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MEMORANDUM

April 6, 2011

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FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: FDA Holds Public Meetings on Import Provisions of Food Safety Modernization Act

The Food and Drug Administration (FDA) held two public meetings this week on implementation of the import provisions of the FDA Food Safety Modernization Act (FSMA):

- A public meeting on March 29, 2011 entitled “FDA Food Safety Modernization Act Title III: New Paradigm for Importers”
- A public hearing on March 30-31, 2011 entitled “Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries”

While FDA officials offered some information about the agency’s plans for implementation of the FSMA, these meetings were mainly listening sessions in which FDA sought the views of various stakeholders. As Michael Taylor, FDA Deputy Commissioner for Foods, explained in his opening statement, of all the provisions of the FSMA, those dealing with imported foods represent the most dramatic paradigm shift. Therefore, FDA intends to move forward in an open process with input from all interested parties.

FDA has opened the following dockets related to the FSMA import provisions, and is requesting comments with the following deadlines:

<u>Topic</u>	<u>Docket No.</u>	<u>Deadline</u>
Foreign Supplier Verification Program	FDA-2011-N-0143	April 29, 2011
Voluntary Qualified Importer Program	FDA-2011-N-0144	April 29, 2011
Authority to require import certificates	FDA-2011-N-0145	April 29, 2011
Accreditation of third-party auditors	FDA-2011-N-0146	April 29, 2011

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Comparability of food safety systems FDA-2011-N-0135 June 30, 2011

The March 29th Public Meeting

The purpose of this meeting was to seek input regarding the following provisions of the FSMA: Foreign Supplier Verification Program (FSVP), Voluntary Qualified Importer Program (VQIP), FDA authority to require import certificates for foods, and accreditation of third-party auditors.

Michael Taylor opened the meeting by noting that the core principle of the FSMA is early prevention (“pushing prevention offshore”). The law’s other three principles, he noted, are the following:

- The food industry has primary responsibility for food safety
- The government’s role is to set standards and ensure a high rate of compliance with those standards
- The food safety system requires partnership between government and industry

Murray Lumpkin, Deputy Commissioner for International Programs, briefly discussed FDA’s foreign offices, which he described as FDA’s “eyes and ears” in other countries. The foreign offices work and share information with FDA’s counterpart foreign agency, engage with the regulated industry in the foreign country, engage with other U.S. agencies, and enable FDA to perform more foreign inspections. They are also a resource for food importers and exporters.

David Elder, Acting Deputy Association Commissioner for Regional Operations, stated that he is chair of FDA’s Import Implementation Team, together with vice chairs Camille Brewer and Lesley Kux. In addition, FDA has created four working groups to implement the import provisions of the FSMA:

- Import Work Group: Foreign Supplier Verification Program (led by Brian Pendleton)
- Import Work Group: Voluntary Qualified Importer Program (led by Dominic Veneziano)
- Import Work Group: Third-Party Accreditation (led by Charlotte Christin)
- Import Work Group: Import Certifications for Food (led by Michelle Twaroski)

There are also task forces dealing with implementation of other import-related provisions of the FSMA, such as smuggled foods.

The remainder of the public meeting consisted of listening sessions and breakout sessions. During the listening sessions, comments were made by invited speakers who were then asked questions by a panel of FDA officials, followed by public comments from meeting participants.

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Listening Session: Accredited Third-Party Certification

During this listening session, the following comments were made:

- Caroline Smith DeWaal of the consumer group Center for Science in the Public Interest (CSPI) stated that third-party certification should only be used for imported foods, not domestic foods. She ranked food oversight in the following order of trustworthiness: FDA inspection, inspection by another U.S. government agency, foreign government inspection, and certification by an accredited third-party auditor. She stated that safeguards against conflicts of interest should extend to consultative audits performed by accredited third-party auditors, as well as to inspections by foreign governments and other U.S. government agencies. Ms. DeWaal also expressed skepticism about consensus on the use of international standards, stating that imported food must be certified to meet “our U.S. standards.”
- Roger Muse of ACLASS Corporation, and a member of the American National Standards Institute Accreditation Services (ANSI-ASP) National Accreditation Board, stated that ANSI-ASP uses a generic third-party assessment model based on ISO standards to accredit third-party certifiers.
- Michael Robach of Cargill, and a member of the Global Food Safety Initiative (GFSI) board, said that GFSI is managed by a consortium of food companies. The GFSI benchmarking process seeks continuing improvements in food safety management systems. GFSI has a number of working groups (*e.g.*, Auditor Competence Working Group) with the common objective of providing a global framework for regulatory harmonization. GFSI has a capacity building model that can bring a company in a developing country to certification within 24 months.
- Kristian Moeller of Global Partnership for Good Agricultural Practice (GLOBAL G.A.P.), an organization that certifies farms, stated that 100,000 farms in 100 countries participate in its program, more than half of them under locally adapted guidelines (*e.g.*, China GAP). He stated that third-party certification has four pillars: certification standards (*e.g.*, Codex, ISO standards), certification rules, certification registry, and certification integrity (*i.e.*, prevention of conflicts of interest). He noted that auditor competence is addressed in ISO/IEC Handbook 65.
- Kenneth Peterson, Audit Programs Manager with the U.S. Department of Agriculture’s (USDA) Agricultural Marketing Service (AMS), noted that AMS’ Fruit and Vegetable Programs has experience conducting audits for compliance with good agricultural practices (GAPs) and other programs. He said that competent and trained auditors are essential to any audit program. He also emphasized the need to offer affordable audit services for small producers.

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- Robert Guenther of the United Fresh Produce Association noted that many fresh produce producers are vertically integrated with operations on both sides of the US-Mexican border, making any distinction between certification of domestic and foreign operations unworkable.

Listening Session: FSVP and VOIP

During this listening session, the following comments were made:

- Allison Moore of Fresh Produce Association of the Americas suggested that FDA coordinate with other governments (*e.g.*, through harmonization of standards, comparability assessments) and standardize procedures at all ports of entry.
- Andy Shiles of FedEx Express recommended that FDA expedite the import clearance process by having a centralized on-screen review team, updating agency databases faster, and standardizing procedures in all District Offices.
- Leon Bruner of the Grocery Manufacturers Association (GMA) proposed that FDA regulations build on existing international standards (*e.g.*, Codex standards, ISO standards), avoid redundancy and unnecessary complexity, allow for innovation in manufacturing and safety processes, and be practicable and cost-effective.
- Lisa Weddig of the National Fisheries Institute (NFI) proposed that the importer requirements in FDA's seafood HACCP regulations should be a model for the FSVP foreign supplier verification activities. The seafood HACCP regulations require that seafood importers maintain product specifications, perform one of several affirmative steps, and maintain records. The verification activities required of importers should allow flexibility. She noted that one step done well is sufficient to ensure safety, whereas several steps done poorly may not be.
- Bob Bauer of the Association of Food Industries (AFI) suggested that FDA be aware of the significant linkages between different provisions of the FSMA. For example, foreign supplier verification is intended to ensure that foreign food facilities implement preventive controls plans. He also recommended that foreign supplier verification be modeled on the importer requirements in FDA's seafood HACCP regulations.
- John Bode of OFW Law, commenting on behalf of the Cheese Importers Association of America, stated that foreign supplier verification should apply only to an importer's immediate foreign supplier. He also suggested that FDA use its authority to require an import certificate judiciously, only where FDA has scientific evidence that food has not been produced under preventive controls.
- Chris Waldrop of the Consumer Federation of America (CFA) said that consumer groups remain skeptical of third-party certification and hope that its use for regulatory purposes would be limited to imported foods.

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Listening Session: Perspectives of State Agencies

During this listening session, the following comments were made:

- Vance Bybee of the Oregon Department of Agriculture argued that, if FDA is concerned about the safety of foods imported from a particular country, accepting import certificates issued by that country's government does not make sense.
- Stephen Stich of New York's Department of Agriculture and Markets said he would like to see more information sharing by FDA and FDA acceptance of state lab test results.
- Marion Aller of Florida's Department of Agriculture and Consumer Services stated that states do not have the resources to address imported foods; they are busy enough with domestically produced foods.
- FDA officials asked the panel whether FDA should rely on certifications by foreign government agencies that have dual missions (*i.e.*, food safety and promotion of agribusiness). The state officials indicated that they are able to handle both missions, but always give food safety priority. Ms. Aller said that FDA may rely on certifications by foreign agencies with a dual mission, but only where the foreign government has an open, transparent program. Mr. Bybee suggested that foreign governments may be less protective of public health when issuing export certificates, because they are not protecting the health of their own citizens.
- FDA officials asked whether states would be interested in accrediting third-party auditors. Mr. Bybee indicated Oregon might be interested, but Ms. Aller said Florida would be concerned about costs and appearances.

Breakout Listening Sessions:

Import Certifications for Food

Michelle Twaroski of FDA facilitated and sought input on two topics during this breakout session:

- How the certification process should work
- Establishing an electronic certification process

Lisa Weddig of NFI suggested that the import certificate should be issued when the food is in the exporting country, not after it arrives at a U.S. port. Caroline Smith DeWaal of CSPI proposed that FDA based the submission procedures on the existing procedures for submission of prior notice

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of imported food. She also proposed that FDA conduct some verification of import certificates by checking imported foods that have been certified (or come from certified foreign facilities) when they arrive at U.S. ports. FDA officials asked how the agency can prevent fraudulent import certificates. One participant suggested placing a bar code on the import certificate that would match a bar code on the product case or other container. The bar code could also be posted on a server as an added check.

Foreign Supplier Verification Program

Brian Pendleton of FDA facilitated and sought input on four questions during this breakout session:

- Who are “importers” that must comply with the FSVP requirement?

The FSMA defines the “importer” for purposes of the FSVP requirement as the U.S. owner or consignee of the imported food at time of entry or, if none, the U.S. agent or representative of the foreign owner or consignee of the imported food at time of entry. Participants discussed the appropriateness of requiring the importer of record or the U.S. agent (as designated in the foreign supplier’s FDA food facility registration under the Bioterrorism Act) to comply as the “agent” of a foreign owner or consignee.

- How should the importer be identified?

Several participants suggested that the importer should be required to be identified in the foreign supplier’s food facility registration under the Bioterrorism Act. Others suggested that the prior notice submitted to FDA identify the importer.

- How should differences between importers and types of food be handled?

The FSMA instructs FDA, in promulgating regulations on the FSVP requirement, to “take into account” differences in risk among types of importers and types of imported food. Participants discussed how FDA should determine an imported food’s level of risk. Some suggested using third-party certification, the history of an importer or imported food, and participation in C-TPAT. There was also discussion of a possible small lot exemption from the FSVP requirement. One participant recommended that foreign supplier verification should be limited to cases of higher risk imports, such as where the imported food is subject to an FDA Import Alert.

- What verification activities should be required?

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Participants discussed whether the importer requirements under FDA's existing HACCP regulations should serve as a model for foreign supplier verification. Brian Pendleton stated that he would "have to read up on the HACCP rules" but did not reveal FDA's thinking on this point. While he suggested that the FSVP requirement should not be limited to the importer verification requirements of the HACCP regulations, he later noted positively that the HACCP importer requirements allow considerable flexibility.

Third-Party Accreditation

Charlotte Christin of FDA facilitated and focused on three topics: Conflict of Interest, Records, and Auditor Competence. During the first half of this breakout session, there was a good exchange of comments on conflict issues and record-keeping provisions. The discussion of these first two points was sufficiently active that the subject of auditor competence was never reached. The second half of the breakout session began where the first had left off, focusing on auditor competence. There was discussion of what tools are used for setting auditor competence. There was also a good discussion of the extent to which auditors are able to check all of a facility's relevant data.

Voluntary Qualified Importer Program

We were unable to attend this breakout session.

The March 30-31, 2011 Public Hearing

The purpose of this public hearing was twofold:

- o To discuss FDA's use of international comparability assessments to enhance the safety of imported food; and
- o To discuss the policies, practices, and programs that other countries use to ensure the safety of imported food

Comparability of Food Safety Systems

In his opening comments, Michael Taylor conceded that the concept of "comparability assessments" does not appear in the FSMA, but FDA sees it as an important tool and fully consistent with the FSMA. He stated that FDA has been working on a comparability assessment tool for some time. He added that FDA is keenly aware of its obligations under international trade agreements, and that comparability would not be used as a prerequisite for admission into the United States.

A draft International Comparability Assessment Tool (ICAT) was distributed at the public hearing and is attached to this memorandum. Generally, FDA will consider the food safety system of a foreign country to be "comparable" to the U.S. food safety system if, based on a complete

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assessment, FDA determines the foreign system: (1) is similar, though not identical, to the U.S. food safety system; (2) comprises elements analogous to the elements of the U.S. food safety system; and (3) is a system that provides the same level of public health protection as the U.S. food safety system.¹

Camille Brewer, chair of FDA's Comparability Work Group, moderated the public hearing. Other members of the working group include Roberta Wagner, Mike Wehr, Don Kraemer, John Sheehan, and Julie Moss.

The first day of the public hearing consisted of presentations by three panels, which were then asked questions by FDA officials, followed by public comments from participants. The three panels were:

- FSMA: Caroline Smith DeWaal of CSPI, Marsha Echols of the National Association for the Specialty Food Trade, and Mary Ann Green of the Canadian Food Inspection Agency (CFIA).
- Equivalence: Clete Willems of the Office of the U.S. Trade Representative, Mary Stanley of the USDA's Food Safety and Inspection Service (FSIS), and Karen Stuck, the U.S. Codex Manager.
- FDA Comparability Pilots: Roberta Wagner of FDA, Donald Kraemer of FDA, Julie Callahan of FDA, Bill Jolly of the New Zealand Food Safety Authority, Carlos Alvarez Antolinez of the European Commission, and Mary Ann Green.

Julie Callahan of FDA outlined the steps in the Comparability Review process:

- Pre-review meeting between FDA and the foreign inspection authority;
- Completion of the ICAT self-assessment by the foreign inspection authority;
- FDA paper review of the completed ICAT by FDA's Office of Regulatory Affairs and Center for Food Safety and Applied Nutrition's (CFSAN) Office of International Affairs;
- Bilateral meeting between FDA and the foreign inspection authority to discuss any items needing clarification; and
- FDA onsite review.

She also mentioned some lessons learned from the New Zealand pilot comparability assessment, including the following:

- Good communication throughout the process is essential;
- FDA's paper review of the ICAT should include commodity specialists;

¹ 76 Fed. Reg. 13638, 13639 (March 14, 2011).

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- FDA's onsite review team should be customized to the particular country and commodity;
- FDA should not invest the resources in conducting an onsite review unless it is highly likely the foreign country's system will be found to be comparable; and
- Prior to conducting the onsite review, FDA should provide the foreign inspection authority with a detailed list of issues and documents it will need to review.

The following questions were discussed:

- What is the difference between comparability and equivalence?

Several speakers felt there is no significant difference between comparability and equivalence. However, Don Kraemer of FDA stated that comparability assessments do not review a foreign country's food safety system in the same level of detail as equivalence determinations (*i.e.*, look at each food safety measure).

- If a foreign country's food safety system is determined to be comparable, what should be the consequences or effects of that determination?

Roberta Wagner of FDA stated that FDA may increase the number of "may proceed" notices it issues for foods imported from comparable countries. Other speakers suggested that FDA might be able to perform fewer foreign inspections in comparable countries and that FDA and the foreign inspection authority might accept or "count" each other's inspections. Bill Jolly of NZFSA stated that there must be benefits in terms of improved conditions of trade to justify the expenditure of resources. He suggested that U.S. importers should be required to perform less foreign supplier verification when importing food from foreign suppliers in a comparable country. Caroline Smith DeWaal suggested that FDA should still conduct spot checks or other verification to ensure the safety of food imports from comparable countries. She also stated that FDA may need to prioritize the foreign countries that undergo comparability assessment, because the assessment process is resource-intensive.

- Are there any data on long-term resource savings from comparability assessments?

No, however significant savings can be achieved simply by doing fewer lab tests, which are very expensive.

- If a foreign country's food safety system has not been determined to be comparable, what of a manufacturer in that country that is following state of the art food safety practices?

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In countries whose food safety systems have not been determined to be comparable to the U.S. system, manufacturers will have the option of enrolling in the Voluntary Qualified Importer Program to receive expedited clearance of their imports. Julie Callahan of FDA noted that comparability assessment will not be a prerequisite to U.S. market access, and that many countries will likely choose not to undergo a comparability assessment.

FDA officials also asked many questions of Mary Stanley about FSIS' equivalence determinations of foreign country's food safety systems for meat, poultry, and egg products, including the following questions:

- Does FSIS always conduct an onsite audit?

Yes, FSIS believes that auditing a foreign inspection system's "delivery" by means of an onsite audit is just as important as reviewing the system itself.

- How are individual establishments listed and de-listed?

The listing and de-listing of individual establishments is done by the foreign country's inspection authority. When conducting an onsite audit, FSIS is looking at how the government inspection authority does its job, not at particular establishments.

- Has FSIS every suspended or revoked an equivalence determination regarding a foreign country?

Ms. Stanley was not aware of any instances in which FSIS had suspended or revoked an equivalence determination, but it could happen. If an audit reveals problems, the foreign inspection authority is asked to take corrective actions.

- Does FSIS consider animal feed, or only slaughter and processing inspection, in making equivalence determinations?

FSIS' authority starts when animals arrive at a slaughter facility, so FSIS does not consider animal feed, but it may consult with FDA on drug residue controls.

- Should some measures (*e.g.*, labeling, maximum residue limits or MRLs) be excluded from equivalence determinations?

FSIS' regulations outline what measures should be considered in equivalence determinations.

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Import Best Practices of Foreign Countries

The second day of the public hearing consisted of presentations by two panels, which were then asked questions by FDA officials, followed by public comments from participants. The two panels were:

- Import best practices: Julie Moss of FDA, Anne Johnson of the Government Accountability Office (GAO), Renata Clarke of the U.N. Food and Agriculture Organization (FAO), Simon Smalley of the Australian Embassy, Bill Jolly of NZFSA, Marry Ann Green of CFIA, and Carlos Alvarez Antolinez of the EC.
- Capacity building: Katherine Bond of FDA, Peggy Rochette of GMA, Renata Clarke, John Lamb of Abt Associates, Inc., Marcus Sanchez-Plata of the Inter-American Institute for Cooperation on Agriculture, and Carlos Alvarez Antolinez of the EC.

Julie Moss of FDA announced that FDA is conducting a study of import best practices. The countries to be studied are those with “mature” food safety systems with which the United States has significant trade: Canada, Mexico, Ireland, the Netherlands, Israel, South Africa, New Zealand, Australia, Chile, and Japan. The study will be completed by September 2011, and FDA will issue a report on its findings. Ms. Moss also noted that the National Academies’ Institute of Medicine is conducting a study of import best practices.

Katherine Bond of FDA explained how FDA intends to implement the capacity building provisions of the FSMA (FSMA §§ 303(b), 305, and 308). FDA has created a working group on capacity building that is co-chaired by Julie Moss and Katherine Bond. The working group will assess the needs of foreign countries with a focus on prevention, sustainable programs, and metrics to link capacity building efforts with public health outcomes. It will conduct a “global landscape” review of training programs and develop a database of these programs, and enter into agreements with multilateral agencies. Other public and private capacity building efforts were also discussed including those of the Partnership Training Institute Network (PTIN), the Inter-American Institute for Cooperation on Agriculture (IICA), and the EU’s Better Training for Safer Food (BTSF) program.

The following questions were discussed:

- Do other countries require registration of food importers? Do they charge importers a registration fee and, if so, is the fee a flat, comprehensive fee or an a la carte fee (*i.e.*, a fee that varies depending upon what services are provided)?

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New Zealand requires importers to register and charges an a la carte registration fee. Australia also requires importers to register and charges fees based on the time required to perform services. Canada is moving towards registration, but each industry must agree to fees before they can be charged. For example, the seafood industry has agreed to pay a per-kilogram fee.

- When imported foods are found to be in violation, what enforcement actions are taken? Is the imported food required to be destroyed or re-exported? Is there an impact on future shipments?

In New Zealand, imported food has already entered domestic commerce by the time NZFSA learns of a violation, so the food must be destroyed or reconditioned. In Australia, imported foods are designated as either “risk foods” (test and hold) or “surveillance foods” (test and release). If a “risk food” is found to be in violation, it may be either destroyed or re-exported. If a “surveillance food” is found in violation, it is destroyed and the sampling rate for that food is increased. In Canada, violative imports are usually destroyed, but the CFIA has no authority to prevent re-exportation. In the European Union, violative foods are destroyed if they pose a health risk, and the level of controls (*e.g.*, sampling and testing) for that food is increased.

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We hope this information is helpful. If you have any questions, please contact Bob Hahn at (202) 518-6388 or rhahn@ofwlaw.com.

Attachment

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