

## At this time, FDA does not intend to enforce certain provisions in four regulations implementing FSMA.

### Which provisions and why?

The FDA has announced that it does not intend to enforce certain provisions in four of the rules that implement the FDA Food Safety Modernization Act (FSMA). The enforcement discretion covers certain entities or activities covered by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal food rules (PC Human Food and PC Animal Food or CGMP & PC rules), Foreign Supplier Verification Programs rule (FSVP), and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety rule).

While this enforcement policy is in place, FDA will consider the most effective and practical approaches to address issues that have been raised since the FSMA rules became final and provide long-term certainty for stakeholders.

#### 1. CERTAIN FACILITIES CONDUCTING FARM-RELATED ACTIVITIES THAT ARE SUBJECT TO THE PREVENTIVE CONTROLS REQUIREMENTS.

Farms are exempt from the preventive controls and CGMP requirements in the CGMP & PC rules. Produce farms are typically covered by the Produce Safety rule, unless an exemption applies. The enforcement policy applies to certain facilities conducting farm-related activities. Some of these facilities also conduct activities not within the farm definition even if conducted on farms (e.g., coloring RACs).

**FARM-RELATED ACTIVITIES:** These are activities within the definition of “farm” if performed on farms. These activities include growing and harvesting crops and some manufacturing/processing activities: drying/dehydrating raw agricultural commodities (RACs) to create a distinct commodity, treating RACs to manipulate ripening, and packaging and labeling RACs.

**RAW AGRICULTURAL COMMODITY:** RACs are a food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled form. Grains and eggs are examples of non-produce RACs.



**■ Why does FDA intend to exercise enforcement discretion for certain facilities that conduct farm-related activities?**

Some establishments that fall outside of the current “farm” definition conduct activities that also are typically conducted on farms. However, because those establishments are not considered farms, they are subject to the preventive controls and CGMP requirements (unless another exemption applies).

The agency intends to initiate a rulemaking that could change the way the requirements in the PC rules apply to facilities that conduct activities similar to those that occur on farms, as farms are currently defined. The FDA intends to exercise enforcement discretion for the requirements in the PC rules for these specific entities and activities until the completion of a future rulemaking related to farm activities.

**■ Which facilities and activities does this enforcement discretion apply to?**

**TABLE 1.** Summary of Enforcement Policy with Regard to Human Food

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for human food preventive controls requirements?	Does enforcement discretion apply for human food CGMPs?
<ul style="list-style-type: none"> <li>Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>No, for farm-related activities conducted on produce RACs.</li> <li>Yes, for farm-related activities conducted on non-produce RACs.</li> </ul>
<ul style="list-style-type: none"> <li>Facilities that would qualify as farms if they did not color RACs</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>No, for coloring produce RACs.</li> <li>Yes, for coloring non-produce RACs.</li> </ul>
<ul style="list-style-type: none"> <li>Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity such as dried beans</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>No, for produce RACs.</li> <li>Yes, for non-produce RACs.</li> </ul>

**TABLE 2: Summary of Enforcement Policy with Regard to Animal Food**

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for animal food preventive controls requirements?	Does enforcement discretion apply for animal food CGMPs?
<ul style="list-style-type: none"> <li>Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>
<ul style="list-style-type: none"> <li>Facilities that would qualify as farms if they did not color RACs</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>
<ul style="list-style-type: none"> <li>Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity such as dried beans</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>
<ul style="list-style-type: none"> <li>Farm mixed-type facilities making silage food for animals</li> </ul>	<ul style="list-style-type: none"> <li>N/A for small and very small businesses (because they are exempt from animal food preventive controls requirements).</li> <li>Yes, for businesses that are not small or very small.</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> </ul>

A few notes about the charts:

- For those entities covered by the enforcement discretion, the enforcement discretion applies to all their preventive controls requirements, all animal food CGMPs, and all human food CGMPs for non-produce RACs. The enforcement discretion for human food CGMPs does not include activities conducted on produce RACs, many of which have long been subject to human food CGMPs. Further, the human food CGMPs provide an option for establishments to comply with the produce rule for certain activities involving produce RACs.
- The ownership issue pertains to the current requirement that a secondary activities farm be majority-owned by the primary production farm and that the majority of the RACs come from the primary production farm. FDA is considering changes to this requirement.
- A facility that only packs, packages, labels and/or holds RACs that have been dried or dehydrated to create a distinct commodity currently falls outside of the farm definition because the facility is not involved in growing or harvesting the produce so it is not a primary production farm. Further, the facility is not devoted to harvesting, packing and/or holding RACs because these dried/dehydrated commodities are processed foods, so it cannot be a secondary activities farm.

- Coloring RACs is not included within the farm definition. Although it is a type of manufacturing/processing, unlike most manufacturing/processing, it does not convert a RAC into a processed food.
- Silage is food for animals made by storing and fermenting green forage plants, such as corn stalks, bean plants and grass.

#### ■ How will the FDA continue to protect public health while following this enforcement policy?

The FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

## 2. WRITTEN ASSURANCES IN THE “CUSTOMER PROVISIONS” IN THE PC HUMAN FOOD, PC ANIMAL FOOD, FSVP, AND PRODUCE SAFETY RULES.

Each of the four rules — PC Human Food, PC Animal Food, FSVP, and Produce Safety — includes “customer provisions” intended to provide written assurance to a manufacturer, processor, importer, or farmer that the food will be processed to control for hazards before the food reaches consumers.

For the PC rules, these provisions apply when a manufacturer/processor relies on other entities (commercial customers) in the distribution chain to control certain identified hazards, i.e., when there will be further processing of the food before it reaches consumers.

The FSVP rule includes customer provisions that apply when an importer imports food for which the hazards are controlled after importing.

Additionally, produce is eligible for an exemption from many of the requirements in the Produce Safety rule if it will receive commercial processing that adequately reduces the presence of microorganisms of public health significance, and certain other conditions are met including requirements for disclosure statements and written assurances similar to what’s required by the CGMP & PC rules and FSVP.

In these provisions, “customer” means the commercial customer, not consumers.

#### ■ Why does the FDA intend to exercise enforcement discretion for the written assurance requirements?

The FDA has received feedback that certain product distribution chains would require vastly more written assurances and resources to comply than was anticipated by FDA during the rulemaking process. The agency intends to exercise enforcement discretion for the written assurance requirements, while it considers rulemaking that takes into consideration the complexity of supply chain relationships and the resources required to meet the current requirements of these provisions.

#### ■ How does the FDA intend to protect public health while following this enforcement policy?

During this enforcement policy period, manufacturers, processors, importers, and farmers are still required to disclose to their customer that the relevant hazards have not been controlled. Subsequently, those customers (or other customers thereafter) will still be required to comply with all other applicable requirements in federal and/or state and local laws, including the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

### 3. IMPORTATION OF FOOD CONTACT SUBSTANCES UNDER FSVP

A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The FSVP regulation applies to the importation of “food” as that term is defined in the Federal Food, Drug and Cosmetic Act, which includes food contact substances.

#### ■ Why does the FDA intend to exercise enforcement discretion for food contact substances under FSVP?

After considering the issue, including comments and information provided by stakeholders, the FDA has determined that because of certain characteristics related to the nature of food contact substances, FDA’s premarket review and oversight of food contact substances, and the regulatory framework for these substances, it is appropriate to exercise enforcement discretion with regards to the FSVP regulation. In other words, FDA does not intend to require importers of food contact substances to comply with the requirements of FSVP.

#### ■ How does the FDA intend to protect public health while following this enforcement policy?

Food contact substances undergo extensive premarket review under the agency’s Food Contact Notification (FCN) and food additive petition processes, which require petitioners to demonstrate that the intended use of the food contact substance is safe. Furthermore, if a food contact substance has not been authorized by the FDA through the FCN or food additive petition processes, the agency would consider the food product adulterated. The FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

### 4. CERTAIN MANUFACTURING/PROCESSING ACTIVITIES FOR HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD

Human food facilities that are subject to and in compliance with the human food CGMPs and FDA’s other food safety requirements, and that **do not** further manufacture/process their human food by-products once the by-products have been separated for use as animal food are **only** subject to a limited holding and distribution CGMP for their by-products.

Human food facilities that are subject to the PC Human Food rule that **do** further manufacture/process their human food by-products after they separate them for use as animal food are subject to **all** of the requirements in the PC Animal Food rule, unless an exemption applies. However, these facilities have the choice of complying with the PC and CGMP requirements in either the PC Human Food or Animal Food rules.

#### ■ Why does the FDA intend to exercise enforcement discretion in this situation?

In 2016, the FDA published Draft Guidance for Industry #239, “Human Food By-Products For Use As Animal Food,” in which the agency identified some activities it does not consider to be further manufacturing/processing for the purpose of determining whether the human food facility is subject to just the limited holding and distribution CGMPs, or the full range of PC and CGMP requirements.

Since issuing that guidance, the FDA has become aware of concerns about how the preventive controls requirements apply to certain activities performed on human food by-products for use as animal food before they are stored or transported and which do not affect their safety profile.

The agency intends to exercise enforcement discretion for the following activities:

- Drying/dehydrating, evaporating, pressing, chopping and similar activities to reduce weight, bulk, or volume and/or
- Mixing, centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids).

This enforcement discretion does not apply when these activities are performed to prevent or significantly minimize animal food hazards, or when these activities introduce animal food hazards.

#### ■ How does the FDA intend to protect public health while following this enforcement policy?

The enforcement discretion does not apply to the specified activities when they are performed to prevent or significantly minimize animal food hazards, or when the activities introduce animal food hazards. Additionally, the FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.