



FSMA Enforcement: The First Year

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December 6, 2017

Topics to Include

- Compliance & Enforcement
- FSMA Inspections
 - Human Food PC Citations
 - FSVP Citations
- Training and Outreach

Compliance/Enforcement

- Key Implementation Principles:
 - Develop and implement inspection/enforcement strategies that facilitate consistent decision making by regulators
 - Encourage industry to comply and make corrections on its own
 - Recognition that not all observations are equal relative to risk and potential for public health impact
 - Regulatory strategy that is dynamic

Compliance Dates

- Preventive Controls Rule
 - Other than Small, CGMP Compliance – September 19, 2016
 - Small, CGMP Compliance – September 18, 2017
 - Other than Small or Very Small, PC Compliance – September 18, 2017
 - Small, PC Compliance – September 17, 2018
 - Qualified Facilities (including very Small), CGMP Compliance – September 17, 2018
 - Qualified Facilities (including very Small), PC Compliance – September 17, 2019
- FSVP Rule
 - First compliance for FSVP importer whose foreign supplier is not subject to the PC or produce safety rules: May 30, 2017

Compliance Dates

- Produce Rule
 - All Others (except for water) – January 26, 2018
 - Small Farms (except for water) – January 26, 2019
 - Small Farms, all provisions – January 26, 2021
 - Very Small Farms, all provisions – January 26, 2022
- Sprout Rule, All Provisions
 - All Others – January 26, 2017
 - Small – January 26, 2018
 - Very Small – January 26, 2019
- Transportation Rule
 - Businesses other than “small” – April 6, 2017
 - Business with over 500 FTEs, except motor carriers
 - Motor carriers if over \$27.5 million in annual receipts
 - Small Businesses – April 6, 2018
 - Less than 500 FTEs, except motor carriers
 - Motor carriers if less than \$27.5 million in annual receipts



PC & FSVP Inspections

PC Citations (21 CFR 117)

- 21 CFR 117.135(c)(3) – Your sanitation controls procedures did not ensure cleanliness of food-contact surfaces, prevention of allergen cross-contact and prevention of cross-contamination.
- 21 CFR 117.145(a) – You did not implement adequate written procedures for monitoring process controls.
- 21 CFR 117.130(a)(1) – Your hazard analysis did not identify a known or reasonably foreseeable hazard that required a preventive control.
- 21 CFR 117.135(c)(3) – Your sanitation controls procedures did not ensure cleanliness of food-contact surfaces, prevention of allergen cross-contact and prevention of cross-contamination.

FVSP Citations FY 2017

Top 5 Citations used in FY17

Cite Id	Ref Num	Cite Short Desc	LONG DESC	# of Times Used
1825 4	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP. Specifically, ***	109
1826 2	21 CFR 1.504(a)	Hazard analysis written	You did not have a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards [to determine whether there are any hazards requiring a control]. Specifically, ***	14
1828 3	21 CFR 1.505(b)	Supplier approval - document	You did not document your approval of your foreign supplier. Specifically, ***	9
1827 2	21 CFR 1.504(d)	Document review entity's hazard analysis	You did not document [your review and assessment of a hazard analysis conducted by another entity] [that a hazard analysis conducted by another entity was conducted by a qualified individual]. Specifically, ***	7
1829 3	21 CFR 1.506(b)	Supplier verification - establish written procedures	You did not establish [adequate] written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to a food you import. Specifically, ***	7

Accountability / Stakeholder Engagement

- Key Implementation Principles:
 - Develop meaningful public health/performance metrics to measure success
 - Recognize the role of the marketplace in influencing and expanding industry compliance with FSMA rules
 - Work closely with industry, government agencies, academia, and other key stakeholders/partners



Technical Assistance/Training for Regulators

- Key Implementation Principle: Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making:
 - FSMA Rule Readiness: Industry Best Practices
 - Alliance Courses with Industry
 - Regulator Specific Training
 - Technical Assistance Network / Resources

Industry Education, Outreach, Technical Assistance

- Key Implementation Principle: Facilitate industry compliance with prevention-oriented standards through guidance; developing tools/resources for education, outreach and technical assistance
 - Website
 - Guidance Documents
 - Alliances
 - Technical Assistance Networks

Technical Assistance Network (TAN)

- Goal: to provide central, consistent sources of outreach and technical assistance for industry and regulators
- Two phases:
 - Phase I: FSMA Rule Interpretation Questions
 - Phase II: Food Safety Regulatory Community

Regulator Technical Assistance Network (rTAN)

- Resource for field investigators and state inspectors to request technical assistance from FDA Subject Matter Experts (SMEs) during inspections.
 - Initial role-out is focused on FDA investigators
 - State inspectors will be addressed in future plans
- Not intended to replace the current enforcement communication mechanism between investigators and compliance officers or states.



Regulator Technical Assistance Network (rTAN)

- Regulator TAN is currently supporting the Preventive Controls regulations and the Foreign Supplier Verification Program (FSVP).
- Working with the Produce Safety Network and Sprouts Work Group to support the Produce and Sprout regulations.
- Ultimately will support all of the FSMA regulations.

For More Information

- FDA Food Safety Modernization Act (FSMA)
<http://www.fda.gov/fsma>
- Subscription feature available
- To contact FDA about FSMA and find the online form for submitting questions:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

