Regulatory Aspects of New Food Processing Technologies

June 21, 2014

NIFA – 2011-68003-20096
Process Types

• Low Acid Canned Foods
  • Commercially Sterile
  • Shelf Stable
  • $F_0 \left( F^{18}_{250} \right) \sim 6.0 \text{ minutes}$

• Pasteurized Foods
  • Refrigerated
  • $F_{194F} = 10.0 \text{ minutes}$

• Cooked Foods
  • Refrigerated/Frozen
  • $F_{185F} = 1.2 \text{ seconds}$
FDA Requirements

- LACF
  - MATS

- Pasteurized Food
  - MAPS

- Cooked Food
  - MACS?

- Filing Submission

- Validation of Cook Step CCP

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FDA Requirements

LACF *(MATS)* – Filing Submission

1. Food Canning Establishment (FCE) registration
2. Verify System Temperature Distribution
3. Establish Scheduled Process – MW Assisted
   • Confirm Cold Spot
   • Conduct Heat Penetration tests
   • Process Authority recommended process
4. Submit scheduled process to FDA for filing consideration
5. Biological validation – For initial filings
FDA Requirements

Pasteurized (MAPS) & Cooked – CCP Validation

1. Validate Cook Step CCP
   - Confirm Cold Spot
   - Conduct Heat Penetration tests
   - Conduct Temperature Distribution Tests
   - Process Authority recommended process

2. Cook Step CCP
   - Set Critical Factors and Critical Limits
   - Monitoring Procedures
   - Records
   - Corrective Actions
1. New Technology Notification
   - *New technology that affects product safety* is defined as one that might have a beneficial or adverse effect on the safety of the food product. A *notification* is defined as a document written to inform the Food Safety and Inspection Service that a new technology is going to be tested or used in an establishment.

2. Protocol for In-plant Trials
   - A *protocol* is defined as a detailed plan of a scientific experiment, treatment, or procedure that is submitted to the Food Safety and Inspection Service if the scientific experiment, treatment, or procedure affects inspection procedures, the safety of Federal inspection program personnel, or requires a change to the Agency's regulations.
3. HACCP Plan - Validation of Cook Step CCP (9 CFR 417)

- Test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan.

- Ongoing verification activities. Ongoing verification activities include, but are not limited to:
  - (i) The calibration of process-monitoring instruments;
  - (ii) Direct observations of monitoring activities and corrective actions; and
  - (iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.
What About FSMA?

Preventive Controls means;
“those risk based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard Analysis.......”
Validating Preventive Controls

The validation of the preventive controls:

• Must be performed by (or overseen by) a qualified individual:
• Prior to implementation and for changes to the food safety plan
• Must include collecting and evaluating scientific and technical information, or conducting studies when such information is not available or is insufficient
Verifying Preventive Controls

The **verification** of the preventive controls includes:

- Proper monitoring
- Proper recordkeeping and record review
- Consistent and effective implementation, including identification of CL deviations and associated corrective actions
- **Instrument accuracy checks and calibration**
- Overall “validation” of the to ensure the PC program effectively controls the hazards
Customer/Third Party Requirements

- All new products and changes to **product formulation**, packaging or **methods of processing** shall be formally approved by the HACCP team leader or authorised HACCP committee member.

- Trials using production equipment shall be carried out where it is necessary to validate that **product formulation and manufacturing processes** are capable of producing a safe product of the required quality.
Customer/Third Party Requirements

- A food safety plan shall be validated and verified for each **new product and its associated process** through conversion to commercial production and distribution, or where a change to **ingredients, process**, or packaging occurs that may impact food safety.

- Records of all **product design, process development**, shelf life trials and approvals shall be maintained.
Regulatory Milestones

**FDA Filing Submission for MATS-B**
- **June 28, 2013**
- Homogeneous product

**USDA/FSIS reinstates in-plant trial**
- **January 10, 2014** for USDA regulated product
- Multi-ingredient product

**FDA Filing for MATS-B Accepted**
- **March 5, 2014**
- Over 8 months from submission, but no questions
Up Next

• Second MATS-B Filing at second facility
  • Performance repeatability
  • Process control (Critical factors, Critical Limits, etc.)
  • Engineering and instrumentation

• MATS-150
  • Scale up from MATS-B
  • Continuous process (Critical factors and limits will likely change)