Hogan Lovells

The FDA Food Safety Modernization Act: Where Are We in the Process?

Presentation for the American Spice Trade Association

Veronica Colas, Associate

October 16, 2013

Agenda

- Overview
- Key Issues in the Proposed Rules
- Where Are We in the Process?

FDA Food Safety Modernization Act

- Signed into law January 4, 2011
- Requires FDA to publish 7 proposed rules
  - 4 have been published
    - Preventive Controls for Human Food
    - Produce Safety
    - Foreign Supplier Verification Programs (FSVP)
    - Accreditation of Third-Party Auditors
  - 3 more are coming
    - Preventive Controls for Animal Feed
    - Intentional Adulteration (i.e., Food Defense)
    - Sanitary Transportation of Food and Feed

Rulemaking Process

- Pre-rulemaking
- Drafting of Proposed Rule
- HHS/OMB Review and Approval
- Publication of Proposed Rule
- **Public Comment Period**
- Consideration of Public Comments and Preparation of Final Rule
- HHS/OMB Review and Approval
- Publication of Final Rule
- Implementation

Where Are We in the Process?

- Comments on preventive controls and produce safety proposed rules due November 15
  - Comment period has already been extended twice
- ASTA has prepared comments on the preventive controls proposed rule
- Comments on import proposed rules due November 26

Preventive Controls for Human Food – Key Issues for Comments

1. Hazard Analysis and Preventive Controls
   - FDA tried to retrofit the regulations into a strict HACCP model
   - FSMA is broader than HACCP and the regulation should reflect added flexibility
2. Testing
   - Facility must verify preventive controls are effective
   - Proposed rule does not require testing…but testing likely to be a component of the final requirements
   - Issues surround relative emphasis on environmental, raw ingredient, or finished product testing; and need for flexibility, depending on product type

Preventive Controls for Human Food – Key Issues for Comments

4. Supplier Verification
   - FSMA identifies supplier verification as a preventive control
   - Not in proposed rule…but likely to be in the final rule
   - FDA has stated intent to make verification requirements equivalent for domestic and foreign suppliers
5. Records Issues
   - 6 months on-site
   - Part 11 electronic recordkeeping requirements
   - Facility profiles
   - Remote records access

Produce Safety

- Safety standards for raw agricultural commodities
- Generally, more like cGMPs than HACCP in that FDA has identified the relevant hazards
- Exemptions for produce subject to a kill step and produce rarely consumed raw
- Key issues are testing for agricultural water and agricultural water standard
- Affects growers of produce that will be dried to make spices
  - Drying process triggers additional requirements

FSVP Proposed Rule: Overview

- FDA proposes to require that all importers establish and follow an FSVP, unless exempted
- Importers would need to verify that their suppliers are meeting the same U.S. safety standards required of domestic producers (or meet the “same level of public health protection”)
- FDA intends to apply the same rules domestically under the supplier verification requirements of the preventive controls rule

Definition of Importer – Who is Subject to FSVP?

- U.S. Owner: the person in the U.S. who has purchased an article of food that is offered for entry
- U.S. Consignee: if the article of food has not been sold at the time of U.S. entry, the person in the U.S. to whom the article has been consigned at the time of entry
- U.S. Agent/Representative: if there is no U.S. owner or consignee, the U.S. agent or representative of the foreign owner or consignee at the time of entry

Requirements for Importers – Key Issues

- Compliance Check: Importers would be required to review the FDA compliance status of foods and foreign suppliers
  - Warning Letters
  - Import Alerts
  - Mandatory import certification orders
- Written List of Suppliers: Importers would need to maintain a written list of foreign suppliers

Verification Activities

1. Hazards Controlled by Importer
   - Importer would need to document control at least annually
2. Hazard Controlled by Importer's Customer
   - Importer would need to obtain written assurance, at least annually, from its customer is controlling the hazard

- If either of these criteria met (i.e., the foreign supplier is not responsible for controlling the hazard), the importer would not need to conduct verification activities

Verification Activities

3. Hazards Controlled or Verified by the Foreign Supplier
   - FDA presents two alternative co-proposals for verification activities for hazards that are controlled, or for which control is verified by, the importer's foreign suppliers
     - Option 1: prescriptive requirements depending on hazard
     - Option 2: flexible requirements for all hazards

Verification Activities

Option 1 – *prescriptive* requirements depending on hazard

- Mandatory initial and annual audit for categories of foods with hazards presenting the highest risks (SAHCODHA/Class I recall standard)
- For *other* hazards, a "menu" of verification options

Option 2 – *flexible* requirements for all hazards

- For *all* hazards, a "menu" of verification options

Verification Activities

- FDA provides a “menu” of verification activities for importers to choose from:
  - Periodic on-site auditing (no frequency specified)
  - Periodic sampling and testing
  - Review of foreign supplier’s food safety records
  - Any other procedure established to be appropriate
- Importer would need to consider risks, probability of harm, and compliance status when identifying appropriate verification activities and frequency

Verification Activities

- On-site Audits
  - Could be conducted by importer or a third party
  - Under either option, FDA proposes that instead of an on-site audit, an importer may rely on the results of a governmental inspection of the supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or determined to be equivalent to that of the U.S.
    - Inspection must have been within 1 year of the date the on-site audit would have been required to be conducted

FSVP Recordkeeping

- FDA would have access to FSVP records
- FDA would likely view records access as extending to on-site audit reports
- FDA proposes to give itself remote access to records
  - If requested in writing by FDA, importer would be required to send records to agency electronically
- Records must be kept in English

Modified Requirements for Importation from Comparable or Equivalent Country

- FDA proposes to apply modified FSVP requirements for importation of food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable/equivalent to that of the U.S.
  - FDA is authorized under FSMA to recognize foreign governments that provide “comparable” level of food safety oversight
  - Currently, only New Zealand has received this designation

Compliance Date

- Rule would become effective 60 days after publication of final rule in *Federal Register*
- FDA would provide additional time before importers must come into compliance
  - No compliance dates less than 18 months after publication of final FSVP rule

Accreditation of 3rd Party Auditors: Overview

- Certification would be *required* for:
  - Mandatory Import Certification (MIC) under FSMA 303 (i.e., high risk food for import as determined by FDA where foreign regulatory system is deemed inadequate
    - FDA has suggested such a determination will be infrequent
  - Voluntary Qualified Importer Program (VQIP) under FSMA 301
  - (Very narrow scope)
- Same or similar requirements *could* affect:
  - FSVP
  - Consultative audits
  - (Potentially broader scope)

Direct Reporting to FDA

- Immediate Reporting: Auditors required to report to FDA immediately any conditions identified during a food safety audit that present a "serious risk to public health"
  - FDA proposes to define this as both Class I and Class II level recall risks
- Audit Reports: Regulatory audit reports would need to be sent to FDA routinely within 45 days of audit completion
- Lab Results: Laboratory results taken during an accredited audit could be required to be automatically sent to FDA by accredited laboratories

Consultative Audits

- Audit to evaluate compliance with FDA requirements and industry standards
  - For internal purposes only
- Consultative audit reports would not be automatically filed with FDA, *but* would still trigger proposed reporting requirements of serious health risks and possibly of testing results

Impact on Related Programs

- FSVP
  - FDA proposes to require adherence to third-party audit rules whenever an accredited auditor is chosen to conduct the on-site FSVP audit
  - FDA has suggested it might make use of accredited auditors mandatory for FSVP third party audit purposes
  - Would significantly expand scope of accredited audits
- Note: FDA appears to be reconsidering this position based on feedback provided at the public meeting

FSMA Litigation

- FDA was sued for failing to meet the statutory deadlines for issuing proposed rules under FSMA
- Agency is under a court-mandated schedule to issue proposed and final rules
- Must issue two additional proposed rules by November 30, 2013
  - Animal feed
  - Food defense – FDA had planned to issue an ANPR
- FDA received an extension on the Sanitary Transportation proposed rule until January 31, 2014

FSMA Litigation

- FDA must issue all 7 final rules by June 30, 2015
- FDA is appealing the district court's ruling and asking the district court to stay its injunction
  - Briefs due after the November 30 deadline for the animal feed and food defense proposed rules

Next Steps

- All four proposed rules intended to be considered together
  - Review import proposed rules and develop comments by November 26, 2013
- Given FDA's timeline, comments should offer solutions
- One bite at the apple when it comes to comments!
- After comment period closes, think about how to prepare for implementation of final rules

Questions?

Contact Information:

Veronica.Colas@hoganlovells.com
(202) 637-6937

www.hoganlovells.com

Hogan Lovells has offices in:

Alicante	Denver	Jakarta*	Munich	San Francisco
Amsterdam	Dubai	Jeddah*	New York	Shanghai
Baltimore	Dusseldorf	London	Northern Virginia	Silicon Valley
Beijing	Frankfurt	Los Angeles	Paris	Singapore
Berlin	Hamburg	Luxembourg	Philadelphia	Tokyo
Brussels	Hanoi	Madrid	Prague	Ulaanbaatar
Budapest*	Ho Chi Minh City	Miami	Rio de Janeiro	Warsaw
Caracas	Hong Kong	Milan	Riyadh*	Washington DC
Colorado Springs	Houston	Moscow	Rome	Zagreb*