MEMORANDUM

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Re: FDA Proposes Extensive New Food Safety Regulations Under FSMA

On Friday, January 4, 2013, the second anniversary of the enactment of the FDA Food Safety Modernization Act (FSMA), FDA proposed two new food safety rules to implement the law. 1/ These rules, which address preventive controls for human food and produce safety, provide the cornerstone for the agency’s implementation of this landmark legislation. Both proposals address FSMA’s central paradigm shift to move the food safety focus from reactive to preventive. This memorandum provides key take-aways and highlights of major provisions from the proposed rule entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (“Preventive Controls”). We will supplement this initial memorandum with follow-up memoranda on specific topics, as noted below. We also are issuing today a separate memorandum on the produce safety proposed rule. FDA has provided until May 16, 2013 (120 days) for public comment on both proposed rules. 2/

Overview

FDA’s Preventive Controls proposed rule would revise the agency’s food safety regulations in two ways: (1) it would add new preventive controls provisions as required by FSMA; and (2) it would update and revise certain requirements in the existing current good manufacturing practice (cGMP) regulations (current 21 CFR Part 110). Both the new provisions and the revisions would be codified in a new section of Title 21 of the Code of Federal Regulations, Part 117.

With respect to preventive controls, the structure of the proposed rule largely tracks the statute, establishing requirements for: a written food safety plan; hazard analysis; preventive controls; monitoring; corrective actions; verification; and associated records. Below, we highlight 10 key takeaways from the proposed rule. In Attachment A, we provide additional details regarding noteworthy content in the proposal and discuss some exemptions and modified requirements. In Attachment B, we provide a summary of the proposed exemptions, for convenience.

Prior to issuing this proposed rule, FDA conducted broad outreach to stakeholders in an effort to develop requirements that would be both effective and feasible. The food industry participated extensively in this pre-rulemaking process, and feedback provided by the food industry (and other stakeholders) is evident in many parts of this proposal.

1/ The proposed rules will officially publish in the Federal Register on Wednesday, January 16, 2013.
2/ Comments on information collection issues are due February 15, 2013.
10 Key Take-Aways

There are 10 significant take-aways from the preventive controls proposed rule:

1. **Tracking the Statute:** The proposed rule largely tracks the statutory requirements for conducting a hazard analysis, implementing preventive controls, and conducting monitoring, corrective actions, and verification activities. Where FDA goes beyond the statutory terms, or provides its interpretation of them, that is generally identified by FDA in the preamble and public comment openly solicited. (See, for example, the discussion of recordkeeping and records access below.)

2. **Flexibility:** The agency generally was responsive to food industry comments to keep the proposed rule flexible – not prescriptive – so companies could apply the new rules in a risk-based way, consistent with the type of food and extent of controls used in a given facility.

3. **Harmonization with HACCP:** In the preamble, FDA discusses how FSMA is based on HACCP principles and that FDA has sought to align or harmonize the proposed rule with well-known HACCP principles to the extent possible. This is an area that will need close scrutiny by the food industry during the comment period, as there are some significant differences between HACCP and FSMA. Consistent with its HACCP focus in this proposal, FDA deferred addressing “intentionally introduced hazards” until a future rulemaking on Food Defense issues.

4. **Testing and Supplier Verification:** Surprisingly, FDA does not propose specific requirements for either environmental/product testing or supplier verification, even though both are clearly referenced in FSMA. Citing the high costs associated with these activities, FDA instead solicits public comment on whether these requirements should nevertheless be included in a final rule. FDA includes a detailed Appendix describing the agency’s views of how they would expect testing and supplier verification activities to be conducted – a “must read” for all food quality directors. Notably, FDA cites the Global Food Safety Initiative (GFSI) framework, and GFSI-recognized certification schemes such as Safe Quality Food (SQF) 2000, as a valuable tool for supplier verification.

5. **Scientific Validation of Preventive Controls:** The proposal contains an express requirement (implied in the statute) that companies have scientific validation to demonstrate that preventive controls are providing their intended food safety benefit. Food companies would need to be able to produce the scientific basis for their validation during an FDA inspection. Food companies will need to pay particular attention to this proposed requirement.

6. **Warehouse Exemptions:** In response to an industry petition, FDA proposes to exempt from the new preventive controls provisions facilities that hold non-refrigerated packaged food products or raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. FDA also proposes a modified (i.e., more limited) set of preventive controls for refrigerated warehouses. (See Attachment A for discussion of FDA’s treatment of warehouses containing frozen food.)

7. **Recordkeeping and Records Access:** Consistent with the statute, the proposed rule places a high emphasis on proper documentation and recordkeeping, as well as access to those records by FDA inspectors. FDA proposes that all records must be kept on-site for the first six months after their creation and that food safety plans always be kept on-site. FDA solicits comment on three subjects not expressly referenced in FSMA that likely warrant consideration and comment: (a) whether to require facilities to submit “facility profiles” that summarize hazards and controls to the agency; (b) whether to require “remote access” of food safety-related records; and (c) whether there is a basis for exempting food companies from complying with 21 CFR Part 11 regarding electronic records, as FDA did during rulemaking to implement the Bioterrorism Act.
8. **Updating Food cGMPs:** Notably, FDA’s proposal includes updates to the food current good manufacturing practice (cGMP) regulations and would establish them in Subpart B of 21 CFR Part 117, which also would house the preventive controls requirements in Subpart C. The cGMP update is an outgrowth of the agency’s Food cGMP Modernization Initiative, begun in 2002, which had substantial input from the food industry. These provisions also will need close scrutiny and will be the subject of a subsequent memorandum.

9. **Company Size:** As recommended by many in the food industry, the proposed rule provides for small businesses to be defined consistently with the Small Business Administration’s definition as less than 500 employees. For very small businesses, FDA co-proposes three alternative definitions: under $250,000, $500,000, or $1,000,000 in total annual sales of food. Compliance dates and some exemptions from some requirements are dependent on company size.

10. **Compliance Dates:** FDA proposes to set compliance dates to follow the date of publication of the final rule in the Federal Register as follows: One year for large businesses, two years for small businesses, and three years for very small businesses.

**Additional Details**

Additional details on many of these points are contained in the attachments to this memorandum. In addition, as the preventive controls proposal and related analyses total over 1,000 pages, we will prepare separate memoranda on: (a) environmental and product testing; (b) update of cGMPs; and (c) special provisions related to small and very small businesses. Further, as this memorandum reflects our initial review of this extensive proposed rule, we may supplement this memorandum with additional information and analysis as the rulemaking period progresses. As noted above, we also are issuing today a separate memorandum on FDA’s companion proposed rule on produce safety, which itself is over 500 pages in length.

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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 proposed rule, please do not hesitate to contact us.
ATTACHMENT A

Highlights of Major Provisions from the Preventive Controls Proposed Rule

1. Legal Authority

- As its legal authority for the proposed rules, FDA cites the Federal Food, Drug, and Cosmetic Act (FFDCA), the Public Health Service Act (PHS), and FSMA. In particular, FDA cites the FFDCA and the PHS as its legal authority to update the cGMPs in Part 110. FDA cites FSMA, as well as the FFDCA and the PHS, as its authority to require the preventive controls provisions. FDA states “the proposed system is necessary to prevent food from being adulterated because it is unfit for food [FFDCA § 402(a)(3)] or because it has been held under insanitary conditions whereby it may become contaminated with filth or may be rendered injurious to health [FFDCA § 402(a)(4)]; to prevent food from becoming misbranded under section 403(w) of the [FFDCA] [undeclared allergens]; and to prevent the spread of communicable disease [PHS Act §§ 311, 361, and 368].”

- Although FSMA provided only that failure to comply with the preventive controls provision is a prohibited act, FDA is proposing in Part 117 that failure to comply with this part (cGMPs and/or preventive controls) will be considered in determining whether a food is adulterated or in violation of the PHS Act. Thus, non-compliance with these requirements would provide grounds for administrative detention and seizure. Further, companies receiving Warning Letters likely would find that FDA would declare their products adulterated for non-adherence to the preventive controls regulations (as the agency has been doing the past several years for non-adherence to the cGMP regulations).

- In the preamble, FDA concludes that the preventive controls requirements and related provisions in proposed Part 117 should be applicable to intrastate activities because facilities are required to register regardless of whether food from the facility enters interstate commerce.

2. Food Safety Plan

- The facility would be required to prepare (or have prepared for it) and implement a written food safety plan.

- The proposed rule clarifies that the written food safety plan must include, in addition to the hazard analysis and preventive controls, the facility’s written procedures for monitoring (and frequency), corrective actions, and verification. The food safety plan also would need to include a written recall plan.

- Although not required by FSMA, the proposed rule states that the food safety plan would need to be prepared by (or its preparation overseen by) a qualified individual. Further, the proposed rule would require the plan to be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.
3. Hazard Analysis

- The facility would be required to identify and evaluate known or reasonably foreseeable hazards (i.e., “potential hazards”) for each type of food manufactured by the facility to determine whether there are hazards that are reasonably likely to occur. 3/

- The proposed rule specifies the hazards that must be considered during the hazard identification (categorized as biological, chemical, physical, and radiological hazards).

- The proposed rule also specifies factors that must be considered during the hazard evaluation. These include an assessment of the severity of illness or injury should the hazard occur, as well as factors that affect the safety of finished food, such as transportation practices and intended or reasonably foreseeable consumer use.

- For Ready-to-Eat (RTE) foods, the hazard analysis would be required to include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. 4/

- Under the proposed rule, the hazard analysis must be written and include a justification for whatever conclusions are reached, including a conclusion that a hazard is not reasonably likely to occur.

- FDA is deferring consideration of hazards “intentionally introduced, including by acts of terrorism” for a separate rulemaking on food defense issues, but does solicit comment on whether this rule should include potential hazards that may be intentionally introduced for economic reasons (e.g., melamine).

4. Preventive Controls

- General. The facility would be required to identify and implement preventive controls for those hazards that are reasonably like to occur, including at critical control points, if any. The preventive controls would be required to be written.

- Parameters and Values. The proposed rule would require the facility to identify parameters associated with each preventive control (those factors that must be controlled to ensure the hazard will be minimized or prevented), and the maximum or minimum value to which the parameter must be controlled to be effective. The preamble notes that some preventive controls may not have specific parameters associated with them and that preventive controls may be required at points other than critical control points. Nonetheless, the proposed requirement to identify parameters and values for parameters is similar to requiring critical limits at critical control points under HACCP.

3/ FDA is proposing to define “hazard reasonably likely to occur” as “a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.”

4/ FDA is proposing to define the term “ready-to-eat” food in the regulations to mean “any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards.” FDA states that raw cookie dough and dried soup mixes are examples of such foods.
• **Types of Preventive Controls.** The proposed rule would require preventive controls to include, as appropriate: process controls, allergen controls, and sanitation controls, as well as a recall plan and “other controls” as needed. An example of an “other control” identified in the preamble is temperature control during transportation for a refrigerated food. Further, although FDA is not requiring cGMPs as a preventive control, a facility may determine that it is appropriate to include certain cGMP provisions among its preventive controls as an “other control.”

• **Process Controls:** Process controls would be required to include those procedures, practices, and processes performed on a food during manufacturing/processing in order to significantly minimize or prevent hazards that are reasonably likely to occur (e.g., cooking, cooling, irradiating, acidifying, drying, reducing water activity).

• **Sanitation Controls.** Under the proposed rule, sanitation controls would be required whenever: (a) an environmental pathogen is a hazard that is reasonably likely to occur in a ready-to-eat food exposed to the environment prior to packaging; (b) any microorganism of public health significance is a hazard reasonably likely to occur in a ready-to-eat food due to employee handling; and (c) any food allergen hazard is reasonably likely to occur. Sanitation controls would be required to include procedures for the cleanliness of food contact surfaces and the prevention of cross contact and cross contamination. As such, the facility would be required to have written procedures for these two areas of sanitation controls and they would be subject to other requirements applicable to preventive controls in general (e.g., monitoring and verification); but other areas of sanitation could be addressed through compliance with cGMPs. The facility would be required to take corrective actions for sanitation deviations and document those actions (which would be subject to verification and records review), but would not be required to develop written corrective action procedures for sanitation deviations that could occur.

• **Allergen Controls.** Allergen controls would be required to include procedures, practices, and processes to protect food from cross-contact, including during storage and use, and labeling to ensure the food does not include an undeclared allergen. The preamble includes several examples of such controls.

5. **Recall Plan**

• The proposed rule would require each facility that identifies a hazard reasonably likely to occur to establish a written recall plan.

• FDA is requesting comment on whether it should require a recall plan to include procedures for notifying FDA of a recall, and whether it should include a requirement for mock recalls as a verification activity for the recall plan.

6. **Monitoring**

• The proposed rule would require the facility to implement written procedures for monitoring the preventive controls (including the frequency with which they are to be performed) and to document those activities.

• The proposed rule does not mandate a specific monitoring frequency, but rather states that monitoring must be performed at a frequency sufficient to ensure that the preventive controls are consistently performed.
• Under the proposed rule, the facility would be required to verify that monitoring is conducted and a qualified individual must review (or oversee the review of) monitoring records within a week after the records are made.

7. Corrective Actions

• Like the statute, the proposed rule would require that facilities establish and implement written corrective action procedures that would be used if the preventive controls are not properly implemented.

• In addition, facilities would be required to take corrective actions in the event of an unanticipated problem (i.e., a corrective action procedure has not been established or a preventive control is found be ineffective). This circumstance also would require the facility to reanalyze its food safety plan.

• The proposed rule would mandate that corrective actions be documented in records subject to verification and records review.

8. Verification

• Validation. Although FSMA requires a facility to verify that the preventive controls are adequate to control the identified hazards, the proposed rule explicitly requires the facility to “validate” the preventive controls. Validation would be required to be performed by a qualified individual prior to implementation of the food safety plan (or when necessary during the first 6 weeks of production) and whenever a reanalysis of the plan reveals the need to do so. Validation would be required to include collecting and evaluating scientific and technical information (or conducting studies). Food allergen controls, sanitation controls, and the recall plan would not need to be validated.

• Monitoring. The facility would be required to verify that monitoring is being conducted. The proposed rule does not specify the verification activities that would be required to be conducted for monitoring, but the preamble provides examples including observations and independent tests.

• Corrective Actions. The facility would be required to verify that appropriate decisions about corrective actions are being made, but the proposed rule does not specify what those verification activities must be.

• Verification. The facility would be required to verify that the preventive controls are consistently implemented and are effective.

• Calibration. The facility would be required to calibrate process monitoring and verification instruments. The facility would be required to establish and implement written procedures for the frequency of calibrating such instruments, but the proposed rule would not require written procedures for other verification activities.

• Internal Records Review. A qualified individual would be required to review (or oversee the review of) monitoring, corrective action, and calibration records to ensure they are complete, the activities occurred, the preventive controls are effective, and appropriate decisions were made about corrective actions. Monitoring and corrective action records would be required to be reviewed within the week they were made. Calibration records would be required to be reviewed “within a reasonable time.”
• **Reanalysis.** FSMA requires a facility to reanalyze its food safety plan at least once every three years or whenever a significant change is made in the activities at the facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard. The proposed rule would require a reanalysis in additional circumstances: (a) whenever a preventive control is found to be ineffective; (b) whenever a preventive control is not properly implemented and a corrective action procedure has not been established; and (c) whenever the facility becomes aware of new information about potential hazards. The reanalysis would need to be performed (or overseen by) a qualified individual and completed prior to any change in activities (or when necessary during the first 6 weeks of production). Under the statute, FDA also can require a reanalysis to respond to new hazards and developments in scientific understanding. In the preamble, FDA states that this authority to require reanalysis in such situations would be delegated to the Commissioner (but does not state whether it could be further delegated).

• **Records.** All verification activities would be required to be documented.

• **Consumer Complaints.** The proposed rule does not include a provision requiring that verification activities include a review of any consumer complaints to determine whether the complaints relate to the performance of the food safety plan. Instead, FDA is requesting comment on whether and how a facility’s review of complaints should be required.

9. **Qualified Individual**

• Although not required by FSMA, the proposed rule would require “qualified individuals” to do or oversee the following: preparation of the food safety plan; validation of the preventive controls; review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions; and reanalysis of the food safety plan. The same individual would not need to perform all activities.

• To be qualified, an individual would need to have 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 be otherwise qualified through job experience. Applicable training would be required to be documented, including the type of training, date, and person trained.

10. **Exemption or Modified Requirements for Warehouses**

• Facilities “solely engaged in the storage of [non-refrigerated] packaged food that is not exposed to the environment” would generally be exempt from the preventive controls requirements. Also exempt would be facilities that store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

• For warehouses with refrigerated food, FDA has proposed modified requirements. Such modified requirements would be required for any refrigerated packaged food that requires time/temperature control for safety. In the preamble FDA states that the warehouse would obtain information about whether a food requires time/temperature control for safety and the appropriate temperature for storing the food from documents provided by the manufacturer, label statements, or applicable scientific and technical literature.

• The proposed required activities include: (1) establishing and implementing temperature controls; (2) monitoring the temperature controls; (3) taking appropriate corrective actions; (4) verifying that temperature controls are consistently implemented (through calibrating temperature and recording devices and reviewing calibration, monitoring, and corrective
action records); and (5) establishing and maintaining records documenting the monitoring, corrective actions, and verification activities (which would be subject to the general recordkeeping requirements). The facility would not need to conduct a hazard analysis and identify preventive controls – FDA would specify the hazard and appropriate preventive control (temperature control) in the regulation – nor would the facility need to develop a food safety plan, or validate or reanalyze the plan. Further, none of these requirements would require a qualified individual.

- For warehouses storing frozen food, the preamble states that FDA considers frozen food to be a subset of refrigerated food, and thereby potentially subject to the modified requirements. However, it appears that if a company could make a finding (and document it appropriately) that time/temperature is needed only for product quality and not for food safety, then that frozen food also would be exempt.

11. Testing Programs

- Notably, although FSMA identifies environmental and product testing programs as verification activities, FDA, apparently due to cost concerns, is not proposing to include any testing requirements in the preventive controls regulation. Instead, FDA is requesting public comment on whether to include such requirements in the final rule.

- Nonetheless, FDA recognizes that environmental and product testing programs “can play important roles in effective food safety programs.” For instance, FDA states it believes that environmental monitoring is particularly useful as a verification measure for preventive controls (i.e., sanitation controls) when contamination of food with an environmental pathogen is a hazard reasonably likely to occur.

- In the preamble and in the Appendix, FDA outlines its thinking about product and environmental testing programs and its expectations for such programs, including the factors to consider when establishing a testing program, when testing would be particularly useful, factors that influence the frequency and number of samples tested, and typical investigative and corrective action procedures. For example, the proposed rule contains a number of specific examples of situations where FDA believes testing is warranted (e.g., FDA notes that finished product testing is particularly useful for products where a biological hazard is reasonably likely to occur in an ingredient without a kill step). Similarly, FDA also notes that *Listeria* species may be an appropriate indicator organism for *Listeria monocytogenes*. As such, both the preamble and the Appendix warrant careful review by all food companies, and we will provide a separate memorandum summarizing this topic.

- FDA seeks comment on the inclusion of testing requirements in the final rule, including the appropriate level of specificity of such requirements. For example, FDA asks whether a product testing program should be limited to finished products or include raw material testing. Likewise, the agency asks whether it should specify (i) the organism to be tested for in an environmental monitoring program, (ii) corrective actions, (iii) testing locations, and (iv) testing frequency.

12. Supplier Approval and Verification

- The proposed rule also does not mandate development and implementation of a supplier approval and verification program, likely due to cost factors, and instead seeks public comment on whether to include these requirements in the final rule. Although FSMA refers only to “supplier verification activities,” the preamble discusses verification together with supplier approval.
FDA acknowledges that supplier approval and verification programs (e.g., GFSI-recognized schemes such as SQF 2000) are widely accepted in the domestic and international food safety community, thereby signaling the agency believes the GFSI framework provides a valid form of supplier verification even though such third party certification programs are not formally recognized by FSMA in this way.

Based on the discussion in the preamble and Appendix, it appears that FDA would expect companies to implement supplier verification and approval programs in situations where the hazard presented by a raw material or ingredient is not subject to another preventive control, such as a kill step.

FDA seeks comment on whether to include a supplier approval and verification requirement in the final rule. The agency also requests comments on a broad range of questions regarding when and how supplier approval and verification is appropriate.

The agency intends to align regulations implementing supplier verification as a preventive control with regulations implementing the foreign supplier verification program (FSVP), and also intends to align the comment periods when the FSVP proposal issues.

13. Recordkeeping

General. Recordkeeping requirements would apply to all records required by new Part 117. As outlined above, FDA is proposing that facilities be required to establish and maintain records documenting the following: (1) Written food safety plan, including hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan; (2) Monitoring of preventive controls; (3) Corrective actions; (4) Verification, including, as applicable, validation, monitoring, corrective actions, calibration of process monitoring and verification instruments, records review, and reanalysis; and (5) Training for the qualified individual. Further, the proposed rule would specify requirements for the contents of required records, such as being accurate, complete, and as detailed as necessary to provide history of work performed.

Location. Records would be required to be retained for 2 years after the date they were prepared, but offsite storage at a location other than the plant or facility is permitted 6 months after the date of creation if the records can be retrieved and provided onsite within 24 hours of request for official review. However, the food safety plan would be required to remain onsite. Electronic records would be considered to be onsite if they are accessible from an onsite location.

Electronic Records. FDA proposes requiring electronic records to be kept in accordance with 21 CFR Part 11. Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signature, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The agency notes that for purposes of the records requirements in the Bioterrorism Act, the agency exempted food company records from the requirements of Part 11 due to the very high burden that would be required to meet this requirement. FDA requests comment on whether there are any similar circumstances that would warrant applying a similar exemption here.

Copying. FDA would require that all required records under Part 117 be made “promptly available to a duly authorized representative” “upon oral or written request.” The rule does not explicitly allow FDA to copy records, but in the preamble FDA states that the proposed
• Remote Access. The proposed rule does not explicitly require a facility to send records to the agency in addition to making the records available for review at a facility’s place of business. However, FDA requests comment on whether to explicitly address this circumstance and, if so, whether the agency should require that the records be submitted electronically.

• Disclosure. The proposed rule provides that all records required by Part 117 are subject to the disclosure requirements under the Freedom of Information Act and FDA’s implementing regulations in 21 CFR Part 20. The agency’s general policies, procedures, and practices relating to the production of confidential information received from third parties would apply to information received under this rule. FDA says that the proposed rule is consistent with, but framed differently than, the disclosure provisions for seafood and juice HACCP, although the plain language of those regulations is more protective of confidentiality. 5/

14. Facility Profiles

• FDA is not proposing to require submission of food safety plans to the agency. As explored during the pre-rulemaking stage, FDA believes that advance review of food safety plans prior to inspections would help target inspectional activities and reduce inspection time. However, based on feedback from the food industry, the agency also recognizes that there are “significant obstacles to realizing these benefits from submission of food safety plans.”

• The agency requests comment about whether to require submission to FDA of a subset of the information that would be in a food safety plan (a “facility profile”), such as products, hazards identified for each product, and preventive controls established for each of the identified hazards. FDA previously requested comment about the voluntary submission of food facility profile information 6/, but now is seeking input about whether the submission of such information should be required.

15. Revisions to cGMPs

• We plan to address FDA’s proposed revisions to the cGMP regulations in a more detailed manner in a subsequent memorandum, but note that FDA proposes making the following general revisions:
  o Clarifying that certain cGMP provisions requiring protection against contamination require protection against cross-contact of food in order to address allergens;

5/ The proposed rule states: “Records required by this part are subject to the disclosure requirements under part 20 of this chapter.” In contrast, the seafood HACCP regulation states: “[A]ll plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public . . . or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information . . .,” except that “these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.” 21 CFR § 123.9(d).
Proposing that provisions directed to preventing contamination of food and food contact substances be directed to preventing contamination of food packaging materials as well;

Deleting certain provisions containing recommendations, including the specific temperatures for maintaining refrigerated, frozen, or hot foods; and,

Modernizing and updating the regulatory language (e.g., by replacing the word “shall” with “must” and by using certain terms consistently).

- FDA is requesting comment on whether it should mandate training for employees and supervisors, including a requirement for records that document training, and whether it should require, rather than recommend, certain provisions, such as cleaning non-food contact surfaces as frequently as necessary to protect against cross contact and contamination.

16. Compliance Dates

- FDA proposes allowing 1 year from the date of publication of the final rule for businesses other than small and very small businesses (i.e., large businesses) to come into compliance. Small businesses will have 2 years and very small businesses will have 3 years after the date of publication of the final rule to come into compliance. FDA’s proposed definition of “small business” is a business employing fewer than 500 persons across the entire company – consistent with the Small Business Administration’s definition. The agency proposed three alternative definitions of “very small business,” meaning a business with less than $250,000, $500,000, or $1,000,000 of total annual sales of food, adjusted for inflation.

17. Qualified Facility

- As required by the statute, the proposed rule would establish modified requirements for “qualified facilities.” 7/ In general, a qualified facility is a facility that either:
  (1) is a very small business; or
  (2) had average food sales of less than $500,000 during the preceding 3-year period, and that 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 of the facility and purchasing the food for sale directly to consumers).

- Qualified facilities would be exempt from the requirements for hazard analysis and preventive controls, but would be required to submit certain documentation to FDA. Depending on the documentation they can provide, the qualified facility may be required to declare their full business address on their label or, if no label is required, this information would appear at the point of purchase. We are preparing a separate memorandum that will detail the scope of the qualified facility requirements and further explain the applicability of the proposed rule to small and very small businesses.

18. On-Farm Activities

- FDA proposes revisions to the registration regulations to clarify the types of activities that are included as part of the definition of “facility” and the scope of the exemption for “farms.” These changes are significant because conducting activities outside of the definition of

7/ The modified statutory requirements for very small businesses were added to FSMA by the so-called “Tester Amendment,” which was proposed by Senator Jon Tester (D-MT).
“farm” triggers the requirements to register with FDA and, thus, means that the facility must comply with the preventive controls regulation (unless another exemption applies).

- If a facility conducts activities that fall within the farm definition, as well as activities that trigger the registration regulations, it would be considered a “farm mixed-type facility.” Although a farm mixed-type facility would be required to register, FDA would only require the non-farm portion of the establishment’s activities to comply with the preventive controls rule. (The farm portion of the establishment’s activities would be subject to the produce safety rule.)

- Overall, the changes to the registration regulations would broaden the scope of the farm exemption for manufacturing, processing, packing, holding, and harvesting activities performed on food grown, raised, or consumed on that farm or another farm under the same ownership. The revisions to the definitions result in several changes to the scope of facilities required to register. For example:
  
  - Pesticide treatments of a farm or farm mixed-type facility's own raw agricultural commodities (RACs) for the purpose of safe or effective storage would be considered holding within the farm definition, rather than manufacturing/processing outside the farm definition.
  
  - Anything that transforms a RAC into a processed food would be classified as manufacturing/processing outside the farm definition. Thus, drying herbs such as peppermint or drying grapes into raisins would now be classified as manufacturing/processing outside the farm definition because these activities create a distinct commodity and therefore a processed food.

- The agency proposes to exempt farm mixed-type facilities that are small or very small businesses from requirements under Section 418 of FSMA if the only activities subject to section 418 that the business conducts are low-risk activity-food combinations. The agency developed a list of such combinations based on a draft risk assessment. We will discuss this exemption further in our memorandum regarding the impact of the proposed rule on small businesses.

19. Economic Analysis

- The proposed rule is accompanied by an extensive economic analysis that provides a summary of the proposal’s estimated costs and benefits. FDA notes that it lacks sufficient information to fully estimate the proposed rule’s likely benefits and also had to make numerous assumptions when estimating its costs.

- The cost assessment considered current industry practices to be a baseline, such that if a facility currently voluntarily engages in the activities required by the proposed rule then there would be no costs to comply. Thus, FDA assumes that most large facilities (with 500 or more employees) are already largely in compliance with the proposed rule’s requirements and, therefore, that large facilities will face minimal additional costs to comply with proposed rule.

- The economic analysis also notes that FDA considered but rejected proposing more extensive requirements, such as explicitly requiring supplier approval and verification programs and verification activities such as consumer complaint review, finished product testing, and environmental monitoring.
## ATTACHMENT B

### Proposed Exemptions and Modified Requirements from Preventive Controls for Human Food

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<tr>
<th>Type of facility or operation</th>
<th>Hazard Analysis and Risk Based Preventive Control Requirements</th>
<th>Current Good Manufacturing Practices (CGMP)</th>
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<tbody>
<tr>
<td><strong>Certain low-risk on-farm</strong> manufacturing/processing activities, packing or holding activities that are conducted by small or very small businesses on farms for specific foods. Examples including making jams and jellies and manufacturing honey and maple syrup.</td>
<td>Exempt</td>
<td>Must comply</td>
</tr>
<tr>
<td><strong>Foods subject to and compliant with the low-acid canned food (LACF) regulation (21 CFR Part 113). The exemption for facilities producing low-acid canned food applies only to those microbiological hazards addressed by LACF regulation.</strong></td>
<td>Exempt</td>
<td>Must comply</td>
</tr>
<tr>
<td><strong>Foods subject to seafood HACCP (21 CFR Part 123) and juice HACCP (21 CFR Part 120) regulations</strong></td>
<td>Exempt</td>
<td>Must comply</td>
</tr>
<tr>
<td><strong>Dietary supplements</strong></td>
<td>Exempt</td>
<td>Must comply with dietary supplement CGMPs (21 CFR Part 111)</td>
</tr>
<tr>
<td><strong>Alcoholic beverages</strong> at certain alcohol-related facilities, and certain prepackaged food sold in limited quantities along with alcoholic beverages at the same facilities.</td>
<td>Exempt</td>
<td>Must comply</td>
</tr>
<tr>
<td><strong>A “qualified facility” that has food sales averaging less than $500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end-user is either a consumer (in any location), or a restaurant or retail food</strong></td>
<td>Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is (1) implementing and monitoring preventive controls or (2) complying with applicable non-Federal food</td>
<td>Must comply</td>
</tr>
</tbody>
</table>

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8/ This chart is only a summary and does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult counsel and the proposed rule for specific requirements.
<table>
<thead>
<tr>
<th>Establishment purchasing the food for sale directly to consumers that is located in the same State or not more than 275 miles away</th>
<th>Safety law (which triggers a labeling requirement). Also must maintain records to support certifications.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A very small business.</strong> Three options are being proposed to define a very small business: less than $250,000, less than $500,000, and less than $1,000,000 in total annual sales of food, adjusted for inflation.</td>
<td>Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is (1) implementing and monitoring preventive controls or (2) complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.</td>
</tr>
<tr>
<td>Activities within the definition of “farm” (but note that such facilities are subject to FFDCA § 419 (produce safety standards)</td>
<td>Exempt</td>
</tr>
<tr>
<td>Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment</td>
<td></td>
</tr>
<tr>
<td>- Packaged food for which refrigeration is not required for safety</td>
<td></td>
</tr>
<tr>
<td>- Packaged food for which refrigeration is required for safety</td>
<td>If refrigeration is not required for safety, the facility is exempt</td>
</tr>
<tr>
<td>If refrigeration is required for safety, modified preventive control requirements apply: Requirements concerning temperature controls, including monitoring, verification and records.</td>
<td>Must comply</td>
</tr>
<tr>
<td>Facilities such as grain elevators that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing</td>
<td>Exempt</td>
</tr>
<tr>
<td>Facilities, such as warehouses, that store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.</td>
<td>Exempt</td>
</tr>
</tbody>
</table>