2022 FDA Update: Implementing FSMA in a Post-Pandemic World

Glenn Bass
Deputy Director
Office of Human and Animal Food – West
Office of Regulatory Affairs
U.S. Food & Drug Administration

2022 FSPCA Virtual Annual Conference | Oct 19, 2022
Agenda

• Impact of COVID-19
  – The Field Perspective
FDA Training Courses – FY 2017 – FY 2022

FD254
PC for HF
Regulators
(32+)

VM102
CGMP AF
Regulators
(20+)

VM220
PC for AF
Regulators
(16+)

FD226
Produce Safety
for Regulators
(20+)

Participants
FDA = 600+
State = 300+

Participants
FDA = 300+
State = 300+

Participants
FDA = 200+
State = 200+

Participants
FDA = 80+
State = 300+

Dynamic Workforce
What Have We Been Doing?

Re-thinking Field Activities
Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

**Challenges:**

- Limit the travel time and distance. Some inspections require staff to travel 5-7 hours to get to the firm.
- As conditions on the ground changes and the impact of COVID-19 changes, we continue to revise the field instructions to meet the present conditions.
- Shifting to virtual working conditions such as training, managing new hires, and collaborative meetings (e.g., close-out inspections).
Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

Opportunities:

• Remote Regulatory Assessment (RRAs)
  – VOLUNTARY
  – Center for Food Safety & Applied Nutrition (CFSAN)
  – Center for Veterinary Medicine (CVM)
  – Does not replace onsite inspection (i.e., no change to inspection frequency)
Impact of COVID-19: FDA’s Remote Oversight Tools

• Remote Regulatory Assessments (RRAs)
  – FDA may request establishments (e.g., food producers) participate in a Voluntary RRA.
    • These can be requesting and reviewing records;
    • Virtual meetings via livestream and/or secure email portal
  – Mandatory RRAs are defined in statute and regulation and currently include certain drug establishments and FSVP requests from Importers of an article of food.
Impact of COVID-19: FDA’s Remote Oversight Tools

Remote Regulatory Assessment Fact Sheets

**FDA FACT SHEET**

Types of records that are reviewed during a human food RRA

- FDA’s initial RRA for human food focuses on compliance with requirements under regulations.
- FDA focuses on required records for the initial human food RRAs because human food facilities are required to keep specific records that can be reviewed outside of an on-site inspection to assess a facility’s general compliance with FDA requirements.
- The specific records requested for review are communicated to the human food facility once the facility has voluntarily agreed to participate in the RRA.
- FDA evaluates the success of the initial human food RRA and determines whether to expand the study to other FDA human food safety regulations.

**Key facts about RRA for an animal food facility**

- RRAs are strictly VOLUNTARY for animal food facilities.
- FDA will reach out to selected individual facilities to request their voluntary participation.
- There is no penalty for opting out of the RRA. Facilities can decline to participate at any time.
- Animal Food RRAs help the FDA assess a facility’s compliance with requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act and animal food safety regulations.
- The RRA includes a review of facilities’ records and an interview (call or video-stream) with a facility about their records.
- Any issues will be discussed with management at the close-out meeting.
- If concerns are found with the records, FDA will discuss those concerns with the facility, which gives them time to correct concerns prior to any future inspection.
Draft Guidance: Conducting Remote Regulatory Assessments (RRAs) (posted 7/2022)

- [Conducting Remote Regulatory Assessments Questions and Answers | FDA](#)
Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

Opportunities:

• 2 Tier Inspection Program
Impact of COVID-19: Re-thinking Field Activities

• Tier 1: (RRA or onsite): Supply Chain and Recall Programs
  – Adequacy

• Tier 2: Implementation + other PC components
Impact of COVID-19: Re-thinking Field Activities

- Official Establishment Inventory (OEI) Improvement
  - PSA: Re-registration end of 12/2022
- Limited Scope vs Full Scope-PCHF
- Routine Surveillance vs Compliance F/U;
- Announced vs Un-announced
Impact of COVID-19: Re-thinking Field Activities

• Outbreak Investigations
• For cause sampling
  – Product
  – Environmental
Impact of COVID-19: Re-thinking Field Activities

- Staff Development:
  - Formalized Program: PCHF & PCAF OJE
  - Coach-OJE (Division)
  - OHAFO/NEs: 1 day Webinar/Workshop
  - On-site Coach-OJE with CSO along with OHAFO/NE
Impact of COVID-19: Re-thinking Field Activities

The Numbers
Domestic Inspections, FY 2018 – FY 2022
Preventive Controls for Human Food

Completed: 200+
Planned: 695
Completed: 500+

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Foreign Inspections, FY 2018 – FY 2022
Preventive Controls for Human Food

- FY 2018: 151
- FY 2019: 212
- FY 2020: 98
- FY 2021: Planned 112, Completed: 20+
- FY 2022: 67
Domestic Inspections, FY 2018 – FY 2022
Preventive Controls for Animal Food

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Foreign Inspections, FY 2018 – FY 2022
Preventive Controls for Animal Food

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FDA Data

Food-TRACK

• Preventive Controls and Imported Food Safety measures
• Additional measures in progress

• FDA Data Dashboard