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MEMORANDUM

December 21, 2010

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: The FDA Food Safety Modernization Act

Congress has passed the "FDA Food Safety Modernization Act of 2010," and President Obama has indicated he will sign the bill into law before the end of the year. In a surprise development, the Senate passed SA 4890, a manager's amendment to S. 510, on December 19, and the House passed the Senate bill today.[1] This memorandum provides a summary of the final version of this landmark legislation.[2]

The new legislation represents a major reform of the food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and significantly expands the powers of the Food and Drug Administration (FDA) with respect to food. It should be noted that the new law generally does not apply to meat, poultry, or egg products regulated by the U.S. Department of Agriculture (USDA). However, Secretary of Agriculture Tom Vilsack has stated that the Administration is reviewing the Federal Meat Inspection Act, and it is possible that food safety reforms adopted on the FDA side may also to be proposed and adopted on the USDA side in the next Congress.

This memorandum summarizes the FDA Food Safety Modernization Act (FSMA) and its potential impact on the food industry, emphasizing those provisions of greatest significance to

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[1] House adoption of the Senate bill obviates the need for a conference to reconcile differences between the Senate bill and a similar bill, the "Food Safety Enhancement Act of 2009," that was passed by the House last year.

[2] A copy of the new law is available at: http://www.gpo.gov/fdsys/pkg/BILLS-111hr2751eas/pdf/BILLS-111hr2751eas.pdf. This link is temporary. After enactment, a copy of the law will be made available on the Library of Congress website (http://thomas.loc.gov) under its Public Law number.

our clients. **We recommend your prompt, careful consideration of this substantial addition to the law of food safety.**

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EXECUTIVE SUMMARY

The FDA Food Safety Modernization Act represents the most significant expansion of food safety requirements and FDA food safety authorities since the original enactment of the FD&C Act in 1938. It grants FDA a number of new powers, including mandatory recall authority, which the agency has sought for many years. The FSMA requires FDA to undertake more than a dozen rulemakings and issue at least 10 guidance documents, as well as a host of reports, plans, strategies, standards, notices, and other tasks. Therefore, implementation of the legislation is likely to take several years. An attachment to this memorandum identifies which provisions of the law are self-implementing and which provisions will require FDA regulations to implement.

The FSMA is divided into four titles: prevention of food safety hazards, detection of and response to food safety problems, improving the safety of imported foods, and miscellaneous provisions.

The following are key provisions of the new law:

- **New regulatory requirements**
  - Food facilities are required to register with FDA biennially. Food from an unregistered facility may not be imported into the United States or introduced into interstate or intrastate commerce.

- Registered food facilities are required to conduct hazard analyses and to develop and implement written preventive controls plans.

- Registered food facilities must maintain additional records, including copies of their hazard analyses and preventive controls plans, related records, and additional records to assist FDA in tracking and tracing high-risk foods.

- Food importers are required to implement foreign supplier verification programs and to take steps to verify that the food they import is safe.

- Food facilities and food importers are subject to new fees, including a fee to be paid by each domestic food facility or importer that undergoes a re-inspection because of a material non-compliance identified during an initial inspection.

- Laboratory tests to be used for regulatory purposes must be performed by either a Federal laboratory or an accredited non-Federal laboratory, and lab test results must be sent directly to FDA.

- Food facilities will be inspected with greater frequency and not less often than once every 5 years.

- **New FDA powers**

  - FDA has the authority to order a recall of food.

  - FDA has the authority to administratively detain food based only on a "reason to believe" the food is adulterated or misbranded.

  - FDA has the power to suspend the registration, and thereby suspend the operations, of any food facility if FDA determines that food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

  - FDA is authorized to require that an article of food offered for import be accompanied by a safety certification from an accredited third-party auditor as an additional condition of granting admission.

  - FDA is required to review relevant health data every two years and to issue guidance documents or regulations setting contaminant-specific performance standards for the most significant foodborne contaminants.

- FDA is required to establish a product tracing system within FDA to improve the agency's capacity to effectively and rapidly track and trace food.

A number of provisions of the House bill, and earlier versions of the Senate bill, did not survive the legislative process. These include provisions giving FDA authority to levy civil fines for any prohibited act, giving FDA authority to quarantine food, establishing annual registration fees for registered food facilities and food importers, and establishing a new country-of-origin labeling requirement under the FD&C Act.

The FSMA can be said to move FDA regulation of food closer to the USDA regulatory model in significant ways. For example, FDA now has the power to suspend a food facility's registration, and thereby suspend its operations, similar to USDA's power to suspend inspection. FDA has the authority to set performance standards for contaminants as USDA has done for pathogens in meat and poultry. Food facilities registered with FDA will have to perform hazard analyses and implement preventive controls plans similar to the HACCP (Hazard Analysis and Critical Control Points) plans required of meat and poultry establishments. It is noteworthy that FDA's Deputy Commissioner for Foods, Michael Taylor, and Associate Commissioner for Food Protection in the Office of Foods, Phil Derfler, played a pivotal role in implementation of the meat and poultry HACCP "megareg" while at USDA in the 1990s.

DISCUSSION

I. Registration of Food Facilities (Section 102)

The FSMA amends Section 415 of the FD&C Act (21 U.S.C. § 350d)[3] concerning registration of food facilities,[4] to make the following changes:

A. Covered Facilities

The FSMA requires FDA to amend the definition of "retail food establishment"[5] to clarify that the sale of food directly to consumers includes the sale of food at a roadside stand or

[3] In this memorandum, statutory citations are to one of three sources: (1) the FDA Food Safety Modernization Act (FSMA) as enacted; (2) the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Pub. L. 75-717) as enacted; or (3) the FD&C Act as codified in Title 21 of the United States Code. All regulatory citations are to the Code of Federal Regulations.

[4] A "facility" is "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food." 21 U.S.C. § 350d(b). The definition does not include farms, restaurants, retail food establishments, nonprofit food establishments in which food is prepared and served directly to consumers, or fishing vessels (except for vessels engaged in processing). *See also* 21 C.F.R. § 1.227(b)(2).

farmers' market, sale and distribution of food through a community supported agriculture program,[6] and sale and distribution of food through any other direct sales platform as determined by FDA. FSMA, § 102(c). FDA regulations currently exempt retail food establishments from the food facility registration requirement. 21 C.F.R. § 1.226(c). This amendment will clarify that, for purposes of determining whether a facility is a "retail food establishment," direct sales to consumers include sales at a farmers' market, roadside stand, or other direct sales platform.

B. Registration Frequency

The FSMA requires food facilities to register with FDA biennially, between October 1 and December 31 of each even-numbered year.[7] FDA is to provide an abbreviated renewal process for facilities that have had no changes in their registration information since the previous renewal. 21 U.S.C. § 350d(a)(3).

C. Registration Information.

The FSMA requires the following new registration information: (1) a consent to permit FDA inspection of the registered facility; (2) the email address for the facility's contact person (or, in the case of a foreign facility, the email address of the facility's U.S. agent); and (3) in the section requiring the food product categories manufactured, processed, packed, or held at the facility, any other food categories (besides the food categories listed in 21 C.F.R. § 170.3) determined by FDA to be appropriate, including by guidance document. 21 U.S.C. § 350d(a)(2).

D. Electronic Registration

FDA may require that food facility registrations be submitted in an electronic format, but such requirement may not become effective until 5 years after the date of enactment of the FSMA. 21 U.S.C. § 350d(b)(5)(B).

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[5] FDA regulations define a "retail food establishment" as "an establishment that sells food products directly to consumers as its primary function.… A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term 'consumers' does not include businesses. A 'retail food establishment' includes grocery stores, convenience stores, and vending machine locations." 21 C.F.R. § 1.227(b)(11).

[6] The term "community supported agriculture program" has the same meaning as "community supported agriculture (CSA) program" in 7 C.F.R. § 249.2.

[7] If the FSMA is enacted before December 31, 2010, as appears likely, facilities that are required to register with FDA may be required to renew their registration before the end of this year.

E. Suspension of Registration

If FDA determines there is a reasonable probability that food from a facility could cause serious adverse health consequences or death to humans or animals, FDA may suspend the registration of: (a) any facility that created, caused, or is otherwise responsible for such reasonable probability; or (b) any facility that packed, received, or held such food and that knew of, or had reason to know of, such reasonable probability. 21 U.S.C. § 350d(b)(1). The authority to suspend registration, or vacate a suspension order, may not be delegated by the FDA Commissioner. 21 U.S.C. § 350d(b)(7).

1. Hearing and reinstatement

FDA is required to provide the registrant an opportunity for an informal hearing on the actions required for reinstatement of the facility's registration. The hearing is to be held as soon as possible but not later than 2 business days after issuance of the suspension order, or such other time as agreed upon by FDA and the registrant. If FDA determines the suspension remains necessary, the registrant must submit a corrective action plan, and FDA is required to review the plan within 14 days of submission or such other time period as determined by FDA. If FDA determines that adequate grounds do not exist to continue the suspension, FDA is required to promptly vacate the suspension order and reinstate the facility's registration or modify the order, as appropriate. 21 U.S.C. § 350d(b)(2), (3).

2. Effect of suspension

No person may import, offer to import, or introduce into interstate or intrastate commerce food from a facility whose registration has been suspended. 21 U.S.C. § 350d(b)(4). An article of food offered for import shall be refused admission if it is from a facility whose registration has been suspended. 21 U.S.C. § 381(l).

3. Implementing Regulations

FDA is required to issue regulations to implement 21 U.S.C. § 350d(b) dealing with suspension of registration, but may do so on an interim final basis. Subsection § 350d(b) will become effective on the date that FDA issues implementing regulations or 180 days after the date of enactment of the FSMA, whichever is earlier. 21 U.S.C. § 350d(b)(6).

F. Failure to Comply

The introduction or delivery for introduction into interstate commerce of any food in violation of the facility registration requirement is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(d).

II. Hazard Analysis and Preventive Controls (Section 103)

The FSMA adds a new Section 418 to the FD&C Act (21 U.S.C. § 350g) requiring registered facilities to perform a hazard analysis and implement a preventive controls plan.

A. General Requirement

The owner, operator, or agent in charge of each registered facility is required to conduct a hazard analysis and develop and implement a written preventive controls plan to ensure that food is not adulterated under FD&C Act Section 402 or misbranded under FD&C Act Section 403(w) (allergen labeling). The written plan must include the following elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping.

B. Elements

1. Hazard Analysis

The owner, operator, or agent in charge of a registered facility is required to identify and evaluate all known or reasonably foreseeable hazards that may be associated with the facility (including biological, chemical, physical, and radiological hazards as well as natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives) and prepare a written hazard analysis. 21 U.S.C. § 350g(b).

2. Preventive Controls

The owner, operator, or agent in charge of a facility is required to identify and implement preventive controls (including at critical control points, if any) to provide assurances that (a) hazards identified in the hazard analysis are significantly minimized or prevented; (b) hazards that may be intentionally introduced are significantly minimized or prevented; and (c) the food manufactured, processed, packed, or held by the facility will not be adulterated under Section 402 of the FD&C Act or misbranded under Section 403(w) (allergen labeling). 21 U.S.C. § 350g(c).

The term "preventive controls" means "those risk-based reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis…. and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis." 21 U.S.C. § 350g(o)(3). Preventive controls may include the following:

- Sanitation procedures for food contact surfaces and utensils;

- Supervisor, manager, and employee hygiene training;
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where food is exposed to a potential contaminant in the environment;
- A food allergen control program;
- A recall plan;
- Current Good Manufacturing Practices under 21 C.F.R. Part 110; and
- Supplier verification activities related to food safety.

3. Monitoring

The owner, operator, or agent in charge of the facility is required to monitor the effectiveness of the facility's preventive controls. 21 U.S.C. § 350g(d).

4. Corrective Actions

The owner, operator, or agent in charge of the facility is required to establish procedures to ensure that, if preventive controls are not properly implemented or are found to be ineffective: (a) all affected food is evaluated for safety; (b) all affected food is prevented from entering commerce if the owner, operator, or agent in charge cannot ensure it is not adulterated under Section 402 or misbranded under Section 403(w); and (c) appropriate action is taken to reduce the likelihood of a recurrence. 21 U.S.C. § 350g(e).

5. Verification

The owner, operator, or agent in charge of the facility is required to verify that the facility's preventive controls are adequate to control the hazards identified in the hazard analysis, that monitoring is being performed, that appropriate decisions about corrective actions are being made, and that periodic reanalysis of the plan is conducted. Verification is required to include environmental and product testing programs. 21 U.S.C. § 350g(f).

6. Recordkeeping and Records Access

The owner, operator, or agent in charge of the facility is required to maintain a copy of the facility's written preventive controls plan. It also must maintain, for at least 2 years, records of monitoring, instances of nonconformance material to food safety, corrective actions,

verification, and the efficacy of preventive controls and corrective actions. Such records must be made available to FDA promptly upon oral or written request. 21 U.S.C. § 350g(g), (h).

C. Requirement to Reanalyze

The owner, operator, or agent in charge of the facility must reanalyze the hazard analysis at least once every 3 years and before any significant change is made in the activities conducted at the facility if such change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard. In addition, FDA may require a reanalysis to respond to new hazards, developments in scientific understanding, or results of a Department of Homeland Security (DHS) terrorism risk assessment. After the reanalysis, the owner, operator or agent in charge must also revise the preventive controls plan or document the basis for concluding that no such revision is necessary. 21 U.S.C. § 350g(i).

D. Exemptions

1. Facilities subject to other food safety requirements

Section 418 does not apply to the following: (1) a facility that is subject to and in compliance with the FDA seafood or juice HACCP regulations or FDA low-acid canned foods regulations;[8] and (2) a facility that is subject to Section 419 of the FD&C Act (fresh produce standards) (*see* below). 21 U.S.C. § 350g(j). In addition, Section 418 does not apply to any facility with regard to the manufacturing, processing, packing, or holding of dietary supplements if such facility is in compliance with the Current Good Manufacturing Practice and adverse event reporting requirements for dietary supplements. FSMA, § 103(g).

2. Certain specialized facilities

FDA may, by regulation, exempt or modify the requirements of Section 418 for facilities that are solely engaged in the production of animal feed, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment. 21 U.S.C. § 350g(m). Section 418 does not apply to facilities that manufacture, process, pack, or hold alcoholic beverages, even if they also receive and distribute non-alcohol foods, provided that such non-alcohol foods are pre-packaged to prevent direct human contact and constitute no more than 5% of the facility's overall sales. FSMA, § 116(b).

[8] Facilities subject to and in compliance with FDA's low-acid canned food regulations are exempt only with respect to microbiological hazards. They are still required to conduct hazard analyses and develop and implement preventive controls plans to address other (*e.g.*, chemical and physical) hazards.

3. Certain on-farm operations

FDA is required to issue regulations exempting farms that engage in certain types of on-farm manufacturing, processing, packing, or holding operations from the requirement to implement a preventive controls plan. FDA regulations currently provide that a farm must register with FDA if it (a) packs or holds food that is not grown, raised, or consumed on that farm or another farm under the same ownership, or (b) manufactures or processes food that is not consumed on that farm or another farm under the same ownership. 21 C.F.R. §§ 1.226(b), 1.227(b)(3). Under Section 418, FDA is required to issue regulations specifying what activities constitute on-farm packing or holding of food, and on-farm manufacturing or processing of food. FDA is required to conduct a science-based risk analysis of the types of manufacturing, processing, packing, and holding activities that occur on farms and, based on that risk analysis, exempt (or modify the requirements for) facilities that are small businesses or very small businesses engaged in specific activities FDA determines to be low risk involving specific foods FDA determines to be low risk. FDA is required to publish a proposed rule not later than 9 months after the date of enactment of the FSMA, and a final rule not later than 9 months after the close of the comment period for the proposed rule.

4. "Qualified facilities"

A facility is a "qualified facility" and is exempt from Section 418 requirements during a given calendar if it meets either of the following conditions:

a. (i) The facility, including any subsidiary or affiliate, is collectively a very small business (as defined in regulations to be issued by FDA); and (ii) if the facility is a subsidiary or affiliate of another entity, such subsidiaries or affiliates are collectively a very small business (as defined in such regulations); or

b. (i) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at the facility (or the collective average annual monetary value of such food at any subsidiary or affiliate) that is sold directly to "qualified end-users"[9] during such period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate) sold by such facility (or collectively by any such subsidiary or

[9] The term "qualified end-user," with respect to a food, means (i) the consumer of the food; or (ii) a restaurant or retail food establishment that is located either in the same State as the qualified facility that sold the food to such restaurant or establishment, or not more than 275 miles from such facility, and is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

affiliate) to all other purchasers during such period; and (ii) the average annual monetary value of all food sold by such facility (or the collective average annual monetary value of such food sold by any subsidiary or affiliate) during such period was less than $500,000, adjusted for inflation.

A qualified facility is required to submit to FDA the following:

a. Documentation demonstrating that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address those hazards, and is monitoring the preventive controls; or

b. Documentation as specified by FDA that the facility is in compliance with State, local, county, or other applicable non-Federal food safety laws (*e.g.*, licenses, inspection reports, certificates, permits), and documentation that the facility is a qualified facility, as specified by FDA in a guidance document issued not later than 1 year after the date of enactment.

If a qualified facility does not provide the documentation in (a) above, then it must provide consumers with its name and business address prominently and conspicuously on the product label, or, with respect to a product that is not required to be labeled, on a sign, poster, placard, or document at the point of purchase (or, in the case of Internet sales, an electronic notice).

FDA may withdraw the exemption for a qualified facility if an active investigation of a foodborne illness outbreak is directly linked to that facility, or if FDA determines that withdrawing the exemption is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of food manufactured, processed, packed, or held at such facility. 21 U.S.C. § 350g(l).

E. Implementing Regulations

Not later than 18 months after the date of enactment, FDA is required to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting implementation of preventive controls. Such regulations must also define the terms "small business" and "very small business" for purposes of the exemption for qualified facilities. The FDA regulations are required to: (a) provide sufficient flexibility to be practicable for all sizes and types of facilities (including small businesses such as small food processing facilities co-located on farms); (b) comply with the Paperwork Reduction Act (44 U.S.C. Chapter 35); (c) minimize the number of separate standards that apply to separate foods; (d) not require a facility to hire a consultant or

other third party to identify, implement, certify, or audit preventive controls (except where required by a consent decree); and (e) not require specific technologies, practices, or critical controls for an individual facility. 21 U.S.C. § 350g(n).

F. Failure to Comply

Operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge is not in compliance with Section 418 is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(uu).

G. Effective Dates

Section 418 will become effective 18 months after the date of enactment of the FSMA, except that (a) for small businesses, it will become effective 6 months after the effective date of FDA implementing regulations; and (b) for very small businesses, it will become effective 18 months after the effective date of FDA implementing regulations. FSMA, § 103(i).

III. Protection Against Intentional Adulteration (Sections 106, 108, and 109)

The FSMA adds a new Section 420 to the FD&C Act (21 U.S.C. § 350i). Section 420 requires FDA to conduct a vulnerability assessment of the food system and determine the types of mitigation strategies necessary to protect against intentional adulteration of food. Not later than 18 months after the date of enactment, FDA is required to issue regulations to protect against the intentional adulteration of food. Such regulations are to specify appropriate science-based "mitigation strategies or measures" to protect the food supply at specific vulnerable points. They will apply only to food at high risk of intentional adulteration, as determined by FDA in consultation with DHS. These requirements will not apply to farms, except for farms that produce milk. No later than 1 year after the date of enactment, FDA, in consultation with DHS and USDA, is required to issue guidance documents related to protection against intentional adulteration of food.[10] These guidance documents are to include a model vulnerability assessment and examples of mitigation strategies and measures. FSMA, § 106(b). Failure to comply with Section 420 is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(ww).

FDA and USDA, in coordination with DHS, are required to develop, submit to Congress, and make available on the Internet a National Agriculture and Food Defense Strategy. FSMA, § 108. The strategy must be revised and re-submitted to Congress not less frequently than every 4 years. In addition, within 180 days of the date of enactment, DHS, in coordination with USDA and FDA, is required to submit to the relevant committees of Congress and post on the Internet a

[10] FDA has already issued several guidance documents on food security preventive measures, which are available at http://www.cfsan.fda.gov/~dms/defguids.html.

report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council. FSMA, § 109.

IV. Performance Standards (Section 104)

Not less frequently than every 2 years, FDA is required to review and evaluate relevant health data, including toxicological and epidemiologic studies and recommendations of FDA's Food Advisory Committee, to determine the most significant foodborne contaminants. Based on this review and when appropriate, FDA is required to issue, by regulation or guidance document, contaminant-specific performance standards (which may include action levels). Performance standards may distinguish between human food and animal feed. FDA is required to coordinate with USDA to avoid duplicative performance standards for the same contaminants.

V. Fees (Section 107)

The FSMA adds a new "Part 6 – Fees Related to Food" in Chapter VII, Subchapter C of Title 21, United States Code, which contains new Section 743 [sic] (21 U.S.C. § 379j-23) imposing the following new industry fees for fiscal year 2010 and each subsequent fiscal year:

- An annual fee from the responsible party[11] for each domestic facility, and the U.S. agent for each foreign facility, that is subject to a re-inspection in that fiscal year in an amount sufficient to cover 100% of FDA's total re-inspection-related costs (up to a total of not more than $25 million for any fiscal year).

- An annual fee from the responsible party for any domestic facility and any importer that fails to comply with a recall order in that fiscal year sufficient to cover 100% of FDA's food recall activities associated with such recall order (up to a total of not more than $20 million for any fiscal year).

- An annual fee from each importer participating in the Voluntary Qualified Importer Program in that fiscal year sufficient to cover 100% of FDA's administrative costs of operating the Voluntary Qualified Importer Program.

- An annual fee from each importer that is subject to a re-inspection in that fiscal year sufficient to cover 100% of FDA's re-inspection-related costs at ports of entry (up to a total of not more than $25 million for any fiscal year).

[11] The "responsible party" with respect to an article of food is "the person that submits the registration under section 415(a) for a food facility that is required to register under section 415 (a), at which such article of food is manufactured, processed, packed, or held." 21 U.S.C. § 350f(a)(1).

- A user fee, to be set by regulation, which FDA will charge to accredited third-party auditors and audit agents to reimburse FDA for administering the third-party auditor accreditation system (*see* Section XII of this memorandum below regarding Third-Party Certification).

21 U.S.C. §§ 379j-23(a)(1), (b)(2)(A), 388(c)(8).

For purposes of Section 743, the term "re-inspection" means:

i. With respect to domestic facilities, one or more inspections conducted subsequent to an inspection that identified non-compliance materially related to a food safety requirement, specifically to determine whether compliance has been achieved to FDA's satisfaction.

ii. With respect to importers, one or more examinations conducted subsequent to an examination that identified non-compliance materially related to a food safety requirement, specifically to determine whether compliance has been achieved to FDA's satisfaction.

The term "re-inspection-related costs" means all expenses, including administrative expenses, incurred in connection with (a) arranging, conducting, and evaluating the results of re-inspections, and (b) assessing and collecting re-inspection fees. 21 U.S.C. § 379j-23(a)(2).

FDA is required to publish the fee amounts for each fiscal year, as well as the time and manner in which fees will be collected, in the *Federal Register* not later than 60 days before the start of such fiscal year.[12] 21 U.S.C. § 379j-23(b)(1), (e)(1). Not later than 180 days after the date of enactment of the FSMA, FDA is required to publish in the *Federal Register* proposed guidelines "in consideration of the burden of fee amounts on small business," which may include reduced fees for small businesses. However, FDA may adjust the fee schedule for small businesses only through notice-and-comment rulemaking. 21 U.S.C. § 379j-23(b)(2)(B)(iii).

FDA is also authorized to collect a fee for issuing export certificates for food, including animal feed. 21 U.S.C. § 381(e)(4)(A). FDA may issue export certificates in such form and on such basis as FDA deems appropriate. 21 U.S.C. § 381(e)(4)(C).

VI. Inspections (Section 201)

The FSMA adds a new Section 421 to the FD&C Act (21 U.S.C. § 350j) on targeting of inspections.

[12] It is not clear whether FDA intends to collect fees for re-inspections conducted during fiscal year 2010 and, if so, when FDA will publish a notice setting the fees for FY 2010.

A. High-Risk Facilities

FDA is required to identify high-risk facilities and to allocate resources to inspect registered facilities according to their risk profile, based on the following factors: the known safety risks of the food manufactured, processed, packed, or held at the facility; the facility's compliance history including recalls, outbreaks, and violations; the rigor and effectiveness of the facility's hazard analysis and preventive controls; whether the facility or its food have been certified by an accredited third-party auditor; whether the food manufactured, processed, packed, handled, prepared, treated, distributed, or stored at the facility meets the criteria for priority under FD&C Act section 801(h)(1) (*i.e.*, possible intentional adulteration); and any other criteria deemed appropriate by FDA. 21 U.S.C. § 350j(a)(1).

B. Inspection Frequency

The FSMA establishes a minimum inspection frequency of once every 5 years for domestic food facilities. FDA is required to inspect domestic high-risk facilities at least once during the 5-year period following the date of enactment, and at least once every 3 years thereafter. FDA is required to inspect domestic facilities that are not high-risk facilities at least once during the 7-year period following the date of enactment, and at least once every 5 years thereafter. FDA is required to inspect at least 600 foreign facilities during the first 1-year period following the date of enactment, and to inspect at least twice the number inspected during the previous year in each of the next 5 years. 21 U.S.C. § 350j(a)(2). These provisions imply a distinction between domestic and foreign food facilities with regard to inspection frequency.

C. Inspection of Imports

FDA is required to allocate resources to inspect imported foods according to their risk profile, based on the following factors: the known safety risks of the imported food; the known safety risks of the countries or regions of origin and transport of the imported food; the importer's compliance history including recalls, outbreaks, and violations; the rigor and effectiveness of the importer's Foreign Supplier Verification Program (*see* below); whether the importer participates in the Voluntary Qualified Importer Program (*see* below); whether the food meets the criteria for priority under FD&C Act Section 801(h)(1) (*i.e.*, possible intentional adulteration); whether the food or the facility that manufactured, processed, packed, or held the food has been certified by an accredited third-party auditor; and any other criteria deemed appropriate by FDA. 21 U.S.C. § 350j(b).

D. Inspection of Foreign Facilities

The FSMA adds a new Section 807 to the FD&C Act (21 U.S.C. § 387) regarding inspection of foreign food facilities. It provides that FDA may enter into agreements and arrangements with foreign governments to facilitate inspection of foreign food facilities. If the

owner, operator, or agent in charge of a foreign factory, warehouse, or other establishment, or the government of a foreign country, refuses to permit entry of U.S. inspectors or other individuals duly designated by FDA to inspect such factory, warehouse, or other establishment, upon request, food from that foreign factory, warehouse, or other establishment shall be refused admission into the United States. For purposes of this provision, an owner, operator, or agent in charge will be deemed to have refused an inspection request if such person does not permit an inspection during the 24-hour period after a request is made, or after such other time period as agreed upon by FDA and the foreign factory, warehouse, or other establishment. In targeting inspections of foreign facilities, FDA will consider participation in the Voluntary Qualified Importer Program and third-party certification. 21 U.S.C. § 388(c)(2)(A) (*see* Sections XIII.B and XIII.C of this memorandum below regarding the Voluntary Qualified Importer Program and FDA authority to require third-party certification for designated imports).

E. Annual Report on Food Inspections

FDA is required to submit an annual report to Congress, not later than February 1 of each year, with information about food inspections conducted during the previous fiscal year. For food facilities, the report is required to include such information as the number of domestic facilities and the number of foreign facilities inspected, the number of high-risk facilities inspected, and the average cost of both a high-risk facility inspection and a non-high-risk facility inspection. For food imports, the report is required to include such information as the number of entry lines of imported food physically sampled or inspected, the number of lines of imported food not physically sampled or inspected, and the average cost of physically sampling or inspecting a line of imported food. The report is required to be posted on FDA's website. 21 U.S.C. § 393(h), (i).

F. Inspection of On-Farm Operations

FDA is required to conduct a science-based risk analysis of the types of manufacturing, processing, packing, and holding activities that occur on farms. Based on that risk analysis, FDA is required to exempt from the mandatory inspection frequency in Section 421, or modify the inspection frequency for, facilities that are small businesses or very small businesses engaged in specific types of on-farm manufacturing, processing, packing, or holding activities that FDA determines to be low risk involving specific foods FDA determines to be low risk. FDA is required to publish a proposed rule not later than 9 months after the date of enactment, and a final rule not later than 9 months after the close of the comment period for the proposed rule. FSMA, § 103(c)(1)(A), (C), (D).

G. Seafood Inspection

FDA, DHS, the Department of Commerce, the Federal Trade Commission, and other appropriate agencies may enter into agreements to improve seafood safety, including agreements

regarding coordination of inspections of foreign facilities and use of employees of the National Oceanic and Atmospheric Administration (NOAA) to carry out FDA seafood inspections. 21 U.S.C. § 350j(c). In addition, the Department of Commerce is authorized to send inspectors to a country or facility that exports seafood to the United States to assess practices used in farming, cultivation, harvesting, preparation, and transportation of seafood and to provide technical assistance. The Department of Health and Human Services, in coordination with the Department of Commerce, is required to prepare an inspection report for each such inspection and provide the country or exporter a 30-day period to comment on the report's findings. Such inspection reports shall be considered in allocating FDA inspection resources. 21 U.S.C. § 387(b).

H. Reliance on State Inspectors

For domestic inspections, FDA may rely on inspections conducted by other Federal, State, or local agencies under interagency contracts, memoranda of understanding, or other obligations. 21 U.S.C. § 350j(a)(2)(E). The FSMA adds a new Section 1011 to the FD&C Act (21 U.S.C. § 399b) that requires FDA to set standards and administer training programs for State, local, territorial, and tribal food safety officials, including training in conducting inspections, sampling, and performing laboratory analyses. FDA contracts and memoranda of understanding with State, local, territorial, and tribal government agencies are required to include provisions to ensure adequate training and to reimburse such agencies for their regulatory activities.

VII. Laboratory Accreditation; Direct Submission of Lab Tests to FDA (Section 202)

The FSMA adds a new Section 422 to the FD&C Act (21 U.S.C. § 350k) regarding accreditation of food laboratories.

A. Laboratory Accreditation

Not later than 2 years after the date of enactment, FDA is required to establish a program for the testing of food by accredited labs. This laboratory accreditation program would encompass independent private laboratories; foreign laboratories; and laboratories operated by Federal, State, and local government agencies. FDA is directed to work with recognized accreditation bodies to increase the number of accredited labs beyond the number in existence on the date of enactment. 21 U.S.C. § 350k(a)(1), (2), (3), and (5).

B. Public Registry

FDA is required to establish a publicly available registry of accreditation bodies recognized by FDA and labs accredited by a recognized accreditation body. The registry is to include contact information for accredited labs and indicate the sampling and/or analytical methods for which each lab is accredited. In the interest of national security, FDA, in

coordination with DHS, may determine the time, manner, and form in which the registry is made publicly available. 21 U.S.C. § 350k(a)(1)(B), (4).

C. Requirement to Use Accredited Labs for Regulatory Tests; Direction Submission of Test Results to FDA; Exceptions

Not later than 30 months after the date of enactment, all testing of food by or on behalf of its owner or consignee for the purposes listed below must be conducted by either a Federal laboratory or a non-Federal laboratory that has been accredited by a recognized accreditation body:

- To support the admission of an imported food;
- To support removal from an Import Alert;
- To comply with a specific testing requirement under the FD&C Act or FDA regulations to address an identified or suspected food safety problem; and
- As otherwise required by FDA to address an identified or suspected food safety problem.

21 U.S.C. § 350k(b)(1).

The results of such tests must be sent directly to FDA. However, FDA may, by regulation, exempt test results from direct submission to FDA if FDA determines that such test results do not contribute to the protection of public health. Test results required to be submitted directly to FDA may be sent by electronic means. 21 U.S.C. § 350k(b)(2).

FDA may waive the requirement to use an accredited lab and to submit results directly to FDA if: (i) a lab has not yet been accredited to perform a new validated methodology; and (ii) the use of that new methodology is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. 21 U.S.C. § 350k(b)(3).

D. FDA To Develop Model Standards for Accreditation of Laboratories, Criteria for Recognition of Accreditation Bodies

FDA is required to develop model standards that laboratories must meet to be accredited to perform specified sampling and analytical testing methods. Such model standards are required to include methods to ensure that: (i) appropriate sampling, analytical procedures, and commercially available techniques are followed; (ii) reports of analyses are certified as true and accurate; (iii) internal quality systems are established and maintained; (iv) procedures exist to evaluate and respond promptly to complaints; and (v) individuals who conduct sampling and

analyses are qualified by training and experience. The legislation does not specify the form in which FDA must issue these model standards. 21 U.S.C. § 350k(a)(6).

FDA is also required to develop criteria for recognition of accreditation bodies and to periodically, at least every 5 years, reevaluate recognized accreditation bodies. FDA also may accompany auditors from an accreditation body to determine whether the accreditation body meets the FDA criteria for recognition. FDA is required to promptly revoke the recognition of any accreditation body found not to be in compliance with Section 422. 21 U.S.C. § 350k(a)(2), (7).

As a condition of recognition or accreditation, recognized accreditation bodies and accredited labs are required to notify FDA of any changes that would affect the recognition of such accreditation body or the accreditation of such lab. 21 U.S.C. § 350k(a)(1)(C).

E. Expansion of State Recalls

If sampling and testing performed by an accredited State or local laboratory results in a State recalling a food product, FDA is required to review the sampling and testing results to determine the need for a nationwide recall or other enforcement actions. 21 U.S.C. § 350k(c).

F. Food Emergency Response Network

Not later than 180 days after the date of enactment, and biennially thereafter, FDA, in coordination with USDA, DHS, and State, local, and tribal governments, is required to submit to the relevant committees of Congress and post on the Department of Health and Human Services website a report on progress in implementing a national food emergency response laboratory network. This provision appears to refer to the existing Food Emergency Response Network (FERN). FSMA, § 202(b).

VIII. Traceability; Recordkeeping; Records Access (Sections 101, 204)

A. Product Tracing System

FDA, in consultation with USDA, is required to establish, as appropriate, "within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States." FSMA, § 204(c). Prior to establishing this tracing system, and not later than 270 days after the date of enactment, FDA is required to conduct at least 2 pilot projects (1 or more for processed foods, and 1 or more for fresh produce) to evaluate methods for improving traceability. Not later than 18 months after the date of enactment, FDA is required to report to Congress on the findings of these pilot projects. FDA is also required to engage in additional data gathering, including assessing the costs and benefits of

several different product tracing technologies and evaluating domestic and international tracing practices in commercial use. FSMA, § 204(a), (b).

B. Additional Recordkeeping Requirements for High-Risk Foods

FDA is also required to issue regulations containing new recordkeeping requirements applicable to facilities that manufacture, process, pack, or hold high-risk foods.[13] Not later than 2 years after the date of enactment, FDA is required to publish a proposed rule to establish new recordkeeping requirements for high-risk foods.[14] Not later than 1 year after the date of enactment, FDA is required to designate high-risk foods subject to additional recordkeeping based on the following factors: known safety risks of a particular food, including the history and severity of outbreaks attributed to such food; the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support growth of pathogens; the point in the manufacturing process where contamination is most likely to occur; the likelihood of contamination and steps taken during the manufacturing process to reduce the risk of contamination; the likelihood that consuming a particular food will result in foodborne illness; and the likely or known severity of foodborne illness attributed to a particular food. At the time FDA issues a final rule, the agency is required to publish a list of high-risk foods on its website. FDA may add or remove foods from the list of high-risk foods by publishing a notice in the *Federal Register*. FSMA, § 204(d)(2).

The new recordkeeping requirements for high-risk foods are subject to a number of limitations. For example, such requirements shall:

- Not require a "full pedigree" of a food (*i.e.*, a complete record of the food's previous distribution history from point of origin);
- Not require records of recipients of a food beyond the immediate subsequent recipients;
- Not require "product tracking to the case level";
- Not require use of specific technologies for the maintenance of records;
- Not require retention for more than 2 years;

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[13] For foods that are not high-risk, the recordkeeping requirements of FD&C Act Section 414 (21 U.S.C. § 350c) and FDA regulations at 21 C.F.R. Part 1, Subpart J will continue to apply. FSMA, § 204(d)(7).

[14] No deadline is specified for the final rule. However, any final rule will apply to small businesses beginning 1 year after the effective date of the final rule, and to very small businesses beginning 2 years after the effective date of the final rule. FSMA, § 204(i).

- Minimize the number of different recordkeeping requirements for facilities that handle more than one type of food; and

- Include a process whereby FDA may issue a waiver of the recordkeeping requirements if FDA determines they would result in economic hardship for an individual facility or type of facility.

FSMA, § 204(d)(1), (5). There are also specific limitations applicable to farms, fishing vessels, grocery stores, and "commingled raw agricultural commodities."[15] If FDA determines the additional recordkeeping requirements for high-risk foods are not needed to protect public health, FDA may, by *Federal Register* notice, exempt or modify the requirements with respect a particular food or type of facility. FSMA, § 204(d)(6). Nothing in Section 204 may be construed to impose any limitation on commingling of food. FSMA, § 204(g).

Not later than 1 year after FDA issues a final rule, the Comptroller General is required to submit a report to Congress evaluating the public health benefits and risks of these recordkeeping requirements and recommending whether they should be extended to restaurants and to additional foods. FSMA, § 204(e).

C. FDA Records Access Authority

Currently, section 414 provides that, if FDA has a reasonable belief that a particular article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA may, upon presenting credentials and a written notice, inspect and copy all records relating to that particular article of food that are needed to determine whether, in fact, the food is adulterated and presents a risk of serious adverse health consequences or death to humans or animals.

The FSMA expands FDA's records access authority in a number of ways, including the following:

- If FDA has a reasonable belief that a particular article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA may have access to all records relating to that article of food and "any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner." 21 U.S.C. § 350c(a)(1).

[15] A "commingled raw agricultural commodity" is "any commodity that is combined or mixed after harvesting, but before processing." It does not include types of fruits and vegetables that are raw agricultural commodities and that are subject to FD&C Act Section 419. FSMA, § 204(d)(6)(D)(ii).

- During an active investigation of a foodborne illness outbreak, or if FDA determines it is necessary to prevent or mitigate an outbreak, FDA may request an owner, operator, or agent of a farm to identify potential immediate recipients (other than consumers) of an article of food that is the subject of investigation if FDA reasonably believes such article of food is adulterated, was adulterated on a particular farm, and presents a threat of serious adverse health consequences or death to humans or animals. The owner, operator, or agent of the farm would be required to provide the requested information in a prompt and reasonable manner. FSMA, § 204(f).

- Registered food facilities required to have a preventive controls plan are required to make such plan and related records (including records of monitoring, verification, and corrective actions) available to FDA upon written or oral request. 21 U.S.C. § 350g(h).

- Importers are required to maintain records related to their Foreign Supplier Verification Program for at least 2 years and to make them available to FDA upon request. 21 U.S.C. § 385(d).

D. Failure to Comply

The violation of any recordkeeping requirement under Section 204 (except those committed by a farm) is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(e). In addition, an article of food offered for import shall be refused admission if the recordkeeping requirements of Section 204 (except those applicable to farms) have not been complied with regarding such article. 21 U.S.C. § 381(a).

IX. Improving the Reportable Food Registry; Consumer Notification of Reportable Foods (Section 211)

Under existing Section 417 of the FD&C Act (21 U.S.C. § 350f), a "responsible party" is required to report to FDA if it determines that a food it has manufactured, processed, packed, or held is a "reportable food." A "responsible party" is a person who submits the registration for the food facility where the article of food is manufactured, processed, packed, or held. A "reportable food" is a food (other than a dietary supplement or infant formula) for which there is a reasonable probability that use or exposure will cause serious adverse health consequences or death to humans or animals.

The FSMA amends Section 417 to provide that, beginning 18 months after the date of enactment, FDA may require a responsible party to submit "consumer-oriented information" regarding a reportable food (other than fresh produce). Such information is to include: a description of the article of food; its product identification codes (*e.g.*, UPC, SKU, or lot numbers); contact information for the responsible party; and any other information FDA deems

necessary to enable consumers to accurately identify the reportable food. FDA is required to prepare this information in a standardized one-page summary and post it on the FDA website in a format that can easily be printed by a grocery store for purposes of consumer notification. Any grocery store that sold the reportable food and that is part of a chain with 15 or more locations is required to prominently display the FDA notice within 24 hours after it is posted on the FDA website and maintain such display for 14 days. Not more than 1 year after the date of enactment, FDA is required to develop and publish a list of acceptable conspicuous locations and manners for providing such notice (*e.g.*, the in-store location of the reportable food, at or near the cash register), and grocery stores will be required to post the notice using at least one of these. The knowing and willful failure to comply with this consumer notification requirement is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(yy).

X. Mandatory Recall Authority (Section 206)

The FSMA adds a new Section 423 (21 U.S.C. § 350l) to the FD&C Act giving FDA, for the first time, mandatory recall authority with respect to all FDA-regulated foods.[16]

A. Voluntary Procedures

If FDA determines there is a reasonable probability that an article of food (other than infant formula) is adulterated under FD&C Act Section 402 or misbranded under Section 403(w) (allergen labeling) and that use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals, FDA is required to give the responsible party[17] the opportunity to cease distribution and recall the product. 21 U.S.C. § 350l(a).

B. Order to Cease Distribution and Give Notice

If the responsible party does not voluntarily cease distribution and recall the food within the time and in the manner prescribed by FDA, FDA may issue an order requiring the responsible party to immediately cease distribution and notify other persons to immediately cease distribution of the food. Such notification must be given to: (a) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such food; and (b) all persons to which the food has been distributed, transported, or sold.[18] The order

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[16] Prior to the FSMA, FDA had mandatory recall authority only with respect to infant formula. 21 U.S.C. § 350a(e).

[17] For purposes of Section 423, the term "responsible party" is defined as it is defined in FD&C Act Section 417 (21 U.S.C. § 350f).

[18] Any such notification given by a responsible party to a warehouse-based third party logistics provider would be required to include the information necessary to identify the food covered by the order.

to cease distribution may be limited in terms of geographic area and markets affected. 21 U.S.C. § 350l(b).

C. Informal Hearing

FDA is required to provide the responsible party with an opportunity for an informal hearing to be held no later than 2 days after issuance of the order to cease distribution. If FDA determines adequate grounds do not exist to continue the order to cease distribution, FDA is required to vacate or modify the order. 21 U.S.C. § 350l(c), (d)(2).

D. Recall Order

If, after an opportunity for a hearing, FDA determines that removal of the food from commerce is necessary, FDA is required to amend the order to require a recall or other appropriate action, specify a timetable for the recall, require periodic recall status reports, and provide notice to consumers to whom the food may have been distributed. 21 U.S.C. § 350l(d)(1). The authority to order a recall or vacate a recall order may not be delegated by the FDA Commissioner. 21 U.S.C. § 350l(h). FDA may not issue a recall order for an alcoholic beverage without first providing TTB with a reasonable opportunity to take regulatory action. 21 U.S.C. § 350l(e).

E. Public Notification

In conducting a recall, FDA is required to ensure that a press release is issued and to post an image of the recalled food, if one is available, on the FDA website. FDA is also directed to "consider" making public the names of retail consignees of recalled foods for Class I recalls, as USDA does for meat and poultry recalls. 21 U.S.C. § 350l(g). Not later than 90 days after the date of enactment, FDA is required to create a user-friendly search engine on the FDA website that enables members of the public to find relevant information about recalled foods, including whether a recall is ongoing or has been completed. FSMA, § 206(b).

F. Incident Command Operations

FDA is required to establish an incident command operation or similar operation that will operate not later than 24 hours after initiation of a mandatory recall or other recall of an article of food that presents a threat of serious adverse health consequences or death to humans or animals. 21 U.S.C. § 350l(j).

G. Failure to Comply

Refusal or failure to comply with an order under Section 423 is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(xx). In addition, FDA is authorized to

assess a civil fine for failure to comply with a recall order. Any person who fails to comply with a recall order is liable for a civil penalty not to exceed $50,000 for an individual, $250,000 for a corporation. 21 U.S.C. § 333(f)(2)(A).

H. Possible Restitution for Recalls in Error

Not later than 90 days after the date of enactment, the Comptroller General is required to submit a report to Congress that, among other elements, identifies new or existing mechanisms used by other Federal, State, and local agencies to compensate persons for recall-related costs when a recall is subsequently determined to have been in error, as well as models for farmer restitution used in other countries in cases of erroneous recalls. If the Comptroller General concludes existing mechanisms are inadequate, USDA would be required to conduct a study of the feasibility of a "farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error." USDA would be required to submit a report and recommendations to Congress. FSMA, § 206(e).

I. Annual Report to Congress

Not later than 2 years after the date of enactment, and annually thereafter, the Secretary of Health and Human Services is required to submit a report to Congress on the use of mandatory recall authority under Section 423, as well as any public health advisories that advise against the consumption of an article of food. The report is to include any instances in which an article of food that was the subject of a recall order or public health advisory was not confirmed by testing to be adulterated. FSMA, § 206(f).

XI. Administrative Detention Authority (Section 207)

The FSMA significantly expands FDA's power to administratively detain foods. Under current law, FDA must have "credible evidence or information" that an article of food "presents a threat of serious adverse health consequences or death to humans or animals" to detain that article of food. The new law amends Section 304(h)(1)(A) of the FD&C Act (21 U.S.C. § 334(h)(1)(A)) to give FDA the authority to administratively detain an article of food if FDA has "reason to believe" that the article of food is adulterated or misbranded. FDA is required to issue an interim final rule implementing this amendment not later than 120 days after the date of enactment, and the expanded administrative detention authority will become effective 180 days after the date of enactment.

XII. Third-Party Certification (Section 307)

The FSMA adds a new Section 808 to the FD&C Act (21 U.S.C. § 388) requiring FDA to create a system for FDA recognition of accreditation bodies that accredit third-party auditors to certify eligible foreign facilities.

A. Accreditation of Third-Party Auditors

Not later than 2 years after the date of enactment, FDA is required establish a system in which FDA recognizes accreditation bodies, and these accreditation bodies accredit third-party auditors to certify "eligible entities."[19] Thus, FDA's role is to recognize other entities as accreditation bodies, and those recognized accreditation bodies accredit the third-party auditors. FDA is authorized to directly accredit third-party auditors itself if FDA has not recognized any accreditation bodies within 2 years after the accreditation system is established. 21 U.S.C. § 388(b)(1)(A).

Importantly, third-party certification under Section 808 is limited to foreign entities. The term "eligible entity" is defined as a foreign entity, including a foreign facility registered with FDA, in the food import supply chain that chooses to be audited by an accredited third-party auditor. 21 U.S.C. § 388(a)(6).

B. Purposes and Uses of Third-Party Certification

FDA is required to use third-party certifications for the following purposes: (a) to determine whether a foreign facility is eligible to be a facility from which food may be imported under the Voluntary Qualified Importer Program; (b) to provide an assurance of safety for designated food imports; and (c) to target foreign inspection resources. 21 U.S.C. § 388(c)(2)(A), (B). Each eligible entity is required to be re-certified annually by an accredited third-party auditor if it intends to participate in the Voluntary Qualified Importer Program or if it is required to provide an import certificate for any of its products. 21 U.S.C. § 388(d). (*See* Sections XIII.B and XIII.C of this memorandum below regarding the Voluntary Qualified Importer Program and FDA authority to require import certificates.)

C. Accreditation Bodies

Each recognized accreditation body is required to submit to FDA a list of the accredited third-party auditors it has accredited and their audit agents. FDA is required to revoke the

[19] A "third-party auditor" is defined as a foreign government, agency of a foreign government, foreign cooperative, or any other qualified third party (including an individual), as FDA determines appropriate, that conducts audits of eligible entities. An "accredited third-party auditor" is a third-party auditor accredited by an accreditation body. An "audit agent" is an individual who is an employee or agent of an accredited third-party auditor and is qualified to conduct food safety audits. 21 U.S.C. § 388(a).

recognition of an accreditation body found not in compliance with FDA requirements, and to establish procedures for reinstatement of recognition. 21 U.S.C. § 388(b)(1)(B), (C), and (D). FDA is required to reevaluate each recognized accreditation body at least once every 4 years. 21 U.S.C. § 388(f)(1).

FDA is required to develop model accreditation standards, including requirements for regulatory audit reports, no later than 18 months after the date of enactment. It is the responsibility of the accreditation body to ensure that the third-party auditors it accredits meet those standards. 21 U.S.C. § 388(b)(2). In addition, prior to accrediting a foreign government or an agency of a foreign government, the accreditation body (or FDA in the case of a direct accreditation) must perform such audits of food safety programs, systems, and standards as FDA deems necessary. Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party, the accreditation body (or FDA in the case of a direct accreditation) must perform such audits of the training and qualifications of audit agents used by the cooperative or third party, conduct reviews of internal systems, and such other investigations as FDA deems necessary. 21 U.S.C. § 388(c)(1). An accreditation body may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic certification to accompany each shipment of food for import into the United States from the eligible entities it certifies.

D. Accredited Third-Party Auditors

An accredited third-party auditor may issue a food certification (under FDA&C Act Section 801(q)) or a facility certification (under Section 806(a)) only after conducting a regulatory audit and such other activities as may be necessary to establish compliance.[20] Not later than 45 days after conducting an audit, an accredited third-party auditor or its audit agent must prepare an audit report in a form and manner specified by FDA. FDA may at any time require an accredited third-party auditor to submit a report of a regulatory audit to FDA, as well as such other documents and reports required as part of the audit process, for any eligible entity certified by the third-party auditor. FDA may not obtain reports of consultative audits except pursuant to FD&C Act Section 414 (*i.e.*, where FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals). An accredited third-party auditor or its audit agent is required to immediately notify FDA if it discovers a condition that could cause or contribute to a serious risk to public health. Not later than 18 months after the date of enactment, FDA is required to issue regulations to protect against conflicts of interest between accredited third-party auditors and eligible entities. Such regulations will require that audits be unannounced. FDA is also required to issue regulations establishing fees to be paid by accredited third-party auditors so that the accreditation system is revenue-neutral. 21 U.S.C. § 388(c)(2), (3), (4), (5), (8).

[20] Section 808 distinguishes between "regulatory audits" and "consultative audits." A "consultative audit" is an audit the results of which are for internal facility purposes only.

FDA is required to withdraw accreditation from a third-party auditor under the following circumstances: (a) if food certified by the third-party auditor, or food from a facility certified by the third-party auditor, is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death to humans or animals;[21] (b) if FDA determines the third-party auditor no longer meets accreditation requirements; (c) following a refusal to allow U.S. officials to conduct such audits and investigations as may be necessary to ensure continued compliance; or (d) if the third-party auditor was accredited by an accreditation body whose recognition is revoked and FDA determines there is good cause for the withdrawal. FDA shall establish procedures to reinstate the accreditation of third-party auditors whose accreditation has been withdrawn. 21 U.S.C. § 388(c)(6), (7).

FDA is required to evaluate the performance of each accredited third-party auditor at least once every 4 years. FDA is to do this by reviewing the third-party auditor's regulatory audit reports, the compliance history of the eligible entities it has certified, and other measures deemed necessary by FDA. In addition, FDA may at any time conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present. 21 U.S.C. § 388(f)(2), (3).

E. Public Registry

FDA is required to establish a public registry of accreditation bodies and accredited third-party auditors including their names, contact information, and other information FDA deems necessary. 21 U.S.C. § 388(g).

XIII. Import Requirements (Sections 301-309)

Title III of the FSMA concerns the safety of imported foods.

A. Foreign Supplier Verification Program (Section 301)

The FSMA adds a new Section 805 to the FD&C Act (21 U.S.C. § 385) requiring every U.S. importer[22] to perform risk-based foreign supplier verification activities to verify that the food it imports is (a) produced in compliance with the requirements of Section 418 (hazard analysis and preventive controls) or Section 419 (produce standards); and (b) is not adulterated

[21] However, FDA may make an exception where FDA conducts an investigation and determines the accredited third-party auditor was not at fault. 21 U.S.C. § 388(c)(6)(C).

[22] For purposes of Section 805, the term "importer" means, with respect to an article of food, either: (a) the U.S. owner or consignee of the article of food at the time of entry into the United States; or (b) if there is no U.S. owner or consignee, the U.S. agent or representative of a foreign owner or consignee at the time of entry into the United States. 21 U.S.C. § 385(a)(2).

under Section 402 or misbranded under Section 403(w) (allergen labeling). 21 U.S.C. § 385(a)(1). Section 805 will become effective 2 years after the date of enactment. FSMA, § 301(d).

1. Regulations and Guidance

Not later than 1 year after the date of enactment, FDA is required to issue regulations specifying the content of importers' Foreign Supplier Verification Programs. Such regulations shall require that an importer's Foreign Supplier Verification Program provide assurances that each foreign supplier produces the imported food in compliance with: (a) processes and procedures that provide the same level of protection as those required under Section 418 or 419, as appropriate; and (b) Section 402 and 403(w). Each importer is required to perform foreign supplier verification activities, which may include monitoring records of shipments, lot-by-lot certification, annual on-site inspections of foreign suppliers, checking the hazard analysis and prevent controls plans of foreign suppliers, and periodic sampling and testing of shipments. In addition, not later than 1 year after the date of enactment, FDA is required to issue a guidance document to assist importers in developing Foreign Supplier Verification Programs. 21 U.S.C. § 385(b), (c).

2. Recordkeeping

Each importer is required to maintain records related to its Foreign Supplier Verification Program for at least 2 years and to make them available to FDA upon request. 21 U.S.C. § 385(d).

3. List of Importers

FDA is required to maintain on its website a current list of the names, locations, and other information deemed necessary about importers that are in compliance with Section 805. 21 U.S.C. § 385(g).

4. Exemptions

Section 805 does not apply to a facility if the owner, operator, or agent in charge of the facility is subject to and is in compliance with (i) FDA seafood or juice HACCP regulations, or (ii) FDA low-acid canned foods regulations.[23] FDA is required to establish, by *Federal Register*

[23] This exemption appears to mean that an importer is not required to have a Foreign Supplier Verification Program or to conduct verification activities with respect to food imported from a foreign facility that is in compliance with FDA HACCP or low-acid canned foods regulations. For facilities in compliance with FDA's low-acid canned foods regulations, the exemption is limited to microbiological hazards. An importer is still required to have a Foreign Supplier Verification Program that addresses other (*e.g.*, chemical and physical) hazards.

notice, an exemption for articles of food imported in small quantities for research and evaluation purposes (*i.e.*, product samples) or for personal consumption, provided that such foods are not intended for resale and are not sold or distributed to the public. 21 U.S.C. § 385(e), (f).

5. Failure to Comply

Importing food, or offering food for import, if the importer does not have in place a Foreign Supplier Verification Program in compliance with Section 805 is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(zz). A food offered for import will be refused admission if it appears that the importer does not have a Foreign Supplier Verification Program. 21 U.S.C. § 381(a)(3).

B. Voluntary Qualified Importer Program (Section 302)

The FSMA adds a new Section 806 to the FD&C Act (21 U.S.C. § 386) requiring FDA to establish, in consultation with DHS, a Voluntary Qualified Importer Program to expedite movement of food through the import process.[24] Not later than 18 months after the date of enactment, FDA is required to issue a guidance document regarding participation, revocation of participation, reinstatement, and compliance with the Voluntary Qualified Importer Program.

To be eligible to participate in the Voluntary Qualified Importer Program during a given fiscal year, an importer must be importing food from a facility that has been certified by an accredited third-party auditor under Section 808 (*see* above) and such certification must accompany the imported food. An importer that wishes to participate must submit a notice and application to FDA at the time and in the manner established by FDA. In reviewing applications, FDA shall consider the risk of the food to be imported by the importer based on such factors as: the known safety risks of the food, the compliance history of the foreign suppliers used by the importer, the importer's Foreign Supplier Verification Program and food safety practices, the importer's regulatory history, the regulatory system in the country of export, the potential risk of intentional adulteration, and such other factors as FDA deems appropriate. FDA is required to reevaluate participating importers at least once every 3 years.

C. Authority to Require Import Certificates (Section 303)

FDA is authorized to require, as a condition of granting admission to an article of food imported or offered for import, that an agency or representative of the government of the country from which the food originates or an accredited third-party auditor (*see* above) provide a certification, or such other assurance as FDA deems appropriate, that the food complies with

[24] For purposes of Section 806, an "importer" is defined as "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States." 21 U.S.C. § 386(g).

FD&C Act requirements. If required, the certification may be in the form of a shipment-specific certificate, a listing of certified facilities, or such other form as FDA may specify. 21 U.S.C. § 381(q)(1), (3).

In determining whether to require such certification, FDA shall consider such factors as: the known safety risks of the food; the known safety risks of the country, territory, or region of origin of the food; and a finding by FDA that the food safety programs, systems, and standards in the country, territory, or region of origin are inadequate to ensure safety and that certification would assist FDA in making an admissibility determination. If FDA determines that the food safety programs, systems, and standards in a foreign country, territory, or region are inadequate to ensure safety, FDA is required to identify such inadequacies and establish a process whereby the foreign country, territory, or region may inform FDA of improvements to its food safety programs, systems, and standards and demonstrate their adequacy. The information submitted to FDA under such a process must be considered by FDA in determining whether to require an import certification. 21 U.S.C. § 381(q)(2), (7).

FDA may refuse to accept an import certificate if FDA determines it is not valid or reliable, and FDA may require renewal of an import certificate at any time. FDA is required to provide for electronic submission of import certificates. 21 U.S.C. § 381(q)(4), (5). An imported food that is required to have an import certificate but fails to comply shall be refused admission. 21 U.S.C. § 381(a).

D. Inspection of Foreign Food Facilities (Section 306)

See Section VI.D of this memorandum above.

E. Refusal to Permit Inspection

If the owner, operator, or agent in charge of a foreign factory, warehouse, or other establishment, or the government of a foreign country, refuses to permit entry of U.S. inspectors or other individuals duly designated by FDA to inspect such factory, warehouse, or other establishment, upon request, food from that foreign factory, warehouse, or other establishment shall be refused admission into the United States. For purposes of this provision, an owner, operator, or agent in charge will be deemed to have refused an inspection request if such person does not permit an inspection during the 24-hour period after a request is made, or after such other time period as agreed upon by FDA and the foreign factory, warehouse, or other establishment. 21 U.S.C. § 387(b).

F. Other Import Provisions

1. Prior Notice (Section 304)

The FSMA amends the FD&C Act to require that prior notice of imported foods must include "any country to which the article of food has been refused entry." 21 U.S.C. § 381(m). Not later than 120 days after the date of enactment, FDA is required to issue an interim final rule implementing this amendment. The amendment will take effect 180 days after the date of enactment. FSMA, § 304(b), (c).

2. Port Shopping (Section 115)

Until FDA issues a final rule on "port shopping," FDA is required to notify DHS of all instances in which FDA refuses admission of a food under FD&C Act Section 801(a). The purpose of this notification is to enable U.S. Customs and Border Protection to prevent food previously refused admission at one port of entry from being admitted at another port.

3. Smuggled Food (Section 309)

Not later than 180 days after the date of enactment, FDA is required to develop and implement, in coordination with DHS, a strategy to better identify smuggled food and prevent its entry.[25] Not later than 10 days after FDA identifies a smuggled food that FDA believes would cause serious adverse health consequences or death to humans or animals, FDA is required to provide a notification to DHS (in accordance with FD&C Act Section 417(n)) describing the smuggled food and, if available, the names of the individuals or entities that attempted to import it. FDA is required to promptly issue a press release and use other emergency communication networks to warn consumers and vendors if FDA identifies a smuggled food, reasonably believes it would cause serious adverse health consequences or death to humans or animals, and reasonably believes the food has entered domestic commerce and is likely to be consumed.

XIV. Whistleblower Protection (Section 402)

The FSMA adds a new Section 1012 to the FD&C Act (21 U.S.C. § 399c) that provides "whistleblower protections" to any employee of an entity engaged in the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of food. Generally, no entity involved in the food industry may discharge an employee or discriminate against an employee with regard to compensation, terms, conditions, or privileges of employment because the employee has (a) provided, caused to be provided, or is about to

[25] "Smuggled food" is broadly defined as "any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead." 21 U.S.C. § 387(e).

provide information about any violation of the FD&C Act, or any act or omission the employee reasonably believes to be a violation, to the employer, the Federal government, or a State attorney general; (b) testified or is about to testify in a proceeding about a violation; (c) assisted or participated, or is about to assist or participate, in a proceeding about a violation; or (d) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee or another person reasonably believes to be in violation of the FD&C Act. 21 U.S.C. § 399c(a). Whistleblower protections may not be waived by any agreement, policy, form, or condition of employment. 21 U.S.C. § 399c(c)(2). Section 1012 includes procedures for filing of whistleblower complaints with the Department of Labor, investigations, hearings, and adjudication.

XV. Fresh Produce Safety (Section 105)

The FSMA adds a new Section 419 to the FD&C Act (21 U.S.C. § 350h) that requires FDA to establish standards for the safe production and harvesting of fresh produce.

A. Regulations

Not later than 1 year after the date of enactment, FDA, in coordination with USDA and State departments of agriculture, is required to publish a proposed rule to establish minimum standards for the safe production and harvesting of those types of fruits and vegetables, "including specific mixes or categories of fruits and vegetables," that are raw agricultural commodities for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death.[26] Such regulations must include standards addressing soil amendments, hygiene, packaging, temperature control, animal encroachment, and water. Such regulations may not include any requirements that would cause certified organic produce to run afoul of USDA's National Organic Program. The regulations also must define the terms "small business" and "very small business" for purposes of Section 419. 21 U.S.C. § 350h(a).

Not later than 1 year after the close of the comment period for the proposed rule, FDA is required to issue a final rule. The final rule shall include a process whereby States and foreign countries may request a variance necessary in light of local growing conditions, provided the practices to be followed under the variance are reasonably likely to ensure the produce is not adulterated. 21 U.S.C. § 350h(b). FDA is directed to hold at least 3 public hearings in diverse geographical areas during the comment period on the proposed rule.

[26] FDA has already begun working on a proposed rule.

B. Flexibility for Small Businesses

In developing safe production and harvesting standards, FDA must take into account the needs of small businesses. Additional protections for small businesses include the following: (1) the regulations are required to define and have delayed implementation dates for "small businesses" and "very small businesses" (1 year and 2 years after the effective date of the final rule, respectively); (2) FDA is authorized to exempt or modify the requirements for small and very small businesses that produce and harvest fruits and vegetables that FDA has determined are low risk; (3) the regulations may not require any facility to hire a consultant or other third party to implement or certify compliance (except when required by a consent decree); and (4) FDA is required to issue a small entity compliance guide.

C. Exemptions

A farm is exempt from Section 419 during a given calendar year if: (a) during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to qualified end-users[27] exceeded the average annual monetary value of the food sold to all other buyers; and (b) the average annual monetary value of all food sold by such farm during the 3-year period was less than $500,000, adjusted for inflation. FDA may withdraw this exemption if an active investigation of a foodborne illness outbreak is directly linked to the farm or if FDA determines doing so is necessary to protect public health. An exempt farm must provide its name and business address prominently and conspicuously on the label of its packaged produce or, with respect to food not required to be labeled, on a sign, poster, placard, or documents at point of purchase (or, in the case of Internet sales, in an electronic notice). 21 U.S.C. § 350h(f).

FDA may exempt or modify the requirements of the regulations with respect to small businesses and very small businesses that produce and harvest fruits and vegetables that FDA determines are low risk. 21 U.S.C. § 350h(a)(1)(B).

Section 419 does not apply to: (a) produce produced by an individual for personal consumption; or (b) activities of a registered food facility that is subject to Section 418 (hazard analysis and preventive controls plans). 21 U.S.C. § 350h(g), (h).

D. Enforcement

FDA will contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with the regulations. 21

[27] For purposes of Section 419, the term "qualified end-user," with respect to a food, means (a) the consumer of the food; or (b) a restaurant or retail food establishment located either in the same State as the farm that produced the food or not more than 275 miles from such farm. 21 U.S.C. § 350h(f)(4)(A).

U.S.C. § 350h(d). Implementation of the regulations is required to prioritize specific fruits and vegetables that have been associated with foodborne illness outbreaks. 21 U.S.C. § 350h(a)(4).

E. Failure to Comply

Producing or harvesting fresh produce not in accordance with FDA minimum standards, or a variance, is a prohibited act, subject to injunction and criminal prosecution. 21 U.S.C. § 331(vv).

F. Good Agricultural Practices

FDA is required to publish updated Good Agricultural Practices and guidance for the safe production and harvesting of specific types of fresh produce no later than 1 year after the date of enactment. 21 U.S.C. § 350h(e). The FSMA does not specify which fruits and vegetables will be the subject of these guidance documents, but those fruits and vegetables that have been associated with foodborne disease outbreaks are likely to be addressed by FDA.

XVI. Other Provisions

A. Sanitary Transportation of Food (Section 111)

Not later than 18 months after the date of enactment of the FSMA, FDA is required to issue regulations on the sanitary transportation of food, as required by Section 416(b) of the FD&C Act. FDA is also required to conduct a study of the transportation of food for consumption in the United States, including transportation by air and an examination of the unique needs of rural and frontier areas.

B. New Dietary Ingredients (Section 113)

Not later than 180 days after the date of enactment, FDA is required to publish a guidance document clarifying when an ingredient in a dietary supplement is a new dietary ingredient requiring a new dietary ingredient (NDI) notification to FDA, the evidence of safety needed in an NDI notification, and the appropriate methods for establishing the identity of an NDI. FSMA, § 113(b).

FDA is required to notify the Drug Enforcement Administration if FDA determines that a new dietary ingredient notification is inadequate to establish the safety of a dietary supplement containing that new dietary ingredient because the new dietary ingredient may be, or may contain, an anabolic steroid or anabolic steroid analogue (*i.e.*, a substance whose chemical structure is substantially similar to that of an anabolic steroid). 21 U.S.C. § 350b(c).

C. Jurisdiction (Sections 116 and 403)

The FSMA provides that it is not intended to alter the current division of jurisdiction between FDA and USDA, nor that between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB). FSMA, § 403.

The new law also includes a limited exemption for alcoholic beverage facilities. Facilities that are required to register with FDA because they manufacture, process, pack, or hold alcoholic beverages but that are also required to obtain a permit or register with the U.S. Treasury Department under the Federal Alcohol Administration Act or the Internal Revenue Code are exempt from most provisions of the FSMA. Such alcoholic beverage facilities are exempt, for example, from the hazard analysis and preventive controls plan requirement, the new industry fees, and traceability and recordkeeping requirements. Such facilities, however, are not exempt from Sections 102, 206, 207, 302, 304, 402, 403, and 404 of the FSMA (*i.e.*,, the provisions regarding facility registration, mandatory recall, administrative detention, Voluntary Qualified Importer Program, prior notice of imports, whistleblower protection, and compliance with international agreements). This exemption includes alcoholic beverage facilities that also receive or distribute non-alcohol foods, provided such food is in a prepackaged form that prevents direct human contact with the food and constitutes no more than 5% of the overall sales of the facility. FSMA, § 116.

D. Update of Fish and Fishery Products Hazards and Control Guidance (Section 103(h))

Not later than 180 days after the date of enactment, FDA is required to update the Fish and Fisheries Products Hazards and Control Guidance, which is used by seafood processors to develop their HACCP plans, to take into account recent advances in technology.

E. Post-Harvest Processing of Raw Oysters (Section 114)

Not later than 90 days before FDA takes any action relating to post-harvest processing of raw oysters (*e.g.*, an amendment to its seafood HACCP regulations, a guidance, a suggested amendment to the National Shellfish Sanitation Program's Model Ordinance), other than the update of the Fish and Fishery Products Hazards and Control Guidance discussed above, FDA is required to issue a report to Congress that includes, among other items, the projected costs and benefits of the proposed post-harvest processing measures; the projected impact on the sales, cost, and availability of raw oysters; criteria to ensure post-harvest processing standards will be applied equally to domestic and imported raw oysters; and an evaluation of alternative measures. The Comptroller General shall review this report and report to Congress on its analysis. This requirement is waived if FDA issues a guidance that represents a consensus agreement between Federal and State regulators and the oyster industry acting through the Interstate Shellfish Sanitation Conference.

F. Compliance with International Agreements (Section 404)

The FSMA provides that it may not be construed "in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party." FSMA, § 404.

G. Foodborne Illness Surveillance (Section 205)

The Centers for Disease Control and Prevention (CDC) is required to enhance surveillance systems for foodborne illness to improve the collection, analysis, reporting, and usefulness of data on foodborne illness. CDC is required to improve surveillance by such activities as coordinating Federal, State, and local surveillance systems; by facilitating sharing of surveillance information on a more timely basis among Federal, State, and local agencies and with the public; augmenting surveillance systems to improve attribution of outbreaks to a specific food source; allowing timely public access to aggregated, de-identified surveillance data; and publishing findings at least annually. For each of fiscal years 2011 through 2015, $24 million is authorized to be appropriated for this purpose.

H. Food Allergy and Anaphylaxis Voluntary Guidelines (Section 112)

Not later than 1 year after the date of enactment, FDA, in consultation with the Department of Education, is required to develop voluntary guidelines for managing the risk of food allergy and anaphylaxis in schools and early childhood education programs. The guidelines are required to address, among other issues, strategies to reduce the risk of exposure to allergens in classrooms and cafeterias.

I. Unique Identification Numbers (Section 110)

Not later than 1 year after the date of enactment, FDA is required to conduct a study regarding the need for, and the costs and challenges associated with, a requirement that each food facility registered with FDA and each import broker have a unique identification number. FDA is required to submit a report of the study's findings to Congress not later than 15 months after the date of enactment.

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If you have any questions about the FDA Food Safety Modernization Act or this memorandum, please contact John Bode at (202) 518-6323 or jbode@ofwlaw.com, or Bob Hahn (202) 518-6388 or rhahn@ofwlaw.com.

OFW: mhh

EFFECTIVE DATES FOR KEY PROVISIONS OF FDA FOOD SAFETY MODERNIZATION ACT

SELF-IMPLEMENTING PROVISIONS

Effective Immediately Upon Enactment

- Section 101 – Inspection of Records
- Section 102 – Registration of Food Facilities
  - Requirement to register biennially
  - Additional registration information required
- Section 107 – Fees
- Section 115 – Port Shopping
  - Requirement that FDA notify DHS when FDA refuses to admit a food
- Section 116 – Alcohol-Related Facilities
- Section 201 – Inspections
  - Inspection frequency
  - Identification of high-risk facilities
- Section 206 – Mandatory Recall Authority
- Section 303 – Authority to Require Import Certifications for Food
- Section 402 – Whistleblower Protection

Effective at a Later Date

- Section 103 – Hazard Analysis and Preventive Controls Plan (18 months after date of enactment; longer for small and very small businesses)
  - Requirement of hazard analysis and preventive controls plan
  - Recordkeeping requirements
  - Requirement to reanalyze
- Section 202 – Laboratory Accreditation (2 years after date of enactment)
- Section 204 – Traceability
  - FDA pilot projects (not later than 270 days after date of enactment) and product tracing system (report to Congress 18 months after date of enactment)
- Section 211 – Consumer Notification of Reportable Foods (not more than 18 months after date of enactment)
- Section 301- Foreign Supplier Verification Program (2 years after date of enactment)
- Section 307 – Accreditation of Third-Party Auditors
  - Establishment of system (not later than 2 years after date of enactment)
  - Development of model accreditation standards (not later than 18 months after date of enactment)

PROVISIONS REQUIRING FDA RULEMAKING OR GUIDANCE TO IMPLEMENT

- Section 102 – Registration of Food Facilities
  - Suspension of registration
  - Amendment to definition of "retail food establishment"
- Section 103 – Hazard Analysis and Preventive Controls
  - Establishment of standards for hazard analysis and preventive controls
  - Exemption of certain on-farm activities
- Section 104 – Performance Standards
- Section 105 – Standards for Fresh Produce
- Section 106 – Protection Against Intentional Adulteration
- Section 111 – Sanitary Transportation of Food
- Section 113 – New Dietary Ingredients
- Section 201 – Inspections
  - Exemption or modification for on-farm operations
- Section 204 – Traceability
  - Additional recordkeeping requirements for high-risk foods
- Section 207 – Administrative Detention of Food
- Section 301 – Foreign Supplier Verification Program
- Section 302 – Voluntary Qualified Importer Program
- Section 304 – Prior Notice of Imported Food Shipments
  - Requirement to include any country in which food was refused entry
- Section 307 – Accreditation of Third-Party Auditors
  - Conflict of interest prevention
  - Fees to be paid by accredited third-party auditors