Contains Nonbinding Recommendations

Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities:

Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number Docket No. FDA-2017-D-6592 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, you may contact the FSMA Technical Assistance Network online at https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm, by mail at Food and Drug Administration; 5001 Campus Drive; Wiley Building, HFS-009; Attn: FSMA Outreach; College Park, MD, 20740, or by phone at 1-888-SAFEFOOD (1-888-723-3366).

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

January 2018

Table of Contents

Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities:

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this document is to state the Food and Drug Administration's (FDA's) intent to exercise enforcement discretion regarding application of the regulation on foreign supplier verification programs (FSVPs) to importers of grains imported into the United States as raw agricultural commodities (RACs). For the reasons stated below, we intend to exercise enforcement discretion with respect to the FSVP regulation for importers of grain RACs that are solely engaged in the storage of grain intended for further distribution or processing and grain importers that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing (such as certain commodity brokers with respect to the FSVP regulation).

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

This guidance provides information to facilitate understanding of the applicability of the FSVP requirements to the importation of grain RACs. The pronouns "I," "me," and "you" are used in this guidance to refer to the importer. "Agency" and the pronouns "we" and "our" are used to refer to FDA.

II. Background

Many RACs that are not fruits or vegetables, including grains, are imported into the United States. Grain RACs imported into the United States include barley, dent- and flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds for oil extraction (e.g., cotton seed, flax seed, rapeseed, soybean, sunflower seed).

Mycotoxin contamination is one of the primary hazards associated with grain RACs. Some grains may also contain other hazards, including microbial pathogens such as *Salmonella*. Grains in which microbial pathogens may be present are usually destined for further processing (for example, extraction of oil from oilseeds and cooking of rice) such that these hazards are controlled. Most grains are dried in the field (rice being the exception, being dried following harvest) and then stored dry, typically in grain elevators, under conditions that minimize fungal growth and mycotoxin production. Although some controls for mycotoxins in grain crops can be applied during cultivation, mycotoxins generally cannot be fully controlled on the farm. Therefore, other post-harvest mitigation measures are employed. These measures include moisture and temperature controls to prevent fungal growth and mycotoxin production; sorting to remove moldy, discolored, and damaged kernels; and milling grains. Sampling and analytical testing are used as a means of segregating lots with higher and lower mycotoxin concentration as appropriate for specific uses. In the United States, most food facilities have programs for mycotoxin control in domestic and imported grains, such as safe practices for storage, drying, sorting, and testing of grain. These programs result in low concentrations of mycotoxins in finished grain-based foods.

The importation of grain RACs into the United States is subject to certain supplier verification requirements established in the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add, among other food safety requirements, provisions requiring the verification of the safety of food imported from foreign suppliers of that food.

Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of FSVPs. We issued the FSVP final rule on November 27, 2015 (80 FR 74225). The FSVP regulation requires food importers to develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier uses processes and procedures that provide the same level of public health protection as those required under the preventive controls and produce safety provisions of FSMA (if applicable) and regulations implementing those provisions, as well as assurances that the imported food is not adulterated and that human food is not misbranded with respect to allergen labeling (21 CFR 1.502(a)). Among other things, the FSVP regulation (21 CFR 1.500-1.514) requires most food importers to do the following:

- Analyze the hazards for the foods they import (21 CFR 1.504);
- Evaluate the performance of their potential foreign suppliers and the risk posed by the foods to be imported (21 CFR 1.505); and
- Determine and conduct appropriate foreign supplier verification activities, such as onsite auditing of foreign suppliers, sampling and testing, and review of supplier food safety records (21 CFR 1.506).

The FSVP regulation applies (with certain exceptions) to the importation of "food" as defined in section 201(f) of the FD&C Act (except that "food" for FSVP purposes does not include pesticides as defined in 7 U.S.C. 136(u)) (see 21 CFR 1.500). Thus, the FSVP regulation applies to importers of RACs, including RACs that are grains.

FSMA also includes provisions (codified in section 418 of the FD&C Act) requiring certain food facilities to implement preventive controls to, among other things, provide assurances that hazards identified in a hazard analysis will be significantly minimized or prevented. The preventive controls provisions of FSMA include supplier verification activities as one type of procedure, practice, or process that food facilities might need to use as a preventive control to significantly minimize or prevent hazards arising in the manufacture, processing, packing, or holding of food (section 418(o)(3)(G) of the FD&C Act). FDA's final rules on current good manufacturing practice (CGMP), hazard analysis, and risk-based preventive controls for human food (80 FR 55908, September 17, 2015) and for animal food (80 FR 56170, September 17, 2015) include provisions requiring receiving facilities to conduct a hazard analysis and to establish and implement supply-chain programs for domestic and imported raw materials and other ingredients for which the facility has identified a hazard requiring a supply-chain-applied control (21 CFR part 117, subpart G, and 21 CFR part 507, subpart E, respectively).

Under the supply-chain program provisions of the preventive controls regulations, a "receiving facility" is a facility subject to the preventive controls and supply-chain program requirements and that manufactures/processes a raw material or other ingredient it receives from a supplier (21 CFR 117.3 and 507.3). A "supply-chain-applied control" is a preventive control for a hazard in a raw material or other ingredient when the hazard is controlled before its receipt (21 CFR 117.3 and 507.3). The supply-chain program requirements include, among other things, determining and conducting appropriate supplier verification activities (such as onsite auditing, sampling and testing, and review of supplier food safety records) to provide assurance that hazards requiring a supply-chain-applied control have been significantly minimized or prevented. Importers of grain RACs that manufacture/process the grain are subject to the preventive controls requirements, including the supply-chain program provisions. In addition, under 21 CFR 1.502(c), grain RAC importers that are also receiving facilities subject to the preventive controls regulations for human or animal food will be deemed in compliance with most of the FSVP requirements when they implement preventive controls for the hazards in the grain in accordance with 21 CFR 117.135 (for human food) or 507.34 (for animal food).

The preventive controls requirements, including the supply-chain program provisions, do not apply to facilities that are solely engaged in the storage of non-produce RACs (including grain RACs) intended for further distribution or processing (21 CFR 117.5(j) and 507.5(g)). This exemption reflects the Agency's finding that outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-produce RACs (see 78 FR 3646 at 3709, January 16, 2013 and 78 FR 64736 at 64764, October 29, 2013). Consequently, we concluded that subjecting facilities that only store non-produce RACs intended for further distribution or processing to the preventive controls requirements would provide no significant public health benefit.

However, as stated above, the FSVP regulation applies to all importers of non-produce RACs, including importers that are solely engaged in the storage of these RACs intended for further

processing. Unless exempt from FSVP (under other provisions) or importing the grain under modified FSVP requirements (e.g., for very small importers), importers of grain RACs such as grain elevators, brokers, and manufacturers/processors may be required to conduct the standard FSVP activities, including evaluating and approving a foreign supplier (21 CFR 1.505) and conducting foreign supplier verification activities (21 CFR 1.506).[1] However, as discussed above, suppliers of grain RACs (i.e., farmers) generally do not control the hazards in the grain. Therefore, the standard FSVP requirements to evaluate potential foreign suppliers and conduct verification of the suppliers generally would not apply to importers of grain RACs.

Rather than the standard FSVP requirements, certain modified requirements would apply when there is a hazard in the grain and either of the following is applicable:

- The grain cannot be consumed without application of an appropriate control (e.g., soybeans, which require heat treatment to denature a natural toxin found in soybeans) (see 21 CFR 1.507(a)(1)). The importer would need to document its determination that the grain cannot be consumed without application of a control.

- The importer's customer or a subsequent entity will control the hazards in the grain. In such cases, the importer would need to disclose that the grain had not been processed to control the identified hazards and obtain written assurance from the customer that the customer or some subsequent entity will control the hazards (see 21 CFR 1.507(a)(2)-(4)). (We have issued guidance for industry entitled "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs" stating we are exercising enforcement discretion with regard to the written assurance requirements to complete rulemaking to address feasibility concerns with the provision (83 FR 598, January 5, 2018).)

III. Discussion

To better align the FSVP regulation with the exemption from preventive controls requirements for facilities solely engaged in the storage of non-produce RACs, and because of the nature of the hazards associated with grain RACs and how they are generally addressed in the distribution chain, we intend to exercise enforcement discretion for importers of grain RACs that are solely engaged in the storage of grain intended for further distribution or processing (in accordance with 21 CFR 117.5(j) or 507.5(g)) with respect to the FSVP regulation. This means that we will not expect these FSVP importers of grain RACs (i.e., grain elevators and other facilities solely engaged in the storage of grain RACs intended for further distribution or processing) to meet any of the FSVP requirements. However, these grain RAC importers remain subject to the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a)).

[1] Other FSVP requirements include, but are not limited to, determining whether there are any hazards requiring a control in imported foods (21 CFR 1.504), taking corrective actions (when appropriate) (21 CFR 1.508), ensuring that the importer is identified at U.S. entry (21 CFR 1.509), and recordkeeping (21 CFR 1.510).

This intent to exercise enforcement discretion with respect to the FSVP regulation also applies to grain importers that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others for storage, packing or manufacturing/processing (such as certain commodity brokers). Thus, if a firm that is the FSVP "importer" (as defined in 21 CFR 1.500) of a grain RAC arranges for the distribution of the grain without taking physical possession of it (e.g., does not engage in storage, packing, or processing of the grain), we intend to exercise enforcement discretion for the FSVP requirements.

This intent to exercise enforcement discretion with respect to the FSVP regulation for certain importers of grain RACs does not apply to importers that manufacture/process grain RACs. However, as discussed above, we do not expect FSVP to pose a regulatory burden for these manufacturers/processors, because of the nature of the hazards in grain RACs and specific provisions already included in the preventive controls regulations for human or animal food requiring manufacturers/processors to control the hazards that are identified as requiring a preventive control. The only FSVP requirement that the importer that manufactures/processes grain RACs and is also a receiving facility will need to meet is to ensure that it is identified as the FSVP importer of the grain at U.S. entry (in accordance with 21 CFR 1.509). Those importers that manufacture/process grain RACs and are not receiving facilities will likely be able to use the modified provisions in 21 CFR 1.507 rather than perform supplier verification activities.

When a food product under FDA oversight is offered for entry into the United States, the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit an entity role code or affirmation of compliance code related to FSVP. The entity role code "FSV" indicates that the entry line is subject to the FSVP regulation and currently subject to FSVP enforcement, so the importer must provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA (see 21 CFR 1.509). If the food entry line is exempt from the requirements of the FSVP regulation, not yet subject to the regulation, or eligible for enforcement discretion with respect to the FSVP regulation, the filer should transmit the applicable Affirmation of Compliance code. "FSX" should be used if FDA has provided guidance that the agency intends to exercise enforcement discretion for the relevant shipment with respect to the FSVP regulation.

Therefore, importers of grain RACs that are solely engaged in the storage of grain intended for further distribution or processing and grain importers that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing should transmit the affirmation of compliance code "FSX" when making entry in the U.S. For more information on importer identification, consult "Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation," available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm.