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MEMORANDUM

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Date: September 26, 2014

Re: **FDA Re-Issues Key Sections of Produce Safety Proposed Rule Under FSMA**

As part of its continued implementation of the FDA Food Safety Modernization Act (FSMA), on September 19th, FDA issued a supplemental proposed rule that offers revised language on several key provisions in the produce safety proposed rule. In response to the extensive comments received, FDA states that it has made "significant changes" in its thinking on certain provisions of the proposed rule, which was initially published in January 2013. The agency is reopening the comment period only with respect to these specific issues.

The provisions included within the re-proposal fall into three general categories: (1) the scope of the proposed rule, including which farms and activities are covered; (2) new provisions regarding the withdrawal and reinstatement of a qualified exemption from the produce safety standards; and (3) revisions to specific produce safety standards for agricultural water, biological soil amendments, and domesticated and wild animals. Below we describe each of the proposed changes, with emphasis given to the first two categories. Comments on the supplemental proposed rule are due December 15, 2014.

Changes to the Scope of the Proposed Rule

Which Farms Are Covered?

FDA's first proposed change relates to which farms are considered "covered farms" subject to the produce safety rule in part 112. Originally, FDA proposed to apply the produce safety regulation to only farms and farm mixed-type facilities with an average annual monetary value of all food sold during the previous 3-year period of more than $25,000 (on a rolling basis). Farms with average sales less than $25,000 during the previous 3-year period would be completely excluded from the rule's coverage. Under the supplemental proposal, FDA would apply the $25,000 limit to sales of produce rather than sales of all food. FDA states that it believes this modification will accommodate the concerns expressed by some commenters that making coverage turn on sales of all food would make it difficult for farms to diversify their operations and would have an adverse impact on diversified farms. The agency declined, however, to apply the $25,000 limit to the average annual monetary value of covered produce, finding that the likely frequent changes to a farm's covered or non-covered status presented challenges in terms of compliance and enforcement, as well as in determining the public health impact of this approach. FDA seeks comment on this proposed amendment.

FDA is also proposing to make corresponding revisions to the definitions of "very small business" and "small business" so that the monetary thresholds for all categories of business apply to the average annual sales of "produce" rather than of "all food." In particular, a "very small business" would be defined as a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $250,000. A "small business" would be defined as a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $500,000. FDA did not make a corresponding change to the eligibility criteria for a "qualified exemption" because the statutory language specified that "all food" must be considered in calculating sales.

Definition of Farm

Second, FDA proposes an expanded definition of the term "farm" in response to comments about overlap between the produce safety and preventive controls rules. Under the initial proposal, packing or holding of produce would be subject to either the preventive controls rule or the produce safety regulation, depending on whether or not the produce was grown or harvested on a farm under the same ownership. Commenters objected that this distinction lacks a public health basis, would be burdensome and arbitrary, and would infringe upon the common industry practice for neighboring farms to pack or hold produce grown or harvested by the other. FDA agreed that packing or holding of produce presents similar reasonably foreseeable hazards regardless of whether the produce is grown and harvested on farms under the same or different ownership, and that such hazards associated with packing or holding activities would best be addressed under the produce safety standards (rather than under the preventive controls rule).

Therefore, FDA is proposing to revise the definition of "farm," such that packing or holding others' raw agricultural commodity (RAC) produce on a covered farm would now be subject to the produce safety standards. The agency is also proposing corresponding revisions to the definitions of "covered activity," "harvesting," "holding," and "packing" so that each of these definitions would encompass the relevant activities regardless of the ownership of the farm where the RACs were grown.

The agency is proposing additional amendments to the definitions of "farm," "holding," and "packing," consistent with proposed changes in the amended proposed rule on preventive controls for human food. 1/ Specifically, FDA would make the following changes:

1. Revise the definition of "farm" to include: (a) establishments that manufacture/process food by drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; as well as (b) manufacturing/processing food by packaging and labeling RACs, when these activities do not involve additional manufacturing/processing (e.g., a covered farm placing strawberries in a plastic "clamshell" package);

2. Refer to "establishments" rather than to "facilities" in the definition of farm;

3. Amend the definition of "holding" to also include activities performed incidental to storage of a food (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 blending of the same RAC and breaking down pallets)); and

1/ *See* HL Memorandum, *FDA Issues Supplemental Preventive Controls Rules Under FSMA*, September 26, 2014.

4. Revise the definition of "packing" to also include activities performed incidental to packing a food (e.g., activities performed for the sale or effective packing of that food (such as sorting, culling and grading)).

Beyond these proposed changes, FDA requests comments on three key issues related to the definition of "farm":

1. Should the phrase "in one general physical location" be included in the farm definition in the final rule? If so, how should FDA interpret this phrase?

2. In instances where a farm supplies its produce to another farm to pack, hold, or store the produce, should the farms involved be subject to a requirement to establish and maintain a record of the produce shipment for tracking purposes in the event of an illness outbreak?

3. Should on-farm packinghouses under cooperative ownership by multiple growers be considered under the same ownership as any or all of the growers' farms, for the purposes of this regulation?

New Provisions Regarding the Withdrawal and Reinstatement of a Qualified Exemption

Withdrawal of a Qualified Exemption

The agency is proposing new provisions related to the "qualified exemption," which provides modified requirements for farms with average food sales during the previous 3-year period of $500,000 or less that sell primarily to consumers, retail food establishments, or restaurants located within the same state or a 275 mile radius of the farm. 2/ FDA originally proposed that it could withdraw a farm's qualified exemption in the event of a foodborne illness outbreak directly linked to the farm or if FDA determines it is necessary to protect public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the produce.

In the supplemental proposed rule, FDA proposes to require that before FDA issues an order to withdraw a qualified exemption, FDA would need to provide to the farm a notification of the problems identified by the agency and an opportunity to respond to the notification within 10 calendar days. The agency would be required to consider the farm's response prior to proceeding with issuing an order withdrawing the exemption. FDA also proposes changes to clarify that a withdrawal order must be approved by an FDA District Director in whose district the farm is located, or an FDA official senior to such Director (or, for a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)).

The supplemental proposal would also state that prior to withdrawing an exemption, the agency "may" consider "other actions, as appropriate," to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, mandatory recall, administrative detention, refusal of food offered for import, seizure, and injunction. If these other actions address the circumstances at issue, then FDA would likely determine that withdrawal of the exemption is not needed. In the preamble, FDA explains two scenarios that illustrate the agency's likely approach when considering such other actions. 3/

2/ The qualified facility exception was added to the statute via the "Tester amendment." FSMA § 103; FFDCA § 418.

3/ See pages 116-118 of the pre-publication version of the proposed rule. FDA gives the examples of Farm A, which produces heirloom tomatoes that are epidemiologically linked to an outbreak of salmonellosis; and Farm B, which produces green onions that test positive for *Shigella*.

Reinstatement of a Qualified Exemption

The supplemental proposal includes a new provision establishing the process for reinstatement of a qualified exemption that is withdrawn. This provision would provide that if the local FDA District Director (or Director of the Office of Compliance in CFSAN for a foreign farm) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at the farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate an outbreak, he or she is to reinstate the exemption, either on his or her own initiative or at the request of the farm. The amended proposal would also establish a process for a farm to request reinstatement of the exemption by submitting written data and information to demonstrate that the problems have been resolved.

If FDA withdraws a farm's exemption under section 112.201(a)(1) (i.e., in the course of an active outbreak investigation that is directly linked to that farm), and FDA later determines that the outbreak is not directly linked to that farm, FDA will reinstate the exemption on its own initiative. In contrast, if the withdrawal is issued under both sections 112.201(a)(1) and 112.201(a)((2) (i.e., if FDA determines that the withdrawal is necessary based on conduct or conditions associated with the farm that are material to food safety), and FDA later determines that the outbreak is not directly linked to that farm, the farm may submit a request that FDA reinstate the qualified exemption. In the latter case, FDA would not be required to reinstate the exemption on its own initiative.

Changes to the Standards for Three of the Six Specific Hazards

Lastly, FDA proposes significant changes related to three of the six specific hazards in the proposed rule. Below we provide a topline summary of the proposed changes for each hazard, which are generally aimed at providing increased flexibility for covered farms.

- Agricultural Water: FDA would (1) update and incorporate additional flexibility for meeting the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method; (2) amend the provisions regarding frequency of testing agricultural water to provide greater flexibility to farms; and (3) provide that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties in certain circumstances.

- Biological Soil Amendments: The agency proposes to amend the standards for using raw manure and compost. In particular, FDA would (1) remove the proposed 9-month minimum application interval for use of raw manure, deferring the decision on an appropriate time interval until FDA conducts further risk assessment and research work; and (2) remove the proposed 45-day minimum application interval for use of a biological soil amendment of

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In the examples, Farm A conditions and practices are generally consistent with good agricultural practices and management appears to be committed to food safety; while an inspection of Farm B indicates that the establishment is lacking certain prerequisite programs and is not in compliance with the proposed provisions in the produce safety rule. The agency explains that for both farms, it will provide education, request that the farm correct certain procedures and practices, and re-evaluate the company's corrective actions during a future inspection. If, at that time, FDA finds that Farm A has not voluntarily taken appropriate steps to correct the conditions or conduct that led to the outbreak; or during an inspection of Farm B finds continued conditions or conduct that could result in unsafe food, the agency may pursue withdrawal of each farm's respective exemption. For Farm B, FDA might also seek an injunction.

animal origin that is treated by a composting process and applied in a manner that minimizes the potential for contact with covered produce during and after application.

- Domesticated and Wild Animals: FDA would add a provision to explicitly state that the regulation does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the Endangered Species Act, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

FDA also states its intent in the preamble to prepare and publish an Environmental Impact Assessment (EIS) in the final rule. The EIS will evaluate the potential environmental effects of the rule, including those resulting from the standards for domesticated and wild animals.

Additionally, the agency has updated its Preliminary Regulatory Impact Analysis (PRIA) and estimates that, compared to the original proposed rule, the supplemental proposed rule provides a cost savings of $73 million with a decrease in overall net benefits of $7 million.

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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.