



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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