

Regulatory Alert: FSVP Compliance Dates

May 20, 2017

On May 30, 2017, compliance begins for the Foreign Supplier Verification Program (FSVP) Rule.¹ This rule imposes sweeping new changes on food importers and requires review and assessment of the food safety practices of foreign suppliers and their compliance history. Foreign suppliers must be approved pursuant to a written program before sourcing. The rule also requires new information to be submitted for customs entries: the FSVP importer—the person responsible for FSVP compliance—must now be declared for each importation of FDA-regulated food (including dietary supplements) unless exempt.

U.S. Food Imports LLC (USFI) has received a number of questions relating to which food items from which supplier categories are subject to the rule on May 30, 2017 (the first compliance date) and future compliance dates.

USFI assists firms with FSVP compliance, including providing FSVP agent services, and compliance with other FDA, USDA and CBP requirements related to food imports.

¹ 21 CFR Part 1 Subpart L.

Disclaimer: This material is provided as a service to clients and friends of U.S. Food Imports LLC and does not constitute legal advice. As legal advice must be tailored to the specific circumstances of each case and laws and regulations are frequently changing, nothing provided herein should be used as a substitute for the advice of competent counsel.

Compliance is required on May 30, 2017, for the following foods from the following supplier categories:

| FSVP Compliance Required May 30, 2017 | |
|--|---|
| Food Category | Supplier Category |
| Processed Human Foods | Suppliers with 500 or more full time equivalent employees ² |
| Live Food Animals (including livestock, poultry and game) ³ | All suppliers |
| Finished Dietary Supplements | All suppliers |
| Dietary Ingredients | Suppliers with 500 or more full time equivalent employees |
| Animal Food ⁴ /Pet Treats | Suppliers with 500 or more full time equivalent employees subject to CGMP requirements ⁵ |
| Shell Eggs | All suppliers |
| Honey Produced and Bottled on-Farm | All suppliers |
| Produce Not Covered Under the Produce Safety Rule (See Below) | All suppliers |

| Produce Not Covered Under the Produce Safety Rule | | |
|--|--------------|-------------|
| asparagus | chickpeas | horseradish |
| black beans | cocoa beans | lentils |
| great Northern beans | coffee beans | okra |
| kidney beans | collards | peanuts |
| lima beans | sweet corn | pecans |
| navy beans | cranberries | peppermint |
| pinto beans | dates | potatoes |

² The number of FTEs 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. If the result is not a whole number, round down to the next lowest whole number.

³ FDA has authority over live animal importations, game meat processing facilities are required to register as food facilities under Section 415 and thus are subject to the Human or Animal Food Preventive Controls Rules and are considered processed foods for purposes of this memo. We interpret FSVP as applying to livestock as well. We await guidance

⁴ Animal dietary supplements are regulated by FDA as food and not subject to DSHEA. Animal food for purposes of this chart includes animal dietary supplements.

⁵ CGMPs do not apply to: (1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities; (2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and (3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed). 21 C.F.R. § 507.5

| Produce Not Covered Under the Produce Safety Rule | | |
|---|---|---|
| garden beets (roots and tops) sugar beets cashews sour cherries oilseeds | dill (seeds and weed) eggplants figs ginger hazelnuts | pumpkins winter squash sweet potatoes water chestnuts grains |
| All produce (including produce that would otherwise be covered i.e. not on this list) grown by farms with \$25,000 or less in annual produce sales | | Produce subject to further processing for which an exemption is claimed under 21 CFR §112.2 |

| FSVP Compliance Required July 26, 2017 | |
|--|---|
| Food Category | Supplier Category |
| Sprouts | Farms with more than \$500,000 in annual produce sales ⁶ |

| FSVP Compliance Required March 19, 2018 | |
|---|---|
| Food Category | Supplier Category |
| Processed Human Foods | Suppliers with 0-499 full time equivalent employees (excluding Qualified Facilities ⁷) |
| Dietary Ingredients | Suppliers with 0-499 full time equivalent employees (excluding Qualified Facilities) |
| Animal Food/Pet Treats | Suppliers with 0-499 full time equivalent employees subject to CGMP requirements (excluding Qualified Facilities ⁸) |
| Animal Food/Pet Treats | Suppliers with 500 or more full time equivalent employees <u>not</u> subject to CGMP requirements |

⁶ All dollar value thresholds are adjusted for inflation.

⁷ Qualified facilities (human food) means (1) a business with less than \$1,000,000 in annual sales of human food, plus the market value of human food processed, packed or held without sale; or (2) a business that has less than \$500,000 in annual sales and most of the sales are sold to restaurants, retailers or consumers in the same state or within 275 miles. FDA has acknowledged that (1) largely encompasses (2). Dollar figures include subsidiaries and affiliates.

⁸ Qualified facilities (animal food) means (1) a business with less than \$2,500,000 in annual sales of animal food, plus the market value of animal food processed, packed or held without sale; (2) a business that has less than \$500,000 in annual sales and most of the sales are sold to restaurants, retailers or consumers in the same state or within 275 miles. FDA has acknowledged that (1) largely encompasses (2). Dollar figures include subsidiaries and affiliates.

| FSVP Compliance Required July 26, 2018 | |
|--|---|
| Food Category | Supplier Category |
| Produce Covered Under Produce Safety Rule Excluding Sprouts | Suppliers (farms) with more than \$500,000 in annual produce sales |
| Sprouts | Suppliers (farms) with \$250,001-\$500,000 in annual produce sales (includes both suppliers eligible for the Qualified Exemption ⁹ and those that are not) |

| FSVP Compliance Required March 18, 2019 | |
|--|---|
| Food Category | Supplier Category |
| Processed Human Foods | Suppliers that are Qualified Facilities (less than \$1,000,000 in annual sales of human food, plus the market value of human food processed, packed or held without sale) ¹⁰ |
| Processed Human Foods | Suppliers subject to the Pasteurized Milk Ordinance ¹¹ |
| Animal Food/Pet Treats | Suppliers that are Qualified Facilities required to comply with CGMP requirements (less than \$2,500,000 annual sales plus market value of animal food processed, packed and held without sale) ¹² |
| Animal Food/Pet Treats | Suppliers with 0-499 full time equivalent employees <u>not</u> subject to CGMP requirements ¹³ (excluding Qualified Facilities) |

⁹ A farm is eligible for a qualified exemption if the annual monetary value of food (note: not just produce) is less than \$500,000 and most sales occur to restaurants, retailers or consumers within the same state or 275 miles.

¹⁰ This is the broader definition of Qualified Facility. See footnote 6 for more information.

¹¹ Only a very small number of facilities outside of the U.S. are recognized pursuant to the International Certification Program of the National Conference of Interstate Milk Shippers (which oversees the PMO program).

¹² This is the broader definition of Qualified Facility. See footnote 7 for more information.

¹³ CGMPs do not apply to : (1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities; (2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and (3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed). 21 C.F.R. § 507.5

| FSVP Compliance Required May 28, 2019 | |
|--|--------------------------|
| Food Category | Supplier Category |
| Food Contact Substances | All suppliers |

| FSVP Compliance Required July 29, 2019 | |
|--|---|
| Food Category | Supplier Category |
| Produce Covered Under Produce Safety Rule Excluding Sprouts | Suppliers with \$250,001-\$500,000 in annual produce sales (includes both farms eligible for the Qualified Exemption and those that are not) |
| Sprouts | Suppliers with \$0-\$250,000 in annual produce sales (includes both farms that are eligible for the Qualified Exemption and those that are not) |

| FSVP Compliance Required March 17, 2020 | |
|--|---|
| Food Category | Supplier Category |
| Animal Food/Pet Treats | Suppliers that are Qualified Facilities required to comply with CGMP requirements (less than \$2,500,000 annual sales plus market value of animal food processed, packed and held without sale) ¹⁴ |

| FSVP Compliance Required July 27, 2020 | |
|--|--|
| Food Category | Supplier Category |
| Produce Covered Under Produce Safety Rule Excluding Sprouts | Suppliers (farms) with \$0-\$250,000 in annual produce sales (includes both farms eligible for the Qualified Exemption and those that are not) |

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¹⁴ This is the broader definition of Qualified Facility. See footnote 7 for more information.