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FDA PROPOSES REVISIONS TO THE PROPOSED RULE ON PREVENTIVE CONTROLS FOR ANIMAL FOOD AND ADDITIONAL NEW REQUIREMENTS

On Friday, September 19, 2014, the Food and Drug Administration (FDA) proposed several revisions to its proposed rule on preventive controls for animal food (including the hazard analysis and risk-based preventive controls (HARBPC) and current good manufacturing practices (CGMPs)), which was originally released October 25, 2013.[1] Simultaneously, FDA also proposed revisions to the proposed rules on preventive controls for human food, produce safety, and foreign supplier verification.[2]

According to FDA's announcement, the proposed revisions to the animal food safety rule are intended to make the rule more flexible and less burdensome in key areas. In addition, FDA has proposed new requirements for product testing, environmental monitoring, a supplier program, and intentional economic adulteration, all of which FDA identified in the original proposed rule as areas it might address in future rule-making.

FDA is requesting comment only on the proposed revisions and additional new requirements, and will not be accepting comments on the original proposed rule. The 75-day comment period opens Monday, September 29, 2014 and closes Saturday, December 13, 2014. In developing the final rule, FDA will continue to review the comments it received for the original proposed rule along with any supplemental comments received in response to its proposed revisions and additional requirements.

The following summarizes the additional new proposed requirements and key revisions to the 2013 proposed rule.

ADDITIONAL REQUIREMENTS PROPOSED FOR THE FIRST TIME

The 2013 proposed animal food safety rule did not include requirements for product testing, environmental monitoring, supplier verification, or intentional economic adulteration. FDA specified in that publication that it might propose such requirements in future rule-making and posed a series of questions regarding potential requirements. In this notice, FDA announces proposals for these requirements that are essentially identical for animal food and human food.

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[1] The original proposed rule was published in the Federal Register on October 29, 2013 (78 Fed. Reg. 64736, *et seq.*). For a summary of the original proposed FSMA rules, 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, click here for our client alert on the original proposed produce 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 other 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 produce safety rule, and here for our client alert summarizing the revisions to the proposed foreign supplier verification rule.

1. Requirements for Product Testing and Environmental Monitoring

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 for the verification of preventative control implementation and effectiveness, and is seeking comment on whether these requirements should be included in the final rule. Generally, the proposed revisions would, as appropriate, require a facility to:

- conduct product testing for a pathogen or appropriate indicator organism or other hazard to verify implementation and effectiveness of its preventive controls, but would provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate.
- conduct environmental monitoring for an environmental pathogen or appropriate indicator organism to verify implementation and effectiveness of its preventive controls if contamination with an environmental pathogen is a significant hazard,[3] but would provide flexibility for facilities to tailor their environmental monitoring programs based on risk.

The proposed revisions would also add requirements with respect to product testing and environmental monitoring for written procedures, retention of records and corrective action procedures.

2. Requirements for Supplier Verification Activities

In the original animal food safety rule, FDA did not propose requirements for supplier verification activities, but noted that section 418 of the FDCA specifically identifies supplier verification activities as a preventive control. FDA included in that proposal an appendix with 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 proposes 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 foreign supplier verification program (FSVP) requirements and the animal food preventive controls supplier verification requirements should be aligned.

In general, the proposed supplier verification requirements 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 verification program would not be required when the receiving facility or its customer controls the hazard. The supplier verification 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 the customer and obtains written assurance. The proposed requirements 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 to ensure that the hazard is significantly minimized or prevented.

Facilities 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

[3] Based on significant feedback on its proposed definition of "hazard reasonably likely to occur," FDA has proposed eliminating this term and instead using the term "significant hazard," which it defines as a "known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control."

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 original proposed animal food safety rule, FDA communicated its intent to address hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking and also indicated 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. FDA requested comment on whether to include requirements related to such hazards in the final rule.

Citing to the animal health issues resulting from the use of melamine in pet food, FDA proposes 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 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).

REVISIONS TO THE ORIGINAL PROPOSED ANIMAL FOOD SAFETY RULE

The following are key revisions to FDA's original animal food safety rule proposal. We encourage stakeholders to review FDA's proposed revisions and to submit comments where necessary to ensure FDA has adequate information upon which to finalize its rule.

1. Human Food Diverted to Animal Food Processing

FDA clarified in its notice of proposed revisions to the human food HARBCP and CGMP proposed rules that human food processors already complying with FDA's human food safety requirements would not need to implement additional preventive controls or CGMPs when supplying a human food by-product for use in animal food, except for certain holding and distribution activities to ensure, for example, that such products are not commingled with trash or other sources of contamination.

2. The "Farm" Definition and Related Revisions to the "Holding" and "Packing" Definitions

"Farms" as FDA defines them, are exempt from the animal food preventive control requirements because they are not required to be registered with FDA as food facilities. FDA proposes to expand the definition of "farm" beyond the original proposal of establishments that pack or hold food that is grown, raised, or consumed on that farm or on another farm of similar ownership to include establishments that pack or hold food grown on another farm under different ownership. Any establishment that meets the definition of "farm," therefore, would not be subject to animal food preventive control requirements, but would instead be subject to the requirements in the produce safety proposed rule.

The proposed revision to the "farm" definition required conforming revisions to the proposed definitions of "harvesting," "holding," and "packing" in § 1.328 to remove similar limitations that the food be grown on the same farm or a farm under the same ownership.

In conjunction with its proposed revision to the definition of "farm," FDA proposes to revise the proposed definitions of "holding" and "packing" so that such exempt activities would not be limited to farms and farm mixed-type activities and so that these definitions encompass activities that are "incidental" to holding and packing animal food.

As FDA explained, the revised definitions of "holding" [4] and "packing"[5] are intended to encompass incidental storage and packing activities conducted by facilities that are exempt because they are solely engaged in the storage either of packaged food for animals that is not exposed to the environment or of raw agricultural commodities (RACs) (other than fruits and vegetables) intended for further distribution or processing.

FDA explains that incidental holding activities encompass activities performed for safe or effective food storage and as a practical necessity for food distribution, which might include:

- Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation.
- Using modified atmosphere treatments to control pests.
- Using biological controls for pests.
- Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds.
- Weighing grain.
- Sampling and grading grain.
- Aerating grain to control temperature.
- Blending of the same commodity.
- Breaking down pallets.

FDA explains that incidental packing activities might include sorting, culling, and grading, and other activities performed for the safe or effective packing of animal food.

Based on its proposed revised definition, FDA concludes that facilities such as grain elevators and silos would most likely qualify as exempt facilities because they are engaged solely in the storage of RACs (other than fruits and vegetables) and that facilities such as warehouses would most likely qualify as exempt facilities because they are engaged solely in the storage of packaged animal food that is not exposed to the environment.

[4] FDA proposes to revise "holding" in proposed 21 C.F.R. § 507.3 to mean: "storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity . . . into a processed food . . . . Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks."

[5] FDA proposes to revise "packing" in proposed 21 C.F.R. § 507.3 to mean: "placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, and grading)), but does not include activities that transform a raw agricultural commodity . . . into a processed food . . . ."

3. Feed Mills Associated with Contract and Fully Integrated Farming

As summarized in today's client alert on FDA's proposed revisions to the human food safety rule[6], FDA proposes to re-define "farm", but explains that under either definition (in the original rule or as revised), feed mills associated with fully integrated farming operations would be considered part of a farm and therefore would be exempt from registering as food facilities and would not be subject to the proposed rule for preventive controls.

FDA is requesting comment on whether such feed mills should be required to register as food facilities and, if so, how FDA should revise the definition of "farm" so that such feed mills would not be considered farms (and would, therefore, be required to register with FDA and comply with the proposed rule as well as FDA's requirements for recordkeeping, the Reportable Food Registry, and mandatory recalls).

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 original proposed animal food safety rule defined "qualified facility" to include "very small businesses" and certain other small businesses that sell primarily to "qualified end-users." As the statute requires, the original proposed rule also included provisions that specify the process 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 for a qualified facility; in response, FDA has now proposed a number of revisions to that proposed process.

Specifically, FDA has proposed to revise the rule 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 has also proposed to provide a process for reinstating an exemption that was withdrawn and to increase from 60 days (as originally proposed) to 120 days the amount of time a facility would have to come into compliance with all preventive control requirements once its exemption is withdrawn.

5. The Definition of "Very Small Business"

The definition of "very small business" is relevant to a number of provisions in animal food safety rule, including modified requirements as a "qualified facility" and a longer compliance period. The 2013 animal food safety rule proposal discussed three options for the definition of "very small business," all based on total annual sales of food -- $500,000; $1,000,000; and $2,500,000 -- 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 $2,500,000 in total annual sales of animal food, adjusted for inflation, would adequately protect public health, and has proposed to amend the definition of "very small business" 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.

6. Regulatory Impact Analysis

As part of the notice, FDA includes an estimate of the burden on industry of the revised and additional requirements. We recommend that industry review and, if warranted, submit comments

[6] Click here for a summary of FDA's proposed revisions to the proposed human food safety rule.

on the accuracy of FDA's estimates and whether there are ways in which FDA can minimize the burdens.

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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