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

September 17, 2015

Food & Drug

Today, the Food and Drug Administration (FDA) issued its long-anticipated final food safety rule for human food, which includes revised current good manufacturing practices (CGMPs) and requirements for hazard analysis and risk-based preventive controls (the PC requirements).[1] This final rule implements the statutory requirements set forth in the Food Safety Modernization Act (FSMA) and is the result of significant efforts on behalf of both FDA and stakeholders. As explained by FDA, the final rule is more flexible than FDA's proposals[2]--a result of the extensive feedback FDA received during the extended rule-making period and the additional public meetings and other forums in which FDA solicited feedback.

This alert highlights key differences between the proposed rules and final rule and discusses key 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 all foods that the facility manufactures, processes, packs, or holds, which must include a written hazard analysis, preventive controls (if applicable, including a supply-chain program and a recall plan), procedures for monitoring the implementation of the preventive controls, corrective actions

[1] *See* 80 Fed. Reg. 55,908 (Sep. 17, 2015) (FDA also published today its final food safety rule for animal food, which Covington has addressed in a separate client alert).

[2] *See* our prior client alerts, "FDA Releases Proposed Rule for Hazard Analysis and Risk-Based Preventive Controls and Current Good Manufacturing Practices for Human Food" (January 10, 2013) and "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" (September 23, 2014).

[3] *See* FDA Website for FSMA Final Rule for Preventive Controls for Human Food; FDA FSMA Fact Sheet--Final Rule on Preventive Controls for Human Food; FDA Q&A on Preventive Controls Rules: Human Food and Animal Food.

procedures, and verification procedures. The plan must be prepared, or its preparation overseen, by a "preventive controls qualified individual," a new term used in the final rule to describe the individual who is responsible for the food safety plan, the validation of preventive controls, reviewing records for effectiveness of the controls, and reevaluating the food safety plan. 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.[4]

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, throughout the rule, 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 G).[5] 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 those hazards that are "known or reasonably foreseeable" 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).[6]

Moreover, FDA has expressly incorporated risk assessment into the final definition of "hazard requiring a preventive control" by: (1) ensuring that it includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that 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 that are 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 comments to further emphasize the flexibility that a company has in identifying both preventive controls and their accompanying management components.

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[4] 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.

[5] *See* 21 C.F.R. 117.3.

[6] *See* Response 179.

Exemptions and Modified Requirements

The final rule retains the proposed exemptions from the PC requirements, including the exemptions directed at activities covered by FDA's HACCP regulations (juice and seafood) and dietary supplement CGMP regulations.[7]

FDA retained the exemption from the PC requirements for "packaged foods not exposed to the environment," but now uses the term "unexposed packaged food," which FDA explains must be in a form that prevents any direct human contact. For facilities that store unexposed packaged food that requires 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.[8]

FDA further explains that produce stored in vented crates is not "unexposed packaged food" because vented crates are vulnerable to contamination from the surrounding environment.[9] Therefore, a facility that stores vented crates must still conduct a hazard analysis and determine whether preventive controls are necessary for the facility and the food at issue.[10] FDA acknowledges, however, that such activities likely will not require preventive controls against environmental pathogens, as holding produce in vented crates presents a low risk of contamination from such pathogens.[11]

Additionally, under the final rule, "qualified facilities" are exempt from subparts C and G (the bulk of the PC requirements) 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]

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 (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) simply

[7] FDA received requests for additional exemptions, but declined all the requests and adopted only those that were required by FSMA.

[8] *See* 21 C.F.R. 117.206.

[9] For example, FDA states that produced stored in vented crates may come into contact with condensate in aerosols and particulates in the air handling system, moisture dripping onto containers, the hands of those handling the crates, and pests that can infest the crate through the vents.

[10] *See* Response 232.

[11] *See* Response 525.

[12] *See* 21 C.F.R. 117.3.

[13] *See* Table 32 and accompanying text.

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 its 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.[17] 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 a ready-to-eat 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.

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.[18]

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

[14] 21 C.F.R. 117.136(a)(1); Response 444.

[15] 21 C.F.R. 117.136(a)(2)-(4).

[16] 21 C.F.R. 117.137.

[17] *See* 21 C.F.R. 117.165.

[18] 21 C.F.R. 117.160(b)(1).

preventive control and its role in the facility's food safety system.[19] FDA clarifies 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 provides for the use of exception records for monitoring preventive controls as follows:[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 the growth of, or toxin production by, pathogens.
- Exception records may be adequate for monitoring of preventive controls other than refrigeration (e.g., monitoring for foreign material with x-rays).
- 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 for only an applicable portion.[22] For example, if a specific preventive control is found to be ineffective, but it only affects a portion of the food safety plan, the preventive controls qualified individual need only reanalyze the affected portion, rather than the entire food safety plan.

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:

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[19] 21 C.F.R. 117.160(c); Response 491.

[20] 21 C.F.R. 117.145(c).

[21] Response 468.

[22] 21 C.F.R. 117.170(b); Response 558.

- 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 these to 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 G)

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 facility[25] and its supplier[26] 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 that is 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 has documented such compliance. In addition, these requirements do not apply to food that the facility receives for the purposes of research or evaluation, provided that the food is not intended for retail sale and meets other specific requirements.

In addition, 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 food received, the supplier's ability to

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[23] Response 539.

[24] Response 501 (validation of preventive controls); Response 557 (reanalysis of food safety plan).

[25] The final rule adopts, without revision, the proposed definition of "receiving facility," which means "a facility that is subject to subparts C and G and that manufactures/processes a raw material or other ingredient that it receives from a supplier." 21 C.F.R. 117.3.

[26] The final rule defines "supplier" to mean "the establishment that manufactures/processes the 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. 117.3.

[27] 21 C.F.R. 117.3.

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 that is applied by an entity other than the actual supplier. This could occur, for example, if the receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer. The grower would be the "supplier," but the harvester could be responsible for applying certain controls. 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 (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 Food CGMPs

FDA has finalized the majority of its proposed revisions to the umbrella food CGMPs, most of which are minor in nature. Thus, companies in compliance with the current food CGMPs will not need to make significant changes to their operations to comply with the final requirements.

The final rule incorporates the following proposed revisions: (1) using the term "cross-contact" to distinguish allergen issues from general "contamination"; (2) extending preventing contamination to food-packaging materials; (3) including protozoa and microscopic parasites in the definition of microorganisms; and (4) adding radiological hazards to the list of contaminants. Where the original food CGMPs provided "non-binding guidance" and recommendations, FDA has either made the recommendations mandatory or has deleted the recommendations. FDA intends to transfer some of the deleted CGMP recommendations to a guidance document after making editorial and other changes to reflect current technology and industry practice.[28]

The most significant change, which applies both to the CGMPs and to the PC requirements, is the new provision directed at the "qualifications of all individuals engaged in manufacturing, processing, packing, or holding food."[29] This provision replaces the "education and training"

[28] *See* Responses 67 and 360.

[29] 21 C.F.R. 117.4.

provision in 21 C.F.R. 110.10(c) and requires personnel engaged in manufacturing, processing, packing, or holding food to: (1) be a "qualified individual," i.e., have the education, training, or experience (or combination) as appropriate to the individual's job; and (2) receive training in food hygiene and food safety, as appropriate to the food, facility, and job duties. In addition, those in charge of the establishment or facility must ensure that personnel are qualified to perform their assigned duties. Finally, this provision requires companies to keep training records, in accordance with the record keeping requirements in subpart F, but does not prescribe the contents of the records.

FDA explains that it is not requiring training directed at specific job duties. Rather, FDA expects the training to focus on general food hygiene and food safety principles, with an emphasis on the importance of employee health and personal hygiene applicable to the individual's duties.[30] The rule provides no additional details on the topics to be covered in the training, but FDA explains that it is developing a preventive controls training curriculum that will be available online.[31] Although the rule does not specify the frequency of the training, FDA expects that production personnel will receive training prior to working in production operations and that most companies will provide "some form of refresher training."[32] FDA states that the training requirement is intended to flexible to allow companies to establish the scope and frequency of training, "in a way that works best" for the company.

The final rule provides a handful of exemptions from the food CGMPs.[33] Dietary supplement manufacturers, however, must comply with the umbrella food CGMPs in addition to the dietary supplement CGMPs in Part 111, unless the regulations conflict, in which case the dietary supplement manufacturer would comply with Part 111.[34] Similarly, FDA expects that most qualified facilities will be subject to the umbrella CGMPs.[35]

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. 11 if the records are created *solely* to comply with Part 117. Records that are kept to satisfy both the requirements of other rules and Part 117 would still be subject to the requirements in Part 11.

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[30] *See* Response 172.

[31] *See* Response 177.

[32] *See* Response 172.

[33] *See* 21 C.F.R. 117.5(k), including: (1) farms; (2) certain fishing vessels; (3) establishments solely engaged in the holding and/or transportation of one or more RACs; (4) activities of "farm mixed-type facilities" that fall within the definition of "farm"; and (5) establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing).

[34] *See* Response 197.

[35] *See* Responses 151 & 184.

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

The final rule assures that records will generally be subject to the protections against public disclosure that are set forth in FDA's regulations.[36] FDA notes 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:

- the requirement to submit a "facility profile" (i.e., a subset of the information that would be in a food safety plan);[38]
- the requirement to 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]
- the requirement to validate food allergen controls, sanitation controls, the recall plan, and the supply-chain program;[40]
- the requirement to review complaints (including complaints from consumers, customers, or other parties) as a verification activity;[41] and
- the requirement to conduct mock recalls as a verification activity for a facility's recall plan.[42]

Application of CGMPs and PC Requirements to R&D Facilities

The final rule does not clarify precisely whether entities like R&D facilities, pilot plants, and test kitchens are required to comply with the final PC requirements. FDA acknowledges that it

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

[37] Response 650.

[38] Response 384.

[39] Response 489.

[40] Response 513.

[41] Response 490.

[42] Response 454.

received numerous requests and comments to clarify the status of these entities, which it understands produce samples intended for consumption. While FDA responded that it intends to issue a final rule to revise the definition of "retail food establishment" in the facility registration regulations in the near future, FDA also referred these entities to its Guidance for Industry: Questions and Answers Regarding Food Facility Registration. The Guidance provides that if the entity does not meet the definition of "retail food establishment" (or "restaurant") and produces food that is consumed, FDA requires the entity to register. As a registered facility, the entity would be subject to the CGMPs and PC requirements, although if the entity met the requirements for a "qualified facility" it could comply with the modified PC requirements.

Requirements For Human Food By-Products Diverted to Animal Food

In the animal food safety PC final rule, 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, to be properly identified and labeled by the common or usual name, and be examined prior to use.

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 that is focused on whether firms are implementing systems that effectively prevent food contamination. According to FDA, 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.

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."[43]

Compliance Dates

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

[43] Response 133.

Compliance Dates for the Requirements of Part 117 Other than the Requirements for a Supply-Chain Program (Subpart G)

Size of Business	Compliance Date
Qualified facility (including very small business) as defined in § 117.3	September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016
Small business as defined in § 117.3	September 18, 2017
Businesses subject to the Pasteurized Milk Ordinance	September 17, 2018
All other businesses	September 19, 2016

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 not be subject to the human preventive controls rule or the produce safety rule	September 18, 2017
A receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety 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
A receiving facility is not a small business or a very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule	March 17, 2017
A receiving facility is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule	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, allergen control, CGMPs, human by-products diverted for animal food use, food types and associated hazards, validation, and on-farm activities. When asked about timing, FDA indicated timing was unclear but likely that the first to issue would be guidance documents on CGMPs, human food by-products, and allergen controls. FDA will provide all guidance documents in draft form to allow for public input prior to finalizing them.

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 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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