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MEMORANDUM

September 17, 2015

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Matz PC

RE: *FDA Final Rule: CGMPs and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*

On September 10, 2015, the federal Food and Drug Administration ("FDA") released a major final rule to implement the Food Safety Modernization Act ("FSMA"): Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (the "Final Rule"), 80 Fed. Reg. _____ (Sept. __, 2015). Additional information on the Final Rule can be found on FDA's website at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm.

This memorandum summarizes the major components of the Final Rule with a particular focus on the new provisions that were not included in the Proposed Rule or Supplemental Proposed Rule.[1]

[1] On October 29, 2013, FDA released a proposed animal feed rule that outlined many of the provisions included in the Final Rule. *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls; Proposed Rule, 78 Fed. Reg. 64,736 (Oct. 29, 2013) (the "Proposed Rule"). FDA also introduced revised provisions for comments in a supplemental proposed rule on Sept. 29, 2014. *See* Supplemental Notice of Proposed Rulemaking: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls; Proposed Rule, 79 Fed. Reg. 58,476 (Sept. 29, 2014) (the "Supplemental Proposed Rule").

I. EXECUTIVE SUMMARY

The Final Rule is a culmination of multiple years of rulemaking. Section 103 of FSMA added a new section 418 to the Federal Food, Drugs, and Cosmetics Act (FD&C Act) that required FDA to promulgate regulations that require registered food facilities to establish and implement a food safety system that includes hazard analysis and risk-based preventive controls. Many of the provisions in the Final Rule were initially introduced in prior FDA proposals. After significant input from industry stakeholders, FDA has incorporated many of these suggestions into the Final Rule.

The major provisions of the Final Rule include:

- **Current Good Manufacturing Practices (CGMPs)** – Under Subpart B of the Final Rule, registered animal food facilities will need to comply with CGMPs that address food safety concerns associated with the manufacturing, processing, packing, and holding of food for animals.

- **Hazard Analysis and Risk-Based Preventive Controls** – Under Subpart C of the Final Rule, certain domestic and foreign animal food facilities will need to establish and implement hazard analysis and risk-based preventive controls for animal food. Registered facilities subject to Subpart C must maintain a written food safety plan, perform a hazard analysis, and institute preventive controls to mitigate the identified hazards. Additionally, registered animal food facilities will be required to monitor their preventive controls, conduct verification activities to ensure the preventive controls are effective, take appropriate corrective actions, and maintain records documenting these actions.

- **Supply-Chain Controls** – Under Subpart E of the Final Rule, animal food manufacturing/processing facilities will be required to have a risk-based supply chain program for those raw materials and other ingredients for which the facility has identified a hazard requiring a supply-chain-applied control. If the animal food facility controls the hazard using preventive controls, or follows specific requirements when they rely on a customer to control the identified hazards, they do not need to have a supply-chain program for that hazard.

  Animal food facilities will be responsible for ensuring that raw materials and other ingredients that are controlled by a supply-chain program are received only from approved suppliers.[2]

[2] Raw materials may be received from an unapproved supplier on a temporary basis if the raw materials are subject to verification prior to receipt.

Preventive controls will not be required at facilities when an identified hazard is controlled elsewhere in the distribution chain (*e.g.*, a customer or other processor). The facility will have to disclose that the food is "not processed to control (identified hazard)" and will also have to obtain a written assurance from their customer in regards to actions that the customer agrees to take.

- **Vertically-Integrated Farming Operations** – Feed mills associated with *fully* vertically-integrated farming operations (*i.e.*, farms where the feed mill, animals, land, and establishment are all owned by the same entity) are considered "farms" and are not subject to the CGMPs or preventive controls. This is the case even in instances where the feed mill is not located on the same property as the animals.

  However, in the instance where a feel mill is owned by an entity that contracts out the task of raising the entity's livestock or poultry, the feed mill is not considered to be part of a "farm." FDA reasons that these feed mills cannot be considered part of a farm because they manufacture feed for animals that are not managed by the feed mill's owner. As such, feed mills that serve contract livestock and poultry farmers are subject to the Final Rule's CGMP and preventive controls requirements.

  Fearing that the farm exemption leaves significant gaps in the protection of human and animal health, FDA has indicated that the agency will propose a subsequent rulemaking that would apply CGMP and preventive control requirements to some feed mills that service fully vertically-integrated farming operations.

- **Staggered Compliance Timelines** – The deadlines for compliance with the CGMPs and preventive controls will be staggered. Furthermore, "small" and "very small" businesses will have additional time to comply with the provisions of the Final Rule. Section VII discusses the compliance timelines in further detail.

II. NOTABLE CHANGES

a. Supplier Controls

The rule added a definition for "supply-chain-applied control." The term is defined as "a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt." The Final Rule changed the phrase "supplier-program" to "supply-chain program" and moved the requirements to a stand alone section (Subpart E). The Final Rule increases flexibility for the supply-chain programs and adjusted the compliance dates for these provisions such that a food facility will not have to comply with these provisions prior to the time it is required to comply with the preventive controls for animal food rule or the produce safety rule.

b. Definition of "Farm" & Implications for Vertically-Integrated Operations

The Preventive Controls for Human Food Rule amended FDA's definition of a "farm" for the purposes of the FD&C Act in § 1.227. Specifically, the agency developed two sub-categories of farms: primary production farms and secondary activities farms.

- **Primary Production Farm –** FDA defines a primary production farm as an operation under common management ("under one management")[3] in one general, but not necessarily contiguous, location devoted to the growing of crops, harvesting of crops, the raising of animals (and seafood), or any combination of these activities.

- **Secondary Activities Farm –** Under FDA's revised definition, a secondary activities farm is located separately from a primary production farm and is used, in the animal food context, mostly for packing and holding of grain.

The revision of the "farm" definition has implications regarding the jurisdiction of the Final Rule. For example, suppose Farm X has a feed mill that exclusively services Farm X's beef cattle herd. Farm X purchases some of the grain that it processes at its feed mill from Farm Y. Under FDA's revised definitions, Farm X would not be subject to the Final Rule even though it processes grain that did not originate on the farm.

In contrast, if a poultry integrator operates a feed mill to service its contract growers; that feed mill is subject to CGMPs and preventive controls requirements because the contract growers and the poultry integrator do not share common management.

c. Human Food By-Products (§ 507.12 "Applicability of this Part to the Holding and Distribution Human Food By-Products for Use as Animal Food")

Facilities that are already in compliance with human food safety requirements (*e.g.*, brewers, distillers) do not need to implement additional CGMPs or preventive controls when supplying a by-product (*e.g.*, wet spent grains, liquid whey, or fruit or vegetable peels) for animal food, except to prevent physical or chemical contamination when holding or distributing the by-product. The requirement to prevent contamination applies regardless of whether the facility donates or sells by-products as animal food.

In contrast, further processing a human food by-product for use as animal food (*e.g.*, drying, pelleting, and heat treatment) requires entities to process the by-product in compliance with CGMPs and ensure that hazards are not introduced to animal food. In this circumstance, the

[3] This replaces the term "under one ownership" that was used in the original definition of "farm" to better represent and include the farms whose ownership is by multiple growers, food aggregators, etc., but for which the control of the business is "under one management."

facility may choose to either comply with the Human Food Rule or the Animal Food Rule. It is important to note that § 507.12 does **not** apply to "human food by-products when contamination or other adulteration has occurred that is materially related to food safety". If a human food by-product poses a food safety risk, requests for approval to use the by-product as animal food should be made to FDA following Compliance Policy Guidance Numbers (CPG) Sec. 675.100 or 625. 200. For example, for dry milk powder that has tested positive for *Salmonella* to be diverted to animal food, a request based on one of the CPGs would need to be made to FDA.

d. "Hazard Requiring a Preventive Control" (§ 507.3 Definitions.)

Based on many comments received regarding the use of the term "significant hazard" in the Proposed Rule and Supplemental Proposed Rule, and its proposed definition, it has been changed to "hazard requiring a preventive control." Use of this phrase instead of "significant hazard" is consistent with language explicitly used in FSMA.

FDA reviewed the full regulatory test of proposed Subpart C and replaced "significant hazard" with "hazard requiring a preventive control" in most cases where the term appeared. It also reviewed the regulatory text to evaluate where the term "hazard" was used to determine whether or not it should be replaced with "hazard requiring a preventive control" or "known or reasonably foreseeable hazard." This was done to continue to support FDA's belief that it is necessary to use a tiered approach when evaluating a process so that a facility only conducts a hazard analysis for known or reasonably foreseeable hazards.

The definition for "hazard requiring a preventive control" in the Final Rule is:

> a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the 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 an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records), as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system."

III. CURRENT GOOD MANUFACTURING PRACTICES

Unlike the preventive controls in subpart C, the Final Rule's CGMP requirements apply to all registered animal food facilities. Under subpart B, registered facilities are required to adopt CGMPs for the following aspects of their animal food operation:

- Personnel (§ 507.14);
- Plant and grounds (§ 507.17);
- Sanitation (§ 507.19);
- Water supply and plumbing (§ 507.20);
- Equipment and utensils (§ 507.22);
- Plant operations (§ 507.25); and
- Holding and distribution (§ 507.27).

IV. PREVENTIVE CONTROLS

Subpart C of the Final Rule requires some registered facilities to implement hazard analysis and risk-based preventive controls.

a. Applicability

All registered animal food facilities are required to comply with the Final Rule's hazard analysis and preventive controls unless an exception applies. These exemptions are listed and explained in the table below.

Who or What Is Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls	Notes
"Qualified Facility" as defined by FSMA: 1. Business with avg. annual sales of < $500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or 2. "Very Small Business," defined as an entity (including subsidiaries and affiliates) averaging less than $2,500,000 per year during the prior 3-year period in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale)	Modified requirements apply – *i.e.*, a qualified facility is required to: • Notify FDA about its qualified status and either: o Notify FDA that it is addressing hazards through preventive controls and monitoring; or o Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the animal food was manufactured or processed. • The notification is in the form of an attestation, and must be submitted every 2 years, during the same timeframe as the

	facility is required to update its facility registration
• Low-risk, on-farm activities performed by small business (< 500 full-time employees, company wide); or • Low-risk, on farm activities performed by a very small business (less than $2.5 M in animal food sales/value)	Small and very small on-farm businesses conducting only low-risk activities (*e.g.*, re-packing roughage products or cracking grains) are exempt from the Final Rules hazard analysis and preventive controls requirements.
Activities subject to the "low-acid canned food" requirements (21 C.F.R. part 113)	"Low-acid canned foods" are ***only*** exempt from microbiological hazard controls under the Final Rule because they are covered by part 113
Activities of a facility subject to section 419 of the FD&C Act (standards for produce safety)	These activities will fall under FDA's forthcoming produce safety rule
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	A facility that stores fruits and vegetables is not exempt
A facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.	Modified requirements apply for the storage of unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

Although "qualified" facilities may elect to be exempt from subpart C, FDA may withdraw a qualified facility's exemption: (1) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility; or (2) if FDA determines that it is necessary to protect the public (human and animal) health and prevent or mitigate a foodborne illness outbreak based on relevant conditions or conduct at the qualified facility. The procedure for withdrawal of a qualified facility exemption is located in subpart D of the Final Rule.

b. Food Safety Plan

Subpart C of the Final Rule is anchored by the written food safety plan.[4] The written food safety plan must include the following:

- Written hazard analysis (§ 507.33(a)(2));
- Written preventive controls (§ 507.34(b));
- Written supply-chain program (subpart E);

[4] 21 C.F.R. § 507.31.

- Written recall plan (§ 507.38(a)(1));
- Written preventive control monitoring procedures (§ 507.40(a)(1));
- Written corrective action procedures (§ 507.42(a)(1)); and
- Written verification procedures (§ 507.49(b)).

c. Hazard Analysis

A registered facility subject to Subpart C must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring preventive controls.

A facility's hazard analysis should identify known or reasonably foreseeable biological, chemical, and physical hazards.[5] FDA has indicated that the known or reasonably foreseeable hazards should include: (i) naturally occurring hazards; (ii) unintentionally introduced hazards; and (iii) hazards intentionally introduced for purposes of economic gain that affect the safety of the food (e.g., melamine in pet food). After all known or reasonably foreseeable hazards are identified, a facility is required to identify the hazards that need to be mitigated through the implementation of preventive controls.[6]

d. Preventive Controls

Facilities that are subject to subpart C and have identified hazards that need to be controlled and mitigated to protect human and animal health must implement preventive controls.[7] Under the Final Rule, preventive controls need to be implemented at critical control points (CCPs), if any exist. Preventive controls, other than those at CCPs, should be implemented when appropriate for animal food safety.

Preventive controls include:

- **Process Controls –** Procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. This should include: (1) the parameters associated with the control of

[5] 21 C.F.R. § 507.33.

[6] FDA does recognize in the preamble to the Final Rule that a facility may conduct its hazard analysis and conclude there are no hazards that require a preventive control. It provides several examples of animal food products for which it believes a facility may determine there are no hazards. These include alfalfa cubes, vegetables oils and molasses.

[7] 21 C.F.R. § 507.34.

the hazard; and (2) the maximum or minimum value, or combination of values to which any hazard must be controlled.

- **Sanitation Controls –** Procedures, practices, and processes to ensure that the facility in maintained in a sanitary condition "adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling."

- **Supply Chain Controls –** Facilities must comply with the supply-chain program contained in subpart E (discussed in Section V of this memo).

- **Recall Plans** – Each registered facility must have a recall plan in place for animal foods that are subject to preventive controls.

- **Preventive Controls Qualified Individual** – The Final Rule establishes a new title, the "preventive controls qualified individual (PCQI)." The PCQI is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system[8]. The PCQI was referred to as a "qualified individual" in the Proposed Rule.

- **Preventive Control Management** – There are several preventive control management procedures required by the Final Rule to ensure that preventive controls are effective at mitigating the potential for harm to human and animal health.[9] These include:

    - Monitoring – monitor the preventive controls with adequate frequency to provide assurance that they are adequately performed (§ 507.40);

    - Corrective actions and corrections – establish written corrective actions to be taken if preventive controls are not properly implemented (§ 507.42); and

        - "Corrective action" procedures must describe the steps taken to ensure:
            - Appropriate action taken to identify and correct problem with implementation of a preventive control;

[8] It is important to note that all individuals who perform activities required under Part 507 are expected to know how to do their jobs. Based on this, § 507.4(b) was added specifying all individuals performing required activities be "qualified individuals" – "a person who has the necessary education, training, and experience to perform an activity required under Part 507." Qualified individuals are separate from PCQI who is a specific individual with training to develop and apply a food safety system.

[9] 21 C.F.R. § 507.39.

- Appropriate action taken to reduce reoccurrence of problem;
- All affected animal food is evaluated for safety; and
- All affected food is prevented from entering commerce if a facility cannot ensure the affected food is not adulterated.

▪ "Correction" is defined as "an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure…."[10]

o Verification – conduct, as appropriate to the nature of the preventive control and its role in the food safety system, documented verification and validation[11] activities to ensure that preventive controls are consistently implemented and effective to mitigate risks to human and animal health (§ 507.42).[12]

V. SUPPLY-CHAIN COMPLIANCE

Animal food facilities are required to have a risk-based supply chain program for those raw materials and other ingredients for which they identify a hazard requiring a supply-chain-applied control program.[13] For example, a dry dog food company may purchase corn for their product. The company determines it is appropriate to rely on their supplier for the control of the chemical hazard aflatoxin. They implement a written supply-chain program and verify that the aflatoxin has been significantly minimized or prevented by the supplier and that the level of aflatoxin in the corn does not render it adulterated under the FD&C Act. The dry dog food company recognizes their production process will address the biological hazard *Salmonella*. The dry dog food company implements preventive controls for this hazard.

As demonstrated in the example, the supply-chain program must be written and must provide assurance that the hazard requiring the supply-chain-applied control has been significantly minimized or prevented.

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[10] 21 C.F.R. § 507.3.

[11] FDA recognizes that not all preventive controls require validation such as sanitation controls, the recall plan, and the supply-chain program. It requires that the PCQI prepare a written justification on why validation is not applicable if they determine that to be the case for a preventive control.

[12] Based on comments received on FDA's question on requiring a review of complaints as part of verification, FDA is ***not*** establishing a review of complaints as a verification activity. It does, however, encourage such a review.

[13] The Final Rule provides an exemption for a receiving facility that is an importer and that can demonstrate compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, that maintains documentation of verification activities conducted under § 1.506(e) of this chapter (providing assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented). The requirements also do not apply to animal food supplied for evaluation or research; the food is labeled as such, not sold to the public, and is produced in quantities consistent with research or analysis.

Animal food facilities are responsible for ensuring that raw materials and other ingredients with a supply-chain-applied control are received only from approved suppliers, or are only received on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to verification activities before being accepted for use. Approved suppliers are defined as facility/ies that have been approved after a consideration of factors that include: a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance. The receiving facility will not have to implement a preventive control but will have to disclose that the food is "not processed to control (identified hazard)" and also obtain annual written assurance from its customer[14] regarding certain actions that customer agrees to take.

The supply-chain program must include:

1. Using approved suppliers;
2. Determining appropriate supplier verification activities;
3. Conducting supplier verification activities;
4. Documenting supplier verification activities; and
5. When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification.

Verification activities may include:

- Annual on-site audits;
- Sampling and testing;
- Review of the suppliers food safety records; and
- Other activities based on the risk.

In addition to the written program, records required to be maintained by the receiving facility include:

1. Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements, including documentation of verification activities;
2. Documentation of the approval of a supplier;
3. Procedures for receiving raw materials and other ingredients;
4. Documentation that demonstrates the use of the written procedures for receiving raw materials and other ingredients;
5. Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
6. Documentation of onsite audits. This documentation must include:
    i. Supplier name subject to the onsite audit;

[14] When the term "customer" is used in these provisions, it means a commercial customer – not a consumer.

ii. Documentation of audit procedures;
iii. Audit dates;
iv. Audit conclusions;
v. Corrective actions taken in response to any findings; and
vi. Demonstration completed by qualified auditor.

7. Documentation of sampling and testing conducted. Documentation must include:
   i. Identification of the raw material or other ingredient tested (*e.g.*, lot number)and the number of samples tested;
   ii. Identification of the test(s) conducted, and the analytical method(s) used;
   iii. Date(s) on which the test(s) were conducted and the date of the report;
   iv. The results of the testing;
   v. Corrective actions taken in response to test results; and
   vi. Information on the laboratory conducting the testing.
8. Documentation of the review of the supplier's food safety records. Documentation must include:
   i. Name of the supplier;
   ii. Date of the record and date of review;
   iii. General nature of records reviewed;
   iv. Conclusions of the review; and
   v. Corrective actions taken in response to any findings.
9. Documentation of other verification activities.[15]

With regards to verification of the supplier, the rule does indicate that an inspection by FDA (or their representatives) to verify compliance with FDA requirements may be used rather than an audit if the inspection was conducted in the past year. For foreign suppliers in those countries that FDA has determined to have equivalent food safety systems,[16] documentation of an FDA inspection or an inspection by the competent regulatory authority in the past year could be used.

VI. RECORDKEEPING REQUIREMENTS

Subpart F of the Final Rule details the various records that facilities must maintain related to monitoring and verification of preventive controls.[17] The major recordkeeping provisions include:

[15] A Qualified Facility might provide written assurances of compliance with applicable FDA regulations for their facility.

[16] It should be noted that as of August 30, 2015, the FDA does ***not*** have a systems recognition program for animal food and has no signed systems recognition agreements with any foreign food safety authority for animal food.

[17] FDA decided *not* to establish a requirement that facilities submit a "facility profile" that would have included the facility's food safety plan, and required biannual updates tied to the food facility registration process. This decision was based on the many comments received expressing concern with this proposed requirement.

- **Two-Year Retention Requirement –** All records required under the Final Rule relating to preventive controls must be retained for at least two years.[18] Records that a facility relies upon to support its status as a qualified facility must be retained for three years.

- **Remote Record Storage –** Except for the written food safety plan, all records required under the Final Rule may be stored remotely or electronically, so long as these documents can be retrieved and provided onsite within 24 hours.[19]

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- **Food Safety Plan –** A physical copy of a facility's food safety plan must be maintained onsite.

- **Use of Existing Records –** Records that are kept to comply with other federal, state, or local regulations do not need to be duplicated to satisfy the Final Rule's recordkeeping requirements.[20] Furthermore, the information required by the Final Rule does not need to be kept in one set of records.

- **Records Availability** – Records required by this part must be made available to an authorized representative of the Secretary of Health and Human Services for official review and ***copying upon oral or written request***.[21]

VII. COMPLIANCE DEADLINES

The effective date for compliance with the Final Rule's CGMPs and Preventive Controls is staggered and varies based on the size of the facility's business. "Small" and "Very Small" businesses receive additional time to come into compliance with the Final Rule. The definitions for these special size classifications are as follows:

- *Small Business* – a business employing less than 500 full-time equivalent employees; and

- *Very Small Business*[22] – a business averaging less than $2,500,000 per year (inflation adjusted) in animal food sales *plus* the market value of animal food manufactured,

[18] 21 C.F.R. § 507.208.

[19] 21 C.F.R. § 507.208(c).

[20] 21 C.F.R. § 507.212.

[21] FDA has indicated that they intend to copy records on a case-by-case basis as "necessary and appropriate." In the preamble, FDA indicates that they "primarily intend to copy records such as results of product testing or environmental monitoring when we conduct an inspection for cause…."

processed, packed, or held without sale (held for a fee or supplied to a farm without sale).

The compliance timelines for entities to implement CGMPs and Preventive Controls are detailed in the below table.

Business Size	CGMP Compliance Date	Preventive Controls Compliance Date
Business other than small or very small	Sept. 19, 2016	Sept. 18, 2017
Small business	Sept. 18, 2017	Sept. 17, 2018
Very small business	Sept. 17, 2018	Sept. 17, 2019 (except records to support "very small business" status due by Jan. 1, 2017)

- **Supply-Chain Program Compliance** – There is a modified timeline for facilities to comply with subpart E. The below table outlines the compliance deadlines for different circumstances.

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	The later of: September 18, 2017 or 6 months after the receiving facility's

[22] FDA estimates that of the 7,469 animal food facilities registered with FDA, that approximately 15% could be "qualified" facilities under the "very small business" definition.

supplier will be subject to the animal food preventive controls rule	supplier of that raw material or other ingredient is required to comply with the applicable rule

FDA is committed to providing assistance to industry on the Final Rule. Guidance documents are being prepared by the agency. In addition, FDA is establishing a Food Safety Technical Assistance Network to support the industry during the implementation process.

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We trust that this advice is useful. If you have any questions, please contact Jolyda Swaim at 202-789-1212 or jswaim@ofwlaw.com.

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