

Impacts of FSMA on the Dairy Industry



Michigan Department of Agriculture & Rural Development

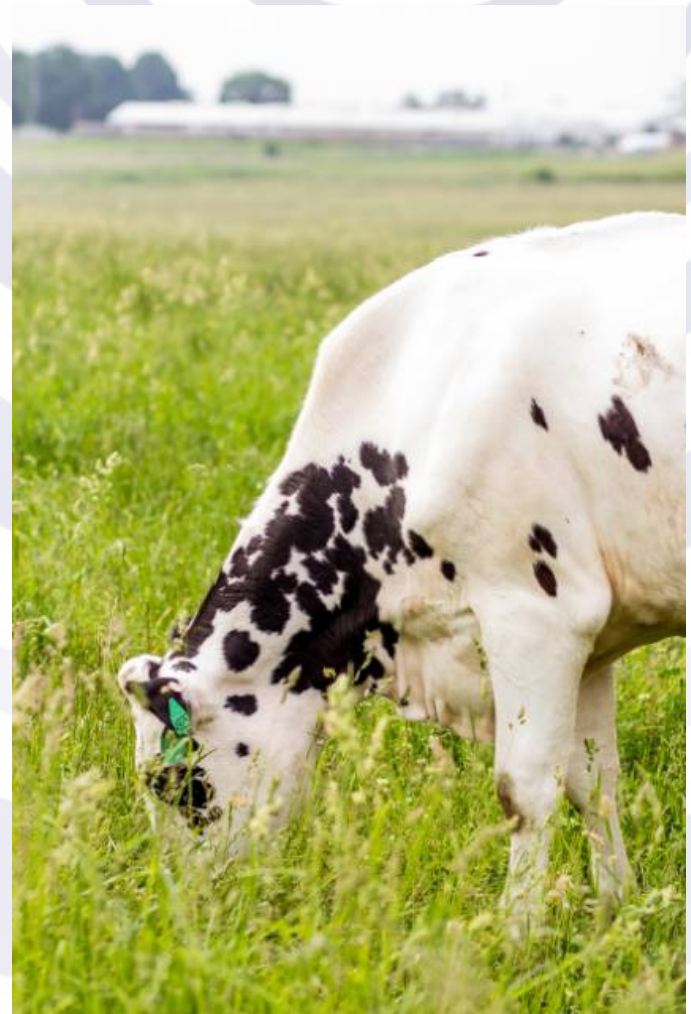
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Preventive Controls for Human Food Implementation Dates

- Very Small Facilities – September 17, 2018
- Grade “A” milk and milk products subject to the PMO – September 17, 2018
- All other manufacturing facilities are already under the FSMA Preventive Controls for Human Food Rule
- Sanitary Transportation Rule – April 06, 2018





Qualified Facilities

- Must submit documentation to FDA by December 17, 2018 attesting that:
 - Make under 1 million in gross annual sales (3 yr avg)
 - Sale of raw milk included
- AND**
- Will comply with PCHF Rules
- OR**
- Will comply with non-federal food safety laws





Qualified Facilities

- Exempt from Subparts C (Hazard Analysis and Risk Based Preventive Controls) and G (Supply-Chain Program)
- FDA may retract exemptions
- Qualified Facility Guidance document available soon – see Dairy Inspector





Retail Exemption

>50% Retail Sales = Exempt from PCHF Rule

- Example: On-farm producer/processor primarily selling direct to consumer

>50% Wholesale = Must comply with PCHF Rule

- May qualify for exemption if under 1 million





FSMA Related Changes to 2017 PMO

- Addition of Appendix T aligns the PMO with FSMA by including requirements for:
 - Written Food Safety Plan updated every 3 years
 - Record keeping, retention, and review requirements
 - Holding, distributing and labeling of human food by-products intended for use as animal food
 - Food allergen control of non-milk allergen containing ingredients (allergen labeling requirements for milk remain)
 - Exclusion of workers with any disease in a communicable form from working in processing capacity where contamination may occur
 - Temperature recording devices for all refrigerated milk and milk product storage rooms
 - Additional environmental and products testing requirements



What can Dairy Plants Expect During a PCHF Inspection

- No PC Inspections for Grade A completed yet (implementation date September 17, 2018)
- Manufacturing Plants:
 - 2-6 days (Full FSMA or FSMA Lite)
 - May include environmental and product sampling
 - Currently being conducted by FDA District Food Staff – State may or may not be informed prior to inspection
 - Please communicate any discrepancies between food and dairy standards identified during inspection to MDARD Dairy Staff and FSMA Unit



Grade “A” Preventive Controls for Human Food (PCHF) Inspections

- Every 36 months per 2017 PMO
- Dairy Inspectors will complete Routine PC Inspections
- SRO’s will conduct FSMA Lite Inspection during survey
 - Score below 90% for PC portion of survey = Resurvey by SRO, but not immediate delist
- FDA Regional Milk Specialist will conduct PCHF Inspection during Federal Check Rating
- Score below 80% for PC portion of check rating = Resurvey by State Rating Officer (SRO), but no delisting
 - Score below 90% on resurvey by SRO = Delisting



PC Inspections for Manufacturing Grade Dairy Plants

- High Risk Product = Inspected every 3 years
- May be a full PC Inspection or a FSMA Light Inspection





Sanitary Transportation Rule

- Includes requirements for vehicle maintenance and design, food safety transportation operations, carrier training, and record maintenance
- Free FDA Carrier Training module available online – “Food Safety for Carriers”
- Exempt from rule:
 - Less than \$500,000 in annual revenue
 - Human food byproducts used as animal food without further processing
 - Foods transported in enclosed container that do not require temperature control for safety
 - Regulated under NCIMS Grade “A” Milk Safety Program



Resources for Facilities

- FDA Food Safety Plan Builder:
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm>
- Michigan's Food Safety Risk Self-Assessment Tool for Dairy Processing Plants (Electronic version or copy available on request)
- FSMA Website: Industry Guidance Documents
- FSPCA Preventive Controls for Human Food Qualified Individual Training: Online and classroom settings at <http://FSPCA.net> or Industry Sponsored Trainings
- Questions?— contact Regional Dairy Inspector or FSMA Unit
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Questions?

