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Regulatory Alert: FDA Defers Enforcement of FSVP for Food Contact Substances; Other FSMA Requirements

FDA Defers Enforcement of Written Assurance Requirements, Application of Animal Food Preventive Controls Rule to Certain Human Food Byproducts

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On January 4, 2018, the U.S. Food and Drug Administration (FDA) released guidance indicating their intent to defer enforcement of aspects of the Foreign Supplier Verification Program Rule,[1] Preventive Controls for Human and Animal Food Rules[2] and Produce Safety Rule.[3]

Foreign Supplier Verification Program Rule

The Foreign Supplier Verification Program Rule (FSVP Rule) as written requires importers to verify that their foreign suppliers are not producing food contact substances in a manner which would render them adulterated under the Federal Food, Drug and Cosmetic Act (FDCA).[4] Items considered to be containing food contact substances by FDA include pots and pans, food packaging that directly contacts food, dinnerware, drinking glasses, and flatware among many other items.

FDA announced in the guidance it will be exercising enforcement discretion (in other words not enforcing FSVP) for food contact substances. FDA justified the position on the basis that food contact substances generally migrate to food in low levels and that FDA has an extensive premarket review processes for these substances under the food contact notification process and food additive petition process.

FDA noted that they will consider revisiting their exercise of enforcement discretion for food contact substances if new information becomes available regarding safety concerns associated with food contact substances. Please note that a future administration could change this position quickly as FDA has not indicated that they intend to revise the FSVP regulation to provide for this enforcement discretion policy.

[1] 21 CFR Part 1, Subpart L.
[2] 21 CFR Part 117, Part 507.
[3] 21 CFR Part 112.
[4] 21 USC Chapter 9.

Enforcement Policy for Certain Facilities Subject to the Preventive Controls Rule for Human Food and/or Produce Safety Rule

FDA is not enforcing the Human Food Preventive Controls Rule preventive controls requirements (Subpart C and related subparts in part 21 CFR Part 117) for the following facilities:

1. **Facilities that would qualify as secondary activities farms except for the ownership of the facility, for example, a produce packinghouse not owned by a farm, a nut hulling/shelling operation, an egg packinghouse, a grain elevator, a cotton ginning facility.** The Human Food CGMPs will still be enforced for farm-related activities conducted on non-produce raw agricultural commodities (RACs) but not for farm-related activities conducted on produce RACs.
2. **Facilities that would qualify as farms if they did not color RACs.** The Human Food CGMPs will still be enforced for coloring non-produce RACS but not for produce RACs.
3. **Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that only consists of RACS that have been dried /dehydrated to create a distinct commodity**, for example, a facility that packs and holds dried beans. FDA will still be enforcing the Human Food CGMPs for produce RACs but not for non-produce RACs.

FDA has indicated they will be revising the FSMA rules to codify these positions.

Enforcement Policy for Certain Facilities Subject to the Preventive Controls Rule for Animal Food

FDA is not enforcing the Animal Food Preventive Controls Rule preventive controls requirements (Subpart C and related subparts in 21 CFR Part 507) for the following facilities:

1. **Facilities that would qualify as secondary activities farms except for the ownership of the facility,** for example, a facility engaged in conditioning seed for cultivation that solely packs and holds seed for use in animal food. FDA will also not be enforcing the Animal Food CGMPs for these facilities.
2. **Facilities that would qualify as farms if they did not color RACs.** FDA will also not be enforcing the Animal Food CGMPs for these facilities.
3. **Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that only consists of RACS that have been dried /dehydrated to create a distinct commodity**, for example, a facility that packs and holds dried beans for animal food. FDA will also not be enforcing the Animal Food CGMPs for these facilities.
4. **Farm Mixed-Type facilities making silage food for animals.** FDA will also not be enforcing the Animal Food CGMPs for these facilities.

FDA has indicated they will be revising the FSMA rules to codify these positions.

Enforcement Policy for Written Customer Assurances

The Preventive Controls for Human Food Rule, Preventive Controls for Animal Food Rule, Produce Safety Rule and Foreign Supplier Verification Program Rules all contain provisions requiring importers, manufacturers and growers to obtain written assurances from customers that such customers are controlling or ensuring control of hazards for certain foods in which hazards have not been controlled up the supply chain.

FDA will not be enforcing the written customer assurance requirements until it completes a new rulemaking to contemplate them.

Enforcement Policy for Certain Human Food Byproducts for Use as Animal Food that is Further Manufactured

FDA is not enforcing the Animal Food preventive controls requirements for human food facilities that comply with the Human Food Preventive Controls Rule and do not further manufacturer human food byproducts for animal food if the manufacturing/processing activities that are performed on the human food by-products for use as animal food are limited to:

1. Drying/dehydrating, evaporating, pressing, chopping, and similar activities to reduce weight, bulk, or volume, and/or
2. Mixing (e.g. combining different vegetable culls and trimmings, combining juice and dairy by-products, stirring), centrifuging, and similar activities to combine ingredients or separate components (e.g. water and solids), and
3. These activities are not performed to prevent or significantly minimize animal food hazards and do not introduce animal food hazards.

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