



# ***Assisting small dairy manufacturers in meeting FSMA requirements***

***Marianne Smukowski  
Dairy Safety Applications Coordinator***

**Center for Dairy Research** *“Solution Based Research Backed by Experience, Passion and Tradition”*





# *Key Contacts*

- Project Director: John Umhoefer, Wisconsin Cheese Makers Association
- Co-Project Director: Marianne Smukowski, Center for Dairy Research
- Assisting: Matt Mathison, Wisconsin Milk Marketing Board  
Rebekah Sweeney, Wisconsin Cheese Makers Association



# *Purpose*

- A practical, hands-on outreach program designed to make the Food Safety Modernization Act a reality, not just a regulation, for small artisan dairy manufacturers with limited resources





# *Need*

- Rapid Growth of Artisan Cheesemaking
  - In 2000: WI Ag. Statistics Service reported 63 sites making 221 million pounds
  - In 2016: 93 sites making 773.7 million pounds (250% growth)
- Data from Wisconsin Milk Marketing Board shows only 11 of the 95 small dairy manufacturers operating in Wisconsin today are certified under the Global Food Safety Initiative or SQF program



# Compliance Dates

- Large businesses (> 500 FT employees): September 19, 2016
- **Small businesses (< 500 FT employees): September 18, 2017**
- Very small businesses (< \$1M in annual food sales): September 17, 2018

U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Food

Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

**FDA Food Safety Modernization Act (FSMA)**

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

**Featured Announcements**

**FSMA Inflation Adjusted Cut Offs**  
May 5, 2017

**Advancing the Safety of Imported Food Identification**  
April 20, 2017

**Most Popular**

- Full Text of the Law
- Rules and Guidance for Industry
- Public Meetings
- Information by Topic
- FSMA Technical Assistance Network (TAN)

**Rules**

- Final Rule for Preventive Controls for Human Food
- Final Rule for Produce Safety
- Final Rule on Accredited Third-Party Certification
- Final Rule for Foreign Supplier Verification Programs (FSVP)



# *Long-Term Project Goals*

- Measurable improvement in food safety parameters for dairy producer and small dairy manufacturer clients with limited staff and resources
- Clients achieving full compliance with regulations in the Food Safety Modernization Act
- Advance artisan dairy producers to achieve SQF Level 2 to open these artisans to potential end markets nationwide
- Build a repeatable model that can be advanced to other states benefiting from growth in artisan dairy production



# *Program Objectives*

- **Broad, enthusiastic participation**
  - Rally 50 or more small dairy manufacturer and artisans in the state to become proactive Initiative clients
- **Face-to-face interaction**
  - Host group workshops at rural locals convenient to clients and hold FSMA compliance training and execution on-site at client production sites
- **Measure food safety**
  - Enhance existing environmental testing and product testing program at client facilities to create measurable food safety targets at client facilities
- **Use existing expertise**
  - Involve current staff at Center for Dairy Research and Wisconsin Cheese Makers Association to minimize costs and maximize outreach to small dairy manufacturer and artisans in Wisconsin
- **Develop new expertise**
  - Support a new food safety educator(s), mentored by CDR, to implement site visits and become an on-going FSMA training and implementation resource in Wisconsin and outside the state

# *Progress Report*

- Four regional FSMA training seminars were held in February of 2017. Locations included:
  - Green Bay
  - Spring Green
  - Eau Claire
  - Fond du Lac



# *Progress Report*

- 139 individuals from 53 companies in Wisconsin, Minnesota, and Iowa received training via seminars.
- Distributions included:
  - 24 Template Documents (also via flashdrive)
  - Employee Food Safety Manual
  - FSPCA Preventive Controls for Human Food Manual



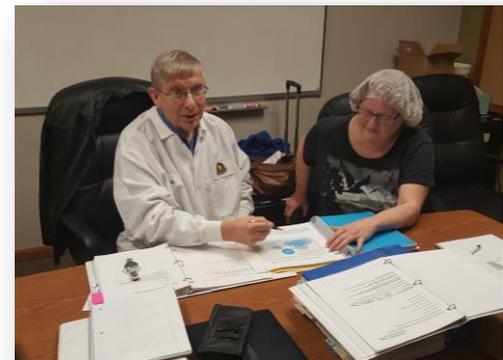


# Progress Report

- 62 of 69 (well more than the target of 50) scheduled on-site consultations completed in Wisconsin, Minnesota, and Iowa
- Site visits emphasize:
  - GMPs
  - Workflow
  - Production practices
  - Ingredient handling
  - Labeling
  - Storage



Food Safety Educator Jim Mueller



Food Safety Educator Larry Bell



# *Early Participant Feedback*

- “We have already completed the ‘adjustments’ and are proceeding with the additional items as discussed... **Thanks again for the valuable input and guidance** you have provided these past few weeks.”
- **“Thank you for coming and sharing your knowledge** with us! We greatly appreciate it! I have reviewed the items on your visitors log and we will work on them.”

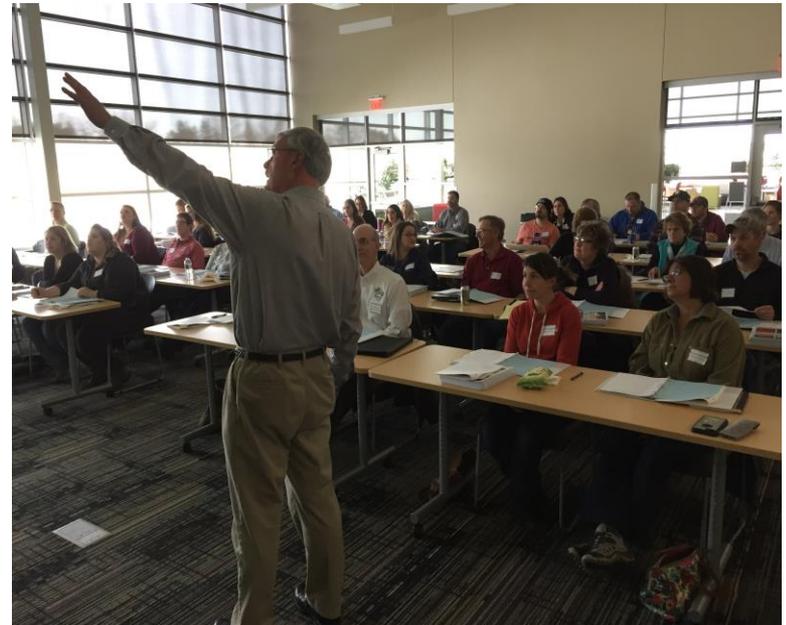


# *Early Participant Feedback*

- “We appreciate the time that you took with us today and **you were very helpful.** It's good to get other insights and ideas from people like yourself. I'll start working on the to-do list as soon as it gets sent over, then we can plan to meet again in a couple of months.”
- “Thanks again for putting this afternoon's session together. We're **very lucky to have all sorts of great dairy resources** here, and people like you are the most valuable of those resources.”

# *Finances*

- Awarded \$152,600 for two year program
- Have spent approximately \$87,000
  - \$3,000 on seminars
  - \$5,000 on materials
  - Remainder on educator time with participants





# *Initiative Findings*

- ***Food Safety Plan***

- Range in Food Safety Plan development from minimum practices with flow chart and hazard analysis to established plans with best practices utilizing corrective action and verification
- State-driven programs with pasteurization and drug residual monitoring are well-documented

- ***Supply Chain Program***

- Need more formal documentation of Supply Chain Program and risk assessments
- Noting a number of smaller purchases (e.g. flavor ingredients) are procured using box stores, etc., providing limited information on supplier and/or ingredient



# ***Initiative Findings, Continued***

- ***Allergen Control***

- Mostly milk allergens but need to document programs to verify labeling and ensure no other allergens are entering the facility, unless approved

- ***Sanitation Control***

- Most use external providers and utilize expertise for documented cleaning procedures and training
- Encourage more aggressive environmental monitoring covering diverse locations within RTE areas to verify effectiveness of sanitation and barrier controls



# *Initiative Findings, Continued*

- ***Recall Program***

- Basic recall programs in place with some improvement needed with documentation of mock recalls

- ***CGMPs***

- Cross contamination issues due to traffic flow, air flow, and equipment placement
- General GMPs look good (e.g. hair nets, hand wash stations)
- Minimal storage space, need to maintain good housekeeping practices



# *Initiative Findings, Continued*

- ***Prerequisites/Support SOPs***
  - Need more formal documentation and record keeping practices
- ***Other***
  - Small and very small operations struggle a bit due to limited resources

# *Moving Forward*

- Complete on-site consultations
- Continue with follow-up visits
- Provide consultative services to all dairy processors/manufacturers via telephone and email
- Develop materials (instructive columns) for industry newsletters and publications
- Build online resources, including making templates available to all

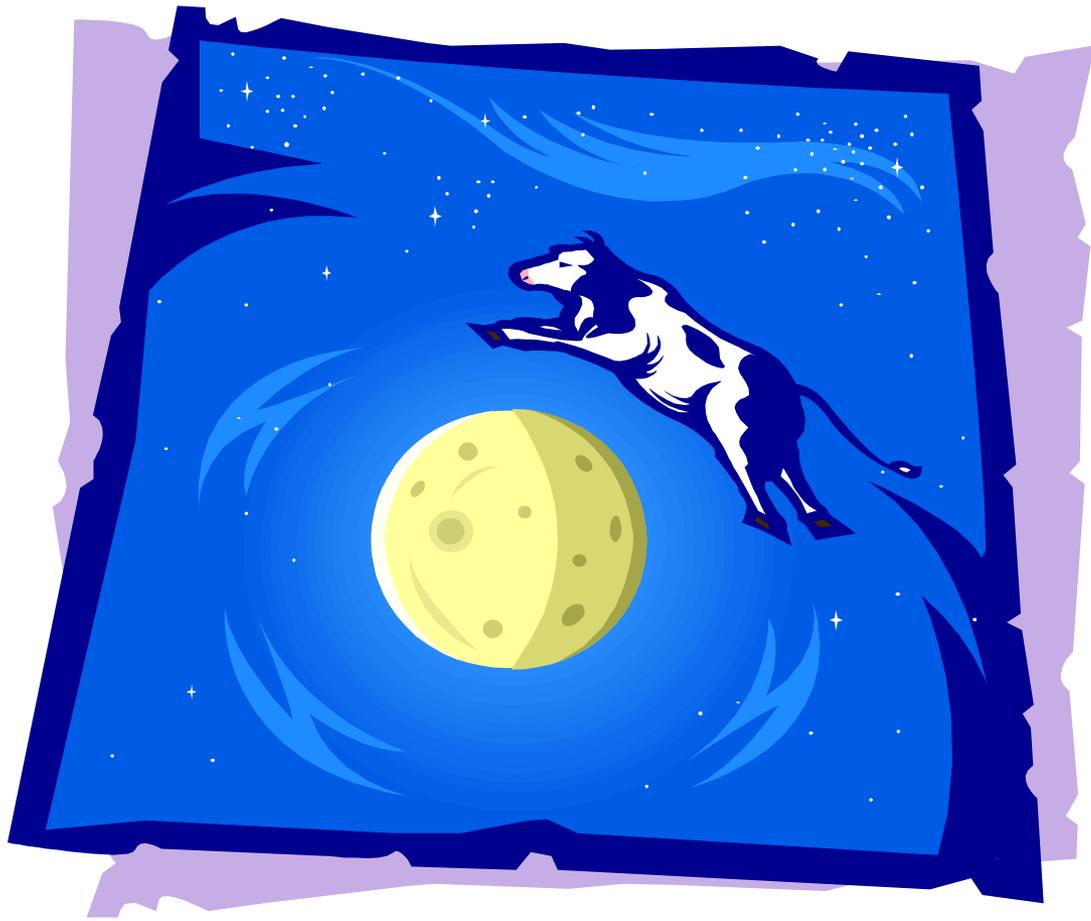




# ***Food Safety, According to Jim***

**“Food Safety is like road construction. Our job is never done. Let’s keep on building bridges together, sharing best practices.”**





***Questions?***