
FSMA: New Requirements for Importers
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Who I Am

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- 20+ years experience successfully facilitating cross-border food trade
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FSMA : New Requirements for Importers-Agenda

Agenda

- ***New importer responsibilities for policing foreign supply chain***
  - Foreign Supplier Verification Program-Section 301
  - Additional Certification for High Risk Foods -Section 303
  - Voluntary Qualified Importer Program-Section 302
- ***Foreign Facilities Inspections***
- ***Spice Import Issues***

FSMA-New Paradigm for Importers

Statement by Michael R. Taylor, Deputy Commissioner for Foods, FDA, on February 17, 2011 entitled: The FDA Food Safety Modernization Act: A New Paradigm for Importers

Tough talk from FDA on New Importer Responsibilities:

- "Importers will, for the first time, have a clearly defined responsibility and accountability for the safety of the food they bring into our country. The new importer accountability provisions require importers to implement a foreign supplier verification program. They will need to provide adequate assurance that imported foods have been produced under appropriate risk-based preventive. . ."
- "This clarification and strengthening of the importer's responsibility for food safety is the centerpiece of the new law's import safety reform, …"
- "Think of it as supply chain management written into law."

FSMA-Foreign Supplier Verification Program

***Section 301-Foreign Supplier Verification Program-Verbatim-Responsibility of Importer*:**

- "Verification activities … **may** include … annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier…"
- "Verification activities … **may** include monitoring records for shipment, lot-by-lot certification of compliance … and periodically testing and sampling shipment."
- "Each importer **shall** perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported … into the United States is as safe as food produced and sold within the United States"
- "Records … **shall** be maintained for a period of not less than 2 years and shall be made available promptly to (the FDA) upon request."

FSMA-Foreign Supplier Verification Program

Section 301-Foreign Supplier Verification Program

Role of "Food Safety Plans"

- Section 103 requires that every facility identify hazards and mitigations-this document is referred to as a"food safety plan"
- Envisioned that importer will have suite of documents (food safety plans) on record for its foreign supply chain.
- Foreign supply chain presumably includes all registered facilities in supply chain (meaning the entire foreign supply chain but not including "farms", which are not required to register under BTA—unless produce) with some clarification from FDA needed
- No requirement that food safety plans be audited.
- If FDA inspects (or if outbreak incident) importer will need to be able to produce food safety plans for foreign supply chain.

FSMA-Foreign Supplier Verification Program

Section 301-Foreign Supplier Verification Program

Role of "Food Safety Plans"

Open questions:

- How far back in supply chain will importer have to provide assurances: FSMA language "produced in compliance with" preventive control requirements of section 103
- What will constitute "risk-based foreign supplier verification activities" required of importer: different for different products based on risk?

FSMA-Foreign Supplier Verification Program

Timing of Implementation of Section 301 Requiring Foreign Supplier Verification by Importer

- Under FSMA foreign supplier verification program requirements become effective 2 years from date of enactment (January 4, 2011). Final Regulation due 1/4/2013 . Not out of compliance yet, but soon.
- "We will place a high priority on implementing the import provisions of the law and the produce safety and preventive controls provisions with which they intersect."
- Therefore, importers have 15 months and counting to develop a way of verifying that their supply chains are using preventive controls at each link. Importers will have to be able to provide assurances through records upon audit by FDA.

FSMA- Additional High Risk Import Certification

FDA has the authority to require additional import certification for high risk foods

- Under Section 303 of FSMA, FDA has discretion to require import certifications for food (in addition to foreign supplier verification)
- FDA has the authority to make the additional requirement (which is in addition to the requirements of the FSVP program requirements) when FDA determines that the higher risk of the good justifies the additional certification.
- FDA has almost total discretion in determining risk based on region of origin, type of food, food safety program of foreign government or other information.
- Certification may be by foreign government or accredited entity, but is at FDA specification.
- So far, FDA appears to intend to use this authority judiciously.

FSMA-Voluntary Qualified Importer Program

FDA required to establish voluntary "fast lane" program for importers

- Under Section 302 of FSMA, FDA is required to develop a program allowing importers to receive expedited review and importation in exchange for participation in voluntary program
- Eligibility must be based on risk, based on such factors as : safety risk of food, compliance history of foreign suppliers, regulatory system of foreign country, recordkeeping and audits, and any other appropriate
- FDA has indicated it intends to charge fees for participation in VQIP
- FDA has not yet fleshed out this program, including benefits of participation, requirements, amount of fee.
- Law says 18 months, but this guidance and regulation on a slower track.

FSMA-Definition of Importer

Definition of Importer

- Importer is the US owner or consignee of the article of food at the time of entry.
- If no owner or consignee, the importer is deemed to be the US agent or representative of a foreign owner or consignee at the time of entry.
- For purposes of assessing re-inspection fees, the FDA has announced it will bill the US agent (as included in BTA registration)
- VQIP definition differs " brings the food or causes food to be brought"

FSMA-Role of Third-Party Auditors

Role of Third-Party Auditors

- "Some importing firms have integrated robust food safety verification procedures into their supply chain management systems and will likely be able to fulfill their verification responsibility on their own. Others have not and may want to rely in whole or in part on the certifications of third-party auditors."

- FSMA authorizes use of accredited third party auditors (private or foreign government) for certifications required under FSMA. Certification are required for high risk foods and the Voluntary Qualified Importer Program (VQIP). (Use of third parties not permitted for other than import supply chain.)

FSMA-Role of Third-Party Auditors

Role of Third-Party Auditors

Open questions:

- Will FDA directly accredit third parties or establish a system for the accreditation of third party auditors?
- Will FDA recognize widely and internationally used food safety standards and programs such as global GAPs, GFSI, etc.
- FDA may directly accredit third-party auditors after 2 years if FDA has not yet recognized an accreditation body to do so

FSMA-Role of Third-Party Auditors-Foreign Governments

Foreign Governments as Third-Party Auditors

- FSMA allows FDA to designate foreign governments as third party auditors for foreign supply chain
- This will be tricky political issue- possible that wealthier countries will have better food safety systems, depending on product
- No matter who audits, importer will be required to have audited food safety plans on record for supply chain
- FDA could recognize a foreign government as an accrediting body for third party auditors

FSMA-Foreign Governments' Food Safety Systems Recognized

FDA Considering Recognizing Food Safety Systems of Foreign Governments as "Comparable"

- As a (very) long term effort, FDA is working on "comparability" determination for foreign governments akin to "equivalency" by FSIS on food safety
- FDA has conducted pilots with New Zealand and EU for determining if the entire food safety system (or for a particular product/commodity) could be determined as recognized
- If FDA were able to recognize some foreign governments as comparable imports from these countries would enter with minimal scrutiny or be exempt as extremely low risk

FSMA-Foreign Supplier Verification Program -Penalties

Penalties if importer does not have foreign supplier verification program in place

- FSMA gives FDA the authority to enjoin (stop the business activity) of the importer if does not have foreign supplier verification program giving assurances for supply chain.
- FSMA requires that all facilities, including importers, in supply chain be registered in order to do business. Registration can be suspended if record access denied or importer creates " a reasonable probability" of "causing serious adverse health consequences."

FSMA-Prior Notice for Imports

Prior Notice for Imports

- Under FSMA required to report if import has been rejected previously at another port, even if foreign (already enacted)
- For example, rejected at Vancouver must be reported in Seattle
- How much due diligence/remains to be seen

FSMA-Smuggling of Imports

Smuggling of imports

- Fraudulent means or “intend to mislead” (opens to broad interpretation)
- How distinguish paperwork mistake (not violation) versus intentionally misleading
- Guidance needed

FSMA-Registration Requirements

Food Facility Registration Under FSMA

- All facilities required to be registered under BTA, but under FSMA used as enforcement tool
- If non-compliance, registration suspended and no shipments
- Includes importers and foreign facilities, but not farms
- FDA considering inclusion of farms
- If foreign facility loses registration, process for reinstatement could be lengthy (if requires foreign inspection/travel)

FSMA-Foreign Facility Inspections

Foreign Facility Inspections

- FSMA requires 600 in 2011 up to 9,200 in 2015 (compare to only 106 in 2010)
- “Facilities” under BTA (i.e., not farms) (but change under consideration by FDA)
- FDA has authority to inspect prior to FSMA but now foreign facility inspections will increase, acting as check on importer records/food safety plans
- Inspection/OAI warning letter and re-inspection: wait time for re-inspection likely lengthy for foreign facilities

FSMA Re-Inspection Fees

FDA now assessing re-inspection fees on importers for :

- Getting off detention and import alerts
- Re-inspection of food facility (including foreign facility) after warning letter of Official Action Indicated (OAI) based on material food safety issue (includes travel at $325/hour for foreign travel)
- Non-compliance with FDA when FDA orders a recall
- Consider time frame between OAI and re-inspection
- Assessed on “US agent” in registration-need to check your registrations to be sure you are not inappropriately listed as “US agent”

FSMA-Spice Import Issues

FSMA Scope/ Product Coverage

In other FSMA product contexts, FDA has indicated that the following may be out of scope and exempt from FSMA:

- Produce destined for "kill step" processing (e.g., LACF, acidified)
- Agronomic crops (e.g., grain, canola, cocoa, cottonseed, flaxseed, legumes, rice, soybean, sugar beets)

Open Question

- Will dried spices (similar to fresh produce) destined for "kill step" processing be exempt from FSMA?
- In general, will determinations under BTA for registration apply under FSMA (under BTA, dehydration is NOT processing and farm that dehydrates does not have to register)?

FSMA-International Agreement Obligations

FDA must not violate US international agreements when implementing FSMA

- As for any federal law, and as explicitly stated in FSMA, FSMA must be implemented in accordance with US international obligations, including those in NAFTA and WTO
- The law and the implementation cannot be discriminatory between imports and domestic; therefore, fees cannot be unjustifiably higher on imports; standards cannot be a disguised way of keeping imports out, etc
- Under WTO, sanitary and phyto sanitary agreement, FDA cannot require an imported product to meet exactly the same standard as the domestic product-only that foreign standard provide same level of food safety protection for consumer
- In addition, FDA must keep in mind that any restriction the US puts on imports our trading partners may impose on US exports

Conclusion

- New requirements are a paradigm shift
- FDA has made significant progress in implementing import provisions of FSMA
- FDA has a long way to go
- FDA has made implementing import provisions a priority and will move forward
- Companies can get started now on food safety plans and record-keeping
- Foreign Supplier Verification Program implementation: 9 months down; 15 months to go … (effective even without regulation or guidance)

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