MEMORANDUM

From: Joseph A. Levitt
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Date: September 26, 2014

Re: FDA Issues Supplemental Preventive Controls Proposed Rules Under FSMA

On Friday, September 19th, the Food and Drug Administration (FDA) released four supplemental notices of proposed rulemaking, proposing changes to the following rules first proposed in 2013 to implement the FDA Food Safety Modernization Act (FSMA): Preventive Controls for Human Food, Preventive Controls for Animal Food, and Foreign Supplier Verification Program (FSVP); and Produce Safety. FDA will accept comments on the revised provisions for 75 days after publication in the Federal Register, while continuing to review comments already received on the original proposed rules. 1/ FDA will not accept additional comments on the original proposals.

This memorandum provides key takeaways and highlights of the major provisions from the supplemental proposed rule for preventive controls for human food and the supplemental proposed rule for preventive controls for animal food. We also are issuing today a separate memorandum on the produce safety supplemental proposed rule. We will then issue a memorandum on the supplemental proposed rule for FSVP. 2/

Overview

The proposed revisions to the preventive controls rules would make the regulations more flexible, practical, and targeted. These changes are based on input from stakeholders in response to the proposed rules and demonstrate the significant effect that public comments can have on the rulemaking process. FDA’s revisions are directly responsive to many of the requests from the food industry and overall result in proposed requirements that are more flexible, risk-based, and tailored to the individual food facility. The proposed revisions are a significant improvement and provide the food industry with a clear indication of what the final requirements likely will look like when they are issued in 2015.

It is important to keep in mind, however, that FDA has not completely re-proposed the preventive controls rules. Although the supplemental proposals address major components of the 2013

1/ The supplemental proposed rules are expected to publish on Monday, September 29th, making the comment deadline approximately Monday, December 15, 2014.
2/ FDA’s desire for consistency between FSVP and supplier verification requirements in the preventive controls supplemental proposed rules means that the summary provided below provides a preview of the requirements in the FSVP supplemental proposed rule.
proposed rules (such as the hazard analysis, the management of preventive controls, and testing and supplier verification as well as GMPs for animal food), they do not address all of the issues on which stakeholders commented. For example, FDA does not address consumer complaints, food safety plans for pilot plants, refrigerated warehouses, or compliance with Part 11 electronic recordkeeping requirements. The agency will not accept additional comments on these issues, but will continue to review comments already submitted to the original proposed rules. These issues, as well as new issues raised by the supplemental proposed rules, will be resolved in the final rules. As a reminder, by court order these final rules must be issued by August 30, 2015.

Below we outline some of the key revisions found in the supplemental notices. Because most human food companies do not intentionally produce animal food, though they may divert by-product or food processing waste, this memorandum focuses on the human food rule. Nonetheless, for the most part, the proposed rule regarding animal food is the same as the one for human food. Where there are key differences between the two rules, we note them.

Highlights of Key Revisions

1. Hazard Analysis:

FDA agrees with industry comments to delete the phrase “reasonably likely to occur” (RLTO) from the regulations. Industry had argued that RLTO has been used as the basis for determining hazards that need to be addressed at Critical Control Points (CCPs) in hazard analysis and critical control point (HACCP) systems and that preventive controls under FSMA are much broader than just CCPs. FDA agrees it could be confusing to have the same term in both the agency regulations for HACCP programs and the FSMA regulations when, indeed, preventive controls under FSMA are broader than CCPs under HACCP. In its place, FDA proposes to use the term “significant hazard.”

FDA would define “significant hazard” as a “known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would . . . establish controls to significantly minimize or prevent the hazard in a food and [would establish] components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.”

FDA also provides in the proposed codified language, in response to industry comments, that the hazard analysis would need to include an evaluation of both the “severity” and “probability” of the hazard. Note that FDA describes “probability” as meaning the likelihood the hazard would occur “in the absence of preventive controls.” FDA explains that, although the term “significant hazard” also has some association with CCPs, the agency believes that the proposed definition and other changes to the regulations make it clear that preventive controls are not limited to CCPs, nor do all necessary preventive controls need to be established at CCPs.

FDA also proposes to include a requirement to evaluate hazards that may be introduced as a result of economically motivated adulteration (see below) and to include radiological hazards as a subset of chemical hazards.

2. Management of Controls:

FDA agrees with food industry comments that not all preventive controls need to be managed with the same level of rigor as CCPs. Indeed, without using the industry characterization of “sliding scale,” FDA nevertheless repeatedly uses the phrase “as appropriate to the preventive control” in each section of the proposed regulations dealing with monitoring, corrective actions, and verification.
(including validation) activities. Going further, FDA explicitly proposes not to require validation for food allergen or sanitation controls. FDA refers to monitoring, correction actions, and verification activities as “management components.” FDA also proposes to clarify that parameters and their values are associated with process controls. The revised regulations also would have separate sections for validation, implementation and effectiveness, and reanalysis.

3. Product Testing:

FDA specifically responds to industry requests and provides proposed regulatory language for product testing requirements. These provide the food industry with flexibility on when to conduct product testing. Indeed, FDA has proposed that all verification activities, including product testing, be conducted “as appropriate to the facility, the food and the nature of the preventive control.” In the provision on corrective actions, the agency does suggest that ready-to-eat foods (RTE) would be appropriate candidates for product testing, by requiring, as appropriate, corrective action procedures to address the presence of a pathogen or indicator organism in a RTE food detected as a result of product testing. Note that FDA agrees with industry comments that this section should be called “product testing” rather than “finished product testing,” consistent with the FSMA terminology, and that product testing is a verification activity, not a control activity.

4. Environmental Monitoring:

Like for product testing, FDA proposes specific regulatory language for environmental monitoring requirements in response to industry requests. FDA also proposes the same general framework for environmental monitoring, by stating that such monitoring would be conducted as a verification activity “as appropriate to the facility, the food and the nature of the preventive control.” The supplemental proposal provides for such testing if “contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.” Each facility would be required to have written procedures for environmental monitoring, but it would be up to the facility to determine where, when, and how much sampling to undertake. Notably, FDA makes no reference to Zone 1 testing. FDA also proposes to revise the definition of “environmental pathogen” to specify that it does not include the spores of pathogenic sporeformers.

5. Supplier Verification:

Likely reflecting concerns with ingredient-based recalls, some of the most detailed requirements in the preventive controls regulations would address supplier verification programs. In response to industry requests, FDA proposes specific regulatory language for supplier verification programs. Overall, these requirements align with the foreign supplier verification program (FSVP) proposed regulations. FDA proposes to limit supplier verification to those circumstances where the supplier is responsible for controlling the significant hazard (biological, chemical, or physical) – i.e., no requirements would apply where the manufacturer (or the manufacturer’s downstream customer) is responsible for controlling the hazard.

On the subject of the frequency of onsite audits, which drew considerable industry comment in the original FSVP proposed rule, FDA proposed a hybrid approach whereby, if the supplier was responsible for controlling a hazard that could cause serious adverse health consequences or death to humans or animals (SAHCODHA): (a) there would be a requirement for an initial audit and an annual onsite audit thereafter; but (b) the receiving facility would have the ability to document why

3/ FDA also proposed to use the term “allergen cross contact” rather than “cross contact” to reduce the potential for confusion with the term “cross contamination” in the human food GMPs.
other verification activities and/or less frequent onside audits provide adequate assurances that the hazards are controlled. In this way, FDA agrees with industry comments that supplier oversight should take into account both the risk of the ingredient and the risk (i.e., track record) of the supplier.

FDA also agrees with industry comments that the audit report itself would not be accessible to the agency; instead, the manufacturer would be required to provide the conclusions of the audit and corrective actions taken in response to significant deficiencies. In addition, FDA proposes that instead of an onsite audit, a receiving facility could rely on the results of an inspection of the supplier by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or equivalent.

Notably, FDA continued to propose that any onsite audit be conducted by a “qualified auditor,” but makes no mention of the accreditation of third party auditors program. This may be an additional area for comment.

Finally, FDA proposes regulatory language in the FSVP supplemental proposed rule stating that when importers or their customers are in compliance with the supplier program requirements in the preventive controls regulations, the importers would be deemed in compliance with most FSVP requirements (in cases involving customer compliance with preventive controls supplier program requirements, the importer would need to obtain written assurance of compliance annually).

6. Economically Motivated Adulteration:

Although most recent industry comments regarding economically motivated adulteration (EMA) recommended no regulatory requirements to address EMA at this time, in this supplemental notice FDA has formally proposed that EMA be included within preventive controls rules as part of the hazard analysis (“hazards that may be intentionally introduced for purposes of economic gain”). This is the one area where FDA clearly disagrees with industry comments and therefore warrants close scrutiny.

7. Definition of “Farms”:

FDA is proposing to revise the definition of “farm” as well as definitions for three activities (“harvesting,” “holding,” and “packing”) that play a key role in determining whether an establishment is within the “farm” definition and thus exempt from registration and requirements conditional on facility registration (e.g., preventive controls). In general, the supplemental proposal reduces the occasions where a farm would have to register (e.g., when conducting farm-like activities on produce from neighboring farms). Importantly, the revised definitions would not create any new circumstances where a farm that would not have been required to register under the previous proposal would now be required to register.

8. Human Food By-Products Diverted to Animal Feed:

In the supplemental animal food proposal, FDA agrees with industry comments that human food by-products or waste that are to be diverted to animal feed, should not be subject to the full set of regulations designed for animal food manufacturers. Instead, FDA proposes that, because these foods are subject to the human preventive controls regulations up to the point of diversion, at that point they should only be subject to selective good manufacturing practices (GMP) regulations related to the holding and distribution of animal food.
9. **Animal Food GMPs:**

In response to industry comments, FDA proposes revisions to the GMPS for animal food. Although they use the same structure as human food GMPs, these revisions are designed to make the GMPS for pet food facilities and livestock feed facilities more flexible and tailored to animal food production.

10. **Very Small Businesses and Qualified Facilities:**

In the human food rule, FDA proposed to define “very small business” as one with annual sales under $1,000,000. In the animal food rule, FDA proposes to define a very small business as one that has less than $2.5 million in total annual sales of animal food. Under both sets of regulations, all very small businesses would be “qualified facilities” and subject to modified requirements.

FDA proposes expanded due process procedures that would be employed before any “qualified facility” lost its exemption, as well as a procedure for re-instatement of a withdrawn exemption.

Additional details on many of these issues are contained in the attachment to this memorandum. In addition, FDA will publish redline versions of the proposed regulations for both human and animal food in the respective dockets on regulations.gov.

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We will continue to closely monitor all developments related to FDA’s implementation of FSMA. If you have any questions regarding the supplemental proposed rules, please do not hesitate to contact us.
ATTACHMENT

Summary of Proposed Revisions from the Preventive Controls Supplemental Proposed Rules

1. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

FDA proposes to eliminate the term “reasonably likely to occur” throughout the regulations and to use the new term “significant hazard” instead. A “significant hazard” would mean 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, establish 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 control.”

FDA would expect a facility to first narrow “hazards” to those hazards that are known or reasonably foreseeable. Then the facility would narrow the known or reasonably foreseeable hazards to those “significant hazards” by assessing “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.”

Importantly, the supplemental proposal provides that the level of oversight for the various preventive controls (referred to as “management components”) is flexible based on the nature of the control. This reflects what industry comments referred to as a “sliding scale” and would essentially codify current industry practices (that CCPs require more extensive oversight than non-CCPs and that the level of oversight for non-CCPs varies as well). It would be up to each facility to specify in its food safety plan the level of oversight needed for the preventive controls being utilized.

In addition, the regulations would explicitly provide:

- Preventive controls include controls other than those at critical control points (CCPs) (e.g., zoning, preventive maintenance);
- That there may not be any controls at CCPs; and,
- Recordkeeping requirements do not require duplication of existing records if those records contain all required information and satisfy the recordkeeping requirements. Additionally, required information does not need to be kept in one set of records.

The agency also recognizes that allergen controls and supplier controls are not “process controls”; not all monitoring activities generate records; not all corrections require records; not all preventive controls require validation (such as segregation of allergens, training, preventive maintenance, and refrigeration); and not all corrective actions require verification.

2. Product Testing

FDA proposes to require product testing as a verification activity, as appropriate to the facility, the food, and the nature of the preventive control. The term “product testing” would encompass ingredient testing, in-process testing, and finished product testing. Product testing procedures, which would be written, would be required to specify the procedures for identifying samples and the procedures for sampling. In addition, facility corrective action procedures would be required to
address the presence of an environmental pathogen or appropriate indicator organism in a RTE product detected through product testing. In addition to the specific proposed regulatory language, FDA is reopening the comment period with respect to the agency’s previous request for comment on when and how product testing programs are appropriate.

3. Environmental Monitoring

FDA proposes to require environmental monitoring if contamination of a RTE food with an environmental pathogen is a significant hazard and otherwise as appropriate to the facility, the food, and the nature of the preventive control. The regulations also would establish requirements for performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen. Environmental monitoring procedures, which would be written, would need to identify the locations and sites for routine environmental monitoring and the timing and frequency, which would need to be adequate to determine whether preventive controls are effective. Additionally, facility corrective action procedures would need to address the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring. Like with product testing, in addition to specific proposed regulatory language, FDA is reopening the comment period with respect to the agency’s previous request for comment on when and how environmental monitoring programs are appropriate.

4. Supplier Verification

Scope. FDA proposes to require a “supplier program” for raw materials and ingredients for which the receiving facility has identified a significant hazard (biological, chemical or physical) when the hazard is controlled before receipt of the raw material or ingredient. Supplier program requirements would not apply to materials for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance the customer is controlling the hazards. “Suppliers” are establishments that manufacture/process food, raise animals, or harvest food that is provided to a receiving facility without further processing by another establishment (except for further manufacturing that is solely the addition of labeling or similar activity of a de minimis nature). “Receiving facilities” manufacture/process raw materials or ingredients that they receive from suppliers.

Thus, a facility that packs or holds food without any manufacturing would not be a supplier and a facility would not be required to establish a supplier program for food it only packs or distributes. However, if a receiving facility receives material from a distribution center and the receiving facility has identified a significant hazard in that material that is controlled by the supplier (the manufacturer or farm), the receiving facility (not the distribution center) would need to establish supplier verification activities related to the manufacturer or farm that provided the material to the distribution center. If a facility receives an ingredient from a supplier, but the hazard is controlled by the supplier’s supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard (i.e., the receiving facility would review the supplier’s food safety records for its supplier’s control of the hazard). FDA is seeking comment on how supplier verification activities should address gaps in the system where: (a) materials pass through more than one facility that would not be required to verify control of hazards (e.g., various distributors which ship to retailers); and (b) raw agricultural commodities such as fresh produce will not be handled by any facilities that would be required to have preventive controls (and, hence, supplier verification responsibilities) before reaching consumers.
Verification Activities. FDA proposes to require verification activities, and documentation of such, to ensure materials are received only from approved suppliers. (When necessary and appropriate, materials could be received on a temporary basis from unapproved suppliers whose materials the receiving facility subjects to adequate verification activities before acceptance for use). The agency also proposes to require verification activities to verify the hazard is significantly minimized or prevented, the material is not adulterated or misbranded under section 403(w) (undeclared allergens), and the material was produced in compliance with applicable FDA food safety regulations. Facilities would have the flexibility to determine the appropriate verification activities based on several factors: (1) the severity of the hazard; (2) where the preventive controls for those hazards are applied; (3) the supplier’s food safety practices; (4) the supplier’s compliance with FDA food safety regulations; (5) the supplier’s food safety performance history; and (6) any other factors, such as storage and transportation.

When there is a reasonable probability that exposure to the hazard will result in SAHCODHA, the regulations would require an initial onsite audit and annually thereafter unless the facility documents its determination that other verification activities and/or less frequent audits provide adequate assurance that the hazards are controlled. Further, facilities could conduct alternative verification activities for materials received from qualified facilities or a farm not subject to requirements under the produce safety rule. Audits would need to be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience. Inspections by FDA or an officially recognized or equivalent food safety authority may substitute for an audit. Companies would need to take action to address supplier non-conformance and document such action.

Documentation. FDA also proposes to require documentation of the activities associated with the supplier program, including requiring a written supplier program and documentation demonstrating that products are received only from approved suppliers (but importantly, a list of approved suppliers would not be required). FDA also proposes to establish minimum requirements for records documenting an audit, records of sampling and testing, records documenting review of the supplier’s relevant food safety records, and documentation of alternative verification activities for suppliers that are qualified facilities or farms not subject to the produce rule. Audit related records would need to document the procedure used, the conclusions of the audit, and corrective actions taken in response to significant deficiencies, but would not need to include the underlying audit report. In the preamble to the supplemental proposed rule, FDA explains that even if a supplier program is established and maintained by a facility’s corporate headquarters or parent entity, the agency would expect many of the records for such a program to be accessible during facility inspections because they would be in electronic form (electronic records would be considered onsite if they are accessible from an onsite location). This runs counter to industry comments that inspection of supplier verification programs would best be conducted at the headquarters facility where the program is conducted and the records are maintained.

FDA is reopening the comment period with respect to its previous request for comment on when and how supplier programs are appropriate. The agency also is requesting comment on whether it should include requirements to address conflicts of interest for individuals conducting supplier verification activities and the scope of such requirements.

Relationship to FSVP. Also note that in the FSVP supplemental proposed rule, FDA proposes to specify, in the revised regulatory text, that if an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States). Similarly, if an importer’s customer is required to establish and
implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States and the requirement to maintain records of the written assurances). Further, if the preventive controls that an importer and/or its customer implements under the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in a food, the importer is not required to determine or conduct foreign supplier verification activities. If the importer’s customer controls one or more significant hazards in a food, the importer must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

5. Economically Motivated Adulteration

FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain. In the preamble, FDA explains that the focus would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value. FDA believes that it is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of such adulteration in the past, suggesting there could be the potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product. FDA cites a recent report from the Congressional Research Service as a source of information on past EMA incidents.

6. The “Farm” Definition

FDA is proposing to revise the definition of “farm” as well as definitions for three activities (“harvesting,” “holding,” and “packing”) that play a key role in determining whether an establishment is within the “farm” definition and thus exempt from registration and requirements conditional on facility registration (e.g., preventive controls, mandatory recall, the reportable food registry, and one-up, one-back recordkeeping).

Significantly, a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm not under the same ownership. In addition, a “farm” could manufacture/process RACs by drying/dehydrating to create a distinct commodity (e.g., drying grapes to create raisins), and package and label the dried commodity, as long as there was no additional processing (such as slicing fruit before drying it or applying sulfites). Although the “farm” conducting drying/dehydrating that is akin to harvesting would be exempt from registration and preventive controls requirements, because the drying/dehydrating of RACs to create distinct commodity creates a processed food, the packaging, packing, and holding of such food (e.g., the raisins) would be subject to GMP requirements. However, FDA proposes to specify in the regulations that compliance with the GMPs may be achieved by complying with the applicable requirements for packing and holding produce RACs in the produce safety rule.

Under the revised “farm” definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the “farm” definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing (e.g., application of modified atmosphere packaging). Packaging activities would continue to be considered manufacturing/processing; however, packaging a RAC would not transform the RAC into a processed food. A farm that also manufacturers/processes
products such as dried, cut apples would be a farm mixed-type facility, subject to registration and preventive controls requirements.

Other changes would:

- Provide for “field coring” as an example of a harvesting activity to make clear that on farm “field coring” of a RAC is an activity that is within the “farm” definition;

- Provide that activities performed incidental to packing a food would be “packing” activities (e.g., activities performed for the safe or effective packing of that food, such as sorting, culling, and grading) and provide that this definition would apply to all establishments that pack food, not just to farms and farm mixed-type facilities; and,

- Provide that activities performed incidental to holding a food would be “holding” activities (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food, such as affixing labels and breaking down or assembling pallets, controlling pests, blending of the same commodity) and provide that the revised definition applies to all food, not just RACs, and all facilities that hold food, not just farms and mixed-type facilities.

FDA also is proposing to clarify that the human food GMPs do not apply to fishing vessels that are not subject to food facility registration requirements. Likewise, the human food GMPs do not apply to hulling, shelling, and drying nuts (without manufacturing/processing such as roasting). These are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in current § 110.19. Fermenting cocoa beans and coffee beans would be classified as “holding” rather than as “harvesting.”

7. Diversion of By-Products to Animal Food

Human food processors already complying with human food safety requirements would not need to implement additional preventive controls or current Good Manufacturing Practice (GMP) regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except for proposed GMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., ensuring the by-product is not comingled with garbage). However, further processing a by-product for sale and use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with the Preventive Controls for Animal Food rule.

FDA notes that the exemption for human food by-products for use in animal food would not apply when contamination or adulteration has occurred that is material to food safety. The agency has two Compliance Policy Guides (Sec. 675.100 and Sec. 675.200) that provide guidance to facilities that want to divert contaminated or adulterated human food for animal use. FDA requests comment on these guides and whether it should include regulations for requests to divert such product to animal food. Further, the exemption would not apply to human food by-products derived from animal products such as meat, offal, or poultry.

The new GMP requirements for holding and distributing human food by-products for use as animal food would include the following:

- Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;
- Animal food held for distribution must be held in such a way to prevent contamination from sources such as trash and garbage;

- Labeling identifying the by-product by the common or usual name must be affixed to or accompany animal food; and,

- Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

These limited GMP requirements for holding and distribution would appear in both the human food GMPs in Part 117, as well as the animal food GMPs, Part 507, for ease of reference.

8. Revisions to the Animal Food GMPs

FDA's proposes extensive revisions to the GMPs for animal food that are designed to reflect the difficulty of applying human food GMPs to pet food facilities and livestock feed facilities. The agency believes these revised GMPs are more applicable to the animal food industry and provide flexibility for a wide diversity of types of facilities.

Changes to the proposed GMPs include the following:

- No longer requiring employees to report illnesses to their supervisors;

- Dividing sanitation requirements into two categories—(1) pertaining to buildings, fixtures, and other physical facilities and (2) pertaining to utensils and equipment;

- Changing the section on “sanitary facilities and controls” to address only “water supply and plumbing;”

- Revising the section on “processes and controls” to address “plant operations” and
  - Adding requirements in this section that all animal food operations be conducted under conditions and controls as necessary to minimize the potential for the growth of microorganisms or for the contamination of food;
  - Omitting the requirement that raw materials and ingredients must not contain microorganisms injurious to human or animal health, or the raw materials and ingredients must be treated to eliminate them. This change was made because FDA does not intend that incoming raw materials and ingredients must be tested for pathogens, though the facility may choose to do so.
  - Deleting requirements pertaining to processes and products used for human food but not animal food, such as heat blanching, batters, breading, sauces, and dressings.

- Changing the section on warehousing and distribution” to “holding and distribution” and adding specific requirements such as:
  - Animal food held for distribution must be held under conditions (for example, appropriate temperature, relative humidity, appropriate holding time) that minimize
the potential for growth of undesirable microorganisms and must be held in a way that prevents contamination from sources such as trash and garbage;

- Labeling identifying the product by the common or usual name must be affixed to or accompany the animal food;

- Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food; and,

- Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

9. Definition of a Very Small Business

FDA is proposing to define a very small business as a business that has less than $1 million in total annual sales of human food, adjusted for inflation. In the animal food rule, FDA proposes to define a very small business as one that has less than $2.5 million in total annual sales of animal food. Which facilities are considered part of a very small business affects the compliance date for those facilities, the exemption for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity/food combinations and on-farm low-risk manufacturing/processing activity combinations.

Specifically, the proposed definitions of $1 million or $2.5 million in annual sales would simplify a facility's determination of whether it is a qualified facility and essentially make “very small business” and “qualified facility” synonymous. Under the statute, a facility is a qualified facility if it is either a “very small business” or it had average food sales of less than $500,000 during the preceding 3-year period, and it primarily sells food directly to “qualified end-users” (i.e., consumers of the food or restaurants or retail food establishments located within the same state or 275 miles or the facility and purchasing the food for sale directly to consumers). Because the dollar threshold for qualifying as a “very small business” encompasses the second set of criteria, the facility would only need to calculate its total sales of human (and/or animal) food rather than determine how much food was sold to qualified end-users and whether food was only distributed within a specified radius.

10. Withdrawal of an Exemption for a Qualified Facility

Under FSMA, “qualified facilities” are exempt from the preventive controls requirements and are subject to modified requirements. This exemption, however, can be withdrawn (1) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or (2) if FDA determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the facility that are material to food safety. In the supplemental proposed rule, FDA proposes to revise the proposed regulations governing the withdrawal of qualified facility’s exemption.

FDA proposes to include specific regulatory actions the agency must take before issuing an order to withdraw an exemption, including notifying the facility in writing of the circumstances that may lead FDA to withdraw the exemption, providing an opportunity for the facility to respond in writing within 10 days, and considering the corrective actions taken by the facility. The agency, before issuing an order, could consider alternative actions such as a warning letter, recall, administrative detention, suspension of registration, import alert, or seizure. The regulations would clarify that an order to
withdraw an exemption must be approved by an FDA District Director before it can be issued and would provide a process for reinstating an exemption that had been withdrawn. The order would explain that the facility must either comply with the preventive controls requirements within 120 days or appeal the order within 10 days. FDA also is proposing to provide for re-instatement of an exemption either on its own initiative or in response to a written request from the facility that includes information demonstrating that the facility has adequately resolved the problematic conditions or conduct.