Digesting The FDA's Changes To Animal Food Regulations

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

According to the 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, the FDA has proposed new requirements for product testing, environmental monitoring, a supplier program and intentional economic adulteration, all of which the agency identified in the original proposed rule as areas it might address in future rulemaking.

The 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 opened Monday, Sept. 29, 2014, and ends on Dec. 15, 2014. In developing the final rule, the 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. The FDA specified in that publication it might propose such requirements in future rulemaking and posed a series of questions regarding potential requirements. In the notice, the FDA announced proposals for these requirements that are essentially identical for both animal and human food.
**Significant Hazard**

Based on significant feedback on its proposed definition of “hazard reasonably likely to occur,” the 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, facility and nature of the control.”

Although as proposed the definition of significant hazard resembles the definition of hazard in that both turn on whether illness would result if the hazard was not controlled, the FDA explains in the preamble that the revision was intended to narrow the types of hazards that require preventive controls. The FDA explains that determining whether hazards are significant hazards requires a two-part analysis based on experience, illness data, scientific reports, and other information. First, a facility would narrow hazards to those hazards that are known or potentially associated with the food or the facility. Second, a facility would analyze the probability that such a hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur to determine if the hazard was a significant hazard.

The bulk of the proposed requirements, including the requirements for preventive controls, the supplier program, the recall program, monitoring, corrective actions, verification and validation are triggered by a significant hazard.

The FDA has requested comment on both the proposed name of the term significant hazard and the proposed meaning of the term.

**Requirements for Product Testing and Environmental Monitoring**

Based in part on comments the FDA received in response to the 2013 proposal, the agency has now revised that proposal to include specific requirements for product testing and environmental monitoring for verification of preventive 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; and

- conduct environmental monitoring for an environmental pathogen or appropriate indicator organism to verify implementation and effectiveness of its preventive controls for ready-to-eat food if contamination with an environmental pathogen is a significant hazard, 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.

**Requirements for Supplier Verification Activities**

In the original animal food safety rule, the FDA did not propose requirements for supplier verification activities, but noted that Section 418 of the Food, Drug, and Cosmetic Act specifically identifies supplier verification activities as a preventive control. The 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, the FDA proposes to include specific requirements for supplier verification activities. The 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 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 significant hazard is controlled before receipt. A supplier verification program would not be required when the receiving facility or its customer controls the significant 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 supplier and obtains written assurances from the supplier. 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 significant hazard(s) and to ensure that the significant 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 circumstances, the proposed revisions would require an annual on-site 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.

**Requirements for Hazard Analysis to Address Economically Motivated Adulteration**

In the original proposed animal food safety rule, the 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. The 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, the 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 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, and of those hazards, only those that are significant hazards would trigger implementation of preventive
controls and the other proposed requirements. 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. The 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.

**Revision to the Original Proposed Animal Food Safety Rule**

The following are key revisions to the FDA's original animal food safety rule proposal. Stakeholders should review the FDA's proposed revisions and submit comments where necessary to ensure the agency has adequate information on which to finalize its rule.

**Human Food Diverted to Animal Food Processing**

The FDA clarified in its notice of proposed revisions to the human food HARBCP and CGMP proposed rules that human food processors already complying with the agency's human food safety requirements would not need to implement additional preventive controls or CGMPs when supplying a human food byproduct 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.

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

Farms, as the FDA defines them, are exempt from the animal food preventive control requirements, because they are not required to register with the agency as food facilities. The FDA proposes to expand the definition of farm beyond what it original proposed, which was limited to 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 Section 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, the FDA proposes to revise the proposed definitions of holding[4] and packing[5] 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 the FDA explained, the revised definitions of holding and packing 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, other than fruits and vegetables, intended for further distribution or processing.

The 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; or
• breaking down pallets.

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

Based on its proposed revised definition, the 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.

**Feed Mills Associated with Contract and Fully Integrated Farming**

In its proposed revisions to the human food safety rule that published the same day as the proposed revisions to the animal feed safety rule, FDA proposed to redefine farm, but explained 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.

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

**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 the FDA would follow when withdrawing an exemption for a qualified facility under certain circumstances posing a risk to the public’s health. The FDA received a number of comments raising questions about the process the agency proposed for withdrawing an exemption for a qualified facility. Responding to those questions, the FDA proposed a number of revisions to the process.

Specifically, the FDA proposed to revise the rule to provide that the agency may consider other
regulatory actions (e.g., warning letter, recall or administrative detention) before issuing an order to withdraw an exemption and that the agency must provide a facility notice and the opportunity to respond before issuing such an order. The 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.

“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 million and $2.5 million — and requested comment on these options.

After reviewing the comments received, the FDA tentatively concluded that defining very small business as a business that has less than $2.5 million in total annual sales of animal food, adjusted for inflation, would adequately protect public health, and has proposed to amend the definition of the term to reflect this conclusion. The FDA has also requested additional comments on whether it should consider other dollar limits in defining very small business in the final rule.

Regulatory Impact Analysis

In the proposed revisions, the FDA addresses several issues facilities found problematic in the original proposal. Most notably, the proposed revisions do away with the imposition of most of the additional preventive controls and CGMPs the original animal proposal imposed on human food processors already complying with the FDA’s human food safety requirements when those processors supply a byproduct for animal food. In addition, the proposed revisions limit the requirements and implementation of preventive controls to “significant hazards.” The proposed revisions also significantly broaden the farm exemption, both with respect to activities farms can perform and the origin of the food farms can handle under the exemption. These revisions, if finalized, would alleviate some of the burdens imposed by the original proposed rule because they narrow the scope of the original proposed rule and expand the number of exempt facilities.

In contrast, the new proposed requirements for product testing, environmental monitoring, supplier verification and intentional economic adulteration would likely increase the impact and burden on industry, depending on the whether the food or facility is associated with “significant hazards.” For example, the impact of the new verification activities — product testing and environmental monitoring — will vary between product categories and facility types, and the FDA built flexibility into the proposals so that facilities could determine whether and when such testing and monitoring would be appropriate for assessing the preventive control(s). Similarly, the impact of the proposed supplier verification program, if finalized, will depend on whether an incoming material or supplier facility is associated with a significant hazard, whether the receiving facility or the supplier controls the significant hazard and the rigor of the supplier’s controls. Finally, the impact of the requirement to consider whether intentional economic adulteration is a significant hazard requiring control will depend on whether the food type is known to be susceptible to intentional economic adulteration and if so, whether such adulteration presents a significant hazard.

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[1] The original proposed rule was published in the Federal Register on Oct. 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 the 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.

[3] The FDA proposes to revise “holding” in proposed 21 C.F.R. Section 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.”

[4] The FDA proposes to revise “packing” in proposed 21 C.F.R. Section 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.”

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