Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

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Re: **FSMA Implementation Update: Written Assurances, Food Defense, Human Food By-Products, and More**

FDA recently shared information regarding a number of ongoing FDA Food Safety Modernization Act (FSMA) implementation issues. This memorandum summarizes updates and developments regarding the following matters:

1. The written assurance requirements under several FSMA regulations;
2. Industry concerns regarding the Intentional Adulteration regulation;
3. Regulation of human food by-products for use as animal food when these materials are further processed to facilitate storage and distribution;
4. Various initiatives regarding implementation of the Produce Safety rule; and
5. Compliance with the Sanitary Food Transportation rule.

1. FDA Developing Proposed Rule to Rescind Written Assurance Requirements

FDA is working on a proposed rule that would remove certain requirements in the FSMA regulations that require companies to obtain written assurances from their customers that hazards are being controlled further down the distribution chain. The recently released Fall 2017 Unified Agenda of Regulatory Actions, which outlines the rulemaking actions currently under development in each federal agency, states:

> This proposed rule, if finalized, will remove certain requirements that currently apply when a manufacturer/processor of human food or animal food has identified a hazard that requires a preventive control, but does not control that hazard. Although that manufacturer/processor would still be required to provide documentation that the food has not been processed to control the identified hazard, that manufacturer/processor would no longer be required to obtain written assurance from the customer that the identified hazard will be controlled. This action, if finalized, also will remove analogous requirements that apply to importers of food for humans and animals.

Notably, based on this summary it does not appear that FDA has plans to repeal the written assurance requirement in the Produce Safety rule.

FDA is aiming to release the proposed rule by August 2018. FDA has extended the compliance dates for the written assurance requirements by two years, with the first such extension expiring

September 19, 2018 (for larger companies covered by the Preventive Controls for Human Food rule). 1/

2. FDA Comments on Industry Concerns Regarding Intentional Adulteration Rule

In a "Conversation" format that was recently posted to FDA's website, two FDA staff—Ryan Newkirk, Senior Advisor for Intentional Adulteration with the Food Defense and Emergency Coordination Staff at FDA, and Jon Woody, Director of the Food Defense and Emergency Coordination Staff—discussed industry concerns related to the Intentional Adulteration rule, forthcoming training opportunities, as well as the agency's strategy for initial inspections. 2/ They said FDA is aware that industry has many questions regarding the rule, in particular that the costs of complying are too high when considering the remote chance of an incident occurring.

FDA explained that it is working on draft guidance to provide industry with additional information to comply with the rule, which they believe will help address many of the concerns raised by industry. Issues addressed in guidance include conducting a vulnerability assessment; identifying and implementing mitigation strategies; and writing procedures for food defense monitoring, corrective actions, and verification. Newkirk and Woody also explained that FDA built as much flexibility into the rule as possible to keep costs down for industry. The agency did not commit to a timeline for release of the guidance.

Newkirk and Woody identified the need for training for both industry and inspectors, and they reported that the Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance (FSPCA) is developing food defense training resources for both industry and inspectors. This forthcoming training will include a combination of online and instructor-led formats. They expect it to be completed by summer 2018.

Finally, they explained that once the rule's compliance dates arrive (starting in July 2019 for companies with 500 or more full-time equivalent employees), FDA plans to initially do "quick check" inspections that will be combined with previously scheduled FDA inspections that focus on food safety issues. According to Woody, "[i]nspectors will simply evaluate the food defense plans to make sure the required components are there." FDA's second stage of inspections will be more comprehensive, and will require more detailed training for inspectors. They also noted that there are no specific food categories being targeted because no foods are more or less inherently at risk for intentional adulteration.

3. FDA Addresses Concerns About Further Processed Human Food By-Products Used for Animal Food

A recent Constituent Update from FDA reports that various industry food sectors have asked the agency to consider streamlining the regulatory requirements when various "manufacturing/ processing" activities are performed to facilitate storage and transportation of human food by-products intended for use as animal food. 3/ The regulations provide that if a human food facility further manufactures or processes by-products intended for use as animal food, rather than simply "holding" these materials, it must comply with the current Good Manufacturing Practice (CGMP) and Preventive Controls for Animal Food regulations for the by-products. This means that "manufacturing/processing" activities like commingling ingredients, evaporating, chopping,

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1/ 81 Fed. Reg. 57784 (Aug. 25, 2016).
2/ "Protecting the Food Supply from Intentional Adulteration, such as Acts of Terrorism," (Dec. 7, 2017), available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm587803.htm.
3/ "Frequently Asked Questions on FSMA," PC.19-20 (Nov. 27, 2017), available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm.

mechanical mixing, pressing, trimming, freezing, and washing that are performed to prepare by-products for storage and distribution would trigger the CGMP and Preventive Controls requirements.

FDA stated:

> The agency takes these concerns seriously and understands the practical value of these activities in preparing human food by-products for storage and transportation. As we implement FSMA requirements, we recognize the need to balance how these requirements impact current industry practices and the need to protect human and animal health. We are committed to working with industry to address these concerns, and are considering approaches that balance practical and public health considerations.

FDA also notes that it is not conducting routine regulatory inspections for compliance with the preventive controls aspects of the Preventive Controls for Animal Food regulation until the fall of 2018. FDA also reiterated that this delay includes inspection of human food by-products that are further processed and therefore required to comply with the preventive controls requirements.

4. Produce Safety Rule Updates

a. FDA Commissioner Gottlieb Reinforces Commitment to Working with the States

In a letter to the National Association of State Departments of Agriculture (NASDA), FDA Commissioner Scott Gottlieb expressed his commitment to communicating regularly with officials in every state about the work they and FDA will be doing together to implement the Produce Safety rule. 4/ In addition to detailing the next steps on implementation of the Produce Safety rule, discussed below, the letter is noteworthy because it is a public signal from FDA that the agency is making an effort to work with the states on Produce Safety rule implementation.

- **Agricultural water:** FDA will hold a summit to discuss the agricultural water and testing requirements under the Produce Safety rule. NASDA is expected to actively participate, along with other key stakeholders. Additionally, FDA's produce safety team at CFSAN will work to develop a comprehensive plan and timeline for consideration of agricultural water standards that can be shared with NASDA and other stakeholders.

- **Packinghouse/terminal markets:** FDA intends to clarify whether a packing house or terminal market is required to comply with the Preventive Controls or Produce Safety rule, but this may require rulemaking. In the meantime, FDA plans to exercise enforcement discretion, and it will make its policy public by January 2018.

- **Policy for On-Farm Readiness Review (OFRR) visits:** FDA and NASDA will release a revised draft policy for OFRRs (self-assessments for farmers) later this month. OFRRs are self-assessments for farmers, which can, upon the farm's request, include a team of state regulators, FDA regulators, and other educational partners who visit the farm to offer observations, advice, and resources.

  Under the forthcoming policy, during OFRRs over the next year, if state reviewers or FDA

4/ Letter from FDA Commissioner Scott Gottlieb to State Agriculture Commissioners, Secretaries, and Directors (Nov. 30, 2017), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM587183.pdf.

investigators observe certain serious conditions or practices, but the farm makes immediate corrections to the reviewer's satisfaction and no affected produce has entered or will enter commerce, then the reviewer need not alert FDA (or if FDA is doing the OFRR, its investigators need not refer the farm for inspection). However, if such conditions are observed and produce already has entered commerce, then the observation will be documented and/or reported to FDA, and a recall or other action may be triggered.

- **Training:** This month, FDA will host NASDA for a multi-day workshop on training needs for state regulators and extension staff. The goal of the workshop will be to finalize the number of regulators and extension staff who must be trained and ensure adequate training is planned and scheduled.

- **Dispute resolution for the Produce Safety rule:** FDA continues to explore documentation and review process for inspections that is tailored to Produce Safety inspections and that will enhance fairness and consistency in FDA and state inspections.

b. FDA Explains Produce Safety Network

In a recent "Conversation" posted on FDA's website, FDA explained its Produce Safety Network (PSN). 5/ The PSN's purpose is to support the efforts of farmers, state regulators, and other key stakeholders to implement the Produce Safety rule. The PSN does two things:

- It establishes regionally based policy and regulatory experts throughout the country, rather than just in the Washington, D.C. area, making them uniquely suited to address the issues specific to the states they are supporting.

- It places these experts, from two very different FDA offices, within one team. The network combines the regulatory expertise from the FDA's Office of Regulatory Affairs (ORA) with the policy and science expertise from the Center for Food Safety and Applied Nutrition (CFSAN).

Currently, the PSN consists of seven produce safety experts and one team leader from CFSAN and 14 investigators and two branch chiefs from ORA. Through the PSN, the regulators collaborate in areas such as education, outreach, and training. Additionally, CFSAN and ORA are collaborating to build a Regulator Technical Assistance Network for produce to serve as a resource for FDA investigators and state inspectors during inspections. Finally, the PSN also is a serving as a resource for farmers and other stakeholders to help achieve compliance with the Produce Safety rule. The goal is to give regulatory partners or farmers someone they can call who is familiar with their region and the conditions and practices there.

c. GAO Reports on FDA's Evaluation and Response to Concerns Regarding Produce Safety Rule

The U.S. Government Accountability Office (GAO) released a report entitled "FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule." 6/ The report addresses FDA's efforts to evaluate and respond to business concerns about the rule. This is the second of two reports the Agricultural Act of 2014 requires GAO to complete on this topic. The GAO found that

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5/ "The Produce Safety Network: Supporting Regulators and Growers Across the Country," (Dec. 6, 2017), available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm587803.htm.
6/ "FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule," (Nov. 27, 2017), available at http://www.gao.gov/assets/690/688596.pdf.

since its previous report in November 2016, FDA has continued to use its Technical Assistance Network (TAN) to evaluate and respond to questions about the rule.

In its previous report, the GAO reported that 2,626 TAN questions had been submitted between September 2015 and early September 2016. In its recent report, the GAO says that since September 2016, 2,665 more questions were submitted to the TAN, 230 of which related to the Produce Safety rule. The majority of these questions concerned the agricultural water standards.

According to FDA, as of June 2017, the agency had responded to 84 percent of questions specifically about the Produce Safety rule since the TAN began operating in September 2015. FDA's median response time to these questions was 48 business days. As of June 2017, FDA also had responded to 81 percent of all questions submitted to the TAN, with a median response time of 16 business days. FDA said that the longer median response time for questions concerning the Produce Safety rule was because of unique Produce Safety rule questions that had not been considered during the rulemaking process. In addition to the TAN, GAO reports that FDA's additional steps to evaluate and respond to business concerns include funding training for industry and visiting farms, including conducting OFRRs.

According to GAO, FDA officials reported facing two challenges in evaluating and responding to business concerns: identifying businesses subject to the Produce Safety rule and providing consistent, region-specific information in response to concerns. FDA officials also reported that the agency's cooperative agreement with 43 states plays a key role in addressing these challenges, as does the Produce Safety Network, which (as discussed above) is a network of region-based FDA food safety experts.

5. FDA Issues Small Entity Compliance Guide for Sanitary Food Transportation Rule

FDA issued a Small Entity Compliance Guide (SECG) for the Sanitary Transportation of Human and Animal Food (Sanitary Food Transportation) rule. 7/ The SECG provides information explaining when entities are subject to the rule and when they qualify for exemptions or waivers. For carriers, loaders, shippers, and receivers that are covered by the rule, the SECG identifies the requirements that are applicable. The SECG also discusses requirements that apply to all transportation operations and transportation equipment, generally, as well as the rule's training requirements for carriers and recordkeeping requirements. Comments on the guidance may be submitted at any time to Docket No. FDA-2013-N-0013.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

7/ "Sanitary Transportation of Human and Animal Food: What You Need to Know about the FDA Regulation – Small Entity Compliance Guide," (Nov. 2017), available at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm584406.htm.