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E-ALERT | Food & Drug

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FDA ANNOUNCES REVISIONS TO THE PROPOSED PRODUCE SAFETY RULE

Last Friday, September 19, 2014, FDA released, along with revisions to three other proposed food safety rules, revisions to the proposed rule for produce safety[1] issued as part of the Food, Safety, and Modernization Act (FSMA). According to the Agency's notice, the revisions were intended to provide additional flexibility. In addition to this client alert, Covington also released today our client alerts on FDA's proposed revisions to the proposed rules for human food safety, animal food safety, and foreign supplier verification.[2]

FDA's key proposed revisions to the proposed safety rule include revisions to the definition of "farm," the requirements for agricultural water, the safe use of raw manure in growing areas, wild animals, the process for withdrawing qualified exemption status, and compliance times.

According to the notice, the comment period will open Monday, September 29, 2014 for a 75-day comment period, closing on Saturday, December 13, 2014. FDA is accepting comments only for the proposed revisions and will not be accepting comments on the original proposed rule. Stakeholders should review the revisions and participate, where warranted, in the public comment period.

REVISIONS TO THE DEFINITION OF "FARM"

Based on public comments it has reviewed to date, for purposes of establishing who would be subject to the proposed produce safety rule, FDA proposes to revise the definition of farm and farm mixed-type facility to include facilities with average annual produce sales of at least $25,000. Facilities with less than $25,000 in annual produce sales would be exempt from the final produce safety rule. As originally proposed, the monetary amount was calculated based on all food sales, rather than produce sales.

FDA also proposes to revise the definition of farm to clarify that a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under different ownership. Such activities would be subject to the produce safety rule rather than the human food safety rule.

Lastly, FDA is proposing to harmonize the monetary thresholds that determine whether an entity is a "very small business" or a "small business" by revising these definitions to be based on sales of produce rather than total food sales. FDA, however, is not proposing to revise the dollar amount that

[1] The original proposed rule was published in the Federal Register on January 16, 2013 (78 Fed. Reg. 3504 (Jan. 16, 2013), *et seq.*). For a summary of the original proposed FSMA rules, click here for our client alert on the original proposed produce safety rule, click here for our client alert summarizing the original proposed animal food safety rule, click here for our client alert summarizing the original proposed human food safety rule, and click here for our client alert on the proposed foreign supplier verification rule.

[2] For a summary of FDA's revisions to the proposed FSMA rules, click here for our client alert summarizing the revisions to the proposed human food safety rule, here for our client alert summarizing the revisions to the proposed animal food safety rule, and here for our client alert summarizing the revisions to the proposed foreign supplier verification rule.

triggers the qualified exemption with modified requirements, because that exemption is defined by statute.

REVISIONS TO AGRICULTURAL WATER QUALITY STANDARDS

FDA proposes several revisions to the microbial standards for water that is directly applied during the growing of produce (other than sprouts) to reflect data that supports the 2012 Environmental Protection Agency (EPA) recreational water quality criteria.

Under the proposed revisions, FDA anticipates that farmers with agricultural water that does not initially meet the proposed microbial standard would have additional means by which to meet the standard and then be able to use the water, including:

- Establishing a sufficient interval of days between last irrigation and harvest to allow time for potentially dangerous microbes to die off.
- Apply an interval of days between harvest and the end of storage using appropriate microbial die-off or removal rates, if there is adequate supporting data.
- Calculate and apply appropriate pathogen removal rates for activities such as commercial washing. (According to FDA, this option would address a number of comments requesting that FDA allow for microbial die-off that occurs naturally in the field before the crop is harvested.)

Any of these options, however, would have to provide the same level of public health protection and must not increase the likelihood that the covered produce will be adulterated.

Finally, due to the fact that different water sources have different levels of contamination risk, FDA proposes a tiered approach to testing each source of untreated water. FDA expects that this approach will be less burdensome on farmers while still protecting public health. These proposed revisions would reduce how often farmers must test the water, which would depend prior test results and on the water source (*i.e.*, surface or ground water).

THE SAFE USE OF MANURE IN GROWING AREAS

Until it has conducted adequate research and a complete risk assessment on the safe use of raw manure in growing areas, FDA proposes to remove the originally proposed nine-month minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. FDA is deferring its decision on an appropriate time interval until it has sufficient data, and will work with stakeholders and the U.S. Department of Agriculture in conducting the risk assessment and the research necessary to obtains the scientific support necessary for any future proposal. In the interim, FDA indicates that it would not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.

In addition, FDA is proposing to eliminate the previously proposed 45-day minimum application interval for compost (also known as humus), including composted manures. According to the Agency, properly treated and handled compost is safer than raw manure from a public health standpoint. Therefore, FDA anticipates that this revision to the proposed requirements would help facilitate humus use while still providing an appropriate level of public health protection.

NO HARM TO WILD ANIMALS

Based on comments FDA received expressing concern that growers might interpret the originally proposed rule in ways that might harm wildlife (e.g., taking measures to exclude animals from outdoor growing areas or destroying animal habitats), FDA clarifies in the notice that the proposed produce regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act.

CLARIFYING THE WITHDRAWAL PROCESS OF AN EXEMPT QUALIFIED FACILITY

In response to public comments, FDA proposes to provide more reasonable procedures it would follow prior to withdrawing an exemption for a farm for food safety reasons, which might include issuing a warning letter, a recall, an administrative detention, or a seizure and injunction. Prior to taking action, FDA must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for the farm to respond, and consider actions taken by the farm to address the issues raised by the agency. Finally, FDA's proposed revisions also provide procedures for reinstating a withdrawn exemption.

COMPLIANCE DATES

Under the proposed revisions, "very small businesses," which include entities with more than $25,000 but no more than $250,000 in annual produce sales, would have four years after the rule's effective date to comply with most provisions; "small businesses," which include entities with more than $250,000 but no more than $500,000 in produce sales, would have three years after the rule's effective date to comply with most provisions; and all other farms would have two years after the effective date to comply with most provisions. The proposed revised compliance dates for water quality standards and the related testing and recordkeeping provisions would be an additional two years beyond the compliance dates for the rest of the final rule.

Covington & Burling LLP will continue to monitor FDA's implementation of FSMA and advise clients on developments. If you have any questions concerning the material discussed in this client alert, please contact any of the following members of our Food & Drug Practice Group or visit our food and beverage practice website:

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