section to the initial packer of the raw agricultural commodity you cool, either directly or through the supply chain.

§ 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

(a) Except as specified in paragraph (c) of this section, for each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;

(2) The date you received the food;

(3) The quantity and unit of measure of the food received (*e.g.*, 75 bins, 200 pounds);

(4) The location description for the farm where the food was harvested;

(5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;

(6) For aquacultured food, the name of the container (*e.g.*, pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;

(7) The business name and phone number for the harvester of the food;

(8) The date of harvesting;

(9) The location description for where the food was cooled (if applicable);

(10) The date of cooling (if applicable);

(11) The traceability lot code you assigned;

(12) The product description of the packed food;

(13) The quantity and unit of measure of the packed food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(14) The location description for where you initially packed the food (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;

(15) The date of initial packing; and

(16) The reference document type and reference document number.

(b) For each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, you must also maintain records containing the following information and linking this information to the traceability lot:

(1) The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available;

(2) The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing;

(3) The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse;

(4) The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter;

(5) A description of the seeds, including the seed type or taxonomic name,

growing specifications, type of packaging, and (if applicable) antimicrobial treatment;

(6) The date of receipt of the seeds by the sprouter; and

(7) The reference document type and reference document number.

(c) For each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack that you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;

(2) The date you received the food;

(3) The quantity and unit of measure of the food received (*e.g.*, 75 bins, 200 pounds);

(4) The location description for the person from whom you received the food;

(5) The traceability lot code you assigned;

(6) The product description of the packed food;

(7) The quantity and unit of measure of the packed food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(8) The location description for where you initially packed the food (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;

(9) The date of initial packing; and

(10) The reference document type and reference document number.

§ 1.1335 What records must I keep when I am the first land-based receiver of a food on the Food Traceability List that was obtained from a fishing vessel?

For each traceability lot of a food obtained from a fishing vessel for which you are the first land-based receiver, you must maintain records containing the following information and linking this information to the traceability lot:

(a) The traceability lot code you assigned;

(b) The species and/or acceptable market name for unpackaged food, or the product description for packaged food;

(c) The quantity and unit of measure of the food (*e.g.*, 300 kg);

(d) The harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught;

(e) The location description for the first land-based receiver (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;

(f) The date the food was landed; and

(g) The reference document type and reference document number.

§ 1.1340 What records must I keep and provide when I ship a food on the Food Traceability List?

(a) For each traceability lot of a food on the Food Traceability List you ship, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;

(2) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(5) The location description for the location from which you shipped the food;

(6) The date you shipped the food;

(7) The location description for the traceability lot code source, or the traceability lot code source reference; and

(8) The reference document type and reference document number.

(b) You must provide (in electronic, paper, or other written form) the information in paragraphs (a)(1) through (7) of this section to the immediate subsequent recipient (other than a transporter) of each traceability lot that you ship.

(c) This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).

§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?

(a) Except as specified in paragraphs (b) and (c) of this section, for each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;

(2) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate previous source (other than a transporter) for the food;

(5) The location description for where the food was received;

(6) The date you received the food;

(7) The location description for the traceability lot code source, or the traceability lot code source reference; and

(8) The reference document type and reference document number.

(b) For each traceability lot of a food on the Food Traceability List you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this paragraph does not apply if you are a retail food establishment or restaurant);

(2) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);

(3) The product description for the food;

(4) The location description for the immediate previous source (other than a transporter) for the food;

(5) The location description for where the food was received (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;

(6) The date you received the food; and

(7) The reference document type and reference document number.

(c) This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

§ 1.1350 What records must I keep when I transform a food on the Food Traceability List?

(a) Except as specified in paragraphs (b) and (c) of this section, for each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:

(1) For the food on the Food Traceability List used in transformation (if applicable), the following information:

(i) The traceability lot code for the food;

(ii) The product description for the food to which the traceability lot code applies; and

(iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.

(2) For the food produced through transformation, the following information:

(i) The new traceability lot code for the food;

(ii) The location description for where you transformed the food (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;

(iii) The date transformation was completed;

(iv) The product description for the food;

(v) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and

(vi) The reference document type and reference document number for the transformation event.

(b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in §1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in §1.1330(b).

(c) Paragraphs (a) and (b) of this section do not apply to retail food establishments and restaurants with respect to foods they do not ship (*e.g.*, foods they sell or send directly to consumers).

PROCEDURES FOR MODIFIED REQUIREMENTS AND EXEMPTIONS

§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?

(a) *General*. Except as specified in paragraph (b) of this section, FDA will modify the requirements of this subpart applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this subpart, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

(b) *Registered facilities*. If a person to whom modified requirements or an exemption applies under paragraph (a) of this section (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under paragraph (a) of this section) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (and in accordance with the requirements of subpart H of this part) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§1.337 and 1.345. Such records must be maintained for 2 years.

§ 1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?

FDA will consider modifying the requirements of this subpart applicable to a food or type of entity, or exempting a food or type of entity from the requirements of this subpart, on our own initiative or in response to a citizen petition submitted under §10.30 of this chapter by any interested party.

§ 1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?

In addition to meeting the requirements on the content and format of a citizen petition in §10.30 of this chapter, a petition requesting modified requirements or an exemption from the requirements of this subpart must:

(a) Specify the food or type of entity to which the modified requirements or exemption would apply;

(b) If the petition requests modified requirements, specify the proposed modifications to the requirements of this subpart; and

(c) Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health.

§ 1.1375 What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1380 What process applies to a petition requesting modified requirements or an exemption?

(a) In general, the procedures set forth in §10.30 of this chapter govern FDA's response to a petition requesting modified requirements or an exemption. An interested person may submit comments on such a petition in accordance with §10.30(d) of this chapter.

(b) Under §10.30(h)(3) of this chapter, FDA will publish a notice in the FEDERAL REGISTER requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition.

(c) Under §10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the FEDERAL REGISTER setting forth any modified requirements or exemptions and the reasons for them.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

§ 1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?

(a) If FDA, on our own initiative, determines that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notice in the FEDERAL REGISTER setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notice will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a notice in the FEDERAL REGISTER stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

§ 1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?

Any modified requirements that FDA adopts or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the FEDERAL REGISTER, unless otherwise stated in the notice.

§ 1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?

FDA may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health.

§ 1.1400 What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?

(a) If FDA tentatively determines that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:

(1) We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition; and

(2) We will publish a notice in the FEDERAL REGISTER of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

(b) After considering any comments timely submitted, we will publish a notice in the FEDERAL REGISTER of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. If we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

WAIVERS

§ 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?

FDA will waive one or more of the requirements of this subpart when we determine that:

(a) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;

(b) The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(c) The waiver will not otherwise be contrary to the public interest.

§ 1.1410 When will FDA consider whether to waive a requirement of this subpart?

FDA will consider whether to waive a requirement of this subpart on our own initiative or in response to the following:

(a) A written request for a waiver for an individual entity; or

(b) A citizen petition requesting a waiver for a type of entity submitted under § 10.30 of this chapter by any person subject to the requirements of this subpart.

§ 1.1415 How may I request a waiver for an individual entity?

You may request a waiver of one or more requirements of this subpart for an individual entity by submitting a written request to the Food and Drug Administration as described at *www.fda.gov*. The request for a waiver must include the following:

(a) The name, address, and point of contact of the individual entity to which the waiver would apply;

(b) The requirements of this subpart to which the waiver would apply;

(c) Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements;

(d) Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(e) Information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1420 What process applies to a request for a waiver for an individual entity?

(a) After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.

(b) Any waiver for an individual entity that FDA grants will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

§ 1.1425 What must be included in a petition requesting a waiver for a type of entity?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting a waiver for a type of entity must:

(a) Specify the type of entity to which the waiver would apply and the requirements of this subpart to which the waiver would apply;

(b) Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship

for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements;

(c) Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(d) Present information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1435 What process applies to a petition requesting a waiver for a type of entity?

(a) In general, the procedures set forth in §10.30 of this chapter govern FDA's response to a petition requesting a waiver. An interested person may submit comments on such a petition in accordance with §10.30(d) of this chapter.

(b) Under §10.30(h)(3) of this chapter, FDA will publish a notice in the FEDERAL REGISTER requesting information and views on a submitted petition requesting a waiver for a type of entity, including information and views from persons who could be affected by the waiver if we granted the petition.

(c) Under §10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the FEDERAL REGISTER setting forth any requirements we have waived and the reasons for the waiver.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

§ 1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?

(a) If FDA, on our own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notice in the FEDERAL REGISTER setting forth the proposed waiver and the reasons for such waiver. The notice will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a notice in the FEDERAL REGISTER stating whether we are granting the waiver (in whole or in part) and the reasons for our decision.

(c) Any waiver for a type of entity that FDA grants will become effective on the date that notice of the waiver is published in the FEDERAL REGISTER, unless otherwise stated in the notice.

§ 1.1445 Under what circumstances may FDA modify or revoke a waiver?

FDA may modify or revoke a waiver if we determine that:

(a) Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies;

(b) The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats

of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; or

(c) The waiver is otherwise contrary to the public interest.

§ 1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

(a) *Waiver for an individual entity.* (1) If FDA tentatively determines that we should modify or revoke a waiver for an individual entity, we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked.

(2) Upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. If we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

(b) *Waiver for a type of entity.* (1) If FDA tentatively determines that we should modify or revoke a waiver for a type of entity, we will provide the following notifications:

(i) We will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition.

(ii) We will publish a notice in the FEDERAL REGISTER of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

(2) After considering any comments timely submitted, we will publish a notice in the FEDERAL REGISTER of our decision whether to modify or revoke the waiver and the reasons for the decision. If we do modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

RECORDS MAINTENANCE AND AVAILABILITY

§ 1.1455 How must records required by this subpart be maintained and made available?

(a) *General requirements for records.* (1) You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under this subpart.

(2) All records must be legible and stored to prevent deterioration or loss.

(b) *Establishment and maintenance of records by another entity.* You may have another entity establish and maintain records required under this subpart on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.

(c) *Record availability.* (1) You must make all records required under this subpart available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required under this subpart.

(2) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is

likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act, you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) of a request made in-person or remotely (*e.g.*, by phone) by an authorized FDA representative, the information you are required to maintain under this subpart, for the foods and date ranges or traceability lot codes specified in the request.

(i) If FDA's request for the information specified in paragraph (c)(3) of this section is made by phone, we will also provide the request to you in writing upon your request; however, you must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request.

(ii) Except as specified in paragraph (c)(3)(iii) and (iv) of this section, when the information requested by FDA under paragraph (c)(3) of this section is information you are required to maintain under §§ 1.1325 through 1.1350, you must provide such information in an electronic sortable spreadsheet, along with any other information needed to understand the information in the spreadsheet.

(iii) You may provide the information requested by FDA under paragraph (c)(3) of this section in a form other than an electronic sortable spreadsheet if you are:

(A) A farm whose average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment;

(B) A retail food establishment or restaurant with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment; or

(C) A person (other than a farm, retail food establishment, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(iv) FDA will withdraw a request for an electronic sortable spreadsheet under paragraph (c)(3)(ii) of this section, as appropriate, to accommodate a religious belief of a person asked to provide such a spreadsheet.

(4) Upon FDA request, you must provide within a reasonable time an English translation of records required under this subpart maintained in a language other than English.

(d) *Record retention.* Except as specified otherwise in this subpart, you must maintain records containing the information required by this subpart for 2 years from the date you created or obtained the records.

(e) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter, if not otherwise exempt.

(f) *Use of existing records.* You do not need to duplicate existing records you have (*e.g.*, records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(g) *Use of multiple sets of records.* You do not have to keep all of the information required by this subpart in a single set of records. However, your

traceability plan must indicate the format and location of the records you are required to keep under this subpart, in accordance with § 1.1315(a)(1).

(h) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

CONSEQUENCES OF FAILURE TO COMPLY

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

(a) *Prohibited act.* The violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act, including the violation of any requirement of this subpart, is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.

(b) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of that section), including the requirements of this subpart, have not been complied with regarding such article.

UPDATING THE FOOD TRACEABILITY LIST

§ 1.1465 How will FDA update the Food Traceability List?

(a) When FDA tentatively concludes, in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act, that it is appropriate to revise the Food Traceability List, we will publish a notice in the FEDERAL REGISTER stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes.

(b) After considering any information and views submitted on the proposed changes to the Food Traceability List, FDA will publish a notice in the FEDERAL REGISTER stating whether we are making any changes to the list and the reasons for the decision. If FDA revises the list, we will also publish the revised list on our website.

(c) When FDA updates the Food Traceability List in accordance with this section, any deletions from the list will become effective immediately. Any additions to the list will become effective 2 years after the date of publication of the FEDERAL REGISTER notice announcing the revised list, unless otherwise stated in the notice.

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

Subpart A—General Provisions

Sec.

Subpart B—Human and Animal Foods

Subparts C–E [Reserved]

Subpart F—Caustic Poisons

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

AUTHORITY: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

SOURCE: 42 FR 15559, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 2.5 Imminent hazard to the public health.

(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent