FDA ISSUES THREE NEW FOOD SAFETY RULES

BY

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The U.S. Food and Drug Administration (FDA) finalized a three new food safety regulations for produce farms and imported foods. The new rules are a major component of the Agency's efforts to reduce the risks of foodborne illnesses, and implement the bipartisan Food Safety Modernization Act of 2011 (FSMA). That law seeks to shift the FDA's regulatory focus from an oversight system that responds to contamination, and redirected the Agency's efforts towards coordination with food producers and suppliers to pursue a pro-active approach to preventing foodborne illnesses and the conditions that cause them. The three recently finalized FSMA rules define safety standards for produce farms and make importers accountable for verifying that imported food meets U.S. safety standards.

The FDA is a federal agency within the U.S. Department of Health and Human Services. It is responsible for protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The Agency also is responsible for the safety and security of America's food supply, cosmetics, dietary supplements; additionally, the Agency regulates tobacco products, as well as products that emit electronic radiation.

After much litigation over their timing for development and implementation, the three new rules were finalized and released by the FDA on November 13, 2015. The new regulations are summarized as follows:

The Produce Safety Rule establishes science-based standards for growing, harvesting, packing, and holding produce that are designed to work effectively for food safety across the wide diversity of produce farms. The standards in the final rule include requirements for water quality, employee health and hygiene, wild and domesticated animals, biological soil amendments of animal origin (such as compost and manure), and equipment, tools, and buildings. When followed, the standards are designed to help minimize the risk of serious illness or death from consumption of contaminated produce. Public comments and input received during hundreds of farm visits, public meetings and listening sessions shaped the rule

to reduce the risk of harmful contamination while also allowing appropriate flexibility for farmers and producers.

The expected primary benefit of the Produce Safety Rule is a reduction in illnesses (and death) from contamination. The FDA expects 10-year annualized benefits of $925 million, against annualized costs of $366 million. The new rule does not apply to farms with a specified "average annual monetary value of produce" of less than $250,000 (very small business), and provides qualified exemptions for farms with qualified value of less than $500,000.

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period: four years
- Small businesses, those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period: three years
- All other farms: two years
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule
- For all other modified requirements:
    - Very small businesses, four years after the effective date of the final rule
    - Small businesses, three years after the effective date of the final rule

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

The effective date of the final rule is 60 days after it is published in the Federal Register. Currently the Produce Rule is scheduled to be published on November 27, 2015. Thus January 26, 2015 is the approximate effective date triggering the various compliance dates discussed above.

The Foreign Supplier Verification Programs (FSVP) Rule requires food importers to verify that foreign suppliers are producing food in a manner that meets U.S. safety standards and that they

are achieving the same level of food safety as domestic farms and food facilities. In 2013, USDA estimated that imported food accounted for about 19 percent of the U.S. food supply, including about 52 percent of the fresh fruits and 22 percent of the fresh vegetables consumed by Americans.

FDA establishes an application threshold at $1,000,000/year in sales, and estimates the ten-year annualized costs of the final rule at approximately $435 million/year under both 3% and 7% discount rates. The rule does not establish safety requirements for food manufacturing and processing, but "benefits the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations."

Note that all of these costs will become part of the cost of the regulated foods which consumers will pay at the point of purchase. The domestic / foreign distinction likely will continue to produce debate because of the difficulty of managing the higher risk of contamination in foreign foods. For example, the applicability thresholds in the regulatory text refer to "average annual monetary value of produce (as defined in paragraph (c) of this section)" but the definition seems to be missing.

Compliance dates by which importers must comply with the FSVP regulations are the latest of the following dates, depending on the circumstances of a particular supplier or importer:

- 18 months after publication of the final rule;
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations;
- For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions. A range of compliance dates were established in the preventive controls rules for the supply-chain program provisions, which vary based on the size of the receiving facility and when the receiving facility's supplier is required to comply with the new FSMA regulations.

This rule is also scheduled to be published in the Federal Register on November 27, 2015.

The Accredited Third-Party Certification Rule is part of FSMA's new food import safety system. This rule establishes a program for the accreditation of third-party certification bodies (auditors) to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements. To prevent potentially harmful food from reaching U.S. consumers, the FDA can require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

The new accreditation rule ensures that importers conduct verification activities (such as audits of a supplier's facility, sampling and testing of food, or a review of the supplier's relevant food safety records) based on risks linked to the imported food and the performance of the foreign

supplier. Accreditation of inspection allows foreign facilities and importers to choose to use onsite audits conducted by third party accredited certification bodies under the rule to help meet supplier verification requirements under FDA's other FSMA final rules.

Implementation of this accreditation rule and the related accreditation program will occur following publication of the final Model Accreditation Standards guidance, and the final user fee rule, both of which will be published separately in the Federal Register (the currently estimated publication date is November 27, 2015).

Accreditation bodies could begin applying for recognition when the program goes into effect, and third-party certification bodies could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

With the issuance of these three new rules, the FDA has finalized five of the seven major rules that implement the core elements of the FSMA. Two previously-issued rules finalized in September of 2015 deal with preventive controls and mandate modern preventive practices in food processing and storage facilities. The two remaining FSMA rules, governing the sanitary transportation of food and protection of food against intentional contamination, must be finalized by March 31, 2016 and May 31, 2016, respectively. For more information regarding these new FDA rules, or any aspect of food-related regulation, please contact GrayRobinson's Food Law Group.

RBLAU - # 6218125 v1
11/16/15