The Impact of The FSMA on R&D of Aseptic and Extended Shelf-Life Products

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This Presentation

1. FSMA overview
2. FSMA and R&D of aseptic and ESL products
3. FSMA and MicroThermics® equipment
4. FSMA and your facility

What Is The FSMA?

1. FSMA: Food Safety Modernization Act
2. Signed into law by President Obama in 2011
3. Gave the FDA new authority
4. Applies a "Preventative Control Rule"
    1. Changes FDA involvement from reactive to pro-active.
    2. Requires food facilities to be proactive in safety.
5. Requires HACCP.

The FSMA

1. Broad sweeping…from farm to table.
2. Requires registration of “Food Facilities”
3. There are specific exclusions
4. Applies to R&D laboratories: See Question 16.11

   http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm331959.htm
5. Applies to Importers of Food to the US.

FSMA Preventative Controls

1. Requires HACCP
2. Preventative controls
3. Monitoring of their effectiveness
4. Correction of controls where needed
5. Verification of the corretion's effectiveness
6. Scientific justification of a hazard's not being likely.

IFTPS Implementation Deadlines
(A/O February 26, 2014)

August 30, 2015: Preventive controls for human food

October 31, 2015: Produce safety, the foreign supplier verification program and third-party accreditation

March 31, 2016: For sanitary transport

May 31, 2016: Intentional adulteration

FSMA References

1. Useful References For FSMA:
    1. http://www.fda.gov/Food/GuidanceRegulation/FSMA/
    2. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm
    3. http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm416121.htm

FSMA's Significance
What's The Big Change?

Prevention is the cornerstone of the FSMA.

For the first time, FDA will have a legislative mandate to require comprehensive, science-based *preventive controls* across the food supply.

FSMA-The *Facilities* Preventative Control Plan:

1. Written preventive controls plan (HACCP Plan)
    1. This involves:
        1. Evaluating the hazards that could affect food safety
        2. Specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards
        3. Specifying how the facility will monitor these controls to ensure they are working (verification)
        4. Maintaining routine records of the monitoring
        5. Specifying what actions the facility will take to correct problems that arise.

FSMA & HACCP Plan Implementation

1. A qualified individual would be required to prepare the food safety plan, develop the hazard analysis, validate the preventive controls, review records and conduct a reanalysis of the food safety plan (or oversee these activities).

1. To be qualified, an individual would be required to successfully complete training in accordance with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system

FSMA and R&D of Aseptic and ESL Products?

The FSMA pushes us toward sanitary standards like 3A and EHEDGE or BPE.

FSMA does not require compliance with any of these but encourages adoption of designs and materials that follow these principles or are compliant.

FSMA and R&D of Aseptic and ESL Products?(2)

Moves R&D to higher level of safety performance.

Record keeping of process data for internal samples and especially external samples.

Records of calibration and calculation.

Records of equipment sanitization or sterilization.

Higher level of operator training and its documentation.

FSMA and MicroThermics®
Current Equipment & Services

Fully Sanitary Design

- All food grade materials
- 316L stainless steel with fully blanketed OTW (robotic)
- Sanitary components, 3A or 3A compliant
- All Elastomers are CFR 21 Part 177 and often USP Class IV compliant.

Surface finishes are <32Ra and often <25Ra (microinch)

- Alternates with <20 RA are available

Process Record keeping: On-board Data Acquisition

- Optional circular chart recorders

Calibration: On-board Calibration of all inputs.

FSMA and MicroThermics® Current Equipment & Services

Options are available for sterilization of process side and raw side components.

- (Sterile Product Outlet and Closed Loop Sterilization)

Operator Training: Certified Operator Program Training – COP

- Not required for equipment operation.
- Enhanced training to ensure that operators understand how to properly operate the equipment and maintain safety.
- Requires renewal to retain certification.

PMO “compliant” system options are available

FSMA and Older MicroThermics® Models

Does this mean that older “swaged” systems cannot be used: No.

- Proactively use the options for the SPO or hot water sterilization or sanitization.
- Use the options for data acquisition if these were purchased for your equipment.
- Calibrate your data acquisition unit.
- Take advantage of the Certified Operator Program, COP.
- Make plans to upgrade your old MicroThermics® system.

Retrofit Options Supporting FSMA Compliance

"PMO compliance" options

- Full PMO compliance: not always the answer
- Circular chart recorders
- Flow diversion valves

Recommended Reading

Preventive Standards

- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm256826.htm#guidance

FSMA Proposed Rule for Preventive Controls for Human Food

- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**
- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

Part 110 Current Good Manufacturing Practice In Manufacturing, Packing or Holding Human Food

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110

Additional Reading

Current Good Manufacturing Practices (CGMPs)

- http://www.fda.gov/food/guidanceregulation/cgmp/default.htm
  - Food CGMP Modernization — A Focus on Food Safety November 2, 2005
  - Good Manufacturing Practices (GMPs) for the 21st Century - Food Processing August 9, 2004

What Does The FSMA Mean To Your Facility?

Registration

Development of the HACCP plans for the facility, processing and handling products.

Keeping up with this.

The FSMA And General Practices

For the most part, it will mean more deliberate documentation of what you normally do.

It also means that your means to control the lab area will be formalized and documented.

It will likely mean regular periodic environmental control programs like cleaning, sanitization and pest control. These however are already things that you have been doing . Under FSMA, they become programs that are performed regularly and documented. Their efficacy is monitored and they are modified as the need arises based on the results.

If you have been rather casual in preparing samples, this may be more significant.

What Does The FSMA Really Mean To Your Sample Preparation?

It is likely that you will want to adopt a more formal approach to receiving, accounting for, storing and protecting materials. This will be more like a manufacturing facility.

You will also want to properly store the processing records and record the disposition of the products.

You will want to demonstrate at least a 5-log reduction of pathogenic organisms.

You will want to identify and individual who is qualified and responsible for approving samples before their use based on data.

- Ingredient data
- Equipment history, cleaning and calibration
- Process data

FSMA Summary

For R&D of aseptic and ESL products the FSMA is a common sense formalization of what should be our “best-practices”. HACCP plans are necessary.

MicroThermics current models provide excellent compliance with the FSMA and training to support proper equipment operation.

- Older MicroThermics models do not need to be immediately replaced, however hot water sanitization or sterilization should be used to provide better compliance.
- Options are available to support compliance with the FSMA.

There are specific steps you will want to take to be sure your sample preparation is compliant.

Thank You!

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