New FDA Enforcement Discretion Leans Business-Friendly

PUBLISHED ON
January 9, 2018

The Food and Drug Administration seems to have made a New Year's resolution to lessen the regulatory burden under the Food Safety and Modernization Act rules. The FDA issued guidance on January 4 that details four areas of the FSMA rules previously approved which now enjoy enforcement discretion.

So why has the FDA decided to exercise enforcement discretion after FSMA's "biggest overhaul in our nation's food safety laws in more than 70 years"? According to a statement by FDA Commissioner Scott Gottlieb in conjunction with the release of the guidance, the FDA is concerned with reducing the burdens on the industry and the government, while maintaining and improving the safety of the nation's food system. Gottlieb's statement recognizes that "such a fundamental change in our food safety approach may require adjustments along the way." The FDA argues that the need for such adjustments had previously become clear, as many compliance dates were previously delayed multiple times.

Each of the areas where the FDA has chosen to exercise enforcement discretion addresses a different needed adjustment:

Farms: The first of four areas now subject to enforcement discretion is the definition of facilities exempted from the Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventative Controls for Human Food and Animal Food. Currently, "farms" are exempted from the CGMP requirements, but the definition of "farms" excludes, for example, a facility that would be characterized (and therefore exempted) as a secondary activities farm, but for the ownership of the facility. The FDA recognizes the need to reconcile definitions of exempted facilities, and will likely find that the definition of "farm" will be expanded to encompass reasonably alike facilities.

Supply chain: FSMA rules also mandated what has proven to be an overwhelming number of required written assurances from commercial customers to manufacturers/processors of food products that identified hazards will be controlled by some entity in the supply chain before final distribution to the consumer. The FSMA rules mandated assurances that significantly exceed current practices, such that the compliance date has been extended another two years to examine supply chain complexity. It also required assurances for safety, thus limiting the redundancy and unnecessary paperwork. However, food producers are still required to inform commercial customers if products are not controlled for public health risks.

Foreign suppliers:The Foreign Supplier Verification Program for Food Contact Substances has also been identified as an area of redundancy. The current FDA framework already contemplates an extensive premarket review and continuing oversight of food contact substances. In addition, food contact substances, by definition, have no technical effect on food products, and therefore are of such small quantities in consumer products that the FDA has determined that food contact substances are not currently a hazard

requiring further control beyond that of the existing framework.

Animal food:The FDA identified one further area where the safety of a food product should not be considered to be of particular concern. Animal food byproducts that are derived from processing human food may undergo certain further processing that changes the nature of the byproduct but not the safety profile. For example, enforcement discretion will be extended to processes such as drying/dehydrating, chopping and mixing human food byproducts, as long as these processes are not done to change the safety profile.

But what about maintaining and enhancing the safety of the food system? Enforcement discretion is being exercised only in areas that FDA identified unnecessary redundancy and discontinuity. And the prohibition on introducing any adulterated food into interstate commerce will be fully enforced.

This guidance is not legally enforceable, but only a statement regarding FDA's current thinking regarding the topic, and can be changed at any time. However, the FDA has stated that it intends to initiate further rulemaking, which will necessarily include an opportunity for public comment. Affected entities should remain aware for such opportunities.

Please refer to the text of FDA's guidance document for specific areas where the FDA is using enforcement discretion. If facilities have any concerns about how this enforcement discretion policy will affect their operations, please contact me or any of the attorneys in Barley Snyder's Food & Agribusiness Industry Group .

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