

MEMORANDUM

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Re: **FDA Issues Final Preventive Controls Rules Under FSMA**

They're here! On Thursday, September 10, the Food and Drug Administration ("FDA") released two final rules to implement the FDA Food Safety Modernization Act ("FSMA"): "Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Human Food" ("Preventive Controls") and "Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Animal Food." ^{1/} The publication of these final rules is a major milestone in the implementation of FSMA – a landmark piece of legislation. They form the cornerstone of the law and will shape daily food manufacturing operations and FDA inspections for decades to come. As discussed further below, most companies will need to comply with these new requirements in one year, on September 19, 2016.

This memorandum provides key takeaways and highlights of the major provisions from the Preventive Controls final rule, focusing on those elements that changed between the proposed rule or supplemental proposed rule and the final rule. ^{2/} Overall, the revisions to the regulations and the discussion in the accompanying preamble clearly reflect the considerable input from industry and the written comments that were submitted during the rulemaking stage. This outcome shows the significant importance and benefit of being engaged in the rulemaking process.

Overview

FDA's Preventive Controls final rule revises the agency's food safety regulations in two ways: (1) it adds new preventive controls provisions as required by FSMA; and (2) it updates and revises certain requirements in the existing current good manufacturing practice ("cGMP") regulations (current 21 CFR Part 110). Both the new preventive controls provisions and the cGMP revisions will be codified in a new section of Title 21 of the Code of Federal Regulations, Part 117. The final rule also revises

^{1/} The documents were published in the Federal Register on September 17. 80 Fed. Reg. 55908 (Sept. 17, 2015) (human food); 80 Fed. Reg. 56170 (Sept. 17, 2015) (animal food).

^{2/} Because most human food companies do not intentionally produce animal food, though they may divert by-products or food processing waste, this memorandum focuses on the human food rule. For the most part, the proposed rule regarding animal food is the same as the rule for human food.

key definitions in the agency's regulations on facility registration requirements, as registration determines which facilities are subject to the preventive controls provisions.

With respect to the preventive controls provisions, the structure of the regulations largely tracks the statute, establishing requirements for: a written food safety plan; hazard analysis; preventive controls; monitoring; corrective actions; verification (including validation and reanalysis); and associated records. There are also a number of exemptions and several modified requirements for certain types of facilities. Overall, the final rules are substantially the same as the supplemental proposals from September 2014, ^{3/} and where revisions have been made, for the most part they provide additional flexibility to facilities to manage their food safety plans. There are, however, also a few areas where the final regulations are expected to present implementation challenges, and these are highlighted below.

This memorandum highlights the major changes to the proposed and supplemental proposed rules, and presumes general knowledge of them.

Highlights of Key Revisions

1. Hazard Analysis

FDA has removed the term "significant hazard" from the regulations and has replaced it with "hazard requiring a preventive control." The agency made this change, in response to industry comments, to avoid using a term that has been associated with hazard analysis and critical control point ("HACCP") systems and the establishment of critical control points ("CCPs"). Under the final rule, preventive controls may be established at points other than CCPs, and some controls previously considered "prerequisite programs" would be considered "preventive controls." FDA would define "hazard requiring a preventive control" as:

A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

In addition, although most industry comments regarding economically motivated adulteration ("EMA") recommended no regulatory requirements to address EMA at this time, the final rule requires facilities to consider EMA as part of their hazard analysis ("hazards that may be intentionally introduced for purposes of economic gain").

2. Management of Controls

The final rules provide additional flexibility for the management of preventive controls to take into account both the nature of the preventive control and its role in the facility's food safety system. Specifically, preventive controls management components must be applied "as appropriate to

^{3/} See Hogan Lovells memorandum dated September 26, 2014, *FDA Issues Supplemental Preventive Controls Proposed Rules Under FSMA*.

ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system." This is the "sliding scale" approach that was advocated in many industry comments.

Monitoring. The regulations expressly allow for "exception records" for monitoring activities (records demonstrating loss of control, rather than affirmative records demonstrating control).

Corrective Actions. The final rule continues to require corrective action procedures to address positive product testing and environmental testing results. In the preamble, FDA agrees that the nature and extent of any response to testing findings should be proportional to the findings. FDA is not requiring facilities to take corrective action in response to each individual test finding, but rather requires the facility to establish written procedures that outline what actions should be taken and when. FDA also revised the rule to clearly state that corrective action procedures should be tailored not only to the nature of the preventive control, but also to the nature of the hazard.

In addition to taking corrective actions, when "unanticipated food safety problems" occur, facilities also are required to reanalyze their food safety plans. In the final rule, FDA clarifies that reanalysis is conducted "when appropriate." The rule no longer requires reanalysis if a preventive control is not properly implemented and a "specific" corrective action procedure has not been established, and instead only requires reanalysis if "a corrective action procedure" has not been established. Thus, facilities are not required to have corrective action procedures specific to each preventive control.

Corrections. FDA defines "correction" to mean an action to identify and correct a problem without other actions associated with corrective action procedures. Corrections can be taken for sanitation and food allergen controls, as well as for "minor and isolated problems that do not directly impact product safety."

Validation. The final rule continues to exempt food allergen controls, sanitation controls, the supply-chain program, and the recall plan from validation. In addition, other controls do not need to be validated if the preventive controls qualified individual prepares a written justification that validation is not applicable. Validation must be conducted within 90 days (rather than within 6 weeks, as proposed) or within a reasonable timeframe, provided there is a written justification for a different timeframe prepared. In addition to requiring validation (1) prior to implementation of the food safety system and (2) whenever a reanalysis of the food safety plan reveals the need to do so, the final rule also requires validation (3) during production when necessary to demonstrate control measures can be implemented as designed, and (4) whenever a change to a control measure, or combination of control measures, could impact whether the controls will effectively control the hazards. Note that, when appropriate, we expect FDA to place a high emphasis on ensuring proper validation of preventive controls.

Verification Activities Other than Testing.

- The final rule allows for "accuracy checks" in addition to calibration of process monitoring and verification instruments.
- The final rule does not establish a requirement to review consumer complaints as a verification activity, although FDA does encourage such review to improve the facility's food safety system.

- Review of monitoring and corrective action records does not need to occur within 7 working days if the preventive controls qualified individual prepares a written justification of an alternative timeframe.

Reanalysis. The final rule allows facilities to reanalyze only a portion of a food safety plan (rather than the complete plan) in specific circumstances. It also requires reanalysis whenever a preventive control, combination of controls, or the food safety plan as a whole is found ineffective.

3. Product Testing and Environmental Monitoring

The regulatory requirements for product and environmental testing are unchanged from the supplemental proposed rule. Therefore, facilities must conduct product testing and environmental monitoring (if contamination of a ready-to-eat (“RTE”) food with an environmental pathogen is a hazard requiring a preventive control) “as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility’s food safety system.” In the preamble, FDA is clear that based on their hazard analysis, some facilities may conclude that product testing and/or environmental monitoring are not required. FDA also shares its current thinking that routine testing would not need to be conducted by an accredited laboratory and that accredited labs would not need to submit those results to FDA. The final rule continues to require testing procedures to be “scientifically valid.” FDA explains that methods that have not gone through formal validation processes, but have been published in scientific journals, may also be scientifically valid.

4. Supplier Verification

Like the supplemental proposal, the final rule provides that supply-chain controls are a type of preventive control (called a “supply-chain-applied control”). To improve clarity and readability, FDA has moved all of the requirements for the supply-chain program to a new part of the regulation, subpart G, and breaks the regulation into eight distinct sections. The regulation is very specific and detailed, and requires substantial amounts of documentation. We expect that most food companies will need to dedicate considerable time and resources to come into compliance.

The general requirements under the regulation are the same as under the supplemental proposed rule. Facilities must conduct an assessment of each supplier that controls a hazard requiring a preventive control to determine the appropriate verification activities, conduct those verification activities, and document all aspects of the supply-chain program. Like with the supplemental proposed rule, receiving facilities are required to consider several specified factors when assessing the supplier’s performance history, including the supplier’s compliance with FDA food safety regulations through a search of Warning Letters and Import Alerts. The final regulation provides a small amount of flexibility by allowing facilities to consider the specified factors in determining the verification activity as well as in approving suppliers. Suppliers controlling hazards requiring preventive controls that present the risk of serious adverse health consequences or death to humans or animals (“SAHCODHA”) must be audited annually, unless the receiving facility can support another approach and documents this determination. In a significant change, the regulation now recognizes that an entity other than the receiving facility (e.g., a broker, distributor or aggregator) can conduct supplier verification on the facility’s behalf.

The most notable aspects of the final rule on supplier verification are as follows:

Role of Third-Parties. Industry comments raised concerns that there may be multiple establishments between a supplier and the receiving facility, which makes supplier verification very challenging under certain circumstances. To address this issue, entities like brokers, distributors, or aggregators

now have the option of engaging in supplier verification as a service to the receiving facility. The final rule provides that when an entity other than the receiving facility determines and/or conducts supplier verification activities, the receiving facility must review and assess that entity's applicable documentation, and document the receiving facility's review and assessment. In the preamble, FDA emphasizes that the ultimate responsibility for supplier verification still rests with the receiving facility, so only the receiving facility can approve suppliers.

Research and Development Exemption. The final rule establishes an exemption from supplier verification when food is received for "research and evaluation" purposes provided that the food is:

1. Not intended for retail sale and is not sold or distributed to the public;
2. Labeled with the statement "Food for research or evaluation use";
3. Supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and
4. Accompanied with documents, in accordance with the practice of trade, stating that the food will be used for research and evaluation purposes and cannot be sold or distributed to the public.

Intracompany Suppliers. FDA declines to exempt a receiving facility from supplier verification if it receives raw materials or ingredients from an affiliated party within the same corporate or controlling entity. However, the agency advises that the regulation provides "ample opportunities" for an affiliated party within the same corporate entity to establish a supply-chain program that is suited to its relationship with the other entity. For example, a receiving facility may be able to justify conducting a verification activity other than an annual audit when a supplier is an affiliated party, based on the receiving facility's knowledge of the corporate policies regarding food safety practices.

Requirements for Non-Suppliers. There is a new provision of the regulation that addresses the requirements for when a hazard is controlled by an entity other than the receiving facility's supplier. The example FDA provides is where produce covered by the produce safety rule is grown, harvested, and packed under different management. As the regulation defines the "grower" as the supplier, in some instances it may be necessary to verify controls applied by someone other than the "supplier" (e.g., the harvester). The regulation addresses how to handle supplier verification in these situations.

Receipt Procedures. The rule continues to require that a receiving facility ensure raw materials and other ingredients are received only from approved suppliers, but FDA revised the provision to be specific that the receiving facility must do so by establishing and following written procedures for receiving raw materials and must document use of those procedures.

Substitution of an Inspection for an Audit. The final rule provides additional flexibility for government inspections to substitute for required audits. A domestic inspection by a representative of another federal agency (e.g., U.S. Department of Agriculture ("USDA")), or by a representative of a state, local, tribal, or territorial agency can substitute for an audit if it was conducted within 1 year of the date an onsite audit would have been required to be conducted. (§ 117.435(c)(1)). The inspection must be "appropriate" and conducted for compliance "with applicable FDA regulations." Thus, an inspection by USDA to determine whether a farm satisfies the requirements of the produce safety rule could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

Use of Auditors Under FDA's Third-Party Accreditation Program. FDA allows for the use of third-party auditors and provides that a third-party auditor who conducts an audit as a supplier verification activity to satisfy the requirement of the preventive controls rule need not be accredited under the agency's forthcoming third-party certification rule. In addition, the final rule provides that none of the requirements of the third-party certification rule (e.g., direct reporting to FDA) apply to an audit conducted for preventive controls purposes.

Audit Documentation. Like the supplemental proposal, receiving facilities are not required to maintain copies of complete audit reports, but rather must have documentation that includes the conclusions of the audit and corrective actions taken in response to significant deficiencies identified during the audit. In the preamble, FDA declined a request to require a receiving facility to maintain documentation of corrective actions only if the identified deficiencies posed a risk to public health. The agency explained that observations such as filthy conditions may provide a basis for not qualifying a supplier, even though filth often does not pose a risk to public health the food.

Hazards Controlled by the Receiving Facility's Customer. Under the supplemental proposed rule, supplier verification was not required if the hazard was controlled by the receiving facility's customer. FDA has shifted this requirement to a separate part of the regulations, outside of the framework for supply chain management. (See discussion in item 12, below.)

5. Qualified Individuals and Employee Training

The final rule establishes new requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding food, along with associated recordkeeping requirements. These requirements will be codified in Part 117 Subpart A, and thus will be applicable to all employees engaged in manufacturing, processing, packing or holding food, regardless of whether these employees are acting under the cGMP framework or the preventive controls framework. These employees must be "qualified individuals." FDA has redefined "qualified individual" to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. Essentially, this means that employees must be qualified to do their jobs.

The final rules also require each individual engaged in manufacturing, processing, packing, or holding food, or in the supervision thereof, to receive training in principles of food hygiene and food safety, including employee health and personal hygiene. Facilities must keep records of this required training. There is no required frequency of training.

Because FDA established a new, broader definition for the term "qualified individual," the old meaning of that term now applies to the new term "preventive controls qualified individual." A "preventive controls qualified individual" is a "qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system." Specific preventive controls functions, such as preparing the food safety plan and conducting or overseeing validation and verification activities, must be conducted or overseen by the "preventive controls qualified individual." In the preamble, FDA explains it does not intend routinely to directly assess the qualifications of the preventive controls qualified individual. Rather, FDA intends to focus on the adequacy of the food safety plan and, as necessary and appropriate, consider whether deficiencies in the plan suggest that the individual may not have adequate training or experience, including whether reported training and experience are accurately represented.

6. Records

FDA made a few changes to the recordkeeping provisions that are responsive to requests in comments from industry:

- All records, except for the food safety plan, can be stored offsite so long as they can be retrieved and provided onsite within 24 hours of a request for official review. The proposed rule had only permitted offsite storage if the records were at least 6 months old.
- Records only need to include the time of the activity being documented when appropriate. For example, record review and verification activities do not need to include the time that the activity was performed.
- The preamble also explains that the record retention requirements only apply to records created after the applicable compliance date for the final rule. Additionally, FDA agrees that the food safety plan records need not be collected in a single location or “reduced to a binder.”

The regulation also was revised to provide that all required records must be made promptly available “for official review and copying.” In the preamble, FDA states:

We intend to copy records on a case-by-case basis as necessary and appropriate. We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. . . . We primarily intend to copy records such as the results of product testing or environmental monitoring when we conduct an inspection for cause – e.g., as a result of an outbreak investigation, violative sample results, or follow up to a consumer complaint.

The agency also discusses the approach it plans to take for release of records under the Freedom of Information Act. Food safety plans are expected to be exempt from public release as a “trade secret.” Disclosure of verification records, such as the results of product testing and environmental monitoring, would be evaluated on a case-by-case basis.

The recordkeeping requirements also are notable because of what the regulation does not require:

- Electronic records are exempt from the prescriptive requirements in 21 CFR Part 11. In the preamble, FDA advises facilities to “take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.”
- FDA decided not to establish any requirements for facilities to send records to the agency (i.e., there is no remote records access). Instead, records will be reviewed onsite in the course of an inspection.
- FDA also decided against finalizing its proposal to require facilities to submit a subset of the information that would be in the food safety plan to the agency in a “facility profile.”

7. cGMPs

FDA made a number of changes to the terminology used in the cGMPs, including maintaining from the supplemental proposed rule the use of the term “allergen cross-contact” rather than “cross-contact” or “contamination,” to describe the inadvertent incorporation of an allergen into food. As explained above, the provisions on training were moved to subpart A, so that they apply to plants subject to the cGMPs, in addition to facilities subject to preventive controls. The agency also converted certain recommendations into requirements, such as sanitation of non-food-contact surfaces of equipment used in the operation of a food plant, and cleaning and sanitizing of portable equipment with food-contact surfaces and utensils.

In response to industry comments, FDA made a number of helpful preamble statements. Specifically, FDA clarified that:

- The requirements to protect food in outdoor bulk vessels by any appropriate means do not apply to open containers of RACs that are subject to further processing.
- Plants will not be held to any particular standard, such as a zero-tolerance standard, for allergen controls. The rule does not require the use of dedicated lines or equipment for effective prevention of allergen cross-contact. Rather, the requirement is for the manufacturer to take steps to identify potential sources of allergen cross-contact and implement preventive measures.
- The removal of the option to reexamine product that has been found to be adulterated does not apply to product placed on hold as a result of faulty or non-calibrated monitoring equipment, as such product is not adulterated.
- There are some situations in which food-contact surfaces do not need to be sanitized (e.g., dry cleaning methods with no sanitizing steps).
- Food-contact surfaces for manufacturing, processing, or holding low-moisture food must be in a clean, dry, sanitary condition “before use” rather than during the entire operation.

8. Definition of “Farm”

Because the preventive controls regulation applies to facilities that are required to register with FDA, and farms are exempt from FDA registration, the meaning of “farm” has increased importance under FSMA. FDA has revised the definition of “farm” in its facility registration regulation (21 CFR Part 1, Subpart H) to clarify which facilities are exempt from registration. The agency previously made a number of revisions to the definition in the supplemental proposed rule, and provides further modifications in the final rule that generally broaden the scope of entities considered to be farms. The definition of “farm” is very fact specific, and individual entities should carefully assess whether they qualify as a “farm” under the new definition.

The final rule differentiates between two types of farm operations, a “primary production farm” and a “secondary activities farm.” Both types of farms have the same treatment under the final rule and are exempt from facility registration. In general, a “primary production farm” is an operation under one management in one general (but not necessarily contiguous) location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities. A farm can pack and hold raw agricultural commodities (RACs) and may conduct certain manufacturing/processing activities (i.e., drying/dehydrating RACs to create a distinct commodity).

FDA also has defined a “secondary activities farm,” which is an operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm. The definition of secondary activities farm was added to address operations like off-farm packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms). Thus, the recognition of secondary activities farms broadens the scope of the definition.

9. Human Food By-Products Diverted to Animal Feed

The cGMPs include a provision addressing holding and distribution of human food by-products for use as animal food. ^{4/} (This provision also is codified in the animal food regulations.) The final rule is quite similar to the proposed rule, allowing human food facilities that do not further process the by-products to send the food to an animal food use so long as they meet certain conditions when holding the animal food for distribution in order to protect against contamination. The language has been slightly revised in response to industry comments.

Notably, FDA explains that this regulation only applies to facilities that are required to register with FDA and, therefore, does not apply to facilities that are exclusively regulated by the USDA’s Food Safety and Inspection Service (“FSIS”). Dual-jurisdiction facilities (i.e., those facilities subject to both FDA and FSIS regulation) must follow the cGMPs for holding and distribution of their FDA-regulated human food by-products for use as animal food. Additionally, if a dual-jurisdiction facility produces animal food, it must comply with the animal food preventive controls regulation.

The preamble explains that this regulation “does not apply to human food by-products when contamination or other adulteration has occurred that is materially related to food safety.” Requests for diversion of these products are handled on a case-by-case basis under the agency’s Compliance Policy Guides (CPG Sec. 675.100 and CPG Sec. 675.200). For example, FDA states that if milk has been returned to a processing plant because it is contaminated or adulterated, the facility must follow the CPGs for request to divert the milk for use as animal food.

10. Exemptions and Modified Requirements

Warehouses. Facilities “solely engaged in the storage of unexposed packaged foods” are exempt from the general preventive controls requirements, as well as the supply-chain program provisions, and may be subject to a modified set of requirements if such products are subject to refrigeration as described below. In the preamble, FDA clarifies that it interprets the term “solely” strictly and that warehousing operations attached to manufacturing operations are not exempt and must have a hazard analysis conducted. The modified preventive controls requirements for warehouses would only apply to those unexposed packaged foods that require time/temperature control for safety (“TCS”). The preamble states that although FDA cannot say that frozen foods are “never” TCS foods, the agency recognizes it is rare.

The modified requirements for TCS foods are substantially the same as proposed, with temperature control treated as a preventive control, and with the following key revisions:

^{4/} The agency discusses the requirements for human food byproducts that may be used as animal food in the preamble to the preventive controls for animal food final rule.

- Exception monitoring is permitted for temperature control. Facilities may keep temperature monitoring records either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control.
- Verification that temperature controls are consistently implemented may be done either by calibrating temperature monitoring and recording devices, or by checking them for accuracy.

Facilities that are “solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further processing” also are exempt from preventive controls requirements. Like warehouses that store unexposed packaged foods, these facilities must be “solely engaged” in the storage of raw agricultural commodities. The exemption does not apply when the facility also is engaged in other activities. Similarly, establishments “solely engaged in the holding and/or transportation” of raw agricultural commodities are exempt from cGMP requirements, but again the phrase “solely engaged” will be strictly applied. Although off-farm packing or packaging raw agricultural commodities subjects the establishment to cGMPs, if the establishment is handling produce covered by the produce safety rule, it may choose to comply with either cGMPs of the produce rule with respect to those commodities.

Small Business and Very Small Business. Small businesses are defined as those with 500 or fewer “full-time equivalent employees,” a term for which FDA has added a definition. The “small business” definition is relevant for the purposes of compliance dates and eligibility for the low-risk on-farm activity exemption.

Very small businesses are those with less than \$1 million in total annual sales of human food, adjusted for inflation. FDA makes a number of important clarifications about this threshold in the preamble:

- The threshold applies to “sales” of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (e.g., held by a warehouse for a fee).
- The criteria apply based on an average during the 3-year period preceding the applicable calendar year.
- All human food is included – not just food subject to the preventive controls rule.
- The threshold applies not only to sales to the United States, but also includes exports to other countries or, for foreign facilities, sales outside the U.S.

Qualified Facility. The final rule maintains the definition of “qualified facilities,” which are exempt from the preventive controls requirements (as well as the supply-chain program provisions) and instead are subject to modified requirements. Qualified facilities must submit an attestation statement to FDA, but would not be required to submit the underlying documentation that establishes its compliance with the modified requirements. In determining compliance with the modified requirements, FDA intends to focus on records demonstrating that the facility is a very small business.

The final rule establishes specific requirements for how frequently facilities must determine and document their status as a qualified facility (by July 1 of each year), how frequently they must submit the attestation (biennially, coinciding with biennial updates to food facility registration), and how to handle changes in eligibility. The due process procedures that would be employed before any

“qualified facility” lost its exemption, such as due to a foodborne illness outbreak, are substantially the same as proposed.

Small Business or Very Small Business Conducting On-Farm Low-Risk Activities. Farm mixed-type facilities that are small or very small businesses and that only conduct specified low-risk activity-food combinations are exempt from the preventive controls and supply-chain requirements. FDA has finalized its risk assessment, which was used in developing the list of qualifying low-risk activity-food combinations. The risk assessment also will be relevant to companies that are not small businesses or very small businesses, as it may be helpful in conducting the hazard analysis. To the extent a very small business conducts activities in addition to the low-risk on-farm activities (and thus would otherwise be subject to preventive controls requirements), it could rely instead on the qualified facility exemption and comply with the modified requirements for such facilities.

11. PMO Regulated Facilities

In the final rule, FDA declines to exempt facilities regulated under the Pasteurized Milk Ordinance (“PMO”) from preventive controls requirements and also declines to determine that facilities operating in compliance with the PMO are in compliance with preventive controls requirements. The agency concludes that the current version of the PMO does not contain all of the requirements in new Part 117 Subparts C and G. Although the National Conference on Interstate Milk Shipments (“NCIMS”) is working to modify the PMO, that process will not be complete before the final rule is effective for large and small businesses. Thus, FDA is extending the compliance date for PMO-regulated facilities to comply with Subparts C and G to September 17, 2018 (i.e., an additional two years). This is intended to provide the NCIMS time to modify the PMO so that it will align with the preventive controls requirements.

12. Circumstances When Preventive Controls Are Not Required

The final rule addresses two circumstances where preventive controls are not required. These stem from a requirement previously included as part of the supplier program requirements in the supplemental proposed rule.

First, FDA allows a manufacturer/processor not to implement a preventive control if it determines and documents that the type of food could not be consumed without application of the appropriate control. For example, this could apply to RACs such as cocoa beans, coffee beans, and grains.

Second, FDA establishes provisions that apply when a hazard is controlled by a subsequent entity in the supply chain. Under these provisions, the following requirements generally apply: (1) documentation must be provided from the manufacturer/processor to its direct customer that the food is “not processed to control [identified hazard]”; (2) written assurance must be provided from direct customers to the manufacturer/processor regarding appropriate procedures to ensure that the food will be further processed to control the identified hazard; and (3) customers must document that they are satisfying the written assurance. (Note that in these provisions, “customer” means a commercial customer, not a consumer.) Note that these requirements present a significant new record-intensive obligation for virtually every entity in the supply chain.

For example, a facility that supplies unprocessed nuts to a nut roasting company would need to label the nuts as “not processed to control *Salmonella*.” Annually, the company that roasts the nuts would need to provide written assurance to its supplier that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the *Salmonella* hazard. Additionally, the nut roaster must document its actions taken to satisfy the written assurance. The

regulation also addresses the situation where, for example, the *Salmonella* hazard is controlled by a subsequent entity in the chain (e.g., the customer’s customer), in which case the initial customer must provide written assurance that it will (1) disclose in documents accompanying the food that it is “not processed to control *Salmonella*” and (2) only sell to another entity that agrees, in writing, it will (i) follow procedures (identified in the written assurance) to significantly minimize or prevent the hazard (or follow applicable food safety requirements, if the entity is not subject to preventive controls), or (ii) obtain similar written assurance from the entity’s customer.

13. Compliance Dates

Compliance dates are staggered based on facility size, and longer dates are set for the supply-chain program (subpart G), as explained further in the following chart:

cGMP, Preventive Controls, and Supply Chain Program Compliance Dates		
Business Size	cGMP and Preventive Controls Compliance Date	Compliance Date for Supply-Chain Program
Businesses with 500+ Full-Time Equivalent (“FTE”) Employees	September 19, 2016	The later of (1) March 17, 2017, or (2) 6 months after a supplier is required to comply with the applicable rule
Small Businesses (<500 FTE Employees)	September 18, 2017	The later of (1) September 18, 2017, or (2) 6 months after a supplier is required to comply with the applicable rule
Businesses Subject to the PMO	September 17, 2018	September 17, 2018
Qualified Facilities (including very small businesses)	September 17, 2018 (except that the compliance date is January 1, 2016 for records to support the facility’s status as a qualified facility) ^{5/}	N/A

Notably, for the amendments to the facility registration regulation, the compliance date is November 16, 2015. For establishments that become subject to the Bioterrorism Act’s one-up/one-back recordkeeping requirements (established in the regulations at 21 CFR Part 1, Subpart J) for the first time as a result of being required to register with FDA based on this final rule, the compliance dates with that regulation are staggered based on business size as follows:

Bioterrorism Act Recordkeeping Compliance Dates	
Size of Business	Compliance Date
500 or more FTE employees	September 19, 2016
Between 10 and 499 FTE employees	March 17, 2017
10 or fewer FTE employees	September 18, 2017

^{5/} FDA also established December 17, 2018 as the compliance date for submissions of attestations by qualified facilities, and January 1, 2020 as the compliance date for consumer notifications by qualified facilities.

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Publication of the preventive controls final rules is not the final word on development and implementation of food safety plans. FDA will be issuing several important guidance documents regarding the final rules, which will be published in draft form for public comment. There also are more final rules still to come. In early November, FDA is expected to release the final rules on produce safety, the Foreign Supplier Verification Program, and third-party accreditation. In the spring of 2016, FDA is expected to issue final rules on sanitary food transportation and food defense (intentional adulteration).

We will continue to closely monitor all developments related to FDA's implementation of FSMA. If you have any questions regarding the final rules and how to ensure compliance with them, please do not hesitate to contact us.