Incorporating FSMA into the Standards

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Before we get started...

• Proposals are initial thoughts and suggestions only

• Some ideas do not require a change to the MFRPS, but might be something a state regulatory program should consider if implementing a FSMA rule (e.g. PC, IA, Sanitary Transport, FSVP)

• A lot of these suggestions are focused on the PC rule
Standard 1

• Encourages states to review, understand and compare their respective food safety laws to the federal laws
  – Enhance by asking for a timeline/timeframe for when state laws will be updated
• Request that programs review their intent to adopt
  – PC Rule Intentional
  – Adulteration Rule
  – Sanitary Transport
  – FSVP Rule
• Develop rule making strategy if pursuing adoption of FSMA rules
Standard 2

• Training protocols to address FSMA PC rule and other rules impacting manufactured food if PC Food rule adoption is pursued
  – CGMP/PC (OTED training table)
  – FSMA webinars
  – FD254 PC Human Food Regulatory Course
    • Prerequisite online
    • Pre/post course fieldwork
  – FSPC Alliance course
  – OJT Experience/Evaluation
  – cGMP webinar
Standard 3

• Develop protocol for handling self-attestations for exemptions and work with District/Division to identify firms under the PC rule or exempted

• Verify SOP:
  – addresses firms under contract including PC inspections
  – includes education and outreach activities during inspections if required under outreach initiatives or contract

• Verify SOP and forms include PC rule information documentation in EIR and eSAF for contract inspections

• If conducting Environmental Sampling for PC inspections, ensure there is a protocol addressing
Standard 4

• Review definitions in SOP as they apply to PC inspections, e.g. Field Inspection Audit, Qualified Field Inspection Auditor, Verification Audit Inspections
• Review field and desk inspection audit criteria as it applies to the PC rule
• Verify or update new and modified inspection report data elements to be required on PC inspection and sample collection forms
  – Assess IT updates if needed
  – Ensure there is a process for testing timeframes for submission of inspection reports
Standard 6

• Improve coordination/cooperation to maximize the effect of inspection and enforcement activities.
• Develop a framework for a nationally standardized and unified compliance and enforcement response system based on stakeholder input and the assessment of existing tools such as enforcement strategies within states
  – Example: Develop a PC Rule compliance and enforcement strategy in coordination with the District/Division.
    • FDA vs. state
    • Contract vs. non-contract
Standard 7

- Focus of Standard 7 is outreach to consumers and industry

- Examples of opportunities to conduct outreach activities might include:
  - Develop PC education and outreach strategy for industry and stakeholders
  - Identify PC presentations and meetings within jurisdiction, associations
Standard 8

• Review resource strengths and weaknesses and strategies for prioritizing, leveraging, allocating and seeking additional state and FDA resources to meet program needs under the PC rule.
  – FTE calculations
  – Funding
  – Staffing
  – Equipment
  – IT needs
Standard 9

• Develop PC Rule Implementation Strategy using standards framework
• Monitor and verify implementation of new or updated PC rule procedures
• Ensure internally/externally controlled PC documents are added to master list for document control
• Add section on evaluating workplanning
• Conduct analysis of PC Rule and impact on inspection and sampling contract requirements
Standard 10

- Strengthen partnerships and improve effectiveness to coordinate resources
  - Add a requirement for regional and national sampling plans to be developed between regulatory and laboratory professionals
  - Verify lab support for sampling under the PC rule
Contact Information

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