

## **GENERAL**

### **HOW BIG A PROBLEM IS FOODBORNE ILLNESS IN THIS COUNTRY?**

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

### **WHY IS THIS LAW NEEDED?**

Foodborne illness is largely preventable if everyone in today's global food chain could be held responsible and accountable at each step for controlling hazards that can cause illness. Under the new law, FDA will now have new prevention-focused tools and a clear regulatory framework to help make substantial improvements in our approach to food safety. For example, for the first time, FDA has a legislative mandate to require comprehensive, preventive-based controls across the food supply chain. Preventive controls include steps that a food facility would take to prevent or significantly minimize the likelihood of problems occurring. The new law also significantly enhances FDA's ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year.

### **WHAT ARE THE MAJOR ELEMENTS OF THE LAW?**

The elements can be divided into five key areas:

- **Preventive controls:** For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.
- **Inspection and Compliance:** The legislation recognizes that inspection is an important means of holding industry accountable for its responsibility to produce safe food; thus, the law specifies how often FDA should inspect food producers. FDA is committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.
- **Imported Food Safety:** FDA has new tools to ensure that those imported foods meet US standards and are safe for our consumers. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety,

and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.

- **Response:** For the first time, FDA will have mandatory recall authority for all food products. FDA expects that it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.
- **Enhanced Partnerships:** The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal and foreign--to achieve our public health goals. For example, it directs FDA to improve training of state, local, territorial and tribal food safety officials.

## HOW LONG WILL IT TAKE BEFORE OUR FOOD SYSTEM IS MADE SAFER?

A long-term process will be needed to build a new food safety system based on prevention. Congress has established specific implementation dates in the legislation. Some authorities will go into effect quickly, such as mandatory recall authority, and others require FDA to prepare and issue regulations and guidance documents. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

## DOES FDA HAVE SUFFICIENT FUNDING TO IMPLEMENT THE NEW RULE?

The funding we have available through the annual budget cycle and fees impacts the number of FTEs we have and will be a factor in the way that FDA handles its significant and far-ranging activities, including the way that this legislation is implemented. For example, the inspection schedule in the legislation would increase the burden on FDA's inspection functions. Without additional funding, FDA will be challenged in implementing the legislation fully without compromising other key functions. We look forward to working with Congress and our partners to ensure that FDA is funded sufficiently to achieve our food safety and food defense goals.

## HOW WILL THIS LAW MAKE IMPORTED FOOD SAFER?

U.S. consumers enjoy the benefit of imported foods from more than 150 countries. The Food Safety Modernization Act (FSMA) gives FDA new tools to ensure that those imported foods meet US standards and are safe for US consumers. New authorities under the Act include:

- **Importer Accountability:** importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety

- **Third Party Certification:** FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards;
- **High Risk Foods:** FDA now has the authority to require that high-risk imported foods be accompanied by a credible third-party certification as a condition of admission into this country
- Additional resources are directed toward foreign inspections
- FDA now has the authority to refuse entry into the US of a food that has refused U.S. inspection.

FDA expects to hold briefings on the new legislation for its colleagues in embassies in Washington, and to brief the World Trade Organization on the new legislation.

## **HOW DOES THIS ACT CHANGE THE WAY FDA REGULATES FOODS?**

This new law puts prevention up front for FDA. For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Under the Act, implementation of mandatory preventive controls for food facilities and compliance with mandatory produce safety standards will be required. FDA is in the process of developing a proposed rule that will establish science-based minimum standards for the safe production and harvesting of fruits and vegetables and will address soil amendments, worker health and hygiene, packaging, temperature controls, water, and other issues. Food facilities will be required to implement a written preventive control plan, provide for the monitoring of the performance of those controls, and specify the corrective actions the facility will take when necessary.

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## **FEES**

### **GENERAL QUESTIONS ON FEES**

#### **IS THERE A REGISTRATION FEE REQUIRED UNDER FSMA?**

FSMA does not require a registration fee to be paid by registered facilities.

#### **WILL THERE BE A FEE ASSOCIATED WITH FDA INSPECTIONS?**

FSMA authorizes FDA to assess and collect fees related to certain domestic food facility, foreign food facility, and importer reinspections. There is no fee for an initial FDA inspection. The fee for reinspection is to cover reinspection-related costs when an initial inspection has identified certain food safety problems.

## **WILL THERE BE ANY FEES CONNECTED TO THE NEW RECALL AUTHORITY FDA NOW HAS?**

FDA has authority to assess and collect fees for food recall activities associated with a recall order when a domestic food facility or importer does not comply with such order.

## **WHAT OTHER FEES ARE OUTLINED IN THE NEW LAW?**

There are also fees that can be collected for administrative costs of the voluntary qualified importer program, for costs associated with issuing food export certifications and for costs to establish and administer the third-party accreditation program. The law requires FDA to publish a notice of any new fees in the Federal Register no later than 60 days before the start of each fiscal year.

## **HOW MUCH WILL THE FEES BE?**

That is still to be determined. FDA will publish the fees each August with the methodology used to arrive at those fees.

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## **FOREIGN FACILITY REINSPECTIONS, RECALL, AND IMPORTER REINSPECTION USER FEE RATES FOR FISCAL YEAR 2012**

### **WHAT IS FDA ANNOUNCING?**

FDA is publishing through a Federal Register Notice the fiscal year (FY) 2012 fee schedule for certain domestic and foreign facility reinspections, failure to comply with recall orders, and certain importer reinspections.

### **WHY ARE THESE FEES IMPORTANT?**

FSMA represents a critical step in strengthening the U.S. food safety system. The legislation significantly enhances FDA's ability to oversee the millions of food products coming into the United States from other countries each year. However, there are challenges in and costs associated with achieving full implementation of FSMA. The fees announced today allow FDA to recover 100% of its costs associated with certain domestic and foreign facility reinspections,

failure to comply with a recall order, and certain importer reinspections. Previously, FDA bore the burden of these costs.

## **WHO IS AFFECTED BY THESE FEES?**

Only those parties in the food and feed industry whose non-compliance results in the following activities:

- Facility reinspections – follow up inspections conducted by FDA subsequent to a previous inspection that found a violation materially related to food safety requirements. The reinspection must be conducted specifically to determine that compliance has been achieved.
- Recalls – food recall activities performed by FDA that are associated with a recall order with which a responsible party has not complied.
- Importer reinspections – follow up inspections of a food offered for import conducted by FDA subsequent to a previous inspection that found a problem materially related to food safety requirements. The reinspection must be conducted specifically to determine that compliance has been achieved.

## **WHAT ARE THE FY 2012 FEES?**

The rates are as follows: \$224 an hour if no foreign travel is required and \$335 an hour if foreign travel is required.

## **CAN SMALL BUSINESSES HAVE THEIR FEES WAIVED?**

The FY2012 fee schedule does not contain any reduced fee rate for small business. However, FDA recognizes that for some small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, and there may be unique circumstances in which some relief would be appropriate. Thus, during FY2012, FDA will consider waiving in limited cases some or all of an invoiced fee based on a severe economic hardship, the nature and extent of the underlying violation, and other relevant factors.

## **HOW IS FDA ADDRESSING THE IMPACT OF THESE FEES IN FUTURE YEARS ON SMALL BUSINESSES?**

A separate Federal Register Notice (insert link to Notice) is being issued that requests comments on the burden of the fees on small business. The notice is being published at the same time as the FY2012 fee schedule. The notice requests public input to help the agency understand what factors it should consider in developing guidelines in consideration of the burden of fees on such businesses in future years.

## **WHEN DO THE FY2012 FEES GO INTO EFFECT?**

The fees are effective October 1, 2011 through September 30, 2012

## **WHY ARE THESE FEES BEING IMPLEMENTED NOW?**

The FDA Food Safety Modernization Act (FSMA) instructs FDA to establish the fees for certain domestic and foreign facility reinspections, failure to comply with a recall order, and certain importer reinspections to be collected for each fiscal year and to publish the fees in a Federal Register notice not later than 60 days before the start of each fiscal year.

## **HOW DOES FDA PLAN TO IMPLEMENT THESE FEES?**

The responsible party will be invoiced for the direct hours spent to perform the reinspection or recall at the appropriate hourly rate. Detailed payment information will be included in the invoice.

## **HOW LONG DOES THE RESPONSIBLE PARTY HAVE TO PAY THE FEES?**

Payment must be made within 30 days of the invoice date.

## **WHAT HAPPENS IF THE RESPONSIBLE PARTY DOES NOT PAY?**

Any fee that is not paid within 30 days after it is due shall be treated as a claim of the United States government subject to provisions of subchapter II of Chapter 37 of Title 31, United States Code.

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## **INSPECTIONS AND COMPLIANCE**

### **RECORDS AND RECORDS ACCESS**

### **FSMA HAS SEVERAL PROVISIONS ON INSPECTIONS AND COMPLIANCE. WHAT WILL BE NEW?**

For the first time, FDA has been given an inspection mandate. The legislation requires inspections to be based on risk, and the frequency of inspections to increase. It calls for all high-risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that. Further, all other domestic food facilities are to be inspected within seven years of the bill's signing and then at least once every five years thereafter.

## **WHAT ABOUT INSPECTIONS OF FOREIGN FACILITIES?**

Within one year of the bill's signing, FDA is to increase inspections of foreign facilities, and then increase that number every year for five years.

## **FOR HOW LONG ARE RECORDS REQUIRED UNDER THE NEW LAW'S "HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS" PROVISION (FSMA §103/FDCA §418) REQUIRED TO BE KEPT?**

This section of the new law contains a provision (FDCA §418(g)) requiring that certain records established under that section be kept for at least 2 years.

## **WHO WILL CONDUCT THE FOREIGN INSPECTIONS? ARE THERE FEES ASSOCIATED?**

It is not possible at this time to answer the question about who will conduct foreign inspections. Under FSMA, FDA has the authority to assess and collect fees for some types of costs, such as re-inspection-related costs when an initial inspection has identified certain food safety problems. Under the law, there is no fee for the initial FDA inspection. FDA's ability to collect fees is subject to sufficient appropriations for food safety activities in a given fiscal year.

## **RECALLS**

### **UNDER FSMA, FDA NOW HAS AUTHORITY TO ORDER A MANDATORY RECALL. HOW WILL THAT WORK?**

FDA anticipates that mandatory recall authority will be used in rare instances. Companies will be provided with an opportunity for an informal hearing before an order to require recall is made.

### **WOULD A VOLUNTARY RECALL PRECLUDE AN FDA MANDATED RECALL UNDER FSMA §206/FDCA §423?**

Under FDCA §423(a), FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, FDA may proceed under the mandatory recall authority as set forth in FDCA §423.

## **WHAT IS THE STANDARD AND PROCESS FOR A MANDATORY RECALL?**

FDA's mandatory recall authority became effective when President Obama signed the FSMA into law on January 4, 2011. Section 206 of FSMA sets forth the standard for mandatory recall and procedures FDA will follow when it exercises its mandatory recall authority.

## **REGISTRATION**

### **WHEN DOES A FACILITY NEED TO START BI-ANNUAL RE-REGISTRATION IF IT IS REQUIRED TO REGISTER WITH FDA UNDER FDCA §415?**

FSMA amended FDCA §415 to provide that facilities required to register will have to re-register every 2 years, during the period beginning on October 1 and ending on December 31 in even numbered years. This will first occur in October-December 2012.

### **WHAT ARE OTHER KEY PROVISIONS RELATING TO COMPLIANCE?**

The legislation provides FDA authority to suspend a facility's registration under certain circumstances, which would prevent that facility from introducing any food into commerce in the U.S., including importing or exporting food into the U.S. It also provides more flexibility for FDA in using its administrative detention authority to keep potentially adulterated or misbranded products from entering the marketplace.

### **WHAT IS FDA'S AUTHORITY TO SUSPEND THE REGISTRATION OF A FOOD FACILITY?**

Section 415(b) of the Federal Food Drug and Cosmetic Act, as amended by the Food Safety Modernization Act Title 1, Section 102, for the first time explicitly provides FDA the authority to suspend by order the registration of a facility registered under section 415 in certain circumstances involving food manufactured, processed, packed, received or held by a registered facility that has a reasonable probability of causing serious adverse health consequences or death to humans or animals. FDA did not previously have a process for suspending the registration of a food facility in such circumstances.

### **WHEN MAY FDA SUSPEND THE REGISTRATION OF A FACILITY REGISTERED UNDER SECTION 415 OF THE FEDERAL FOOD DRUG AND COSMETIC ACT?**

If FDA determines that food manufactured, processed, packed, received, or held by a facility has reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the



registration of a facility that:

- Created, caused or was otherwise responsible for such reasonable probability; OR
- Knew of or had reason to know of such reasonable probability AND packed, received or held such food

## **WHEN ARE REGISTERED FACILITIES SUBJECT TO THE SUSPENSION OF REGISTRATION PROVISIONS?**

Registered facilities became subject to the suspension of registration provisions in section 415(b) of the Federal Food Drug and Cosmetic Act on July 3, 2011; 180 days after the date of enactment of the Food Safety Modernization Act (January 4, 2011).

## **WHAT IS THE EFFECT OF SUCH A SUSPENSION?**

If the registration of a facility is suspended, no person shall import or export food into the United States, offer to import or export food into the United States, or otherwise introduce food into interstate or intrastate commerce in the United States from such facility. This important authority will further help the FDA assure the safety and security of our nation's food supply.

## **WHO MAY ISSUE AN ORDER TO SUSPEND A FACILITY'S REGISTRATION?**

The authority to issue an order to suspend a registration or to vacate an order of suspension may not be delegated by the Secretary of Health and Human Services to any officer or employee other than the FDA Commissioner.

## **IS THERE AN OPPORTUNITY FOR A HEARING ON SUSPENSION?**

FDA will provide the registrant with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of a suspension of registration order, unless an alternate time period is agreed upon by FDA and registrant. The registrant will have opportunity for an informal hearing on actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. FDA may reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

## **WHAT HAPPENS IF IT IS DETERMINED THAT SUSPENSION REMAINS WARRANTED AFTER THE OPPORTUNITY FOR THE INFORMAL HEARING?**

FDA will require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA.

## **HOW MAY A SUSPENSION OF REGISTRATION ORDER BE VACATED?**

Upon a determination that adequate grounds do not exist to continue the suspension actions required by an order of suspension of registration, or that such actions should be modified, FDA may vacate the order and reinstate the registration of the facility subject to the order, or modify the order, as appropriate.

## **IS FDA GOING TO PROMULGATE REGULATIONS ON SUSPENSION OF REGISTRATION?**

Although FDA's authority to suspend registration under section 415(b) of the Federal Food Drug and Cosmetic Act became effective on July 3, 2011, FDA is required by section 415(b) to promulgate regulations to implement the suspension of registration provisions. Such regulations may more fully document components of the suspension of registration provisions. Registered facilities are subject to the suspension of registration provisions regardless of the status of regulations to implement section 415(b).

## **ADMINISTRATIVE DETENTION**

### **FOR ADMINISTRATIVE DETENTION, WHAT IS THE PROCESS TO DETAIN FOOD AND WHAT IF THE FOOD IS PERISHABLE AND CAN SPOIL?**

FSMA enhances FDA's administrative detention authority by authorizing FDA to administratively detain articles of food that FDA has a reason to believe may be adulterated or misbranded. FDA intends to revise its administrative detention regulations and other relevant documents to reflect this new standard.

## **TRACKING AND TRACING**

### **HOW CAN I BECOME INVOLVED IN ONE OF THE PILOT PROJECTS FOR PRODUCT TRACKING AND TRACING REQUIRED UNDER FSMA?**

The agency continues to work diligently on FSMA implementation. With respect to the provisions under Title II, Section 204, Enhancing Tracking and Tracing of Food and Recordkeeping, FDA has begun to identify mechanisms for conducting

the pilot projects with the processed food sector and the produce industry. These pilot projects will be conducted to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or reduce the impact of a foodborne illness outbreak and to address credible threats of serious adverse adverse consequences or death to humans or animals as a result of adulterated food and certain misbranded food. As soon as available, information about these pilot projects will be publicized on the FSMA website at [www.fda.gov/fsma](http://www.fda.gov/fsma).

### **CAN I MEET WITH FDA TO DEMONSTRATE THE PRODUCT TRACKING AND TRACING TECHNOLOGY THAT MY FIRM CAN OFFER?**

The data gathering process for product tracking and tracing section of FSMA has not yet begun. FDA is exploring a more efficient way than individual vendor/company meetings to gather information on the practices and technologies available to enhance product tracking and tracing. FDA will provide information on its approach on the FSMA website at [www.fda.gov/fsma](http://www.fda.gov/fsma).

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## **PREVENTION**

### **WHAT ARE PREVENTIVE CONTROLS?**

Preventive controls are scientifically- and risk based-based practices that facilities use to address hazards that their products might be exposed to. Once preventive controls are in place, facilities should monitor them to make sure they are working as they were designed.

### **WILL FACILITIES THAT MANUFACTURE, PROCESS, PACK, OR HOLD FOOD BE REQUIRED UNDER FSMA TO WRITE AND IMPLEMENT A PREVENTIVE CONTROLS PLAN?**

FDA's intention is that all covered facilities would need to develop a plan; identify the hazards, identify and implement preventive controls; and then monitor to make certain that the controls work. However, not every facility will have the same hazards or preventive controls. Each plan should be tailored to fit the facility and the risks associated with the facility's food.

**IS THIS REQUIREMENT IN THE STATUTE FOR CREATING AND IMPLEMENTING THESE PLANS EFFECTIVE NOW AND SHOULD FACILITIES CONTINUE TO FOLLOW THE CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)?**

The requirement is not effective now and will not be effective before FDA issues a final rule implementing the requirements. Firms need to continue to comply with CGMPs. Further, FDA does not anticipate that the new preventive control requirements will replace CGMPs. Rather, CGMPs will form the foundation for preventive controls.

**WILL ALL OF THE REQUIREMENTS FOR PREVENTIVE CONTROLS APPLY TO ALL FACILITIES?**

FSMA provides for exemptions or modified requirements in certain circumstances, such as when a facility is already required to comply and is in compliance with seafood or juice HACCP, or if a facility is very small. FDA will address and explain these aspects of the law as part of the rulemaking process to implement the preventive controls provision. There will be guidance and a proposed and final rule issued with ample opportunity for public comment.

**WILL FOOD IN COMPLIANCE WITH THE MANDATORY JUICE OR SEAFOOD HACCP REQUIREMENTS BE SUBJECT TO THE NEW PREVENTIVE CONTROL REQUIREMENTS FOR FACILITIES?**

No. FSMA contains an exemption for a facility with regard to food subject to and in compliance with FDA's juice or seafood HACCP regulations.

**WHAT IS THE SCOPE OF THE EXEMPTION FOR FOOD SUBJECT TO THE LOW-ACID CANNED FOODS (LACF) REGULATIONS?**

The exemption for LACF is limited to microbiological hazards. The preventive control requirements will apply as to other hazards.

**FOR MANDATORY CERTIFICATION OF HIGH RISK PRODUCTS, HOW WILL “HIGH RISK” FOODS BE DETERMINED? IS THIS BY PRODUCT OR FIRM? WHO IS TO CONDUCT THIS CERTIFICATION?**

This is a decision still to be made.

## **PRIOR TO PASSAGE OF FSMA, WERE THERE REQUIREMENTS FOR FARM INSPECTIONS?**

Prior to FSMA, FDA conducted farm inspections as part of investigations into outbreaks of foodborne illness and the associated tracebacks.

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## **PRODUCE SAFETY RULE**

### **HOW WILL FDA TAKE INTO ACCOUNT THE DIVERSITY IN FARMS, GROWING PRACTICES, COMMODITIES, ETC. IN CONDUCTING THE PRODUCE SAFETY RULEMAKING THAT IS REQUIRED BY THE NEW LAW?**

FDA recognizes the tremendous diversity in this industry, in size of operations, growing practices, growing conditions, and more. The regulations must provide for flexibility.

### **WHAT CAN FARMERS DO RIGHT NOW TO PREPARE FOR UPCOMING PRODUCE SAFETY REGULATION AND HOW WILL FDA HELP FARMERS UNDERSTAND AND COMPLY WITH THE UPCOMING REGULATION?**

While it will be some time before a regulation outlining produce safety requirements will be implemented, farmers can begin assessing their operations in terms of food safety right now. Another thing farmers can do is review FDA's "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (also known as the "Good Agricultural Practices" or "GAPs" guide).

At FDA, we have found that a very important key to compliance in any regulation, and what we think needs to happen first in implementing produce safety standards, is education and outreach. There will be considerable effort to develop standardized training programs to help farmers reach the standards FDA will be looking for in the growing and harvesting of produce.

### **HOW WILL FARMERS GET THIS INFORMATION?**

There will be considerable outreach to help producers implement upcoming produce safety standards. FDA is actively working with USDA's Agricultural Marketing Service and Cornell University in a cooperative effort called the Produce Safety Alliance that you'll be hearing a lot about in the months to come. We will consider collaboration and input from our stakeholders, including academia, industry, and consumers, as an integral part of the success in

putting together a meaningful education campaign in this area and ensuring understanding of and compliance with the regulations that will be issued.

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## **IMPORTS**

### **GENERAL INFORMATION ON IMPORTS**

#### **WHAT ARE THE KEY AREAS THAT THE IMPORTER WILL NOTICE THAT WILL BE DIFFERENT UNDER FSMA?**

For the first time, importers will be specifically required to have a program to verify that the food products they are bringing into this country are safe. Among other things, importers will need to verify that their suppliers are in compliance with reasonably appropriate risk-based preventive controls that provide the same level of public health protection as those required under FSMA.

#### **IF A FOREIGN FIRM IS ALREADY REGISTERED IN THE U. S. WILL IT NEED TO RE-REGISTER?**

Under FSMA, all food facilities that are required to register will now need to submit a biennial renewal registration. However, an abbreviated registration process will be available for firms that are already registered, if their registration information has not changed.

### **FOREIGN SUPPLIER VERIFICATION PROGRAM**

#### **WHAT IS THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) AND HOW WILL IT WORK?**

The FSVP requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable.

## **WHO IS SUBJECT TO THE FOREIGN SUPPLIER VERIFICATION PROGRAM?**

When the foreign supplier verification program's requirements take effect, they will apply to all importers, unless there's an exemption. The law defines "importer" as: (A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or (B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

## **WHAT FOOD DOES THE PROGRAM'S REQUIREMENTS APPLY TO?**

The requirements of the foreign supplier verification program will apply to all food imported by the importer or agent of the importer, unless there's an exemption.

## **ARE ANY COMPANIES EXEMPT FROM THIS REQUIREMENT?**

The requirements do not apply to a facility if the owner, operator, or agent in charge is subject to, and in compliance with FDA's seafood, juice, or low-acid canned food products requirements. The exemption relating to low-acid canned food applies only with respect to microbiological hazards. The statute also directs FDA to exempt, by notice in the Federal Register, food imported into the United States in small quantities for research and evaluation purposes or for personal consumption. The statute further directs FDA to issue implementing regulations and guidance on FSVPs.

## **IS THERE AN EXEMPTION FOR SMALL RESEARCH QUANTITIES?**

The law contains an exemption for food imported in small quantities for research and evaluations purposes, provided the food is not intended for retail sale and not sold or distributed to the public.

## **CERTIFICATION**

### **WHAT IS THE RELATIONSHIP BETWEEN THE CERTIFICATION PROGRAM AND THE FOREIGN SUPPLIER VERIFICATION PROGRAM?**

"Certification" differs from the "foreign supplier verification program." Foreign supplier verification is a general requirement applicable to all food importers, unless there's an exemption. In contrast, certification is only required in those situations where FDA requires certification. FDA must base its decision to require certification on the risk of the food, including taking into account certain factors specified in the law.

## **AUDITS**

### **HOW WILL THE THIRD-PARTY AUDITOR ACCREDITATION PROGRAM WORK?**

Section 307 directs FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to, among other things, issue certifications for purposes of the import certification for food. The statute directs FDA to issue implementing regulations, including provisions on conflicts of interest, financial ties, and unannounced audits, as well as model accreditation standards, including requirements for regulatory audit reports.

### **IS THE ACCREDITED AUDITOR REQUIRED TO NOTIFY THE FDA IF A CONDITION OF CONCERN IS FOUND DURING A CONSULTATIVE AUDIT?**

The law requires that during an audit, an accredited third-party auditor or audit agent of such auditors must immediately notify FDA if they discover a condition that could cause or contribute to a serious risk to the public health.

### **WILL AUDITORS HAVE TO SUBMIT THEIR AUDIT REPORTS TO FDA?**

An accredited third-party auditor or audit agent of such auditor will need to prepare an audit report for each audit conducted. In the case of a regulatory audit, which the law distinguishes from consultative audits, it must submit the report to FDA. The law also has a provision whereby FDA may require the submission of certain reports from a regulatory audit and can access the results of a consultative audit in accordance with its records access authority under another provision of the Federal Food, Drug, and Cosmetic Act.

### **CAN A FOREIGN GOVERNMENT SERVE AS A THIRD-PARTY AUDITOR?**

Foreign cooperatives and governments agencies are eligible for accreditation as third-party auditors.

### **WHAT IS THE VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP) AND WON'T THIS FORCE FDA TO RELY HEAVILY ON INSPECTIONS BY FOREIGN GOVERNMENTS?**

Section 302 of the statute requires FDA to establish a voluntary, user-fee funded voluntary qualified importer program (VQIP) to expedite entry into the United States of imported food from eligible, qualified importers. To be eligible to participate in VQIP, an importer must offer food for importation from a facility that has a certification by an accredited third party. FDA will qualify eligible importers to participate in VQIP based on risk considerations. The new law directs FDA to issue guidance on participation in and compliance with VQIP.



## **THERE ARE ISO STANDARDS FOR INSPECTION AND ACCREDITATION BODIES. WILL FDA ALLOW COUNTRIES THAT ADHERE TO THESE STANDARDS AUTOMATIC RECOGNITION UNDER THE ACCREDITATION AND CERTIFICATION PROVISIONS?**

In developing the model standards under the third party auditory accreditation program, there is explicit language in the law that FDA must look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs. FDA will continue to consider international standards and leverage with accreditation bodies in developing these standards.

## **WILL THERE BE IMPORT CERTIFICATION REQUIRED FOR HIGH-RISK FOODS?**

FDA is now working on determining how to define and identify high-risk foods.

## **DOES FDA HAVE NEW COMPLIANCE TOOLS FOR IMPORTS?**

Yes. First, we will increase the number of foreign inspections we do. FDA can deny entry to an import if a foreign facility refuses an FDA inspection it can require certification for high-risk foods; and prior notice submissions will need to include, as an additional element, any country to which the food has been refused entry.

## **ACCREDITATION**

### **WILL IN-HOUSE LABORATORIES (SET UP BY A COMPANY FOR THE TESTING OF ITS OWN FOODS) BE ELIGIBLE FOR LABORATORY ACCREDITATION PER FSMA?**

Valid analytical results are essential to make informed decisions that impact public health. At its heart, laboratory accreditation is about laboratories' consistently producing valid results by focusing on assuring 1) management requirements for the operation and effectiveness of the quality management system within the laboratory and 2) technical requirements that address the correctness and reliability of the tests and calibrations performed in laboratory. FDA supports laboratories' interests in pursuing accreditation but FDA has not yet fully developed its thinking or rulemaking with regard to FSMA implementation so any interpretations of requirements are premature at this time.

## **SMUGGLED FOOD**

### **WILL FDA BE TARGETING ALL SMUGGLED FOOD, INCLUDING THOSE FOODS TRANSPORTED IN LUGGAGE FOR PERSONAL USE?**

Section 309 of FSMA defines smuggled food as “any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.” While this could be interpreted to apply to a single undeclared low risk food item carried in personal luggage, FDA and DHS will focus resources on imported food that poses the greatest risk to public health.

### **HOW WILL FDA NOTIFY THE PUBLIC OF POTENTIALLY DANGEROUS SMUGGLED FOOD?**

FSMA provides for public notifications of harmful and dangerous smuggled food “reasonably believe[d] to [have] entered domestic commerce” and “likely to be consumed”. FDA intends to issue a press release and use other appropriate emergency communications or recall networks in order to warn consumers, distributors, and vendors about the threat.

### **HOW WILL FDA EVALUATE THE IMPACT OF THIS STRATEGY?**

FDA and CBP will measure the number of food import examinations targeted to alert for smuggled food against the number of shipments where food smuggling is actually discovered and acted upon. Outcomes will be measured according to metrics developed under the strategy at regular intervals and any adjustments to strategy will be made after consideration of these results.

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## **SCOPE**

### **DO ALL SECTIONS OF THE LAW APPLY TO PET FOOD AS WELL?**

Yes. However, FDA is expressly authorized to modify the preventive controls requirements for facilities that are solely engaged in the production of animal foods or to exempt those facilities entirely from the preventive controls requirements. FDA would need to promulgate a regulation to accomplish such a modification or exemption.

### **DOES THE LEGISLATION APPLY TO RESTAURANTS AND FOOD RETAILERS?**

Some but not all provisions of the law exclude restaurants and food retailers.

For example, restaurants and retail food establishments are not required to register with FDA, so they are not subject to requirements for registered facilities, such as preventive controls. Other provisions could apply to restaurants and food retailers, such as the foreign supplier verification program, which applies to importers.

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## **FEDERAL/STATE INTEGRATION**

### **DOES FSMA CHANGE ANY OF THE AUTHORITIES OVER FOOD SAFETY CURRENTLY DIVIDED BETWEEN FDA AND USDA?**

No. However, FSMA does provide for FDA and USDA and other federal and state/local food safety agencies to work together more closely.

### **HOW WILL STATE, LOCAL, TRIBAL AND TERRITORIAL AGENCIES PROVIDE INPUT INTO THE SECTIONS OF FSMA DEDICATED TO ENHANCED PARTNERSHIPS?**

Individuals from States, localities, tribes, and territories as well as affiliated organizations will have the opportunity to provide input through a series of project teams. One of the primary methods of input is through the Partnership for Food Protection (PFP). The PFP is a group of dedicated workers from Federal, State, and local governments with roles in protecting the food supply and public health. The PFP workgroups were formed following 50-state workshops in 2008 and 2010 and are working directly with members of FDA to improve food safety at all levels of government.

### **HOW WILL FSMA SUPPORT THE VISION OF AN INTEGRATED FOOD SAFETY SYSTEM (IFSS)?**

FSMA calls for enhanced partnerships and integration with our Federal, State, local, tribal and territorial partners. The Partnership for Food Protection (PFP), of which FDA is a member, has been working to develop an integrated food safety system with strengthened inspection, laboratory, and response capacity. The Federal-State Integration team has been and will continue working closely with State, local, tribal, and territorial partners to develop and implement the IFSS. Examples of current ongoing activities include efforts to standardize training and expertise levels of inspectors. Another example of integration is the effort to develop national standards for federal, state, and

local laboratories. These national standards, including laboratory accreditation, will increase the efficiency of the laboratories in responding to outbreaks and facilitate the rapid acceptance of lab analytical data for regulatory actions. The efforts of the PFP workgroups together with the agency's implementation of provisions of FSMA that support enhanced partnerships will further develop the IFSS. To access the full vision document for the IFSS, go to <http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/UCM183650.pdf>.

**WITH THE CURRENT FINANCIAL STATE OF MANY STATE AND LOCAL HEALTH AGENCIES, HOW WILL STATE AND LOCAL GOVERNMENTS BE ABLE TO ASSIST FDA IN IMPLEMENTING NEW PROVISIONS OF FSMA, SUCH AS THE INCREASED INSPECTION MANDATE?**

FSMA is one of the top priorities in FDA at this time. The Federal-State Integration team is working to determine funding mechanisms and provide other types of support, such as training, to our State and local partners. FSMA created mechanisms for providing necessary funds to our regulatory partners to support enhanced food safety efforts, and FDA is diligently evaluating the implementation of those sections of the legislation to ensure that States and local governments are funded adequately to help implement FSMA.

**WHEN I THINK OF THE FOOD SAFETY MODERNIZATION ACT, I ONLY THINK OF FOOD THAT PEOPLE CONSUME. WHAT IS THE FEDERAL-STATE INTEGRATION TEAM DOING ABOUT FOOD FOR ANIMALS?**

The Federal-State Integration team realizes the importance of improving animal food regulations and standards along with human food. The Federal-State Integration team has members from the Center of Veterinary Medicine at FDA and is partnering with organizations such as the Association of American Feed Control Officials to ensure that food for animals is safe.

**CONSIDERING THE LARGE TASK AT HAND, IS THE FEDERAL-STATE INTEGRATION TEAM GOING TO PARTNER WITH ANYONE ELSE TO HELP THEM IMPLEMENT FSMA?**

The Federal-State Integration team has engaged various associations and State, local, territorial, and tribal agencies in its implementation efforts. The Federal-State Integration team is also partnering with other Federal agencies, including the Center for Disease Control (CDC), the Department of Agriculture (USDA), and the Department of Homeland Security (DHS) to improve foodborne illness outbreak response across the nation.

## **WORLD TRADE ORGANIZATION (WTO)**

### **HAS THE FSMA BEEN NOTIFIED TO THE WTO? WHEN WAS IT OR WILL IT BE NOTIFIED?**

The FDA Food Safety Modernization Act was published by the Secretariat as WTO notification G/SPS/N/USA/2156 on February 14, 2011. Please see the corresponding addendum dated March 2, 2011, G/SPS/N/USA/2156/Add.1 for an internet link to the United States official public law version of the text. FDA welcomes any comments or inquiries for this notification sent to the email address: [FSMAWTO@fda.hhs.gov](mailto:FSMAWTO@fda.hhs.gov).

### **WOULD ANY PROVISIONS OF THE LAW BE CONSIDERED "SANITARY AND PHYTOSANITARY (SPS) PROVISIONS" UNDER THE WTO SPS AGREEMENT?**

The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures provides that "any measure applied . . . to protect human . . . life or health . . . from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods [or] beverages . . . " is an SPS measure. Because the U.S. Congress and President approved FSMA with public health protection and food safety objectives in mind, the United States has notified FSMA to the WTO SPS Committee to allow for comprehensive review by our trading partners. As implementing regulations are drafted that have the potential to impact international trade, FDA will notify them to the WTO pursuant to our transparency obligations under the SPS agreement in order to allow for Members' review and comment.

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## **MORE ON DOCKETS, GUIDANCE, LAWS, AND REGULATIONS**

### **HOW DO LAWS, REGULATIONS, AND GUIDANCE DOCUMENTS DIFFER?**

- FDA is ruled by a set of laws and routinely issues regulations and guidance documents.
- The Federal Food, Drug, and Cosmetic Act (FD&C Act) is a federal law enacted by Congress. It and other federal laws (such as the Family Smoking Prevention and Tobacco Control Act) establish the legal framework within which FDA operates.
- FDA develops regulations based on the laws set forth in the FD&C Act or

other laws under which FDA operates. FDA follows the procedures required by the Administrative Procedure Act to issue regulations. This typically involves "notice and comment rulemaking" process for public input on a proposed regulation before issuing a final regulation. FDA regulations are also federal laws, but they are not part of the FD&C Act.

- FDA follows the procedures required by its "Good Guidance Practice" regulation to issue FDA guidance. FDA guidance describes the agency's current thinking on a regulatory issue. Guidance is not legally binding on the public or FDA.

## **WHAT IS A DOCKET?**

A docket is a collection of documents, often available for public review, that stores information related to a rulemaking or other action. The docket folder may contain:

- One or more Federal Register documents (rules and notices)
- Materials specifically referenced in those documents
- Public comments
- Applications, petitions or adjudication documents
- Other documents used by decision makers

## **HOW DO I LOCATE A DOCKET?**

Log on to [www.regulations.gov](http://www.regulations.gov) When entering your search terms on the Regulations.gov homepage, check the box in the search area that reads, "Open for comment." This selection will bring back only items that are accepting comments. Once your search results come back, you can narrow them by using the filters at the top of the screen. To limit your results to proposed rules and notices only, check the boxes by these items.