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FDA Publishes Final Rule on CGMPs, Hazard Analysis, and Preventive Controls for Animal Food

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Food & Drug

Yesterday, the Food and Drug Administration (FDA) issued its long-anticipated final food safety rule for animal food, which includes revised current good manufacturing practices (CGMPs) and requirements for hazard analysis and risk-based preventive controls (the PC requirements). This final rule implements the Food Safety Modernization Act (FSMA) requirements and is the result of significant efforts on behalf of both FDA and stakeholders. As FDA explains, the final rule is more flexible than FDA's proposals because of the extensive feedback FDA received during the extended rule-making period and the public meetings and other forums in which it solicited feedback.

This alert highlights key differences between the proposed and final rules and discusses points of interest to industry stakeholders. FDA has provided a summary of the rule and additional information on its FSMA website.³

Core Requirements of the Final Rule

Under the final rule, covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. Specifically, covered facilities must develop a written food safety plan that addresses foods the facility manufactures, processes, packs, or holds and includes a written hazard analysis, preventive controls (if applicable, including a supply-chain program and a recall plan), and procedures to monitor

¹ See 80 Fed. Reg. 56170 (Sept. 17, 2015) (FDA also published on the same day its final food safety rule for human food, which Covington has addressed in a separate client alert.)

² See our prior client alerts, "<u>FDA Proposed Revisions to the Proposed Rule on Preventive Controls for Animal Food and Additional New Requirements</u>" (September 23, 2014) and "<u>FDA Releases Proposed Rule to Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (October 31, 2013).</u>

³ See <u>FDA Website for FSMA Final Rule for Preventive Controls for Animal Food; FDA FSMA Fact Sheet-Final Rule on Preventive Controls for Animal Food; FDA Q&A on Preventive Controls Rules: Human Food and Animal Food.</u>

preventive control implementation, for corrective actions, and for verification. The plan must be prepared, or its preparation overseen, by a "preventive controls qualified individual," a new term describing the individual responsible for the food safety plan, preventive control validation, reviewing records for control effectiveness, and the food safety plan reevaluation. The preventive controls qualified individual must have training that is at least equivalent to a program recognized by the FDA or sufficient job experience related to a food safety system.

Clarified Definitions of "Hazard" and "Significant Hazard" (now called "Hazard Requiring a Preventive Control")

One of the most noteworthy provisions in the final rule is the revised definition of "significant hazard," which FDA has replaced with the term "hazard requiring a preventive control" (*i.e.*, only those hazards "requiring a preventive control" trigger the hazard analysis and risk-based PC requirements in subparts C and E). The final rule clarifies the definition of "hazard" to reflect that this is a broad term referring to any biological, chemical, radiological, and physical agent that could cause illness or injury, but not necessarily an agent that requires a preventive control.

FDA explains that the final definitions of "hazard," "known or reasonably foreseeable hazard," and "hazard requiring a preventive control," reflect its expectation for how a facility conducts a hazard analysis: first, by assessing the universe of hazards; second, by narrowing that universe to "known or reasonably foreseeable" hazards for each type of food manufactured, processed, packed, or held at its facility; and third, by determining whether any of the known or reasonably foreseeable hazards require a *preventive* control (as opposed to previous proposals in which a knowledgeable individual would be required to "establish controls" for the hazard).⁷

As part of a hazard analysis, the final rule requires assessment of hazards that may be "intentionally introduced for purposes of economic gain," but only those reasonably likely to cause illness or injury in the absence of control. Facilities are not required to consider economically-motivated adulterants that would only affect the quality or value of a product without posing any health risk.

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⁴ The final rule permits facilities to group types of animal food or production methods under a single food safety plan if the hazards, preventive controls, parameters, and management components necessary to ensure preventive control effectiveness are essentially similar. See Response 235. FDA clarified that an existing written food safety plan, including one intended to satisfy the requirements of a foreign jurisdiction or existing standards developed by other organizations (such as PAS 222), may be used, but, must be supplemented as necessary to satisfy the PC requirements. See Response 236.

⁵ In the final rule, the term "qualified individual" now applies generally to individuals who may be employees of an establishment, and requires a qualified individual to have the education, training, or experience (or a combination) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. Under the revised CGMP rules, being a "qualified individual" is now a required qualification for all personnel who manufacture, process, pack, or hold food.

⁶ See 21 C.F.R. 507.3.

⁷ See Response 62.

FDA has expressly incorporated risk assessment into the final definition of "hazard requiring a preventive control" by: (1) requiring that its identification include an assessment of the severity of the resulting illness or injury and the probability the hazard will occur in the absence of preventive controls; and (2) limiting the management components--e.g., monitoring, corrections, corrective actions, verification, and records--to those appropriate to the food, the facility, and the *nature* of the preventive control and its role in the food safety system. FDA made these changes in response to requests submitted in comments to further emphasize facilities' flexibility in identifying both preventive controls and their accompanying management components.

Exemptions and Modified Requirements

The final rule retains the proposed exemptions from the PC requirements, including exemptions directed at thermally processed low-acid canned foods packaged in hermetically sealed containers and activities subject to the standards for produce safety. FDA also retained the exemption from the PC requirements for "unexposed packaged animal food." For facilities that store unexposed packaged animal food requiring time and temperature controls to significantly minimize or prevent pathogen growth, the final rule requires compliance with modified PC requirements related to time/temperature controls.

The final rule also retains the exemption for facilities engaged in the storage of raw agricultural commodities (RACs) other than fruits and vegetables solely for further distribution, ¹⁰ including facilities that conduct activities as a practical necessity for distribution of such food, such as drying/dehydrating RACs to preserve quality. A facility that stores oilseeds and dries them to preserve quality, for example, would be covered by this exemption. ¹¹

Additionally, "qualified facilities" are exempt from subparts C and E (except as provided in the Subpart D provisions on withdrawal of the qualified facility exemption) and instead are subject to modified PC requirements. The final rule does not make any significant changes to the definition of qualified facilities, which are essentially very small businesses.¹²

⁸ 21 C.F.R. 507.5(b), (c).

⁹ See 21 C.F.R. 507.10.

¹⁰ See 21 C.F.R. 507.5 (g).

¹¹ See Response 117. There are exemptions from cGMPs for facilities solely engaged in the transportation and holding of one or more agricultural commodities. There are also two additional exemptions for facilities engaged in the ginning of cotton and the hulling, shelling, drying, packing and/or holding of nuts and hulls, without further processing. See 21 C.F.R. 507.5(h).

¹² See 21 C.F.R. 507.3.

Exceptions to the Requirement to Implement Preventive Controls

The final rule establishes two new provisions regarding when a manufacturing/processing facility is not required to implement a preventive control:¹³

- When a manufacturer/processor determines and documents that the type of food simply could not be eaten without processing that would control the hazards requiring a preventive control.¹⁴
- When a manufacturer/processor identifies a hazard requiring a preventive control (an identified hazard) but can demonstrate and document that the identified hazard will be controlled by another entity in the distribution chain (e.g., a commercial customer). To avail itself of this exception, the manufacturer/processor must:
 - (1) provide documentation to its direct customer that the food is "not processed to control [identified hazard]"; and
 - (2) annually obtain written assurance from its customers regarding appropriate procedures the customers will undertake to ensure that the food will receive further processing to control the identified hazards.¹⁵ The facility providing such written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance.¹⁶

Product Testing and Environmental Monitoring Provisions

The final rule retains product testing and environmental monitoring (EM) in the PC requirements. The Specifically, a facility, as appropriate, must conduct product testing for a pathogen or appropriate indicator organism or other hazard to verify implementation and effectiveness of its preventive controls. Similarly, a facility, as appropriate, must conduct EM for an environmental pathogen or appropriate indicator organism, and verify implementation and effectiveness of its preventive controls, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control. The final rule provides flexibility for a facility to make risk-based decisions about when product testing and EM would be appropriate.

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¹³ See 21 C.F.R. 507.36.

¹⁴ See 21 C.F.R. 507.36(a)(1).

¹⁵ See 21 C.F.R. 507.36(a)(2)-(4).

¹⁶ See 21 C.F.R. 507.37.

¹⁷ See 21 C.F.R. 507.49.

¹⁸ See id.

Validation of Preventive Controls

The final rule includes a new provision requiring validation whenever a change to a control measure could impact whether that control measure, when properly implemented, will effectively control the hazards requiring a preventive control.¹⁹

The final rule does not require a facility to validate preventive controls if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as (1) the nature of the hazard and (2) the nature of the preventive control and its role in the facility's food safety system. FDA clarified that the list of preventive controls not requiring validation is not an exhaustive list.

Use of Exception Reports to Monitor Preventive Controls

Neither of the proposed rulemakings expressly addressed whether facilities would need to maintain records demonstrating continuous functioning of controls, or whether they could document their monitoring by showing evidence of failures, also known as "exception records." The final rule allows use of exception records to monitor preventive controls:²⁰

- Exception records demonstrating loss of temperature control may satisfy the requirement to monitor refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent pathogen growth or toxin production.
- Exception records may be adequate to monitor preventive controls other than refrigeration (e.g., x-ray monitoring for foreign material).
- A facility that uses exception records must have "evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an 'exception record' is generated."²¹

"For Cause" Reanalysis of a Portion of the Food Safety Plan

As proposed, reanalysis of the food safety plan was required by a preventive controls qualified individual (1) routinely (*i.e.*, at least every three years) and (2) "for cause" (*e.g.*, whenever significant changes are made to activities that would produce new hazards or increase the likelihood of current hazards). The final rule largely retains this proposal but clarifies that the reanalysis "for cause" may be for the entire food safety plan or only an applicable portion. ²² For example, if a specific preventive control is found to be ineffective but only affects a portion of the food safety plan, the preventive controls qualified individual need only reanalyze that affected portion.

¹⁹ See 21 C.F.R. 507.47.

²⁰ 21 C.F.R. 507.40.

²¹ See Response 302.

²² 21 C.F.R., 507.50.

Revised Timeframes for Review of Records, Validation of Preventive Controls, and Reanalysis of the Food Safety Plan

As originally proposed, FDA would have required review of records related to monitoring and corrective action within a week after the records were made. In response to requests for additional flexibility, the final rule extends the timeframe for completing reviews to:

- within 7 working days after the records are made; or
- within a reasonable timeframe, provided that the preventive controls qualified individual prepares or oversees a written justification for such timeframe.²³

Similarly, the final rule revises the timeframe to complete validation of preventive controls and reanalysis of the food safety plan. As originally proposed, FDA required that these occur within six weeks of production of the applicable food. The final rule allows for completion:

- within 90 days after production of the applicable food first begins; or
- within a reasonable timeframe, provided that the preventive controls qualified individual prepares or oversees a written justification for such timeframe.²⁴

A More Flexible Stand-Alone Supply Chain Program (Subpart E)

The final rule provides significantly more flexibility in the supplier program than as proposed, to account for the varied and complex supply-chain scenarios that currently exist. FDA also provided flexibility to allow for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities as a service to the receiving facility, as FDA recognizes that a receiving facility²⁵ and its supplier²⁶ may be separated by several entities in a supply-chain. The final supplier program requires a receiving facility to establish and implement a written risk-based supply-chain program for raw materials and other ingredients for which the receiving facility has identified a hazard that requires a "supply-chain-applied-control" (*i.e.*, a control applied before the facility receives the raw material or other ingredient).²⁷

A receiving facility is not required to establish a supply-chain program if that facility is an importer that is in compliance with the forthcoming Foreign Supplier Verification Program and

²³ 21 C.F.R. 507.51(a)(4)(iii); see Response 389.

²⁴ 21 C.F.R. 507.50(c)(2); see Response 378.

²⁵ The final rule adopts, without revision, the proposed definition of "receiving facility," which means "a facility that is subject to subparts C and E . . . and that manufactures/processes a raw material or other ingredient that it receives from a supplier." 21 C.F.R. 507.3.

²⁶ The final rule defines "supplier" to mean "the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature." 21 C.F.R. 507.3.

²⁷ 21 C.F.R. 507.3.

has documented such compliance. Furthermore, these requirements do not apply to animal food that the facility receives for the purposes of research or evaluation, provided that the animal food is not intended for retail sale and meets other specific requirements.

A receiving facility must approve its supplier and document that approval before receiving raw materials and other ingredients from that supplier. In approving suppliers, the receiving facility must consider the hazard analysis of the animal food received, the supplier's ability to control hazards that require a supply-chain-applied-control, and supplier performance (e.g., compliance with FDA requirements, food safety history, and food handling practices).

The receiving facility generally must determine, conduct, and document appropriate supplier verification activities to provide assurance that any hazard requiring a supply-chain-applied-control has been significantly minimized or prevented. Supplier verification activities could include onsite audits, sampling and testing of the raw material or other ingredient, and review of a supplier's relevant food safety records. Receiving facilities must also verify any supply-chain-applied-control employed by an entity other than the actual supplier. The supplier program, however, provides that an entity other than the receiving facility may determine and conduct appropriate supplier verification activities, so long as the receiving facility reviews applicable documentation. The actual supplier may conduct and document sampling and testing of raw materials and other ingredients for the hazard(s) controlled by the supplier, but may not conduct other supplier verification activities.

The supplier program provides flexibility for the receiving facility to determine the appropriate verification activities for raw materials and ingredients and the frequency of conducting such activities, except that it contains specific requirements related to hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (e.g., FDA has determined that for such hazards, the appropriate verification activity is an onsite audit of the supplier). The supplier program also establishes recordkeeping requirements for documenting the supply-chain program, onsite auditing of suppliers, and written procedures for receiving raw materials and other ingredients.

Revised Animal CGMPs

The final rule adopts, with very limited revisions, its new animal food CGMP regulations, which cover high-level areas such as personnel training, facility maintenance, pest control, sanitation, and contamination.²⁸ Although most of the revisions were minor and primarily editorial, FDA did clarify that certain practices--*e.g.*, protective clothing and adequate ventilation--are only required "where necessary and appropriate."²⁹

²⁸ See 21 C.F.R. 507 Subpart B.

²⁹ See Response 180; Response 181. The provision on ventilation was also changed to clarify that natural ventilation is acceptable. The provisions about containers and equipment used to hold or convey animal food, § 507.27(a)(1) and § 507.28(a)(1), were changed so that cleaning is required only as necessary.

FDA also revised the CGMP provisions on pesticides and toxic substances. It replaced the term "insecticides or rodenticides" with the broader term "pesticides," to reflect that insects and rodents are not the only relevant pests, ³⁰ and broadened its originally-proposed restriction allowing only toxic materials necessary for plant operations or testing to be stored at the "plant," to now allow for storage of other toxic materials at the plant in specific locations. ³¹

Although the final rule includes the proposed basic CGMPs for human food by-products used as animal food, ³² FDA did not adopt any other requested accommodations for different foods or activities. FDA declined to create distinct CGMPs for different food categories based on level of risk. For example, FDA declined the request to create different CGMPs for pet food because, unlike livestock feed, it is often stored close to human food in the home, explaining that the "final requirements are flexible enough to be applied appropriately in various animal food production settings" and that what constitutes adequate cleaning will depend upon both the plant and the animal food. ³³ Similarly, FDA acknowledged that even for low risk ingredients, such as oilseed intermediate ingredients that are subject to a subsequent kill step, food ingredient suppliers are required to meet the new CGMP regulations and emphasized that the CGMPs' flexibility allows different baseline standards depending on the type of food or ingredient.³⁴

Finally, the rule clarifies that the new labeling CGMPs apply to all animal products that leave a facility, including intermediate ingredients for use in other animal food. The final rule also modifies the labeling requirement to clarify that information for safe use of the products must only be included "when applicable," acknowledging that information about safe use is not needed for all animal food.

Notably, FDA expects that most qualified facilities will be subject to the animal CGMPs.

More Flexible Recordkeeping Requirements

The final rule includes recordkeeping requirements that are more flexible than originally proposed. Most prominently, the final rule permits an exemption to FDA's electronic recordkeeping requirements in 21 C.F.R., Part 11 if the records are created *solely* to comply with Part 507. Records that are kept to satisfy both the requirements of other rules and Part 507 would still be subject to the requirements in Part 11.³⁵

³⁰ See § 507.19(e).

³¹ 21 C.F.R. 507.19(d). Paragraph (d)(3) specifies that "other toxic materials" can be stored "in an area of the plant where animal food is not manufactured, processed, or exposed." FDA explains that new buildings or facilities will not need to be constructed just to store toxic materials. *See* Response 186.

³² In the supplemental proposed rule, FDA amended the proposed rule to allow for human food byproducts used for animal food to be excluded from several of the animal food CGMPs if the facilities are in compliance with the CGMPs for human food.

³³ See Response 163.

³⁴ See Response 164.

³⁵ See Response 495.

The final rule also includes revisions to the requirements for record storage. The final rule permits all records except the food safety plan to be stored offsite, provided that they can be retrieved and made available to FDA within 24 hours for review and copying. The final rule does not require stakeholders to send records to FDA; rather, investigators will review those records onsite and copy as needed.

The final rule assures that records will generally be subject to the protections against public disclosure in FDA's regulations³⁶, noting that food safety plans will "generally meet the definition of trade secret."³⁷

Requirements that FDA Proposed or Contemplated but Ultimately Did Not Include in the Final Rule

FDA ultimately decided not to establish several requirements that it had proposed or contemplated during the rule-making process, including requirements to:

- submit a "facility profile" (*i.e.*, a subset of the information that would be in a food safety plan);³⁸
- conduct specific verification activities for corrective actions (FDA agreed with comments that the final rule should provide facilities flexibility to determine the appropriate verification activities for corrective actions);³⁹
- validate sanitation controls, the recall plan, and the supply-chain program;⁴⁰
- review complaints (including complaints from consumers, customers, or other parties) as a verification activity;⁴¹ and
- conduct mock recalls as a verification activity for a facility's recall plan.⁴²

Requirements For Human Food By-Products Diverted to Animal Food

FDA adopted the proposed modified CGMP requirements for holding and distributing human food by-products for use as animal food. These requirements are quite basic and generally require the by-products to be held under conditions that will protect against contamination, properly identified and labeled by the common or usual name, and examined prior to use.

³⁶ These disclosure requirements are set forth in 21 C.F.R. 20.

³⁷ See Response 490.

³⁸ See Response 245.

³⁹ See Response 321.

⁴⁰ See Response 324.

⁴¹ See Response 323.

⁴² See Response 292.

FDA Enforcement of the PC Requirements

In the preamble to the final rule, FDA acknowledges that it is implementing a new inspection paradigm that requires a fundamentally different approach to food safety inspection and compliance focused on whether firms are implementing systems that effectively prevent food contamination. FDA advised that this new paradigm involves a major reorientation and retraining of its personnel and its partnerships, for which it is still actively seeking funding. FDA explains that it is working through the Partnership for Food Protection (PFP) (a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health) to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance of FSMA.

FDA is also partnering with the Food Safety Preventive Controls Alliance (FSPCA) to establish a standardized curriculum, technical assistance programs, and training materials concerning the preventive controls rule that will be publicly available and can be used as a resource for internal training and potentially for understanding FDA's expectations during inspections.⁴³

In response to comments asking FDA what it will do in an inspection setting where a conflict or disagreement arises in interpreting what the PC requirements might be for a specific food and facility, FDA acknowledged that there might be circumstances where it "might disagree with a facility about the measure it has in place," and that it will "address such circumstances on a case-by-case basis."

Compliance Dates

We have included here, for easy reference, the tables of compliance dates that FDA provided in the preamble to the final rule.

Compliance Dates for the Requirements of Part 507 Other than the Requirements for a Supply-Chain Program (Subpart E)

Size of Business	Compliance Date
Qualified facility (including very small business) as defined in § 507.3	Sep. 17, 2018CGMPs
	Sep. 17, 2019PC's, except that the compliance date for a facility to retain records to support its status as a qualified facility is Jan. 1, 2017.
Small business as defined in § 507.3	Sep. 18, 2017CGMPs; Sep. 17, 2018PCs
All other businesses	Sep. 19, 2016CGMPs; Sep. 18, 2017PCs

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⁴³ See Human Food Safety Rule, Response 5.

⁴⁴ See Human Food Safety Rule, Response 133.

Compliance Dates for the Requirements of the Supply-Chain Program (Subpart G)

Situation	Compliance Date	
A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.	
A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule.	The later of: September 17, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with this rule.	
A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.	
A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule.	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.	

Looking Ahead

FDA is developing several guidance documents, including guidance on hazard analysis and PCs, EM, CGMPs, human by-products diverted for animal food use, food types and associated hazards, validation, and on-farm activities. FDA will provide all guidance documents in draft form to allow for public input prior to finalizing them. FDA hopes that "segments of the animal food industry will work together and with the [FSPCA] to develop scientific and technical information that can be used as evidence to validate a variety of preventive controls, and will be helpful to facilities." Furthermore, FDA states that the guidance it is developing on validation "should help industry determine whether their validation approaches are likely to acceptable to IFDAI."

FDA intends to work with the food industry, education organizations, USDA, the U.S. Agency for International Development, and foreign governments to develop tools and training programs to

⁴⁵ Response 329.

⁴⁶ Response 330.

facilitate implementation of the rule. As part of these efforts, FDA has announced several webinars and public meetings:

Date	Activity	
9/15/15	Webinar: Final Rules for Preventive Controls for Human and Animal Food: Who Is Covered? What is the Definition of Farm? (slides and recording available online)	
9/16/15	Webinar: Final Rule for Preventive Controls for Human Food: Significant Provisions of the Rule (slides and recording available online)	
9/17/15	Webinar: Final Rule for Preventive Controls for Animal Food: Significant Provisions of the Rule (slides and recording available online)	
10/20/15	Public Meeting: Preventive Controls for Human and Animal Food Final Rules Chicago Marriott Downtown Magnificent Mile	
	See FDA's website for more details, at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461791.htm	
N/A	FDA Food Safety Modernization Act: A Primer by FDA (video tutorial):	
	http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334765.htm	
N/A	The Rulemaking Process: A Primer by FDA (video tutorial) http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334766.htm	

FDA has also provided expected release dates for the remaining FSMA final rules:

Final Rule	Expected release date
Foreign Supplier Verification Program for Importers of Food (Humans and Animals)	October 2015
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	October 2015
User Fee Program for Accreditation of Third-Party Auditors/Certification Bodies	October 2015
Sanitary Transportation of Human and Animal Food	March 2016
Amendments to Registration of Food Facilities	Unknown

Covington & Burling LLP continues to monitor FDA's implementation of FSMA and to advise clients on developments. If you have any questions concerning FSMA or any other food regulatory matter, please contact any of the following attorneys of our Food & Drug Practice Group or visit our food and beverage practice website:

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