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