FSMA Preventive Controls for Human Food Final Rule

Webinar for the Grocery Manufacturers Association

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Agenda

• Overview and Highlights of Final Rule
  – Hazard Analysis
  – Management of Controls
  – Testing
  – Supplier Verification
  – Qualified Individuals and Employee Training
  – Records
  – GMPs
  – Exemptions and Modified Requirements
  – By-Products Diverted to Animal Food
  – Compliance Dates
Disclaimer

- Every company should conduct its own detailed review of the final rule.

- This presentation provides an overview and uses shorthand, so it should not be relied on as a substitute for reading the final rule, obtaining legal advice, or as a summary of all regulatory requirements.
Milestones

- FSMA Signed: January 4, 2011
- Proposed Rule: January 16, 2013
- Supplemental Proposed Rule: September 29, 2014
- Final Rule: September 17, 2015
Preventive Controls Regulation Overview

- Creates new regulations requiring food safety plans and their implementation
- Updates and revises the cGMPs
- Regulations codified in 21 CFR Part 117
Final Rule Overview

• Overall, the final rules are substantially the same as the supplemental proposals from September 2014
• Where revisions have been made, for the most part they provide additional flexibility to facilities to manage their food safety plans or respond to industry comments in positive ways
• There are a few areas where the final rules will present implementation challenges
The “Feel Good” List (aka “Top 10” List)

1. Preventive controls are general and flexible, and not necessarily CCP-based
2. Oversight of preventive controls is also flexible, incorporating a “sliding scale”
3. Recognition that finished product testing is not mandatory in all facilities – just “where appropriate”
4. Supply chain management focuses on both ingredient risk and supplier risk
5. No Part 11, remote access to records, or facility profiles
The “Feel Good” List (aka “Top 10” List) (cont.)

6. Third-party audits for supplier verification do not trigger the “bells and whistles” of 3PAC rule

7. PMO-regulated facilities have an extra 2 years to comply, so NCIMS has time to make PMO align with FSMA

8. Warehouse exemption for most packaged foods, and modified requirements for TCS products

9. Modified requirements for diversion of human food by-products to animal feed, and full exemption for food from FSIS-registered facilities

10. Staggered compliance dates
The “Pay Close Attention” List

• Records/documentation requirements are extensive throughout regulations and will be a major focus of FDA inspections
  – If you didn’t document it, it didn’t happen!
  – If you did document it, it happened just that way!

• Supply chain management regulations are very detailed and will likely need additional attention by food companies

• Documenting preventive controls managed up or down the food chain creates substantial logistical challenges and paperwork burdens
Hazard Analysis

• Identify and evaluate known or reasonably foreseeable hazards to determine whether there are any “hazards requiring a preventive control”
  – FDA replaced “significant hazard” with “hazard requiring a preventive control” in response to industry comments
• Facilities are required to consider economically motivated adulteration (EMA) as part of their hazard analysis
Preventive Controls

• Identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented (SMOPed)
  – Process controls
  – Food allergen controls
  – Sanitation controls
  – Supply-chain controls
  – Recall plan
  – Other controls
Exclusions from Preventive Controls

• Preventive controls are not required:
  – When the type of food could not be consumed without application of an appropriate control (e.g., coffee beans, cocoa beans, grains)
  – When a hazard is controlled by another entity later in the distribution chain (e.g., your customer)

• Disclose that food is for further processing (e.g., “not processed to control Salmonella”)

• Obtain assurances the hazard will be controlled, including an identification of the procedures
  – “Customer” = commercial customer, not a consumer
  – Customer must document compliance with its own procedures
Management of Controls

• The final rule provide additional flexibility for the management of preventive controls, to take into account both the nature of the preventive controls and their role in the facility’s food safety system
Monitoring

• The regulations expressly allow for “exception records” for monitoring activities
  – i.e., records demonstrating loss of control, rather than affirmative records demonstrating control
Corrective Actions

• The final rule continues to require corrective action procedures to address positive product testing and environmental testing results.

• The rule was revised to clearly state that corrective action procedures should be tailored to the nature of the preventive control, but also the nature of the hazard.

• Corrective action procedures do not need to be “specific” to a preventive control.
Corrections

- FDA defines “correction” to mean an action to identify and correct a problem without other actions associated with corrective action procedures.
- Corrections can be taken for sanitation and food allergen controls, but also for “minor and isolated problems that do not directly impact product safety.”
Verification

- “Accuracy checks” of process monitoring and verification instruments
- Review of consumer complaints
- Timeframe for review of monitoring and corrective action records
Testing

- Regulatory language unchanged from supplemental proposed rule
- In the preamble, FDA discusses use of accredited laboratories
- The final rule continues to require testing procedures to be “scientifically valid”
Validation

- The final rule
  - Clarifies exemptions and the timeframe for conducting validation
  - Requires validation in two new circumstances:
    - During production when necessary to demonstrate control measures can be implemented as designed
    - Whenever a change to a control measure, or combination of control measures could impact whether the controls will effectively control the hazards

*Valid*ation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.
Reanalysis

- The final rule allows facilities to reanalyze only a portion of a food safety plan (rather than the complete plan) in specific circumstances.
- It also requires reanalysis whenever a preventive control, combination of controls, or the food safety plan as a whole is found ineffective.
Supplier Verification

• Supply-chain controls are a type of preventive control
  – Requirements now housed in subpart G
• Linear approach, detailed requirements, and very record intensive
• Structure is the same as the supplemental proposed rule
  – Must consider compliance with FDA food safety regulations through a search of Warning Letters and Import Alerts
  – Annual audits for SAHCODHA suppliers, unless you can support another approach
Supplier Verification – Role of Third Parties

• Entities like brokers, distributors, or aggregators now have the option of engaging in supplier verification as a service to the receiving facility.

• In these cases, the receiving facility must review and assess that entity’s applicable documentation, and document this review and assessment.
Supplier Verification – Additional Highlights

• **R & D Exemption**: Supplier verification is not required if the food is intended for research and development and certain requirements are met.

• **Receipt Procedures**: Receiving facilities must establish and follow written procedures for receiving raw materials, and must document use of these procedures.
Supplier Verification – Additional Highlights

• **Substitution of an Inspection for an Audit:** An inspection can substitute for an audit if it was conducted:
  – By representatives of other federal agencies (e.g., USDA), or by representatives of state, local, tribal, or territorial agencies, and
  – Within 1 year of the date an onsite would have been required to be conducted

• The inspection must be “appropriate” and conducted for compliance “with applicable FDA regulations”
Supplier Verification – Auditors

• **Use of Auditors Under FDA’s Third-Party Accreditation Program**: Third-party auditors need not be accredited under the agency’s forthcoming third-party certification rule
  – If you use an auditor accredited under FDA’s rule, none of the requirements of the rule (e.g., direct reporting to FDA) apply to an audit conducted for preventive controls purposes
Supplier Verification-Audit Reports

• **Audit Documentation:** Complete audit reports are not required. However, the documentation must include the conclusions of the audit and corrective actions taken in response to significant deficiencies identified during the audit.
  – In the preamble, FDA declined a request to require a receiving facility to maintain documentation of corrective actions only if the identified deficiencies posed a risk to public health.
Supplier Verification Recordkeeping Requirements

There are many records required to comply with the supply-chain program.
Qualified Individuals and Employee Training

• The definition of “qualified individual” has changed
  – “Preventive controls qualified individual” now is used, where “qualified individual” previously was used
  – “Qualified individual” now is defined more broadly, essentially to means that employees must be qualified to do their jobs

• All employees must be “qualified individuals”
  – Also, each individual engaged in manufacturing, processing, packing, or holding food, or in the supervision thereof, must receive training in principles of food hygiene and food safety, including employee health and personal hygiene
  – Facilities must keep records of this required training
Preventive Controls Qualified Individual

• Must prepare or oversee certain preventive controls functions, such as preparing the food safety plan and conducting or overseeing validation and verification activities
Records

• Changes responsive to industry comments:
  – All records, except for the food safety plan, can be stored offsite so long as they can be retrieved and provided onsite within 24 hours
  – Records only need to include the time of the activity being documented when appropriate
  – The record retention requirements only apply to records created after the applicable compliance date for the final rule
Records

• Provisions not included in the final rule:
  – Part 11
  – Remote records access
  – Facility profiles
Copying Records

- The regulation specifically allows FDA to copy records
  - “We intend to copy records on a case-by-case basis as necessary and appropriate. We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. . . . We primarily intend to copy records such as the results of product testing or environmental monitoring when we conduct an inspection for cause – e.g., as a result of an outbreak investigation, violative sample results, or follow up to a consumer complaint.”
FOIA

- Food safety plans are expected to be exempt from public release as a “trade secret”
- Disclosure of verification records, such as the results of product testing and environmental monitoring, would be evaluated on a case-by-case basis
Updated cGMPs

• Now housed in 21 CFR Part 117, Subpart B
• Focus on protection against allergen cross-contact
• Certain provisions containing recommendations have been deleted
cGMPs

- Final rule uses term “allergen cross-contact”; FDA recognized this is distinct from contamination
- Training provisions apply to plants subject to cGMPs (previously nonbinding)
- Key preamble clarifications responsive to industry comments:
  - Protection of food in outdoor bulk vessels does not apply to open containers to RACs subject to further processing
  - No zero-tolerance standard for allergen controls
  - Recognized flexibility to use dry cleaning methods with no sanitizing steps
Small Business and Very Small Business

- SB = 500 or fewer “full-time equivalent employees”
  - Relevant for compliance date and low-risk on-farm activities exemption for SB and VSB
- VSB = Less than $1 million in total annual sales of human food, adjusted for inflation
  - Applies to sales PLUS the market value of food manufactured, processed, packed, or held without sale
  - All human food is included (not just that subject to the PC rule)
  - $ threshold applies to all sales, not just those in the U.S.
  - Based on an average of sales during 3-year period
“Farm” Definition

- Farms are exempt from FDA registration, so the meaning of “farm” has increased importance
- FDA further revised the definition of “farm” to address operations like off-farm packinghouses:
  - Primary Production Farm:
    - Operation under one management in one general (but not necessarily contiguous) location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - Secondary Activities Farm:
    - Operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm
Exemptions

• The final rule applies to registered facilities, except:
  – Foods subject to seafood and juice HACCP
  – Dietary supplements
  – Alcoholic beverages at certain facilities
  – Activities subject to low-acid canned food regulations (microbiological hazards only)
  – Certain storage facilities such as grain elevators and warehouses that store only RACs (other than fruits and vegetables) intended for further distribution and processing
  – Specified low-risk on-farm packing or holding activities by a small or very small business

• There also are exemptions specifically from the GMPs
Modified Requirements

• There are modified requirements for:
  – Qualified facilities
  – Facilities, such as warehouses, the only store packaged foods that are not exposed to the environment
  – Certain human food by-products used for animal food
Qualified Facility

- Exception from general PC and supply-chain requirements for (1) VSBs and (2) facilities with <$500,000 annual sales, primarily to qualified end-users
- Subject to modified requirements:
  - Determine and document status by July 1 of each year
  - Submit an attestation to FDA every 2 years that the facility is either (1) implementing & monitoring preventive controls to address potential hazards; or (2) in compliance with other non-federal food safety law (e.g., state or local law)
  - Maintain records supporting attestation (these do not need to be submitted with the attestation)
- Compliance date of January 1, 2016 for records to support the facility’s status as a qualified facility
Warehouses

• Exemption from general preventive controls and supply-chain program requirements for facilities “solely engaged in storage of unexposed packaged foods”

• Subject to modified preventive controls only for time/temperature control for safety (TCS) foods
  – Must establish & implement temperature controls, with (as appropriate) monitoring, corrective actions, verification, and recordkeeping
  – Exception monitoring is permitted for temperature control

• Frozen foods may be (but are not usually) TCS
Animal Food Diversion

- Specific GMPs apply to human food by-products held for distribution as animal food without further manufacturing or processing by the human food processor:
  - Held under conditions to protect against contamination
  - Labeled by the common or usual name during distribution
  - Shipping containers and bulk vehicles generally must be examined prior to use

- If contamination or other adulteration has occurred that is materially related to food safety, requests for diversion will be handled on a case-by-case basis (under existing CPGs)

- The requirements are codified in both the human food and animal food regulations (§ 117.95 and § 507.28)
Animal Food Diversion

• The final rule only applies to facilities that are required to register with FDA
• The animal food diversion requirements do not apply to facilities that are exclusively regulated by FSIS
• Dual-jurisdiction facilities must follow the GMPs for holding and distribution of their FDA-regulated human food by-products for use as animal food
• If a facility produces animal food (or further processes by-products), it must comply with GMPs and the preventive controls regulation
PMO Regulated Facilities

• The agency concludes that the current version of the PMO does not contain all of the requirements in new Part 117 Subparts C and G
  – FDA declines to exempt PMO-regulated facilities from preventive controls requirements
  – FDA also declines to determine that facilities operating in compliance with the PMO are in compliance with preventive controls requirements

• FDA extending the compliance date for PMO-regulated facilities to comply with Subparts C and G to September 17, 2018
  – This will allow time for the National Conference on Interstate Milk Shipments (NCIMS) to modify the PMO in light of FSMA
## Compliance Dates

<table>
<thead>
<tr>
<th>Business Type</th>
<th>Time Until Compliance Date</th>
<th>Compliance Date</th>
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</thead>
<tbody>
<tr>
<td>Businesses with 500+ FTE Employees</td>
<td>1 year</td>
<td>September 19, 2016</td>
</tr>
<tr>
<td>Small Businesses (&lt;500 FTE Employees)</td>
<td>2 years</td>
<td>September 18, 2017</td>
</tr>
<tr>
<td>Businesses subject to the PMO</td>
<td>3 years</td>
<td>September 17, 2018</td>
</tr>
<tr>
<td>Qualified Facilities (including very small businesses)</td>
<td>3 years</td>
<td>September 17, 2018</td>
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# Supplier Verification Compliance Dates

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<td>Businesses with 500+ FTE Employees</td>
<td>The later of:</td>
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<td>• March 17, 2017, or</td>
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<td>• 6 months after a supplier is required to comply with the applicable rule</td>
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Part 1 Compliance Dates

• The compliance date for amendments to the facility registration regulations is November 16, 2015 (60 days)

• Compliance dates for the one-up/one-back recordkeeping requirements (for facilities that become subject this for the first time) are:

<table>
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<th>Size of Business</th>
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<tr>
<td>&lt;10 FTE employees</td>
<td>September 18, 2017</td>
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<tr>
<td>10 - 499 FTE employees</td>
<td>March 17, 2017</td>
</tr>
<tr>
<td>500+ FTE employees</td>
<td>September 19, 2016</td>
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Guidance

- FDA plans to issue a range of guidance documents to help companies implement PC
- Draft documents will be published for comment before they are finalized
- FDA’s FSMA Technical Assistance Network also is live
  - [http://www.fda.gov/food/guidanceregulation/fsma/ucm459719](http://www.fda.gov/food/guidanceregulation/fsma/ucm459719)
The “Other” Final Rules

• Under the court order, FDA is required to submit the remaining final rules to the Federal Register for publication by the following dates:
  – October 31, 2015:
    • FSVP
    • Produce Safety
    • Third-Party Accreditation
  – March 31, 2016:
    • Sanitary Food Transportation
  – May 31, 2016:
    • Food Defense
Conclusion

• The final rules and discussion in the accompanying preamble clearly reflect the considerable input from industry and the written comments submitted during the rulemaking stage.

• There are, however, a few areas where the regulations are expected to present implementation challenges:
  – Supply-chain programs
  – Documentation of/for customers that hazards are controlled
The Future is Now!

- Most significant food safety regulations of our professional lifetime – affects every food company
- Establishing and maintaining a Food Safety Culture is essential in today’s environment
- Get help from legal counsel
- Key Steps:
  - Educate your company leadership and employees
  - Conduct gap analyses
  - Train for and implement good recordkeeping practices
  - Self-audit before the FDA comes

Better to be a month early than a day late!
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