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FDA RELEASES PROPOSAL TO AMEND CERTAIN PROVISIONS OF 2013 PROPOSED RULE FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS AND CURRENT GOOD MANUFACTURING PRACTICE FOR HUMAN FOOD

On September 19, 2014, the Food and Drug Administration (FDA) issued a supplemental notice of proposed rulemaking to amend certain provisions of its proposed rule on preventive controls for human food, which was originally published on January 16, 2013, as part of FDA's implementation of the FDA Food Safety Modernization Act of 2011 (FSMA) (the 2013 proposed rule).[1] Simultaneously, FDA also proposed revisions to the proposed rules on preventive controls for human food, produce safety, and foreign supplier verification.[2] This proposal is FDA's most recent step in implementing section 418 of the Federal Food, Drug, and Cosmetic Act (FDCA), added by section 103 of FSMA, which requires certain food facilities to establish and implement hazard analysis and risk-based preventive controls for human food.

Key proposed revisions include:

- new proposed requirements for product testing programs, environmental monitoring programs, supplier programs, and assessments of hazards that may be intentionally introduced for purposes of economic gain;
- clarifications to the proposed process for withdrawing an exemption for a qualified facility;
- changes to the definition of "farm" to include farms that pack or hold raw agricultural commodities grown on another farm not under the same ownership; and
- changes to the definition of "very small business."

FDA has proposed these revisions[3] in part due to extensive input it received from the public during the public comment period for the 2013 proposal. FDA will publish the proposed revisions in the

[1] Click here for our January 2013 client alert summarizing the original proposed rule for hazard analysis and risk-based preventive controls and current good manufacturing practice for human food.

[2] For Covington's summaries of the original proposed FSMA rules, click here for our client alert summarizing the original proposed animal food safety rule, here for our client alert summarizing the original proposed produce safety rule, and here for our client alert summarizing the original proposed foreign supplier verification rule. For Covington's summary of FDA's new revisions to the three other proposed FSMA rules, click here for our client alert summarizing the revisions to the proposed animal food safety rule, here for our client alert summarizing the revisions to the proposed produce safety rule, and here for our client alert summarizing the revisions to the proposed foreign supplier verification rule.

[3] In addition to the proposed revisions noted above, FDA also clarified its position with regard to the requirements applicable to human food processors that supply a by-product (e.g., wet spent grains, liquid whey) for animal food without any further processing. FDA stated that human food processors that are already complying with human food safety requirements, such as brewers, would not need to implement additional preventive controls when supplying that by-product, except for CGMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., to ensure the by-product is not co-mingled with garbage).

Federal Register on September 29, 2014, and will allow a 75-day comment period; however, FDA will not accept any additional comments on the original proposal.

This client alert includes a summary of the proposed revisions to the 2013 proposed rule and key issues that industry should monitor and consider for comments. We also release today our client alerts on proposed revisions to the proposed rule on produce safety, the proposed rule on preventive controls for animal food, and the proposed rule establishing a foreign supplier verification program.

HIGHLIGHTS OF KEY PROPOSED REVISIONS

1. Requirements for Product Testing and Environmental Monitoring

In the 2013 proposed rule, FDA did not propose to require product testing as a verification procedure or environmental monitoring as a preventive control or a verification procedure. In the preamble, FDA asked a series of questions about whether such processes should be included as requirements in the final rule, and if so, what requirements should be mandated. Based in part on comments FDA received in response to the 2013 proposal, FDA is now revising that proposal to include specific requirements for product testing and environmental monitoring as activities for the verification of implementation and effectiveness of preventive controls, and is seeking comment on whether these requirements should be included in the final rule.

Specifically, the proposed revisions would amend proposed § 117.165 to require a facility, as appropriate, to conduct product testing for a pathogen or appropriate indicator organism or other hazard to verify implementation and effectiveness of its preventive controls. The proposed revisions would provide flexibility for a facility to make risk-based decisions about when product testing would be appropriate. The proposed revisions would also amend proposed §117.165 to require a facility, as appropriate, to conduct environmental monitoring for an environmental pathogen or appropriate indicator organism, and to verify implementation and effectiveness of its preventive controls if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard. Again, the proposed revisions would provide flexibility for facilities to tailor their environmental monitoring programs based on risk. The proposed revisions would also add requirements for written procedures, retention of records, and corrective action procedures for product testing and environmental monitoring.

2. Requirements for Supplier Verification Activities

In the 2013 proposed rule, FDA also did not propose to require supplier verification activities (though foreign supplier verification program (FSVP) requirements were proposed separately). Instead, FDA noted that section 418 of the FDCA specifically identifies supplier verification activities as a preventive control and requested comment on when and how supplier verification activities would be appropriate and whether to include requirements for supplier approval and other verification activities in the final rule. The Appendix to the 2013 proposal also included extensive background materials on the role of supplier programs in a modern food safety system. Based in part on comments received in response to the 2013 proposal, many of which supported flexible supplier program requirements, FDA is now revising the 2013 proposal to include specific requirements for supplier verification activities. FDA is seeking comment on whether these requirements should be included in the final rule and also whether, and to what extent, the FSVP requirements and the human food preventive controls supplier verification requirements should be aligned.

Specifically, the proposed revisions would add § 117.136 to the proposed rule, which would require a facility to establish a written supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard only when that hazard is controlled before

receipt; a supplier program would not be required when the receiving facility or its customer controls the hazard. This would mean that a salad manufacturer, for example, would generally be required to establish a supplier program for the hazards associated with the fresh produce that it uses in manufacturing the salad because those hazards are typically controlled by the supplier during growing and harvesting. By contrast, a manufacturer of an acidified food would not be required to establish a supplier program for the hazards associated with ingredients in that food if it is responsible for the control of those hazards. The supplier program requirement would not apply to raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on its customer to control any hazards and obtains written assurance of such downstream control.

The proposed revisions would also require verification activities and documentation of such activities to ensure raw materials and ingredients are received only from suppliers approved for control of the relevant hazard(s), and also to ensure that the hazard is significantly minimized or prevented. The facility would have flexibility to determine and document the appropriate verification activities for raw materials and ingredients, except when there is a reasonable probability that exposure to a hazard will result in serious adverse health consequences or death to humans. In such circumstances, the proposed revisions would require an annual onsite audit of the supplier by a qualified auditor, or reliance on the results of an FDA inspection (or its equivalent) as a verification activity, unless the receiving facility has determined that other verification activities provide adequate assurance that the hazards are controlled. The new proposed supplier verification provisions would also require that a receiving facility maintain records to document its supplier verification activities.

3. Requirements for Hazard Analysis to Address Economically Motivated Adulteration

In the 2013 proposed rule, FDA communicated its intent to address hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking.[4] FDA also indicated, however, that some types of intentional adulterants (e.g., the addition of melamine to food products to enhance protein content) could be addressed by preventive controls, and requested comment on whether to include requirements related to such hazards in the final rule.

FDA is now proposing to revise proposed § 117.130 to require that a hazard analysis consider hazards that may be intentionally introduced for purposes of economic gain. Because the proposed rule defines "hazard" as an agent that is reasonably likely to cause illness or injury in the absence of its control, this revision would only require facilities to consider economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of control; facilities would not be required to consider economically motivated adulterants that would only affect the quality or value of a product without posing any risk to the public's health. FDA also clarified in the preamble that it does not expect facilities to consider all hypothetical economically motivated adulterants, but instead to focus on situations where there has been a pattern of economically motivated adulteration in the past (such as with melamine).

4. Withdrawal of an Exemption for a Qualified Facility

Section 418(l) of the FDCA provides that certain facilities, described as "qualified facilities," should be subject to modified preventive control requirements. The 2013 proposed rule defined "qualified facility" to include "very small businesses" and certain other small businesses that sell primarily to "qualified end-users." As required by the statute, the 2013 proposed rule also included provisions that set forth the process that FDA would follow when withdrawing an exemption for a qualified facility under certain circumstances posing a risk to the public's health. FDA received a number of comments raising questions about the process that FDA had proposed for withdrawing an exemption

[4] FDA published its proposed rule for protecting food against intentional adulteration in December 2013. Click here for our client alert summarizing this proposal.

for a qualified facility; in response, FDA is now proposing a number of revisions to that proposed process.

Specifically, FDA is now proposing to revise proposed § 117.251 to provide that FDA may consider other regulatory actions (e.g., warning letter, recall, administrative detention) before issuing an order to withdraw an exemption, and that FDA must provide a facility notice and the opportunity to respond before issuing such an order. FDA is also proposing to add § 117.287 to the proposed rule, which would provide a process for reinstating an exemption that was withdrawn. In addition, FDA is proposing to increase the amount of time that a facility would have to come into compliance with all preventive control requirements once its exemption is withdrawn from 60 days (as originally proposed) to 120 days.

5. The "Farm" Definition and Related Revisions

The human food preventive control requirements set forth in section 418 of the FDCA apply to food facilities that are required to register under section 415 of the FDCA. Therefore, a key definition in the 2013 proposed rule was the definition of "farm," because farms are exempt from the registration requirements of section 415 and thus would also be exempt from the requirements of the proposed rule. The definition of "farm" in the original proposed rule included establishments that pack or hold food, but only if that food is grown, raised, or consumed on that farm or on another farm of similar ownership. The revised proposed definition of "farm" no longer contains that limitation. Instead, FDA is now proposing to revise the definition of "farm" in § 1.328 to also include establishments that pack or hold food grown on another farm under different ownership. Any establishment that meets the definition of "farm" would not be subject to human food preventive control requirements, but would instead be subject to the requirements in the produce safety proposed rule.

6. The Definition of "Very Small Business"

The definition of "very small business" is relevant to a number of provisions in the preventive controls for human food proposed rule, including modified requirements as a "qualified facility" and a longer compliance period. The 2013 proposed rule proposed three options for the definition of "very small business," all based on total annual sales of food -- $250,000; $500,000; and $1,000,000 -- and requested comment on these options. After reviewing the comments received, FDA has now tentatively concluded that defining "very small business" as a business that has less than $1,000,000 in total annual sales of human food, adjusted for inflation, would adequately protect public health, and is proposing to amend the definition of "very small business" in § 117.3 to reflect this conclusion. FDA has also requested additional comments on whether it should consider other dollar limits in defining "very small business" in the final rule.

7. Revisions to Requirements for Hazard Analysis to Clarify Intent

The 2013 proposed rule would have required that a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards to determine whether there are hazards that are "reasonably likely to occur." In response to this proposed requirement, FDA received many comments indicating concern that the phrase "hazard reasonably likely to occur" was unclear given that the phrase is also used in FDA's HACCP regulations for seafood and juice, which focus primarily on preventive controls at critical control points. FDA has clarified that it did not intend to require that all preventive controls be established at critical control points. To avoid any confusion related to the phrase "hazard reasonably likely to occur," FDA is now proposing to eliminate this phrase throughout the proposed rule and generally to replace this phrase with the term "significant hazard," which FDA has proposed to define in § 117.3. FDA has explained that the proposed rule would require a facility to conduct a two-part hazard analysis -- first, the facility would identify those hazards that are known

or reasonably foreseeable, and then the facility would identify the known or reasonably foreseeable hazards that meet the definition of "significant hazard" in proposed § 117.3.

KEY ISSUES FOR INDUSTRY

FDA is only accepting comment on the proposed revisions to the 2013 proposed rule; it will not accept any additional comments on the original proposal. FDA has explicitly requested comment on a number of the proposed revisions.

New Proposed Requirements

The proposed revisions that include new requirements for industry are those revisions related to product testing programs, environmental monitoring programs, supplier programs, and hazards that may be intentionally introduced for purposes of economic gain. FDA considered the comments it received in response to questions it posed about such programs in the 2013 proposed rule, and is now providing the first opportunity for public comment on specific requirements for product testing, environmental monitoring, supplier verification, and analysis of hazards due to economically motivated adulterants.

Specifically, FDA emphasizes that the proposed requirements for product testing and environmental monitoring were intended to provide substantial flexibility to a facility to make risk-based decisions based on the nature of the facility and the food it produces. FDA requests comment on whether these requirements should be included in the final rule and, if so, whether any modifications to the requirements would be appropriate.

In addition, with regard to the proposed requirements for supplier verification, FDA acknowledges that in certain circumstances there may be multiple entities in the chain between the supplier and the receiving facility, and that this could make supplier verification particularly challenging. FDA specifically requests comment on the types of supplier verification requirements that would be appropriate in these circumstances, in addition to requesting comment generally on whether supplier verification requirements should be included in the final rule.

Compliance Dates

The proposed revisions to the 2013 proposed rule do not affect the originally proposed compliance dates. FDA is proposing to allow one year after the date of publication of the final rule for most facilities to comply with the requirements.[5] Small businesses (those with less than 500 employees) and very small businesses (those with less than $1,000,000 in total annual sales of human food, adjusted for inflation) would have two and three years, respectively, to come into compliance.

[5] By court order, FDA must publish its final rule on preventive controls for human food by August 30, 2015.

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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