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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.

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

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 <u>and of all of its affiliates and subsidiaries</u> 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 not 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 not 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)

Please contact Erik Lieberman at elieberman1@usfoodimports.com or 202.765.1800 if you have questions or would like additional information.

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