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FSMA - Current Good Manufacturing Practice, Hazard Analysis, and Risk- based Preventive Controls for Human Food

21 CFR Part 117

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>



Compliance & Enforcement Stats



FY17, FY18, FY19

(as of 10/2019)

FY17

- 58 483s
- 19 OAls
- 2 Reg mtgs
- 4 WLs
- 1 Injunction
- 1 UL

FY18

- 222 483s
- 33 OAls
- 1 IA
- 2 Injunctions
- 3 Reg mtgs
- 5 WLs

FY19

- 386 483s
- 82 OAls
- 1 IA
- 1 Injunction
- 3 Rec Pro
- 27 Reg mtgs
- 25 WLs/1 UL



FY19 Inspections

- Extended thru November 2019
- 483 issuance rate: ~40%
- FY19 OAI rate (full scope PC inspections):~11%
- Compared to FY18 (~8%) and FY17 (~5%)
- Due to staggered business size - larger business facilities with more robust food safety programs?

FY20 Inspections

- Started – December 2019
- FDA inspections halted – COVID-19 (surveillance inspections) – March 2020
- End of this month – process to restart inspections based on a risk assessment of the location where the establishment is to be inspected
 - <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-prepares-resumption-domestic-inspections-new-risk-assessment-system>



FY20 Inspections – 7/20/2020

GMP PCHF

- Domestic: 1319
- Foreign: 467
- State: 724

Limited Scope PCHF

- Domestic: 890
- Foreign: 284
- State: 1666

Full Scope PCHF

- Domestic: 409
- Foreign: 98
- State: 147



FY19 Top Cites – Domestic

Hazard Analysis - Identification of Hazard	21 CFR 117.130(a)(1)
Food Safety Plan	21 CFR 117.126(a)(1)
Sanitation Controls Verif Procedures: Establish / Implement	21 CFR 117.165(b)
Preventive Controls - Identify	21 CFR 117.135(a)(1)
Sanitation Controls Monitoring Proced: Establish / Implement	21 CFR 117.145(a)
Supply-Chain Program Establish and Implement	21 CFR 117.405(a)(1)
Process Controls Monitoring Procedures: Establish / Implement	21 CFR 117.145(a)
Sanitation Controls Procedures	21 CFR 117.135(c)(3)
Pest Control	21 CFR 117.35(c)
Allergen Controls Monitoring Proced: Establish /Implement	21 CFR 117.145(a)



FY19 Top Cites – Foreign

Hazard Analysis - Identification of Hazard	21 CFR 117.130(a)(1)
Pest Control	21 CFR 117.35(c)
Preventive Controls - Identify	21 CFR 117.135(a)(1)
Process Controls Verif Procedures: Establish /Implement	21 CFR 117.165(b)
Sanitary Facilities and Control	21 CFR 117.37
Equipment and Utensils - Design and Maintenance	21 CFR 117.40
Food Safety Plan	21 CFR 117.126(a)(1)
Process Controls Monitoring Procedures: Establish /Implement	21 CFR 117.145(a)
Process Controls Monitoring Frequency	21 CFR 117.145(b)
Process Controls Validation Not Performed	21 CFR 117.160(a)



Metrics

- External metrics:

<https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-fda-track-food-safety-dashboard-track-fsma-progress>



How to contact FDA

FSMA Technical Assistance Network (TAN)

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The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? [Start Here.](#)

The Technical Assistance Network staff has compiled answers to [common FSMA TAN questions](#). In addition, the complete set of [frequently asked questions on FSMA](#) contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please [submit your question](#) to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at <http://www.iit.edu/ifsh/alliance>.

- www.fda.gov/FSMA
- Go to Contact Us and **How to Contact FDA on FSMA**
- FSMA TAN Popular Topics posted April 2017
- Inquiries may be submitted by mail, if internet is not available



Sanitary Transportation of Human and Animal Food Rule

21 CFR Part 1 Subpart O



Compliance Dates

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

Implementation Strategy

- Encourage integration of sanitary transportation practices and food safety systems prescribed under FSMA and other regulations
 - Preventive Controls for Human Food and Animal Food
 - Seafood and Juice HACCP
 - Egg Safety Rule
 - Foreign Supplier Verification Program
 - Meat Inspection Act; Poultry Inspection Act (USDA)
- Train FDA inspectors and partner agency personnel to recognize and document deficient practices and educate on corrective actions during routine inspections
- Coordinate with other agencies to identify solutions across distribution channels



Initial Inspection Assignments (Fiscal Years 2018 thru 2020)

- Increase awareness of rule within FDA Registered Facilities
- Promote accountability of “shippers” throughout supply chain
- Assess the readiness of the facilities to effectively support sanitary transportation of human and animal food.
- Focused on expanding awareness of the rule and educating firms of their responsibilities under the rule at the time of inspection
- If conditions are observed that jeopardize the safety of the food in transit, the investigators reach out to the respective Center for appropriate response on case by case basis.



FY18 ST Inspection Assignment

Initiated April 2018:

Limited to Large Firms

Focus on Training of FDA Investigators

Target numbers:

- 120 Human Food Facilities

- 30 Animal Food Facilities

General takeaways:

- Reasonable Level of Awareness

- Documentation of Procedures Often Lacking



FY19 ST Inspection Assignment

Included Large and Small Firms

Inspections Completed

Total: 238

Human Food Facilities

Large: 58

Small: 111

Animal Food

Large: 21

Small: 46

Awareness and Compliance Generally Good

No Warning Letters Issued as Result of Inspections



FY20 ST Inspection Assignment

Includes Large and Small Firms

Inspections suspended in March 2020

Inspections Planned and Completed to date

Total: Planned: 228 Completed to Date: 99

Human Food Facilities

Planned: 144 Completed to Date: 75

Animal Food

Planned: 84 Completed to Date: 24

Awareness and Compliance Generally Good

ST Inspections - Plans for FY21 and Beyond

- Integrate ST Inspections into normal inspection compliance program
- Rather than target a specific number of ST Inspections, investigators to assess applicability of ST Rule during inspection visit and conduction ST inspection as needed
- Citations (inspection criteria) established for each ST Rule Requirement
- State contract inspections not planned for FY21, but likely FY22 and beyond