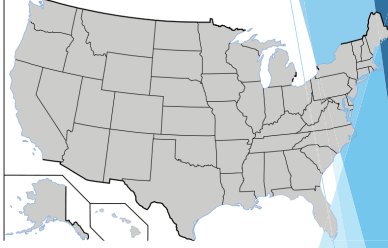


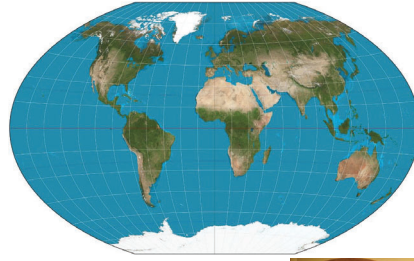
## UPDATE

### National Conference on Interstate Milk Shipments



NADRO Annual Meeting  
Mystic, CT July 15, 2019

Stephen Beam, Ph.D.  
Chair, NCIMS  
California Dept. of Food and Agriculture



## 2019 Conference

- ▶ Australia
- ▶ Canada
- ▶ Cost Rica
- ▶ Ireland
- ▶ Israel



## 2019 Conference



- ▶ 397 registered attendees 2019, St. Louis
- ▶ 398 registered attendees 2017, Grand Rapids
- ▶ 353 attendees at 2015 Conference, Portland
- ▶ 318 attendees at 2013 Conference, Indianapolis

## Orientation Session



- ▶ 31% First-time attendees



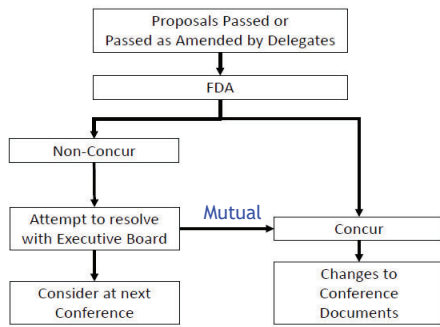
## 2019 Conference

- ▶ 47% Regulatory / 53% Industry
  - 131 - State employees (48 states)
  - 53 - Federal employees (FDA & USDA)
  - 208 - Industry
  - 3 - Academia
  - 2 - Other (Executive Secretary & Parliamentarian)

## 2019 Conference

- ▶ 75 proposals considered / 39 passed / 36 NA
- ▶ 31 passed by delegates (56 non-2400 Forms)
  - 10 as submitted
  - 21 as amended/substitute solution
- ▶ 25 No action
- ▶ 19 - 2400 Forms (8 passed/ 11 No action)
- ❖ Transcript sent to FDA on May 28, 2019
- ❖ FDA Concur/Non-concur letter 90-day deadline per the Procedures is August 26, 2019

## Life of an NCIMS Conference Proposal



5/4/2018

7

## FDA as critical partner

### Scientific Conference Grant

- ▶ \$25,000 from FDA-ORA
- ▶ Support for State Delegate travel
- ▶ Provided assistance to 20 states (\$1,250 per state)



- ❖ If mutual concurrence is not reached then the proposal is referred to the next Conference
- ❖ In the interim FDA is to consider additional information that becomes available and can resubmit to the Executive Board for additional consideration - including an effective date
- ❖ For changes to Conference Documents FDA issues an IMS-a detailing the Conference actions for a minimum 10-day review by Documents Review Committee, and ultimately a 2/3 affirmative vote of the Executive Board.

## Association of Food and Drug Officials Grant Portal for FDA Funds

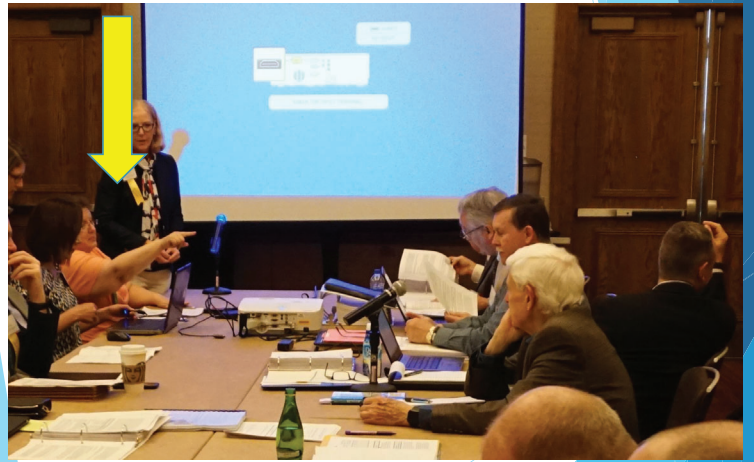
- ▶ Funding to support training and equipment to assist the states with implementation of the National Grade-A Milk Safety Program and National Shellfish Sanitation Program.
- ▶ Joint Advisory Group (JAG). NCIMS included: Chair, Executive Secretary, Liaison Committee Chair, FDA Grade-A Program, Other FDA offices.
  - ▶ Year 1: \$371,350 to Grade A Milk Safety Program (54 awards: Training-\$367,647 / Equipment- \$3,702)
  - ▶ Year 2: \$538,331 to Grade A Milk Safety Program (78 awards: Training-\$468,537 / Equipment- \$69,793)
  - ▶ Year 3: \$848,629 to Grade A Milk Safety Program (98 awards: Training-\$668,362 / Equipment- \$180,267)

## FDA as critical partner



<http://foodsafetygrants.org/msgrants>

# NCIMS Committees



14

## NCIMS Standing Committees

- ▶ Constitution & Bylaws
  - ▶ Documents Review
  - ▶ HACCP Implementation
  - ▶ Hauling Procedures
  - ▶ International Certification Program
  - ▶ Laboratory
  - ▶ Liaison
  - ▶ Method of Making Sanitation Ratings (MMSR)
  - ▶ Other Species Milk
  - ▶ Program Committee
  - ▶ Scientific Advisory
  - ▶ Single Service Container (SSCC)
  - ▶ Technical Engineering Review
- ▶ Appendix N Modification Committee
  - ▶ Proposal 307

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## 2019 Proposal 212

Proposal 212 of the 2019 NCIMS Conference directs the NCIMS Hauling Procedures Committee to conduct a comprehensive review of FDA Form 2399a and report back to the 2021 Conference.

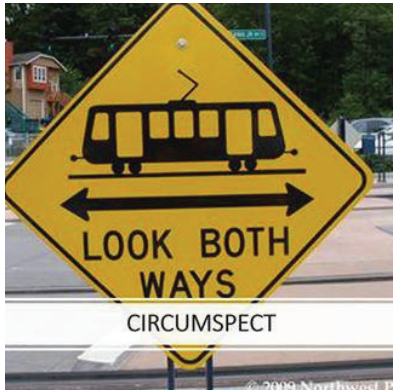
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
BULK MILK HAULER/SAMPLER PERMIT NO.	BULK MILK HAULER/SAMPLER
BULK MILK HAULER/SAMPLER EVALUATION REPORT	
ADDRESS OF BULK MILK HAULER/SAMPLER	NAME AND ADDRESS OF
OWNER	NAME AND ADDRESS OF
ADDRESS OF OWNER	

*An evaluation of your sampling procedures showed violations existing in the items checked below. This evaluation report serves as notification of the intent to suspend your permit if the violations noted are not corrected by the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)*

HAULER SANITATION PROCEDURES	
1. Pickup practices conducted to prevent contamination of milk contact surfaces	<input type="checkbox"/>
2. Hands clean and dry, no infections	<input type="checkbox"/>
3. Clean outer clothing, no use of tobacco	<input type="checkbox"/>
4. Hoses port used; tank top closed during completion of pickup	<input type="checkbox"/>
5. Hoses properly capped between milk pickup operations, hose cap protected during milk pickup	<input type="checkbox"/>
6. Hoses disconnected before tank rinsed	<input type="checkbox"/>
7. Observations made for sediment/abnormalities	<input type="checkbox"/>
8. Sample collected from each producer's bulk tank tank picked up	<input type="checkbox"/>

BULK TANK SAMPLING PROCEDURES

- Assigned to Hauling Committee
- Chair, Randy Chloupek (NE)



## 2019 Proposal 112

The NCIMS Chairman shall assign to either a standing committee or an ad-hoc committee, with input from affected stakeholders, the responsibility of reviewing the NCIMS role in regulating the repackaging of yogurt sour cream, acidified sour cream and cultured milk and/or milk products and report to the 2021 NCIMS Conference.



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## 2019 Proposal JC-1

- Established an option for Appendix T rating/audit to be conducted by a state rating upon agreement between a state rating agency and FDA.
- Conducted by personnel with PHS/FDA Grade-A PMO Prev regulators (FD378), or the Food Regulators Course (FD254)
- Requested Chair assign the proposal to a standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.
- Charged to work cooperatively with FDA to develop a pilot program...to find efficiencies in inspection activities for facilities that manufacture both Grade-A and non-Grade "A" products...to be implemented by FDA and the participating states.

- Assigned to Liaison Committee
- Chair, Casey McCue (NY)

## 2019 Proposal 114

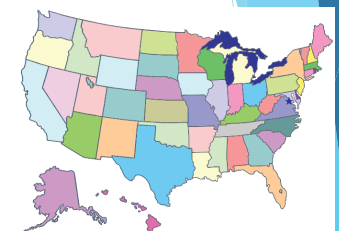
Requests the NCIMS Chair to assign an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board to study the safety of water used in the dairy industry, including technologies to produce disinfected and/or Pasteurized Equivalent Water as prescribed in Section VII, Appendix D and Appendix H and report back to the 2021 NCIMS Conference.



- Assigned to Scientific Advisory Committee
- Chair, Dr. Nicole Neeser (MN)

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## Grade A Milk Inspection Resource Survey



- Conducted by AFDO
- August 2017
- 47 States responded
- 62.5% of Grade A Plants (620+) conduct manufacturing grade processing
- 38% (18/47) conduct dairy plant inspections for FDA under contract or cooperative agreement



**FDA to launch pilot to improve efficiency of inspections at dairy processing facilities under FSMA** -November 1, 2017

“....said FDA Commissioner Scott Gottlieb, M.D. We believe there’s more opportunity for FDA and state regulators to better coordinate oversight efforts of the dairy industry, making the process more efficient while maintaining the high safety of the U.S. milk supply.”

## Proposal 303- Review of M-Is

- ▶ FDA will provide draft M-I to NCIMS Document Review Committee (DRC) for review.
- ▶ The DRC will provide comments to FDA within 45 days
- ▶ Within 45 days FDA will provide responses to DRC comments
- ▶ The DRC and FDA will have 30 days to mutually resolve outstanding issues/concerns.
- ▶ If an issue/concern is not resolved and/or the DRC determines the M-I goes beyond providing guidance/information on FDA’s current thinking on a specific subject/scenario/situation and is more interpretive in nature, then the specific question and answer **will be removed from the draft M-I.**
- ▶ PHS/FDA will finalize the mutually agreed upon M-I and distribute the memorandum

**Douglas Stearn**

**Deputy Director for Regulatory Affairs**

**FDA-CFSAN**



**2019 NCIMS**

## Dairy Inspection Pilot Program

FDA supports a pilot to identify ways to maximize state and federal resources and create greater efficiency through our obligations under the FDA Food Safety Modernization Act.

- Pilot multiple approaches in dual-grade facilities
- FDA intends to learn, explore, and evaluate prior to committing to a decision.

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## Proposal 304

- ▶ Allows States and TPCs the option of having their State Program Evaluations (SPEs) conducted once every 5 years instead of every 3 years.
- ▶ The option to extend the SPEs out to a 5-year timeframe depends on:
  - ▶ State or TPC had two (2) consecutive triennial written Regulatory/Rating Agency Program Evaluations conducted and completed within the established 3-year time frames
  - ▶ Both of these SPEs were classified as being “in compliance” with the requirements of the Grade “A” PMO and the NCIMS Procedures document.

<http://ncims.org>

**NCIMS**  
National Conference on Interstate Milk Shipments

LEADERSHIP CONFERENCES FACILITIES PROGRAMS 2400 FORMS ABOUT

**01 MAY** Automatic Milking Installation (AMI) Subcommittee Activities

The following information is provided on behalf of the AMI Subcommittee:

AMI Subcommittee Quarterly Reports to the NCIMS Executive Board

1. AMI Subcommittee Jan 8 Letter to NCIMS Board
2. AMI Subcommittee March 23 Letter to NCIMS Board
3. AMI Subcommittee June 2018 Quarterly Update to NCIMS Board

NCIMS Memoranda of Information (M-I) related to AMI

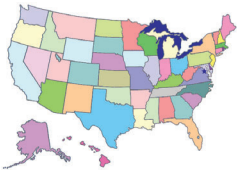
1. M-I-14-8 (AMI CRITERIA) FINAL
2. M-I-14-8 (SUPPLEMENT 1) FINAL (AMI CRITERIA)
3. M-I-14-8 Supplement 2 (Final 3-28-18)
4. M-I-17-3 Guidance AMI Computer System(s) Verification
5. M-I-17-4 FINAL (AMI QUESTION SUBMISSION)
6. M-I-17-5 AMI Check Rating Guidance (1)

NCIMS

— NCIMS Automatic Milking Installation (AMI) Subcommittee Chosen

## NCIMS Executive Board 2017-2019



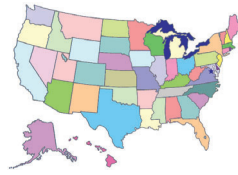


## NCIMS Executive Board Up to 27 members

- ▶ Chair: **Stephen Beam** - California Dept. of Food and Agriculture

Past Chair: John Miller, Florida Dept. of Agriculture and Consumer Services

- ▶ Vice Chair:  
**Antone Mickelson** - NW Dairy Assoc., WA
- ▶ Executive Secretary:  
**Marlena Bordson**, IL

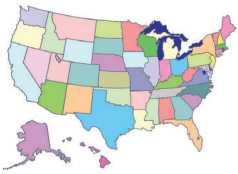


## NCIMS Executive Board



- ▶ Eastern States:

State Enforcement - **Casey McCue**, NY  
 State Enf./Local Health - **Ellen Fitzgibbons**, MA  
 FDA - **John Sheehan**, College Park, MD  
 Industry - **Rebecca Piston**, HP Hood, ME  
 State Rating - **James Williamson**, SC



## NCIMS Executive Board



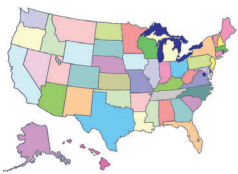
- ▶ Western States:

State Enforcement - **Clint George**, TX  
 State Rating - **Randy Chloupek**, NE  
 State Enf./Local Health - **Stephen Beam**, CA  
 USDA - **Will Francis**, AMS, Washington, D.C.  
 Industry - **Antone Mickelson**, WA



## NCIMS Executive Board Non-voting seats

Council I Chair - **Thomas Benthien**, IL  
 Council II Chair - **Laura Traas**, WI  
 Council III Chair - **Casey McCue**, NY  
 Program Chair - **Cary Frye**, IDFA, Washington, DC  
 Liaison Committee Chair - **Casey McCue**, NY  
 IDFA - **John Allen**, Washington, DC  
 NMPF - **Clay Detlefsen**, Arlington, VA  
 Third Party Certifier - **Ken Anderson**, HW & Associates, IL  
 Consumer Representative - Vacant  
 Lab Committee Chair - **Laura Traas**, WI



## NCIMS Executive Board



- ▶ Central States:

State Enforcement - **Steve DiVincenzo**, Illinois  
 State Rating - **Gene Wiseman**, Missouri  
 State Enf./Local Health - **Roger Tedrick**, Ohio  
 Academia - **Patrick Gorden**, Iowa State  
 Industry - **Neil Bendixen**, DFA, MI  
 Laboratory - **Roger Hooi**, Dean Foods, TX

[www.ncims.org](http://www.ncims.org)



## 2021 Conference



Indianapolis, IN    April 9 - 14, 2021

JW Marriott Indianapolis

*Thank you!*

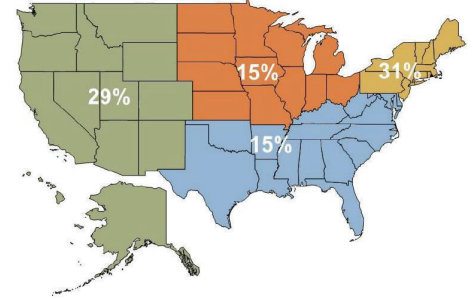
# Overview of Cheese Industry and Safety: Regulatory Concerns and Initiatives

Dennis D'Amico  
National Association of Dairy Regulatory Officials  
Annual Meeting  
July 16 2019



## Demographics

- ~1000 cheesemakers
- 209 respondents



\* Of the cheesemakers responding in 2018, 10% didn't provide their location.



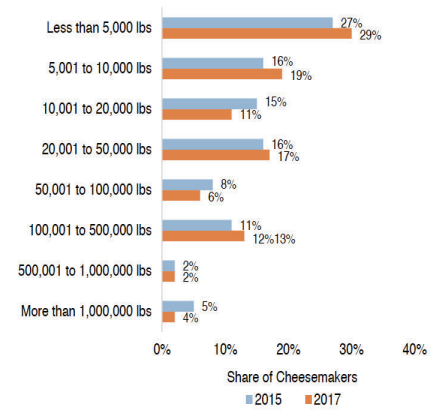
## Overview

- 2018 State of the U.S. Artisan/Specialty Cheese Industry
- Food safety and regulatory concerns
  - FDA FY14-16 Raw Milk Cheese Sampling results
  - Recent cheese-related recalls and outbreaks
- Current cheese safety initiatives and resources
- Questions



## Production volume

- Most are very small
  - ~75% make <50,000 lb
  - ~50% make <10,000 lb
  - ~30% make <5,000 lb

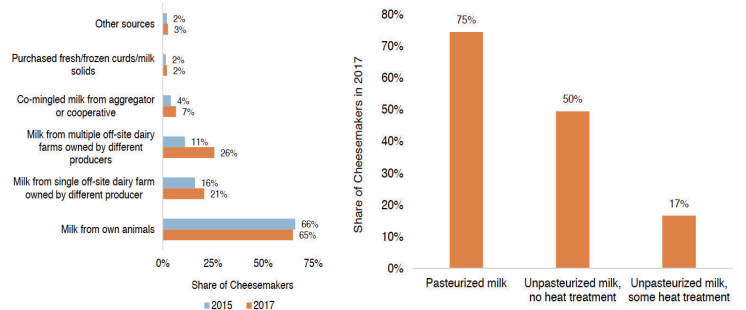


## 2018 State of the U.S. Artisan/Specialty Cheese Industry Survey

- Digital copies available for purchase



## Milk source and heat treatment





## Aging Surfaces

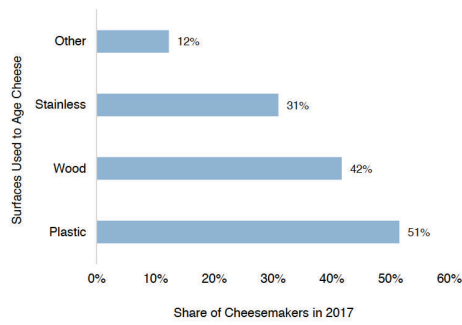
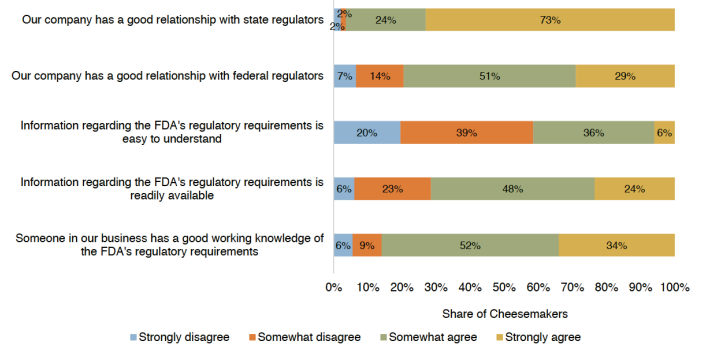
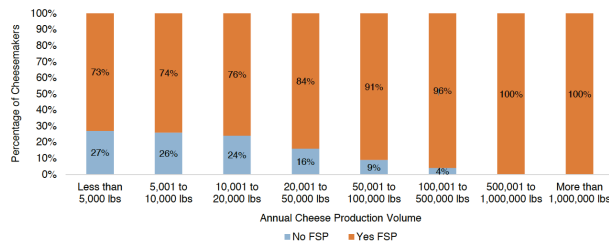


Exhibit 6.1 — Share of Cheesemakers Agreeing with Statements Regarding Regulatory Knowledge and Information, 2018, N=197



- 2018: 81.5% reported having a Food Safety Plan
  - Up from 59% in 2016
- Smaller businesses were less likely to have an FSP
  - Down from 62% in 2016 for producers making <5000 lb

Exhibit 4.2 — Businesses Operating with a Food Safety Plan in 2018 by 2017 Annual Cheese Production Volume, N=200

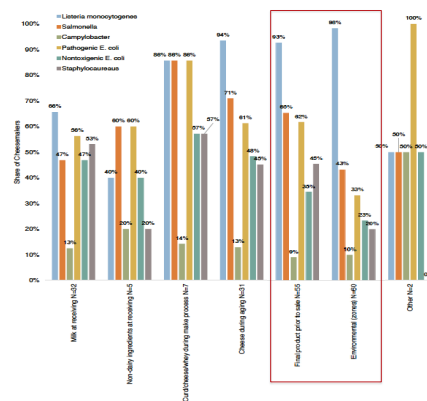


## Concerns with risk inflation

- Consumers of unpasteurized milk and cheese are a small proportion of the US population (3.2% and 1.6%, respectively)
- Dairy Outbreak Data: 2009-2014
  - >800x higher risk for consumers of unpasteurized milk or cheese than for consumers of pasteurized dairy products
  - Outbreak-related illnesses will increase steadily as unpasteurized dairy consumption grows, likely driven largely by salmonellosis and campylobacteriosis

- 45% reported some pathogen testing
- Environment and finished product most common
  - followed by milk and aging
- *Listeria* most common

Exhibit 5.5 — Share of Cheesemakers Conducting Pathogen Testing at Specific Points, 2017



Dairy-related illnesses and hospitalizations from 87 outbreaks, National Outbreak Reporting System, United States, 2009–2014\*

Pathogen	Outbreaks associated with milk and cheese consumption, N = 87†					
	Pasteurized			Unpasteurized		
	Outbreaks	Illnesses	Hospitalizations	Outbreaks	Illnesses	Hospitalizations
STEC	0	0	0	14‡	99	42
<i>Salmonella</i> spp.	0	0	0	8§	83	29
<i>Listeria monocytogenes</i>	10	100	87	1	1	1
<i>Campylobacter</i> spp.	1	2	0	53‡§	465	56
Overall	11	102	87	76	648	128

## Cheese outbreaks in US: 1998-2011

- Past. milk: 44 outbreaks, 987 illnesses
- Raw milk: 38 outbreaks, 816 illnesses
  - 20 linked to soft cheeses: Queso Fresco or Mexican-style
    - rest were homemade, fresh, curds, etc.
  - 3 linked to cheese aged ≥60 days
    - Concerns go beyond use of raw milk



Gould et al., 2014



## FDA Microbiological Surveillance Sampling: FY14-16 Raw Milk Cheese Aged 60 Days

- *L. monocytogenes* in cheeses, particularly semi-soft varieties, remains a concern
  - The FDA believes this contamination rate may be related to product handling practices or procedures
  - FDA plans to continue to work with the cheese industry to identify and correct practices that lead to *L. monocytogenes* contamination in cheese



<https://www.fda.gov/media/99340/download>

## FDA Microbiological Surveillance Sampling: FY14-16 Raw Milk Cheese Aged 60 Days

- 1,606 raw milk cheese samples collected and tested
  - 473 (29 %) were domestic
  - 1,133 (71 %) were of international origin
- 63% semi-soft cheese; 32.5% hard
- *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7 and Shiga toxin-producing *E. coli*, as well as for generic *E. coli*



<https://www.fda.gov/media/99340/download>



Cheese recalled by Portogruaro del Rio

**Listeria deaths in France linked to raw milk cheese brand**

By News Desk on May 29, 2019



Recalled Portuguese Alentejo Cheese

**More ill in Listeria, E. coli outbreaks linked to raw milk cheese**

By Joe Whitworth on May 21, 2019



Provençale des Alpes cheese recalled

**Two sick in France from Listeria in cheese**

By Joe Whitworth on April 15, 2019



Recalled Bledonian cheese

**Sharp rise in French Salmonella outbreak linked to raw milk cheese**

By News Desk on December 8, 2018



**Salmonella outbreak in France linked to raw milk goat cheese**

By Joe Whitworth on August 28, 2019



**One child dead, 13 others sick in raw cheese E. coli outbreak**

By Carol Beach on June 4, 2008

## FDA Microbiological Surveillance Sampling: FY14-16 Raw Milk Cheese Aged 60 Days

- *E. coli* O157:H7: 0%
- Shiga toxin-producing *E. coli*: 0.68%
  - Only 1 was pathogenic (*E. coli* O111:H8) for a rate of 0.06%
- *Salmonella*: 0.19 %
  - All imports (2 from France, and 1 from Italy)
- *L. monocytogenes*: 0.62 % (could be environmental)
  - 5 domestic, with 3/5 collected at a single firm
  - 5 imports (4 from France, 1 from Italy)



<https://www.fda.gov/media/99340/download>

## Listeria in US pasteurized milk cheese

**Yoke's, Lipari, Copperwood cheeses recalled for Listeria risk**

By Carol Beach on March 1, 2017

Three more brands of cheeses – all produced by Dutchess Kasee Foods LLC – are being recalled because of possible contamination with *Listeria monocytogenes* bacteria.

Yoke's Fresh Market and Lipari Foods LLC posted the recall Tuesday with the Food and Drug Administration, both naming the Middlebury, Vt. cheese maker.

The Yoke's branded recalled cheeses were sold in Yoke's stores in Idaho and Washington.



**FDA finds Listeria in 'Margie' cheese; New York company recalls product**

By News Desk on November 20, 2018



**Michigan cheese company recalls product after state finds Listeria**

By News Desk on November 20, 2018



**U.S., dozens of countries received cheese that was recalled for Listeria risk**

By Joe Whitworth on April 19, 2019

# Listeria in US raw milk cheese

## Multistate Outbreak of Listeriosis Linked to Soft Raw Milk Cheese Made by Vulto Creamery (Final Update)

Posted May 8, 2017 1:38 PM EDT

This outbreak appears to be over. However, Listeria remains an important cause of serious, life-threatening human illness in the United States. For more information about Listeria and steps that people can take to reduce their risk of infection, visit CDC's [Listeria webpage](#).

### Highlights

- Read the [Recall & Advice to Consumers and Retailers](#).
- This outbreak appears to be over. However, CDC recommends that consumers do not eat, restaurants do not serve, and retailers do not sell recalled raw milk cheeses made by Vulto Creamery.
- On March 10, 2017, Vulto Creamery recalled 15 all lots of its raw milk cheeses.
  - The raw milk cheeses were distributed nationwide, with most being sold at retail locations in the northeastern and Mid-Atlantic states: California, Chicago, Portland, Oregon, and Washington, D.C.
- CDC, public health and regulatory officials in several states, and the U.S. Food and Drug Administration (FDA) investigated a multistate outbreak of *Listeria monocytogenes* infections.

### At a Glance:

- Case Count: 8
- States: 4
- Deaths: 2
- Hospitalizations: 8
- Recall: Yes



## New York dairy recalls cheese after positive test for Listeria

By Nancy M. Madsen on August 24, 2017

All Cooper Cheese, NY, dairy is recalling three brands of cheese because of a listeria outbreak.

A recall alert issued by the New York State Department of Agriculture says consumers should not eat the recalled cheeses. The cheeses are from Milk "Monkeys" and "Cooperstown Cheese Co." and are sold at various locations in the state.

## Warning: Organic, raw goat milk cheese positive for Listeria

By News Desk on March 5, 2016

New York State Agriculture Commissioner Richard A. Ball warns consumers not to eat The Milkster's Creamery "Wild Meadler" raw goat milk cheese made in South New York because of possible Listeria contamination.

So far, no illnesses have been reported in connection with the goat cheese made by the Milkster's 1277 Cooper Center Road.

The product is sold in various sizes of sealed flexible plastic packaging, displaying the plant number 36-1316, with a



## Mecox Bay Dairy recalls cheese after samples test positive for Listeria

By Nancy M. Madsen on May 10, 2016

## Cooperstown Cheese Co. raw milk cheese positive for Listeria

By News Desk on October 13, 2017

New York inspectors today confirmed Listeria monocytogenes in Tom's brand raw milk cheese, prompting them to warn consumers against eating the product made by Cooperstown Cheese Co. LLC.



# New FDA sampling assignments

- Fiscal Year 2020
  - Raw milk cheeses (200 samples)
    - Staphylococcus aureus* and Staph toxin
  - Bridged cheeses (300 samples)
    - L. monocytogenes*
  - Smear ripened cheeses (300 samples)
    - L. monocytogenes*
- Most will be domestic
  - New York, Pennsylvania, Vermont, New Hampshire, Wisconsin, Washington, Oregon, and California

## Regulatory concern: Generic *E. coli*

- Cheese may be considered adulterated under Section 402(a)(4) of the FD&C when *E. coli* is found at violative levels
- 2010-2011- FDA changed the *E. coli* limits
  - Single criterion for raw and pasteurized milk cheese
  - >10 MPN/g and <100 MPN/g in three or more subsamples of the five
- FY14-16- Violative samples: 3.8% domestic; 6.1% imported
- No association between the presence of pathogens

## Initiatives

- Artisan Cheese Food Safety Advisory Team
- Deliver accessible training and tools for artisan dairy
  - Food safety workshops 2012 -2016: 21 sessions, 750 attendees
  - Re-launched as an online class June 2017
- Consolidated resource website: [www.safecheesemaking.org](http://www.safecheesemaking.org)
- Food Safety coaching and food safety plan writing sessions

## Generic *E. coli*

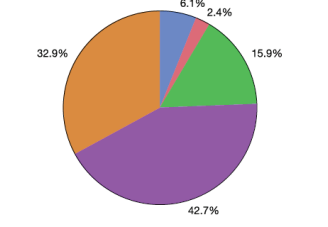
- Presence/absence of index or indicator organisms generally does not correlate well with that of foodborne pathogens
- Not useful for determining pathogen contamination of individual lots
- Useful in assessment of facility hygiene and the potential loss of process control
- February 9, 2016
  - FDA paused its testing for generic *E. coli* in raw milk cheese
  - considering role generic *E. coli* should have in identifying and preventing insanitary conditions and food safety hazards

## Online Food Safety Course

- Developed by, and housed at, NCSU
- 819 participants from 20 countries enrolled in the course
  - 34% course completion rate
- 669 participants from 46 states enrolled in the course
  - 35% course completion

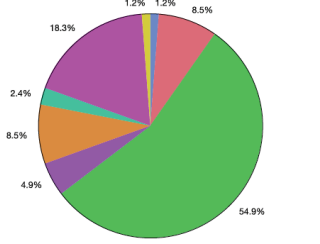


Which of the following best describes your facility?



- Employed at a large-sized cheese company (> 50 employees)
- Employed at a medium-sized cheese company (16-50 employees)
- Employed at a small-sized cheese company (5-15 employees)
- Employed at a very small-sized cheese company (< 5 employees)
- I am not employed at a cheese company

Which of the following best describes your employer?



- Consultant
- Dairy food company that does not make cheese
- Dairy food company that makes cheese
- Educational institution
- Food company that does not make dairy foods
- Government agency
- Other
- Student at an educational institution

# Cheese Safety & Quality Checklist

**PROTECTED: PART 1: PRE-AUDIT QUESTIONS**

This section covers the following topics:

- \* Regulatory Requirements
- \* Owner Operated
- \* Products Produced
- \* Production Capacity
- \* Shared Space
- \* Off Site Facility Used
- \* Insurance
- \* 3rd Party Audits

**PRE-AUDIT QUESTIONS**

**1.01 Does the facility have all required regulatory permits? (State/Local Health/Ag permit, Milk and Dairy, tax id, etc.) \* \***

Yes

No

Please continue to question 1.02

**1.02 Upload a list of products produced at this facility.**

No file chosen



Asset Usage 2019

FSMA Compliant Templates	128
Food Safety Plan for Pepper Jack Cheese	83
Online Education	63
American Cheese Society Best Practices Guide for Cheesemakers	55
Cheese and Microbes	38
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The American Cheese Society's  
**Best Practices Guide for Cheesemakers**

Published February 15, 2017



# Cheese Safety & Quality Checklist

**PROTECTED: PART 1: PRE-AUDIT QUESTIONS**

This section covers the following topics:

- \* Regulatory Requirements
- \* Owner Operated
- \* Products Produced
- \* Production Capacity
- \* Shared Space
- \* Off Site Facility Used
- \* Insurance
- \* 3rd Party Audits

**PRE-AUDIT QUESTIONS**

**1.01 Does the facility have all required regulatory permits? (State/Local Health/Ag permit, Milk and Dairy, tax id, etc.) \* \***

Yes

No

The state or county in which you are doing business might have special permits and requirements. Find what is required in your state and county. You can continue this checklist once you have your required permits, and select "Yes" [Return to Level One Audit/Checklist](#)



# Cheese Safety & Quality Checklist



**PROTECTED: CHEESE SAFETY & QUALITY CHECKLIST**  
The Level 1 Audit was created to help local artisan cheesemakers create a basic food safety plan. With FSMA, even the smallest producers must provide a Risk Assessment and monitor Preventive Controls. This tool includes HACCP and Preventive Controls Information.

**USING THE CHECKLIST**  
\* The Level 1 Audit Checklist ACS Tool is a walkthrough "wizard" and prompts you to act based on your answers. The questions are progressive and users can only move forward in the audit if they respond with "yes" responses.  
\* If the user replies with a "no" they will not be able to move forward on the checklist, but they will be guided to a vetted resource that will help correct the no to a "yes".  
\* **The form must be completed in its entirety** - ACS will not save or store user data.  
\* Upon completion of each form and the user submits their answers, the user will have a completed Level 1 Audit and will be able to download a PDF of the checklist to have for their records.

**GET STARTED**  
Part 1: Company Information and Audit Overview  
Part 2: Pre-Audit Questions  
Part 3: Food Safety Management  
Part 4: Prerequisite and Preventive Controls  
Part 5: Control of Hazards

[Download the Full Audit Here](#)



# Food Safety Plan Writing & National Food Safety Support

- **Food Safety Plan Workshops**
  - 3 year, USDA NIFA Grant
  - Traveling workshops with expert guidance and coaching
  - Enable dairy foods producers to create & enhance their food safety plans
  - [www.dairyfoodsafetycoalition.com](http://www.dairyfoodsafetycoalition.com)
- **National Food Safety Support**
  - Available across the U.S.
  - Answer questions free via e-mail or phone call
  - Refers experts and resources
  - [dairyfoodsafety@cornell.edu](mailto:dairyfoodsafety@cornell.edu)



United States Department of Agriculture  
National Institute of Food and Agriculture



## 2019 workshops

<b>Location</b>	<b>Timing</b>	<b>Partners</b>
Plattsburgh, NY	February 26-27, 2019	Harvest NY/Cornell Extension
Cockeysville, MD	May 9-10, 2019	University of Maryland
Richmond, VA	July 31, 2019	American Cheese Society
Minneapolis, MN	September 26-27, 2019	MDA/ISU/UMN
Napa, CA	October 2019	CA Artisan Cheese Guild
Charleston, SC	November 4, 2019	NICRA Pre-Conference
Hartford, CT	Fall 2019	UConn/UMass/NE Dairy
Brooklyn, NY	TBD 2020	NY Extension/Cornell



## Questions?



## FDA Grade "A" Update Report

NATIONAL ASSOCIATION OF DAIRY REGULATORY OFFICIALS  
GROTON, CT  
JULY 14-17, 2019

Randy Elsberry  
Office of Food Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

## Milk & Milk Products Branch Grade "A" Staff

- Steve Sims
- Frank Flores
- Robert Altobelli (On Detail)
- Randy Elsberry
- Dr. Steve Walker (Engineer)
- Laurie Bucher (Labeling)
- Dr. Jeff Hamer (Veterinarian)

## TOPICS

- ▶ CFSAN/OFS/Milk & Milk Products Branch
- ▶ 2019 NCIMS
- ▶ Coded Memorandums
- ▶ International Certification Program
- ▶ Single Service Consultants
- ▶ Grade "A" Equivalency Determinations
- ▶ CBD Oil
- ▶ National Drug Residue Data Base

## Milk & Milk Products Branch Grade "A" Staff

- Dennis Gaalswyk (Retired)
- Bob Hennes (Retired)
- Vacant Position
- Vacant Position



## CFSAN/Office of Food Safety

- ▶ Dr. Mark Moorman – Director, Office of Food Safety
- ▶ Monica Metz – Acting Director, Division of Dairy, Egg and Meat Products
- ▶ Monica Metz – Chief, Milk & Milk Products Branch

## 2019 NCIMS Conference

April 26 - May  
1, 2019  
St. Louis,  
Missouri



## 2019 NCIMS Conference

**397 REGISTERED**

- REGULATORY-131
- Federal (FDA and USDA) - 53
- INDUSTRY-208
- ACADEMIA-3
- 131 (33%) 1<sup>ST</sup> TIME ATTENDEES
- 47% Government - 52% Industry

Slide 7

## 2019 NCIMS Conference

- ▶ 75 Proposals Submitted and deliberated
- ▶ Council I – 23 Proposals (11 Passed)
- ▶ Council II – 42 Proposals (19 Passed of which 8 were 2400 Forms)
- ▶ Council III – 8 Proposals (7 Passed)
- ▶ Joint Council – 2 Proposals (2 Passed)
- ▶ Total: 39 Proposals Passed of which 8 were 2400 Form Changes)

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## 2019 NCIMS Conference

### ▶ FOREIGN COUNTRIES

- CANADA
- ISRAEL
- AUSTRALIA
- Costa Rica
- IRELAND

Slide 8

## 2019 NCIMS Conference

- ▶ FDA received transcripts on 5/28/2019
- ▶ Concur/non-concur letter due by 8/26/2019
- ▶ Currently working on IMS-a-52 and other IMS documents (PMO, MMSR, Procedures and EML)

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## 2019 NCIMS Conference

### **VOTING DELEGATES:**

**49 STATES AND PUERTO RICO  
SENT DELEGATES**

**(Alaska and Arkansas not in  
attendance)**

Slide 9

## Coded Memorandums

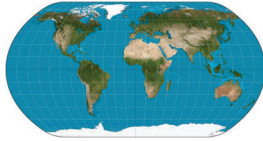
- ▶ M-I-19-3 (June 7, 2019): Interstate Milk Shippers List (IMS) Laboratory Procedures Code(s) Update.
- ▶ M-I-19-2 (February 27, 2019): Updated Information Related to Appendix N Drug Residue Testing . Option 3 not available for tetracycline and/or sulfonamides (11/27/2019).
- ▶ M-I-19-1 (February 21, 2019): 2019 Revisions of the Indexes of Coded Memoranda (IMS-a, M-a, M-b and M-l).

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## INTERNATIONAL CERTIFICATION PROGRAM (ICP)

Two Firms to date:

**Harold Wainess and Associates**  
**Milk Regulatory Consultants, LLC**



- 5 – CANADA (HW&A/MRC) - 4 PLANT and 2 Goat BTU
- 2 – COLOMBIA (HW&A) - 1 PLANT and 2 BTUs
- 2 – MEXICO (MRC) - 1 PLANT (aseptic listing) and 1 BTU
- 2 – GREECE (MRC) - 1 PLANT and 1 BTU

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## Grade “A” Equivalency Determinations

- Grade “A” equivalency determinations that are currently being conducted at the request of several governments and one supra-national entity:

- New Zealand
- European Union
  - Ireland
  - Netherlands
  - France
- Canada

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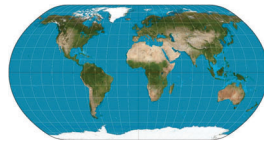
## SINGLE-SERVICE CONSULTANTS

One Firm to date:

- **PACKAGING CONSULTANTS INTERNATIONAL, INC.**

### FDA CERTIFIED SSCs

- Patrick Frontale – Owner
- Kathrene Dutrow



14

## CBD Oil (Cannabidiol)

- Extract from the flowers and buds of marijuana or hemp plants.
- Does not contain THC (tetrahydrocannabinol).
- It does not cause intoxication “marijuana high”.
- There is interest in adding CBD oil to Grade “A” milk and/or milk products.

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## FOREIGN SINGLE-SERVICE LISTINGS

- **3 SS Certifying Firms**
  - Milk Regulatory Consultants Inc. (MRC)
  - Harold Wainess and Associates (HW&A)
  - Packaging Consultants Inc. (PCI)
- **211 Listings**
- **33 Countries**

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## CBD Oil (Current FDA Position)

- CBD is not permitted in any food or dietary supplement involved in interstate commerce.
- CBD cannot be added to any food product that has a standard of identity, even if it is sold in intrastate commerce.
- There are no federal standards of identity which permit CBD, and all state standards of identity are preempted by the federal standards of identity if they are not identical.
- Only non-standardized foods containing CBD can be sold in intrastate commerce if state rules allow it.

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## CBD Oil (FD & C Act)

FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including animal food or feed) to which THC or CBD has been added, regardless of whether these substances are derived from marijuana or hemp.

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22

## National Drug Residue Data Base (Revised) FY 2018 (10/1/2017-9/30/2018)

- ▶ 4,042,567 Samples analyzed (4,201,236 tests)
- ▶ Five different groups of families or individual drugs
  - Beta lactams
  - Cloxacillin
  - Sulfonamides
  - Sulfamethazine
  - Tetracyclines
- ▶ Twenty-two (22) testing methods were used

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## National Drug Residue Data Base (Revised) FY 2018 (10/1/2017-9/30/2018)

TABLE 3 — Tests Conducted October 1, 2017 to September 30, 2018

Source of Sample	Total Tests	Number of Positive Tests	Percent Positive
Bulk Milk Pickup Yanker	3,755,543	364	0.010%
Pasteurized Fluid Milk and Milk Products	32,890	4	0.012%
Producer	356,537	210	0.059%
Other	56,266	6	0.011%
<b>TOTALS</b>	<b>4,201,236</b>	<b>584</b>	

See Table 1 for explanation

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# AUTOMATIC MILKING INSTALLATIONS (AMIs)

Slide 1-1

## DeLaval



## AMI MANUFACTURERS

- DeLaval
- Lely
- GEA
- AMS Galaxy
- BouMatic
- Currently working with two (2) new AMI manufacturers

## AMS Galaxy



Slide 1-5

## Lely



Slide 1-3

## Boumatic



Slide 1-6

## GEA



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<u><b>X. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR AUTOMATIC MILKING INSTALLATIONS (AMIs) FOR GRADE “A” PUBLIC HEALTH CONTROLS</b></u> .....	<u>283</u>

Slide 10

## NCIMS Executive Board

- The Chair of the NCIMS Executive Board charges the Technical Engineering Review Committee to examine the issue of compliance of AMIs with requirements of the PMO with the specific objective of identifying obstacles and potential solutions to aligning PMO requirements with current and next generation AMI equipment and operations. (October 2017)

Slide 1-8

## Table of Contents

<b>APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED</b> <b><u>[RESERVED]</u></b> .....	385
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Slide 11

## 2019 NCIMS (Proposal 118)

- The subcommittee determined that Appendix Q of the PMO contains, in some instances, redundant language when compared to Section 7.
- The consensus of the subcommittee is that U.S. dairy farms utilizing AMI technology should not be regulated any differently than other dairy farms in the U.S.
- It was decided to work on incorporating language from Appendix Q into Section 7 and then remove Appendix Q.
- Appendix Q computer control language that was identified as necessary was revised and that language was placed in a new Section within Appendix H.

Slide 9

## ITEM 1r. ABNORMAL MILK

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Monitoring and controlling functions related to the identification and discarding of milk with abnormalities, shall comply with the criteria set forth in Appendix H of this Ordinance.

Slide 12

## ITEM 1r. ABNORMAL MILK

Milk without abnormalities may be diverted for other uses and the parts of the milking system that came into contact with this milk are not required to be cleaned and sanitized prior to use for milk to be offered for sale.

Slide 13

## ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION

~~14.AMIs shall comply with all applicable Grade "A" PMO requirements and/or 3-A Standards.~~

Slide 16

## ITEM 2r. MILKING BARN, STABLE OR PARLOR – CONSTRUCTION

Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings. For AMI milking unit rooms, the ventilation air shall come from outside the cattle housing area.

Slide 14

## ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers ~~and~~ milk pumps ~~and AMI milking equipment~~ which are designed for CIP cleaning and other equipment, ~~as accepted by FDA,~~ which meets these criteria, may be CIP cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times. ~~Some of the parameters~~ Parameters to be considered in determining protection are:

c. Adequate and properly located lighting and ventilation.

i. Provided, AMI milking unit rooms shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.

Slide 17

## ITEM 3r. MILKING BARN, STABLE OR PARLOR – CLEANLINESS

Outside surfaces of ~~pipeline systems~~ all milking and clean-in-place (CIP) equipment located in the milking barn, stable or parlor are reasonably clean.

Slide 15

## ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

**NOTE:** Additional alternative udder preparation methods, including those used on AMIs, may also be used once they have been evaluated by FDA and found acceptable. A copy of the FDA acceptance will be available for distribution to regulatory agencies, FDA and other interested parties. Verification of an AMI's control functions responsible for proper teat preparation shall comply with the criteria set forth in Appendix H of this Ordinance.

Slide 18

## ITEM 14r. PROTECTION FROM CONTAMINATION

1. Equipment and operations are so located within the milking barn and milkhous as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.

2. During the teat preparation process of an AMI, the teat cups (inflations) shall be adequately shielded to prevent contamination.

3. During milking and milkhous operations, pipelines and equipment, used to contain or conduct milk, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. In addition, AMIs shall provide separation between milk with abnormalities and milk intended for sale. This can be accomplished by:

Slide 19

## ITEM 18r. RAW MILK COOLING

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7°C (45°F) or less, two (2) hours or after the completion of milking, after starting the milking operation.~~ The milk shall then be cooled within two (2) more hours to 7°C (45°F) or less. The start of the milking operation is the moment when milk is first transferred to an empty, clean and sanitized farm bulk milk tank, silo or direct load milk tank truck. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

Slide 22

## ITEM 14r. PROTECTION FROM CONTAMINATION

3. The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

- i) During CIP, ~~a valve actuation of the valve blocking the cleaning/sanitizing solution blocking valve may be used pulsed open for cleaning the valve vent, including piping between blocking valves, provided the blocking valves are fail-safe and the vent is self-draining and free from restrictions. Other means of preventing there shall not be~~ pressurization of cleaning solutions on the exterior of the valve isolating milk may be individually evaluated and found to be acceptable by FDA and the Regulatory Agency, that can equal or exceed the pressure of the milk being isolated, and

Slide 20

## APPENDIX H, SECTION X

### X. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR AUTOMATIC MILKING INSTALLATIONS (AMIs) FOR GRADE "A" PUBLIC HEALTH CONTROLS

#### BACKGROUND

AMIs have computerized systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves. The following criteria are to be used for the evaluation of AMI computerized systems requirements within [Items 1r, 13r and 14r of this Ordinance.](#)

Slide 23

## ITEM 14r. PROTECTION FROM CONTAMINATION

6. Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency. ~~in order to prevent unauthorized changes.~~ Testing verification procedures shall comply with the criteria set forth in Appendix H of this [Ordinance.](#)

Slide 21

## APPENDIX H, SECTION X

1. A verification of all computerized system's control functions responsible for properly detecting and diverting abnormal milk; proper teat preparation; and the fail-safe valve system(s) providing separation between milk with abnormalities and milk intended for sale; and between cleaning/sanitizing solutions and milk intended for sale shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency.

2. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the AMI manufacturer; or other means accepted by the Regulatory Agency.

Slide 24

## APPENDIX H, SECTION X

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- 3. A manufacturer's written or electronic documentation addressing the computerized system's monitoring and controlling functions shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. This document will be available to regulatory agencies, FDA and other interested parties upon request.

Slide 1-25

## UNRESOLVED ISSUES

---

- Review M-I-14-8, M-I-18-8 (Supplement 1) and M-I-14-8 (Supplement 2) Q & A's.
- Address outstanding AMI issues and/or concerns that have not been addressed.

Slide 1-28

## UNRESOLVED ISSUES (M-I-17-3)

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- Until further notice, computer system(s) verification requirements related to Appendix Q, Item 1r, 13r, and 14r will not be debited on federal check ratings.

Slide 1-26

## On-Going Project (3-A SSI)

---

- **Tentative 3-A Sanitary Standard for Unitized Equipment For Automated Milking Installations**
  - **Number B-102-00-A**

Slide 1-29

## UNRESOLVED ISSUES (M-I-17-5)

---

- The maximum debit any non-compliant AMI equipment will incur for design deficiencies will be a single debit, not to exceed 4 points.
- No repeat violation penalties will be assessed for any debits on federal check ratings of AMI equipment for design.
- FDA position until the implementation of the PMO to be published after the 2019 conference.

Slide 1-27

## On-Going Project (3-A SSI)

---

- FDA AMI Task Force (M-I-17-4)
- CFSAN/DDEMP and Milk Specialist
  - Responsible for considering all matters relative to AMIs and recommending FDA policy.
  - Monica Metz, FDA/CFSAN  
[monica.metz@fda.hhs.gov](mailto:monica.metz@fda.hhs.gov)

# NCIMS AMI SUB-COMMITTEE

- FDA commends the NCIMS sub-committee.
- Cooperative/collaborative effort on the part of State, FDA, Industry and AMI manufacturers.

Chris Hylkema, Chair	New York
Brian Wise	Ohio
Paul Dix	Maryland
Gena Reich	Washington
Steve Stoner	Wisconsin
Clint George	Texas
Steve McGinnis	California
David Brown	Iowa
Dr. Stephen Walker	US FDA
Randy Elsberry	US FDA

Adam Sonnenburg	Dairy Farmers of America
Helen Piotter	Dean Foods Company
Jason Martin	Galaxy AMS
Brad Cupery	Lely North America
Matt Stuessel	GEA USA
Brad Schaller	Boumatic
Derek Zepp	DeLaval
William Bernhard	AEM

## QUESTIONS ?



# IDFA Update for NADRO



July 15, 2019

**Cary Frye**  
Senior Vice President, Regulatory Affairs  
International Dairy Foods Association  
Washington, DC

[www.idfa.org](http://www.idfa.org)

MAKING A DIFFERENCE FOR DAIRY



## IDFA LEGISLATIVE TEAM



Dave Carlin

Tony Eberhart

Beth Hughes

Donald Grady

Collin Newman



Represents the nation's dairy manufacturing and marketing industries and their suppliers.

Represents more than 90 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.



## Legislative Priorities



## Our Priorities

Advocacy

Regulatory

Communications



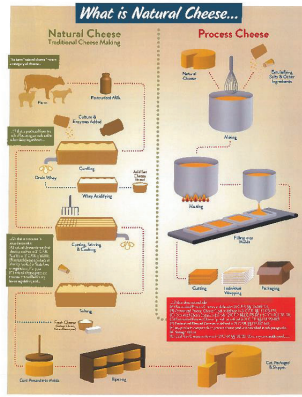
## Natural Cheese





## CURD Act

- Amends the FD&C Act to codify a definition for “natural cheese”
- References CFR for processes cheese and other cheese that would be considered “natural cheese”
- At FDA’s advice describes process and ingredients for making non-standards cheese – Codex definition
- Cheese must be made from “milk” of lactating animals –CFR 131.33
- Ties definition to labeling to a factual descriptor



MAKING A DIFFERENCE

## Child Nutrition Reauthorization Bill



### Pass a Child Nutrition Reauthorization Bill with Positive Dairy Provisions

- Reinstate Reduced-Fat (2%) Milk Into the WIC Program (Kids 2 & Up)
- Allow WIC Families to Purchase Yogurt in Different Container Sizes “Up To” 32 ounces
- Preserve Ability of Schools to Offer Low-Fat (1%) Flavored Milk
- Increase Milk Container Size in High School Competitive Foods Program



MAKING A DIFFERENCE FOR DAIRY

## Natural Cheese Legislation



### Enact legislation that defines the term “Natural Cheese” in statute

- Senate CURD Act re-introduced on May 23<sup>rd</sup> (S. 1669)
- 6 bipartisan cosponsors
- Developing HELP Committee support for Senate “hotline” process
- House bill to be introduced in September/October 2019



MAKING A DIFFERENCE FOR DAIRY

## Appropriations Update



## Child Nutrition Reauthorization



## IDFA FY19 Appropriations Wins



- ✓ \$1.5 million for Agricultural Research Service (ARS) ice cream waste solutions
- ✓ \$2 million increase in funding for FDA’s Office of Nutrition and Food Labeling for standards of identity (SOI) regulations

Status: The FY2019 Consolidated Appropriations Act included both IDFA priorities and was signed into law February 15, 2019.

MAKING A DIFFERENCE FOR DAIRY

## FY20 Agriculture Appropriation Legislation



### House

- Passed through full Appropriation Committee with all IDFA priorities:
  - Additional \$3 million for FDA standards of identity work
  - Protect \$1.5 million for ARS ice cream research
  - Provide new \$1 million for SNAP milk incentive

### Senate

- Senate Agriculture Appropriations Subcommittee has not yet produced legislation for FY20



Rep. Mark Pocan  
(D-WI-02)



Rep. Mike Simpson  
(R-ID-02)



Rep. Chellie Pingree  
(D-ME-01)



Rep. John Moolenaar  
(R-MI-04)



Rep. Steve Womack  
(R-AR-03)



Rep. Pete Aguilar  
(D-CA-31)

MAKING A DIFFERENCE FOR DAIRY

## China Update

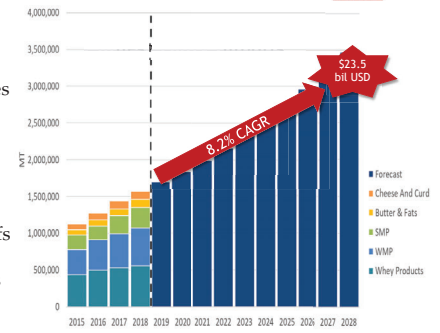


### Talks are currently stalled

- Potential \$23B market for U.S. dairy
- Since July 2018, U.S. whey sales are **down 44%**
- In Q1 2019, the value of U.S. cheese exports is **down 47%**

### Goals for U.S. dairy

- Elimination of retaliatory tariffs
- Meaningful access to Chinese market for U.S. dairy products



MAKING A DIFFERENCE FOR DAIRY

## Trade Updates



## Regulatory Priorities



## U.S.-Mexico-Canada Agreement



### Status update:

- Section 232 tariffs (steel and aluminum) were lifted on May 20<sup>th</sup>
- Draft Statement of Administration Action (SAA) on May 30<sup>th</sup>
  - Implementing Bill can be introduced 30 days later
- USMCA Grassroots food and ag letter to Congress – June 11<sup>th</sup>
- Congressional vote before August recess?



MAKING A DIFFERENCE FOR DAIRY



Cary Frye John Allan Danielle Quist Michelle Matto Taylor Boone

REGULATIONS COMPLIANCE

MAKING A DIFFERENCE FOR DAIRY

## National Conference on Interstate Milk Shipments



### 2019 NCIMS Outcomes



- Approval for Piper automated truck-mounted meter and samplers for farm milk pickup (210)
- Revised reporting requirements for test methods and positive producer drug residue confirmation (215)
- Clarified compliance for the 72 hour start time storage tank emptying (106)
- Cooling requirements for cup set yogurt where added to allow for 96 hours after being moved out of the culturing room (111)

**Grade "A"**  
Pasteurized  
Milk  
Ordinance

MAKING A DIFFERENCE FOR DAIRY

### Outcomes of 2019 NCIMS



#### Advances Food Safety, New Technologies and Inspection Efficiencies

- 2019 National Conference on Interstate Milk Shipments - April 26-May 1, 2019, St. Louis, MO
- 75 proposed changes to the PMO and IMS documents
- 38 proposals passed



MAKING A DIFFERENCE FOR DAIRY

## FDA Work on Standards Modernization



### 2019 NCIMS Outcomes



- Revised pilot for inspecting plants that manufacture both Grade "A" and non-Grade "A" dairy (JC-1)
- Repackaging Grade "A" products yogurt, cultured dairy products and milk products outside of Grade "A" plants will be studied (112)
- Study the safety of water used in the dairy industry, including technologies to produce disinfected and/or pasteurized equivalent water (114 & 115)



MAKING A DIFFERENCE FOR DAIRY

### FDA's Nutrition Innovation Strategy



"Facilitate industry innovation towards healthier foods that consumer's want"

Modernizing Standards of Identity

Dairy standards are outdated  
Petitioning for changes takes decades

Horizontal approach to allow for deviations should be considered for long term

Act on pending petitions now



MAKING A DIFFERENCE FOR DAIRY

## Horizontal Standards Modernization Principals



Ingredients for technical effects – stabilizers, emulsifiers, antimicrobials

Flavors & flavor enhancers – sweeteners, salt substitutes

Advanced processing technologies – ultrafiltration

Alternative make procedures – all foods

Improvements in nutritional properties

MAKING A DIFFERENCE FOR DAIRY

## National Bioengineered Food Disclosure Standard



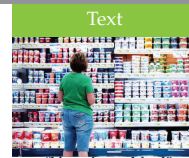
## FDA Hosted Listening Session with IDFA



- Meeting May 6, 2019 - Nestle USA, Danone N.A., Great Lakes Cheese
- Outcomes
  - FDA reexamining 2006 GMA petition and interested in stakeholder ideas for horizontal approaches for standards modernization
  - Fall public meeting on standards modernization and opening up docket for comments
  - IDFA will follow up with written request to extend regulatory discretion to allow for microfiltered milk for cheese with labeling as “milk.”
  - Yogurt standard final rule on Unified Regulatory Agenda going to OMB!

MAKING A DIFFERENCE FOR DAIRY

## USDA’s BE Food Disclosure Regulations



“contains bioengineered food ingredient”

- Narrowly defines “bioengineered food” to mean foods with detectable amount of genetic material modified through in vitro rDNA technology
- Exempts disclosure for:
  - Highly refined ingredients derived from BE crops – may voluntary disclose
  - Foods with the unintentional and inadvertent presence of detectable modified genetic material below a threshold of 5% in any individual ingredient
  - Animal derived products (i.e., milk & eggs) cannot be labeled BE solely because animal consumed BE feed

MAKING A DIFFERENCE FOR DAIRY

## Get ready for Cellular Cultured Dairy



### Using fermentation to create dairy protein

The Emeryville company Perfect Day employs fermentation to make dairy proteins without using cows. This week the company is releasing its first product, an animal-free ice cream.



**Perfect Day Launches First Animal-Free Ice Cream – vegan & lactose free, completely hormone and antibiotic-free**  
**“Frozen Dairy Dessert”**

**Milky Chocolate**  
 WATER, SUGAR, COCONUT OIL, SUNFLOWER OIL, DUTCH COCOA, NON-ANIMAL WHEY PROTEIN; Contains 2% or less of: NATURAL FLAVORS, MALTODEXTRIN, CAROB GUM, MINERAL BLEND (CALCIUM, POTASSIUM, PHOSPHATE, CITRATE, DISODIUM PHOSPHATE, SALT), SUNFLOWER LECITHIN, MONO & DIGLYCERIDES

ENCE FOR DAIRY

## Compliance & Enforcement



**Recordkeeping for Foods/Crops on BE Food List or Known to be BE**

### How do you know it is BE? - Recordkeeping

- Verify ingredient not sourced from a BE crop,
- Verify ingredient subjected to a refinement process “validated” to render the modified genetic material undetectable, or
- Maintain certificates of analysis or testing records to confirm the absence of modified genetic material

**Compliance Deadlines**

- BE disclosures may appear on food packaging labels starting Feb. 21, 2019
- Mandatory compliance date of **Jan. 1, 2022**. Companies may choose to label by Jan. 1, 2020 to align with new Nutrition Facts label

MAKING A DIFFERENCE FOR DAIRY

## Dairy's Priorities for 2020 Update to Dietary Guidelines for Americans



## Dietary Guidelines for Americans 2020-2025



### Dietary Guidelines Advisory Committee Public Meetings

- Meeting 1: March 28-29, 2019 (Washington, DC)
- Meeting 2: July 10-11, 2019 (Washington, DC) - Oral Comments
- Meeting 3: October 24-25, 2019 (Washington, DC)
- Meeting 4: January 23-24, 2020 (Houston, TX) - Oral Comments
- Meeting 5: March 12-13, 2020 (Washington, DC)

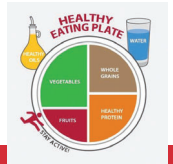


Olympic Athlete Urges USDA To Ditch Dairy From Dietary Guidelines



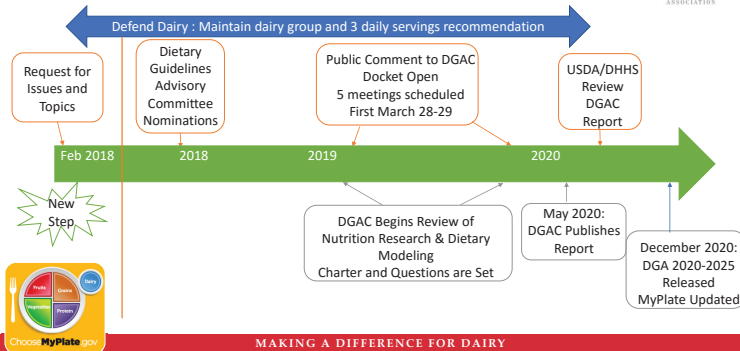
*SURPRISING CLAIM IN FOOD FEEDBACK: DAIRY GUIDELINES ARE RACIST*

Plant-based foods get shout-out at DGAC meeting



MAKING A DIFFERENCE FOR DAIRY

## Dietary Guidelines 2020 Process



MAKING A DIFFERENCE FOR DAIRY

## Dairy Delivers



## IDFA Priorities for DGA 2020-2025



- Major Goals:**
- Maintain dairy as a separate food group
  - Maintain recommendation for 3 servings every day



- Additional Goals:**
- Recommendations include dairy at a range of fat levels
  - Yogurt and dairy as complementary foods for infants and toddlers



3 cups

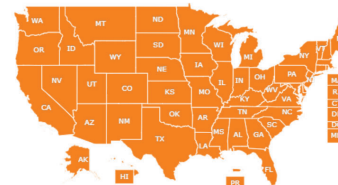
IDFA will be providing oral comments on July 10 and will also be submitting written comments to Advisory Committee and agencies.

MAKING A DIFFERENCE FOR DAIRY

## Telling our Story with Dairy Delivers 2.0



### Dairy Delivers: The Economic Impact of Dairy Products



<b>DIRECT OUTPUT</b>	\$198,855,063,800
<b>DIRECT JOBS</b>	955,913
<b>DIRECT WAGES</b>	\$37,568,472,300
<b>TOTAL TAXES</b>	\$64,540,860,900

Choose State (required):

Choose Report:  Economic Impact Report  Economic Impact Data Table

Choose District: (optional)

MAKING A DIFFERENCE FOR DAIRY

## Dairy Delivers 2.0

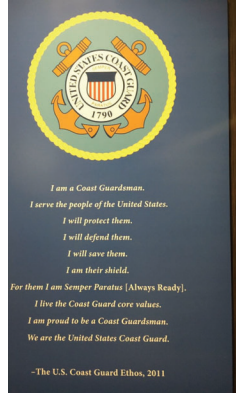
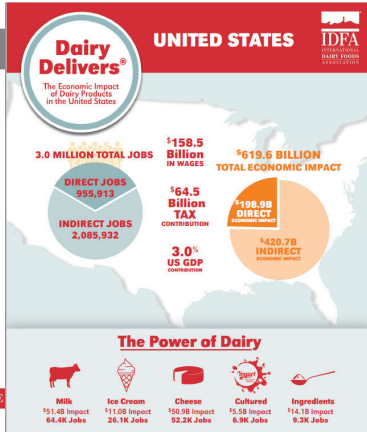
### Jobs

10 3 million

### Economic Impact

10 Greater than \$600 billion  
10 3% of US GDP

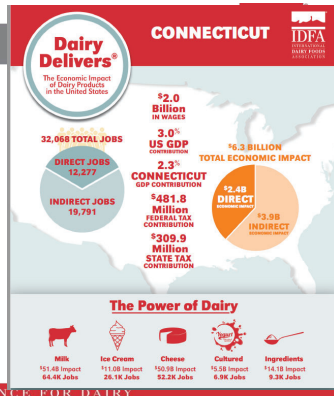
MAKING A DIFFERENCE FOR DAIRY



## Connecticut Dairy Delivers



MAKING A DIFFERENCE FOR DAIRY



## Telling our Story with Dairy Delivers



MAKING A DIFFERENCE FOR DAIRY

Issues | News & Views | **Resource Center** | Events | Menu

Dairy Delivers: The Economic Impact of Dairy Products  
**www.idfa.org**  
**Dairy Delivers**  
Available to everyone

MAKING A DIFFERENCE FOR DAIRY

Thank you to our friends in Connecticut!!



# Qualifying a new technology into the US dairy industry

## The story so far...

Leigh Hamilton  
16<sup>th</sup> July, 2019



### Products



#### Tanker Based Systems

- Single pump systems
- Twin Pump systems



#### Farm Based Systems

- Direct Load Systems
- Silo and Bulk Tank Systems



# Qualifying a new technology into the US dairy industry.

## The story so far...

#### PURPOSE:

- Who is Piper and what technology are we trying to introduce
- Our experience of the "Process"
  - Approach
  - Journey so far
  - Next Steps
- Communication with Regulators
  - What information is available and where can you get it.

### Poducts DynaStream Video

[https://drive.google.com/open?id=1Bf62\\_XASNxAhHv-MWC097E6XqYGfcfc](https://drive.google.com/open?id=1Bf62_XASNxAhHv-MWC097E6XqYGfcfc)

### Who is PIPER?

Piper is a family business based in Ireland.

Providing metering, sampling & traceability solutions to the Dairy Industry.

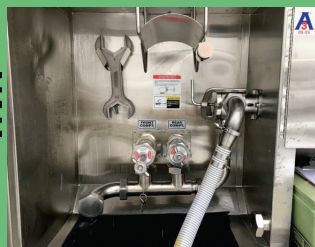
We have a 25 year history of making robust and reliable technology for Dairy Producers, Haulers, Co-Operatives & Processors around the world.

10 years working with US Dairy Industry partners

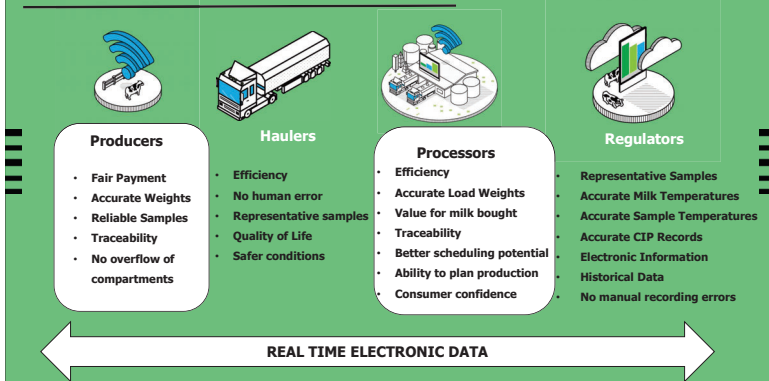
- 4 years since first US systems installed
- 2 years of studies gathering US data
- Tanker metering PMO approved 2019



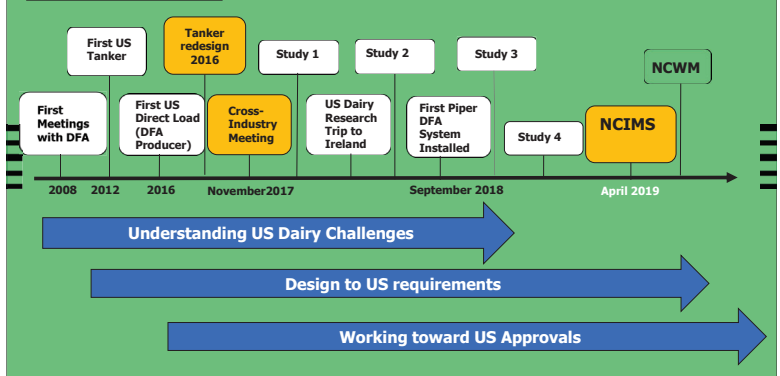
### New Technology: A big change



## Summary Supply Chain Efficiency



## Progress Update



## PIPER Process

### Work together with industry and regulatory

- Branches of Regulatory
- Producers
- Haulers
- Laboratories
- Co-Operatives
- Processors

### Decision to fully engage with PMO process

- Our approach- Existing wording may have covered the process but not the intent

### Our Philosophy of Open Engagement

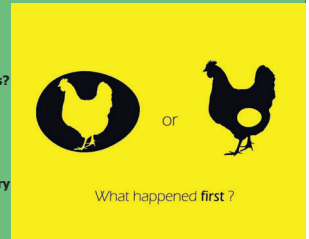
- Special area on Piper website
- Webinars
- Developed & distributed FAQs
- Inviting regulators to visit installations
- Attending Regulatory Conferences



## NCIMS process?

### A two step process

- Prove the technology- Studies, US Data, International Data
  - The Book of Evidence- Piper had to prove:
    - Does Piper DynaStream meet US Sanitary Requirements?
    - Can Piper DynaStream deliver Representative Samples?
    - Can Piper DynaStream deliver Accurate Weights?
    - Is there a risk of Carryover using Piper DynaStream?
- PMO Wording- Mission to generate regulatory guidelines to allow US dairy industry access to this type of technology



## PIPER System Redesign

Piper worked with NY Department of Ag & Markets to ensure that we met US sanitary requirements:

- Design Updates (Valve design, AEV top design)
- PMO Approved Single Use Consumables
- US Sanitary Design Standards (e.g. 3A)
- US Power Sources



- Milk Flow**
- Milk Inlet
  - Pump
  - Strainers
  - Air sterilizer
  - Meter
  - Compartments



## PMO Approval Results Summary

- Target result met
- Path forward identified
- Target result not met
- No result

Objectives	Outcome
<b>Load Performance (Weight)</b> [Study 1 & 2]	<ul style="list-style-type: none"> <li>Piper v Standard Method average difference = -0.16%</li> <li>Piper / Standard method: Correlation Value 99.94%</li> <li>Piper, Standard and Plant scale measurement methods were highly correlated</li> </ul>
<b>Farm Performance (Weight)</b> [Study 2]	<ul style="list-style-type: none"> <li>Piper v Official sample average difference = -0.22%</li> <li>Very strong correlation between Piper and MA results (99.999%)</li> </ul>
<b>Milk components</b> (BF, Protein, Other solids, total solids Lactose & freeze-point) [Study 1]	<ul style="list-style-type: none"> <li>Butterfat av difference = 0.01 pt, and correlation of 98.9%</li> <li>All other component value correlation &gt;99%</li> </ul>
<b>Sanitary:</b>	<ul style="list-style-type: none"> <li>SCC results "Acceptable" on FDA sheets for all 4 groups of samples tested</li> <li>Bacteria growth [Study 3]</li> <li>Antibiotics [Studies 1,2,3]</li> <li>Carryover [Study 4]</li> </ul>
<b>Piper sampling technology performance and associated SOP</b>	<ul style="list-style-type: none"> <li>Validated opportunity to reduce agitation delay and pre-collection wait time, while providing equivalent weight accuracy, component results and sanitary collection of milk compared to the standard method as per PMO.</li> </ul>

Notes: All testing provided by Dairy One. Data analysis provided by Dairy one and Federal Order 1 Market administrator.



## Approval for the official milk sample to be taken using an on-tanker sampler

### Regulatory wording - not vendor specific

#### SOP Must contain a description of

- How sample is collected, identified, handled and stored
- How to maintain sample temperature
- How to obtain temperature of milk
- How to clean sampler if not of single use design
- The method to ensure the representative nature and integrity of the sample
- The method to establish the weight
- Oversight of correct installation
- Oversight of trained operators
- Storage / Access to SOP

#### V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK, ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

1. A protocol specific to the use of an on-tanker farm bulk milk tank aseptic sampler which may be used for the acquisition of official milk samples from multiple and/or single farm pickups shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer and FDA. As a minimum, the protocol (SOP) shall include the following:
  - a. A description of how the milk sample is to be collected, identified, handled and stored.
  - b. A description of the means used to maintain the sample at the required temperature (between 0°C - 4.4 degrees Celsius [32 - 40 F], as per this Appendix) during the sample collection period.
  - c. A description of the process used to obtain the temperature of milk being loaded from the farm bulk milk tank.
  - d. A description of how and when the sampler is to be cleaned and sanitized if not of a single use design.
  - e. A description of the method and the means used to ensure the representative nature of and the integrity of the milk sample acquired from every farm bulk milk

# Questions & Comments

## Next Steps on our Journey

Today - NADRO

Current - SOP review with the FDA (with support from NY, NH & VT)

August - NCWM

September / October - PMO wording Concur / Non-Concur

Afterwards -

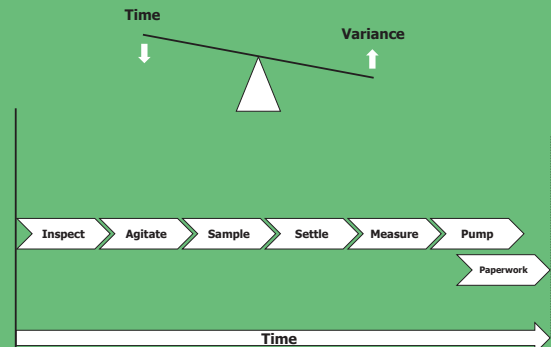
- Executive Board Pass
- FDA MI issue for Piper technology (hopefully)
- Engaging with the States as this rolls out

# Thank You !

## Communication

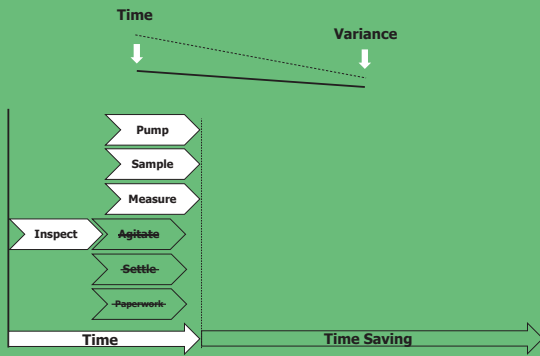
- How do we make it easy for you to get all the info you need
- Took a room at the NCIMS conference for 6 days: demonstrate the system
- Come to NADRO
- Regulators section on our portal (confidential)
  - Proposal wording
  - SOP
  - All the data from the studies
  - FAQ document
- Teleconference / Webcasts
- Travel in the US

## Efficiency: Existing Process



## Efficiency: Piper Process

PIPER



## Representative Sample Standard method v Piper DynaStream

### Standard farm tank sampling SOP overview

- Truck Arrives
- Observe milk and start agitation
- Tank agitated (as per tank spec), to homogenize milk for representative sample collection
- Dip sample taken
- Tank settles
- Measure tank level & associated weight wall chart
- Pump milk onto truck

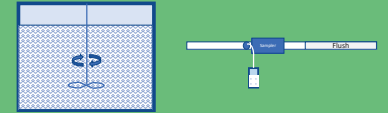
**Representative Sample:** Milk is homogenized via agitation and a dip sample is taken of the homogenized milk



### Piper Farm tank sampling SOP overview

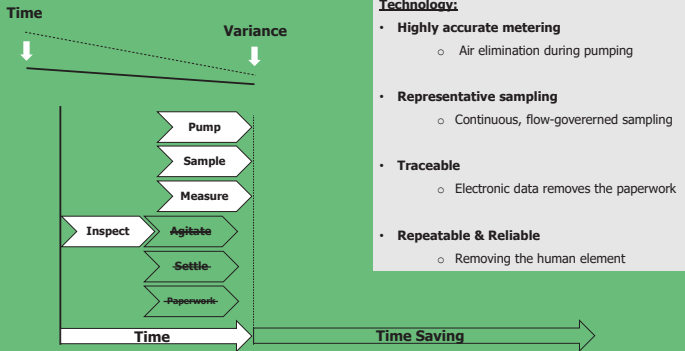
- Truck Arrives
  - Observe milk and start agitation
  - Farm and sample ID verification on Piper DynaStream
  - Milk weight is metered while pumping milk onto truck
  - The Piper DynaStream takes a representative sample, using single use consumables\*, over the volume of milk collected
- (\* Consumables are a PMO approved vial-tube-needle assembly & septum port)

**Representative Sample:** After initial flush volume, milk is continuously sampled over the remaining volume collected



## Efficiency: Technology

PIPER



### Technology:

- **Highly accurate metering**
  - Air elimination during pumping
- **Representative sampling**
  - Continuous, flow-governed sampling
- **Traceable**
  - Electronic data removes the paperwork
- **Repeatable & Reliable**
  - Removing the human element

## Antibiotics International Field Data

### Case studies of large Irish Co-Operatives demonstrating the performance of the Piper DynaStream

#### Co-Operative A

- During 2018, c. 51,000 loads and c. 350,000 pick-ups
- 41 cases of antibiotics detected
- Result: no carry over seen

#### Co-Operative B

- 2014-2018, c. 35,000 loads and c. 280,000 pick-ups
- 22 cases of antibiotics detected
- Result: no carry over seen

**Note:** Standard test in Ireland is the Charm MRL Beta-Lactam 3-minute test for Milk in processors certified industrial lab.

## SOP comparison Standard method v Piper DynaStream

### Standard farm tank sampling SOP overview

- Truck Arrives
- Observe milk and start agitation
- Tank agitated (as per tank spec), to homogenize milk for representative sample collection
- Dip sample taken
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- Measure tank level & associated weight wall chart
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  - Milk weight is metered while pumping milk onto truck
  - The Piper DynaStream takes a representative sample, using single use consumables\*, over the volume of milk collected
- (\* Consumables are a PMO approved vial-tube-needle assembly & septum port)

**Note:** Piper SOP for pick up weights < 2700lbs, requires Tank to be agitated as per tank specifications, before pumping milk onto the truck.



## Supplemental Data Milk – Water Study

### Purpose

Test the potential for carryover in the Piper farm sample

### Experiment

**Study Design based on principles of lab equipment purging efficiency test**

Experiment design by Dairy One in consultation with industry experts  
Experiment overseen by NY Department of Agriculture (Chris Hylkema)

### Sample Sets

**120 samples to be taken, in alternating pairs, to yield 30 sample sets**

### Analysis

**Purging efficiency is calculated as follows:**

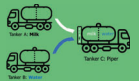
$$\text{Water to Milk} = \frac{(\Sigma M_1 - \Sigma W_2) \times 100}{(\Sigma M_2 - \Sigma W_2)}$$

$$\text{Milk to water} = \frac{(\Sigma M_2 - \Sigma W_1) \times 100}{(\Sigma M_2 - \Sigma W_2)}$$

### Goal

**Purging efficiency should be > 99.0% for butterfat & protein**

**Results: Purging efficiency goal of >99% exceeded for all tested channels**





## 2019 NCIMS REPORT (2015 NCIMS PROPOSAL 211)

- THE APPENDIX N MODIFICATION COMMITTEE IS CHARGED TO DEVELOP A PILOT PROGRAM, **ESTABLISHING A REGULATORY FRAMEWORK** BY WHICH TESTING RAW MILK FOR VETERINARY DRUGS WOULD BE *REQUIRED FOR DRUGS OTHER THAN BETA-LACTAMS*.
- **VETERINARY DRUGS REQUIRED TO BE TESTED**
- **TESTING METHODOLOGY REQUIRED TO BE USED**
- **AVAILABILITY OF SUITABLE TEST METHODS**
- **NUMBER OF SAMPLES TO BE COLLECTED AND ASSAYED**
- **REDUCTION OF REQUIRED BETA-LACTAM TESTING**
- **NATIONAL MILK DRUG RESIDUE DATABASE**
- **REPORT OF CHALLENGES OF PROGRAM IMPLEMENTATION**

# APPENDIX N MODIFICATION STUDY COMMITTEE UPDATE

2019 NADRO



## COMMITTEE



Balanced with 7 Regulatory, 7 Industry (including academia)



Committee members: Roger Hooi (Chair), Roger Tedrick (Vice Chair), Tom Angstadt, Frank Barcellos, Zach Conlin, Steve DiVincenzo, Ellen Fitzgibbons, Pat Gorden, Bob Hagberg (retired), Harris Hollingsworth, Jaime Jonker, Rebecca Piston, Lewis Ramsey, John Sanford



FDA: Laurie Bucher, Phil Kijak, Jeff Hamer, Tom Graham, Tim Roddy, Amber McCoig, Dennis Gaalswyk (retired)



Supplier stakeholders: Charm, IDEXX, Neogen, others

## WHAT ARE THE TETRACYCLINE PILOT RESULTS?



## CHANGES TO THE COMMITTEE

- AD HOC TO STANDING COMMITTEE
- DON FALLS RETIRED REPLACED BY ELLEN FITZGIBBONS
- BETH BRICZINSKI, FDA REPLACED BY JAMIE JONKER, NMPF
- DENNIS GAALSWYK RETIRED – ADDED LAURIE BUCHER
- BOB HAGBERG – RETIRED
- ROGER TEDRICK - RETIRING

## TETRACYCLINE PILOT

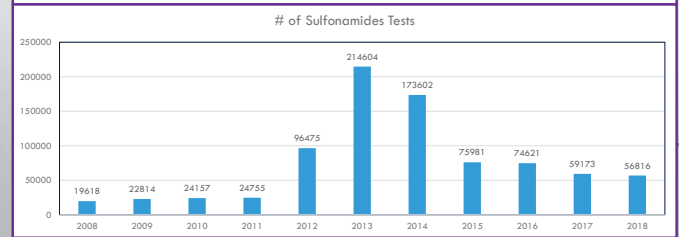
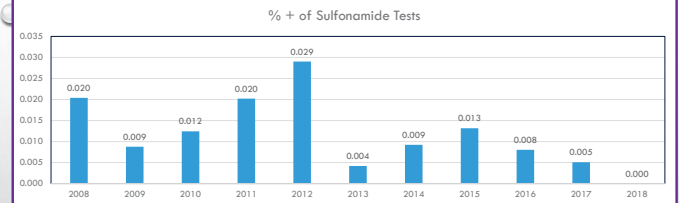
- BULK MILK TANKERS
- 1/15 (6.7%) LOADS PER QUARTER
- NCIMS APPENDIX N ACCEPTED TESTS
- APPENDIX N BETA-LACTAM APPROVED LABS
- LAUNCHED JULY 1, 2017
- ENDED DECEMBER 31, 2018

## ANIMAL DRUGS 1994 – 2018 SUM OF ALL TEST

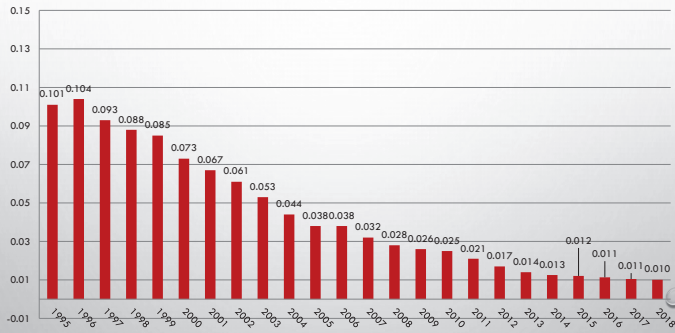
Drug Family	Total Tests	Total Positive	%
Aminoglycosides (Gentamicin)	25691	20	0.08
Amphenicol (Florfenicol, Chloramphenicol)	270	0	0.00
Avermectins (antiparasitics)			
Beta-lactams	76936306	35673	0.05
Fluoroquinolone - Enrofloxacin (Baytril)	50693	10	0.02
Macrolides	12457	3	0.02
NSAID (Flunixin)	2054*	0*	
Sulfonamides	2089905	405	0.02
<b>Tetracyclines</b>	<b>1413179</b>	<b>711</b>	<b>0.05</b>

\* Internal data, 1 unconfirmed positive

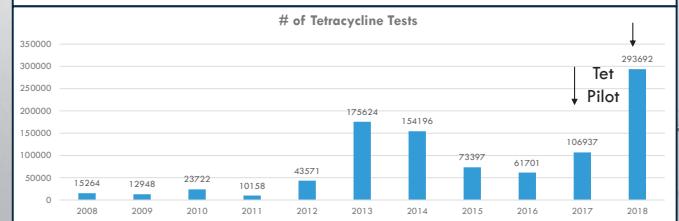
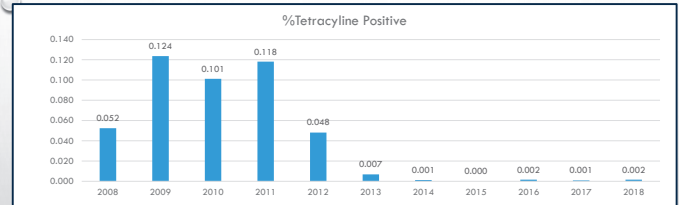
## SULFONAMIDES NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)



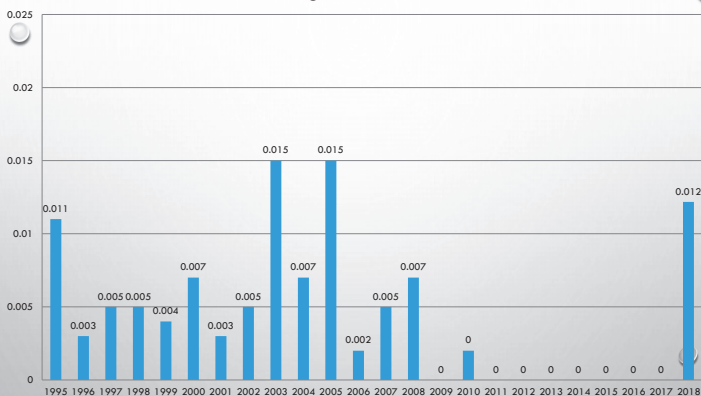
## Bulk Milk Pick Up Tanker Appendix N Beta-lactam % Positive National Milk Drug Residue Database (NMDRD)



## TETRACYCLINES OVER 10 YEARS NATIONAL MILK DRUG RESIDUE DATABASE (NMDRD)



## Pasteurized Milk and Milk Products Beta-lactam % Positive National Milk Drug Residue Database (NMDRD)



## PILOT RESULTS

- OOPS
- STATE PARTICIPATION
- INDUSTRY PARTICIPATION
- COST TO INDUSTRY
- STATE TESTING
- OVERALL TETRACYCLINE RESULTS
- CONSIDERATION OF REDUCING BETA-LACTAM TESTING
- TEST METHODS AVAILABLE
- HURDLES

## OOPS

### OPERATIONAL OPPORTUNITIES PREVENTABLE SITUATIONS

- TIGHT TIMELINES
- NEGATIVE CONTROL AVAILABILITY
- REPORTING ERRORS BETWEEN CHARM SL GREEN AND ORANGE STRIPS
- REPORTING ERROR OF BETA-LACTAMS

## COST TO INDUSTRY

### COST TO INDUSTRY TO PARTICIPATE IN THE PILOT STUDY July 1, 2017 to December 31, 2018 (18 months data)

Family/Drug	Number of Industry Test	Average Cost per Tetracycline Test	Total Cost to Industry
Tetracyclines	~399,900	~\$4.50	~\$1,799,550

\* Does not include controls tested

## STATE PARTICIPATION

STATE PARTICIPATION				
Regulatory Data Reporters	FY 2017 July 2017 – Sept. 2017 (1 QTR)	FY 2018 Oct. 2017 – Sept. 2018 (Full Year)	FY 2019 Oct. 2018 – Dec. 2018 (1 QTR)	Average for FY 2017, FY 2018, and FY 2019
Number of Regulatory Data Reporters*	40 out of 53	43 out of 53**	33 out of 53***	39 out of 53
Percentage of Regulatory Data Reporters Participated	75%	81%	62%	73%

Fifty (50) States, Puerto Rico and two (2) Third Party Certifiers. Puerto Rico submitted partial data. Third Party Certifiers did not submit Tetracycline data.

\*\*FY 2018 is a full 12 months report

\*\*\*FY 2019 reported as of March 2019

## STATE TESTING

- STATES IN SUPPORT OF THE PROGRAM
- 6,516
- NO POSITIVE

National  
Conference on  
Interstate  
Milk  
Shipments

## INDUSTRY PARTICIPATION

- INDUSTRY PARTICIPATION ACCOMPLISHED (TABLE 7 NMDRDB FISCAL YEAR 2018 ANNUAL REPORT, OCTOBER 1, 2017 - SEPTEMBER 30, 2018)
- FULL 12 MONTHS REVIEW
- 1/11 VERSUS 1/15 REQUESTED
- 2.57% HIGHER SAMPLING/TESTING RATE OR 81,722 MORE TESTS

### INDUSTRY PARTICIPATION (NMDRDB 12 months)

Number of Industry Test for Beta Lactams	Number of Industry Test for Tetracyclines over the same period	Sampling Rate of Participation from Industry
3,179,848	293,692	9.24% (1/11)

## OVERALL TETRACYCLINE RESULTS

### Grade A Bulk Milk Pick-Up Tanker Testing – 18 months study July 1, 2017 to December 31, 2018

Family/Drug	Number of Industry Test	Number of Positive Industry Test	Number of Regulatory Test	Number of Positive Regulatory Test	Total Test	Total Positive Test	Total Percent Positive
TETRACYCLINES	~399,900*	9	6,516	0	406,415	9	0.002%

Compared to Beta-lactam Bulk Raw Milk Tanker at 0.01% Tetracycline was at 0.002%

\* 0 in previous FY 2017, 5 FY 2018, and 4 from Q1 FY2019

\*\* 1 misreported Beta-lactam

## TETRACYCLINES TEST USAGE

OCTOBER 1, 2017 TO SEPTEMBER 30, 2018

- CHARM ROSA TETRACYCLINE 295,648
- IDEXX SNAP - TETRACYCLINE 6,634
- CHARM II TABLET COMPETITIVE 1,221
- CHARM TRIO TEST-TETRA 766
- NEOGEN BETASTAR ADVANCED 19

## HURDLES

- COMPLIANCE OR TESTING PROGRAM OR FOOD SAFETY
- DRUG RESIDUE, SAMPLING RATE
- DEVELOPMENT, VALIDATING TEST METHOD(S), APPROVING METHODS
- 2400 FORMS
- NMDRDB REPORTING – CORRECT CODING
- EQUIVALENT METHODS
- REGULATORY ACTION
- COMMUNICATION
- RESOURCES, TRAINING

## TEST METHODS AVAILABLE DRIVING TECHNOLOGY

- CHARM® II TETRACYCLINE DRUG TEST (COMPETITIVE ASSAY)
- CHARM® ROSA TETRACYCLINE-SL\*
- IDEXX SNAP ® TETRACYCLINE\*
- NEOGEN BETASTAR ® ADVANCED FOR TETRACYCLINE
- CHARM® ROSA TRIO BETA-LACTAM, SULFONAMIDE, AND TETRACYCLINE\*\*

\*DILUTION STEP REQUIRED AFTER AN INITIAL POSITIVE

MOST USED: CHARM SL-TETRACYCLINES (GREEN STRIP) AND CHARM ROSA TETRACYCLINE-SL (DILUTION CONFIRMATION) ORANGE STRIP

\*\*CHARM® TRIO 2400 FORM FOR THE APPENDIX N MODIFICATION STUDY COMMITTEE TETRACYCLINE PILOT FOR SCREENING NEGATIVES. AN INITIAL POSITIVE TEST WILL HAVE TO BE SCREENED THROUGH THE NCIMS ACCEPTED CHARM® ROSA TETRACYCLINE-SL TETRACYCLINE TEST.

## A REGULATORY FRAMEWORK

- A FOUNDATION OF UNDERSTANDING THE USE AND IMPLICATION OF AN ANIMAL DRUG RESIDUE TO BE FOUND IN MILK
- DETERMINATION OF A FREQUENCY OF TESTING.
- SETTING OF REGULATORY TOLERANCE AND/OR TESTING LIMITS.
- DESIGNING A TESTING PATH THAT INVOLVES METHODS, AND NCIMS VALIDATION
- NATIONAL MILK DRUG RESIDUE DATABASE (NMDRDB) REPORTING
- DEFINING REGULATORY ACTIONS
- COMMUNICATION, IMPLEMENTATION

## CONSIDERATION OF REDUCING BETA-LACTAM TESTING

- THERE IS THE POTENTIAL OF PROCESSED AND PACKAGED MILK RESULTING FROM A BULK TANKER PICKUP THAT WAS NOT TESTED BUT RESULTED IN A SECTION 6 PRODUCER TEST POSITIVE.
- PASTEURIZED MILK IS REQUIRED TO BE TESTED FOR BETA-LACTAMS AND COULD BE AT RISK IF THERE IS A REDUCTION OF TESTING OF BULK TANKER PICKUP
- MICROBIOLOGICAL TESTING OF PRODUCT REQUIRES INHIBITOR TESTS TO ACCOMPANY ALL PLATE COUNTS.
- IT WAS DETERMINED BY THE APPENDIX N MODIFICATION STUDY COMMITTEE THAT REDUCTION OF TESTING FOR BETA-LACTAMS WAS NOT PRUDENT.

## NEXT STEPS

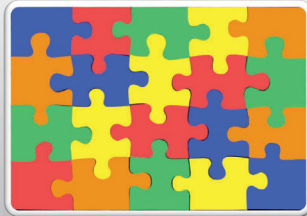
- JUNE 7<sup>TH</sup>, 2019 NATIONAL MILK DRUG RESIDUE DATA BASE, FISCAL YEAR 2018 ANNUAL REPORT **REVISED** TO CLARIFY CHARM APPROVED (GREEN) AND UNAPPROVED (ORANGE)
- CHARM ROSA TETRACYCLINE-SL (DILUTION CONFIRMATION) ORANGE STRIP WAS AVAILABLE AND VALIDATED WITH A REPORT CODE OF 95, FOR THE ENTIRE PILOT STUDY.
- SOME PLANTS AND STATES CONTINUED TO SUBMIT INCORRECTLY CODE 89 TO THE NMDRDB WHEN THE CORRECT CODE SHOULD HAVE BEEN 95.
- THE NUMBER OF TESTS CONDUCTED ON THE CHARM SL-TETRACYCLINES (GREEN STRIP) AND THE CHARM ROSA TETRACYCLINE-SL (DILUTION CONFIRMATION) ORANGE STRIP MAY NOT BE ACCURATE, BUT THE COMBINED TOTAL OF THE TWO (2) TESTS AND POSITIVES SUBMITTED TO THE NMDRDB ARE ACCURATE.

## NEXT STEPS

- PROVIDE FOR A REPORT OF THE TETRACYCLINE PILOT TO THE NCIMS BOARD – FINAL REVIEW IN PROGRESS JULY 22<sup>ND</sup>, 2019
- DETERMINE THE NEXT ANIMAL DRUG – GENTAMICIN
- APPENDIX N MEETING – SEPTEMBER 10 – 11<sup>TH</sup> AT DMI
- TEST THE PILOT VERSUS TO TEST FOR THE DRUG
- TEST THE REGULATORY FRAMEWORK

## SUMMARY

- PICTURE OF SUCCESS
- PILOT TO DEVELOP A REGULATORY FRAMEWORK
- TETRACYCLINE DATA
  - 81% (43/53) OF STATE PARTICIPATED
  - POSITIVE LEVELS LOWER THAN BETA-LACTAMS  
0.002% V 0.01%



## THANK YOU



STATES, INDUSTRY, FDA, SUPPLIERS – COOPERATIVE NCIMS PARTICIPANTS



# Milk Matters – An NMPF Update

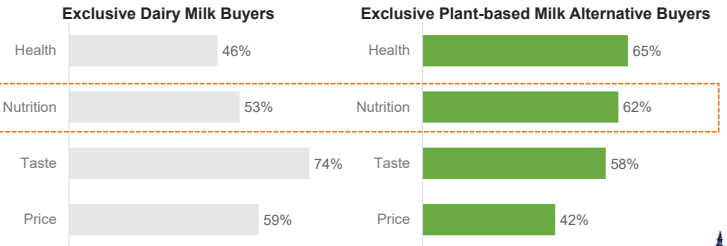
Jamie Jonker  
Vice President, Sustainability & Scientific Affairs

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | 703-243-6111 | www.nmpf.org

Connecting Cows, Cooperatives, Capitol Hill, & Consumers

## Nutrition is a Purchase Driver for Both Dairy and Plant-based Milk Alternatives and has Higher Importance to Milk Alternative Buyers

Top Purchase Decision Factors  
Q. Which of the following are important in your decision to purchase dairy milk and/or plant-based milk alternatives?



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# Fake Milk & Dairy Foods

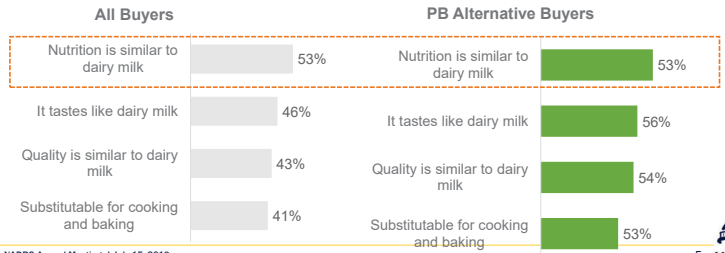
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## #1 Reason Consumers Believe Non-Dairy Products are Labeled "Milk" is Because They Compare to Dairy Milk on Nutrition

Beliefs are Stronger Among Plant-based Milk Alternative Buyers

Why Would a Manufacturer Label a Product Milk if it Does not Contain Milk?  
Q. Below are some reasons why a manufacturer would label a product "milk" even though the product may not contain dairy milk. Please select the reasons why you believe a manufacturer would label a product "milk"



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## FDA Dairy Labeling Docket

- Opened: Sept. 28, 2018
- Closed: January 28, 2019
- Issues:
  - Plant-based food labeling
  - Misleading consumers
  - Consumer perceptions
  - Nutritional inferiority
  - Nutritional equivalence
- 14,016 Comments Filed



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## Two-thirds of Plant-Based Milk Alternative Buyers Believe Alternatives Contain the Same Nutritional Content as Milk

Only 17% of Plant-based Milk Alternative Buyers Disagree

Nutritional Content is the Same as Dairy Milk

Q. How much do you agree or disagree that plant-based milk alternatives have the same nutritional content as dairy milk products?

	Dairy Milk Buyers	Plant-based Milk Alternative Buyers
Strongly/Somewhat Agree (net)	24%	68%
Strongly Agree	4%	32%
Somewhat Agree	20%	37%
Neither Agree or Disagree	42%	17%
Strongly/Somewhat Disagree (net)	34%	15%
Somewhat Disagree	19%	5%
Strongly Disagree	15%	10%

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Product	Milk (1%)	Almond	Cashew	Coconut	Rice	Soy
# of Ingredients	3	3-15	3-15	9-15	8-12	2-18
Calories	102	25-270	40-360	45-80	120-130	70-140
Total Fat (g)	2.4	2-14	3-25	4-5	2.5	0-6
Total Carbs (g)	12	1-32	2-24	1-10	23-26	3-17
Protein (g)	8	1-8	1-11	0-1	1	6-12
Sodium (mg)	107	100-260	105-470	0-180	65-105	5-160
Potassium (mg)	366	0-190	20	40-72	20-70	30-460
Vitamin A (%)	5	0-10	0-10	10	10	0-15
Calcium (%)	28	2-50	2-30	4-45	30-45	0-45
Vitamin D (%)	24	0-25	25-30	0-30	25	25-30
Riboflavin (%)	26	2-30	ns	ns	0	6-30
Phosphorus (%)	22	2-4	ns	ns	6-15	8-25
Magnesium (%)	6	4	10	8-10	8	6-15
Vitamin B12 (%)	18	0-25	50	25-50	0-25	20-50
Niacin (eq) (%)	10	ns	ns	ns	ns	4



Oatly “Oat Drink” has been sold since 1990, with no consumer confusion in Sweden or elsewhere!



If we can't call it milk, what could we possibly call it?

### Margarine Sales are Weak, So Let's Call it Butter

- Margarine sales are down, butter is up!
- These are likely “margarine” products or spreads
- Calling margarine or spreads “butter” is false and misleading
- False and misleading = Misbranded



Canadians and Brits are not confused!

Regulations in Canada and the United Kingdom don't allow the use of “milk” as a name for Almond Breeze, the same brand sold in the United States as “almondmilk.”

### NMPF Citizen Petition

Filed February 21, 2019

Issues:

- Proper labeling of plant-based foods
- Enforce the SOI rules
- 1st Amendment challenges

Next Steps:

- Meet w/FDA
- Gain broad dairy industry support





## Environmental Issues



## Animal Health Updates

## Waters of the U.S.

### NMPF comments on Proposed Rule

- Thank you EPA for getting it right
- Plus a few suggestions to make even better



### What's next from EPA?

- Must first revoke 2015 Rule
- Then finalize new 2019/20 Rule

## Tuberculosis Eradication Program

### ▪ USDA working group:

- Describe performance-based measures instead of prescriptive requirements
- Clarify and/or simplify the requirements
- Revise requirements, and associated guidance, to make them more practical or suitable to implement in the field
- Resolve conflicts with other regulations or policies
- Update requirements based on new scientific information

### ▪ USDA Under Secretary Ibach & NMPF CEO Mulhern meeting

- Commitments to work on modernization of program

## CERCLA/EPCRA

- EPCRA interpretation Oct. 2017
- CERCLA fix March 2018
- September 2018 activists sue
- November 2018 proposed EPCRA rule issued
  - Comments filed Dec. 2018
  - Final rule finalized in June
- Lawsuits TBD



## Antibiotics – EU Article 118

- Restrict the use of “medically important” antibiotics in livestock applied to imported food
- All U.S. approved lactating and dry cow mastitis treatments are medically important
- Working closely with USDEC and barnyard coalition on outreach to USTR and others





# FARM Program Update

# Animal Care: Version 4 Proposed Standards

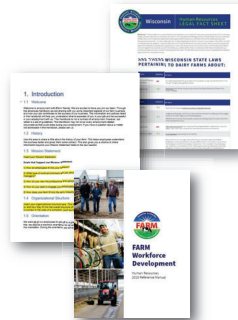
- Immediate Action
  - Tail docking
- Mandatory Corrective Actions (within 9 months)
  - Veterinarian review
    - > VCPR
    - > Herd health plan
  - Pre-weaned calf practices & protocol
    - > Disbudding prior to 8 weeks of age
  - Non-ambulatory practices & protocol
  - Euthanasia practices & protocol
  - Fitness of transport protocol
  - Feed access
  - Water access
  - Continuing ed for Non-family employees
- Continuous Improvement Plans (within 3 years)
  - Animal observations:
    - > Body condition score
    - > Hock/Knee
    - > Locomotion
    - > Broken tails
  - Pain management for disbudding
  - Written drug treatment records available for review by veterinarian of record
  - Continuing ed for family employees

# FARM Workforce Development

## Current Resources (\*= new)

- Safety Manual\*
- HR Manual\*
- HR Templates + Sample Employee Handbook\*
- Legal Fact Sheets
- HR and Safety Self-Assessments

<https://nationaldairyfarm.com/producer-resources/worker-safety-human-resources/>



# Animal Care 4.0 Timeline

- July 15-17, 2019 | Trainer & Evaluator Training | Madison, WI
- July 23-25, 2019 | Evaluator Conference | Denver, CO
- August 19-21, 2019 | Trainer & Evaluator Training | Boise, ID
- September 4-5, 2019 | FARM Stakeholder Forum | Minn., MN
- October 21-23, 2019 | Trainer & Evaluator Training | Phila., PA
- December 2-4, 2019 | Trainer & Evaluator Training | Ft. Worth, TX
- January 2020 | Evaluations on Version 4.0 Begin

# FARM Workforce Development

## 2019 Focus Areas

### Establish baseline

- Nationwide labor survey (anonymous)

### Resources

- Online resource library, including training videos

### Pilot evaluations

- Develop on-farm evaluation, using self-assessment as guide
- Pilot + get feedback
- Focus is on best practices + bringing value to the farm → while also providing assurances to customers

## 2020 + Beyond

### Voluntary evaluations

- 2nd-party evaluation available to FARM participants, based on pilot feedback

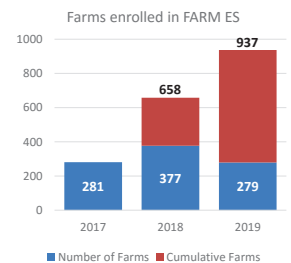
### Additional trainings + resources

- Case studies
- 'Roadmap' for safety
- Etc.

# Environmental Stewardship Status

## Farms

- 1,000+ FARM ES evaluations completed, for approximately 935 facilities enrolled in FARM ES
- 20 participating co-ops and processors that represent 60% of milk supply
- Steady growth year-over-year



*Preliminary data from July 2019. Number of farms is an approximation based on # of facilities, grouped by year of first evaluation.*

## Environmental Stewardship Status

### Strengths

- Backed by sound science
- Regularly updated
- 2<sup>nd</sup> party evaluators
- Track industry goals
- Meet customer demands
- Supply chain collaborations

### Upcoming Activities

- Online evaluator training – September 2019
- Updated model July 2019
  - Solid-liquid separation
  - New crop emissions factors
  - Renewable energy
  - NMP metrics
- Online resource center + state NMP fact sheets



## Immigration Reform

Continues to be a major NMPF priority

- Both parties want a solution; obstacles remain
- Rep. Lofgren (D-CA) working with members and ag stakeholders to build bipartisan consensus on ag labor
- NMPF's Immigration Task Force discussion helps shape negotiations with United Farm Workers and Congress
- Bipartisan group of House members advocating for dairy's unique needs
- White House exploring regulatory options to assist agriculture on this front



## Legislative Update



## Immigration Reform

Continues to be a major NMPF priority

- White House focus continues on enforcement
- Social Security No-Match letters
  - Large volume of letters to farmers and others in food and agriculture
  - No-Match effort puts dairy farmers in difficult situation
- Legal advice shared with NMPF members



## Child Nutrition

Reauthorization is up this Congress

- Senate likely to move first this year
- NMPF working to preserve USDA rulemaking to allow one percent flavored milk in schools
- Reps. Courtney (D-CT) and Thompson (R-PA) have introduced legislation to codify this policy
- Reps. Thompson (R-PA) and Peterson (D-MN) authored bill to allow schools to offer whole milk
  - Related Senate legislation introduced
- 2020 Dietary Guidelines may provide opportunity for further progress



## Trade Policy Update



## U.S. - China Negotiations

- May 2019 escalation of tariff levels in wake of U.S. claims of China back-tracking in deal
  - Largest harm to dairy is from lack of a break-through as dairy already hit by 2018 tariffs. New tariffs bump up rates on lactose, infant formula
- How does dairy factor into negotiations?
  - NMPF has made dairy part of the negotiations, identifying key issues and pushing to get them resolved/improved
- Trade Aid 2.0



## Milk Matters – An NMPF Update

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## End of the Road for 232 Tariffs, Still Truckin' on USMCA



- 232: Shortly after China break-down, break-through achieved on metal tariffs
  - As of May 20<sup>th</sup>, U.S. tariffs on Mexico/Canadian metals lifted and Mexican/Canadian retaliatory tariffs lifted
  - End to this impasse took far longer to secure than we wanted, but the constant press from NMPF and others in ag helped to make it a "must do" when the Administration needed a swift trade win
- USMCA
  - Outstanding issues remain to be addressed by USTR & House Democrats: labor, environment, enforcement, pharmaceutical pricing
  - NMPF focus on dairy benefits well known by key offices; now working with members to push for USMCA vote

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## Other Key Trade Topics: FTAs

- Japan FTA
  - Talks commenced in April. US aiming for swift pace but TBD how fast Japan is willing to move
  - NMPF working with U.S. negotiators, congressional offices to underscore need for robust dairy results vs. prior deals with our competitors
- EU trade talks
  - US-EU standoff on ag's role in agreement
  - NMPF's top priority is ensuring any deal narrows dairy trade deficit, not widens it
- Who else?
  - No other concrete FTA partners identified to date
  - NMPF promoting need for agreements in Southeast Asia at every opportunity



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# Mobile Manifest and Dispatch Solutions

THIS MARK MATTERS. 

## Dairy.com

Mobile manifest and dispatch solutions

- Provides real-time monitoring and data on milk collection, load tracking and wash tag management
- Enhances traceability across the supply chain
- Minimizes errors
- Clean data is transferred directly into DFA's SAP system, eliminating paper verification and manual data input
- Leverages multiple mobile platforms (iOS and Android) and devices (phones and tablets)
- Simplified communication between dispatch, haulers and plants



## Project overview

- Dairy Farmers of America (DFA) is interested in leveraging technology within our milk collection and delivery processes in order to:
  - Improve productivity and efficiency
  - Increase data to information
  - Increase innovation
  - Integrate compliance
  - Increase sustainability
- Technologies continue to provide opportunities for transformation of data to knowledge with near real-time capabilities

## Why mobile manifest?

- Mobile applications are strategic, paper not so much
- Timeliness of data to information
  - Paper takes 2-3 days on average to transform into data
  - Mobile manifest is near real-time (minutes, not days)
- Quality of data to information
  - Paper requires interpretation of driver's handwriting
    - 5,000+ drivers across DFA
  - Mobile is dependent upon a driver's typing skills, which is minimized to weight and temperature primarily
  - Barcode scanning captures majority of the data elements
  - Accuracy improves as drivers become acclimated to the application
- Sustainability
  - Paper consumes natural resources – 1 million multiple-part manifests annually
  - Mobile consumes electronic resources

## Dairy.com platform

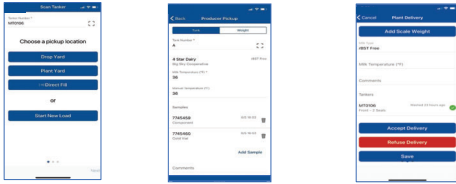
- Approximately 20% of the milk supply in the U.S. is utilizing this technology
- Several of DFA's largest customers are finding benefit in the program as other suppliers have implemented this platform
- The platform is compatible with our current operating system
- Supported by the devices that are currently used by drivers for electronic logs and time card management system
- Provides time and labor savings for the cooperative and its customers



## Why mobile manifest?

- The intent is to implement a mobile manifest application with the following attributes:
  - Utilization of the application on a smartphone or tablet (Apple or Android)
  - Integrates with DFA SAP Milk Marketing Solutions
  - Continue to work with customers to enhance data sharing
  - Design technically to a standard of reusable programs to accommodate the frequent change in technological capabilities
- Mobile manifest is a journey, not a big bang
  - Requires coordination with each DFA customer
  - Requires thorough training for each driver
  - Requires Subject Matter Experts (SME's)

## Hauler data collection



**To Start:** Driver logs in and selects route. Truck ID, seals, wash tags, and other fields are as entered or scanned

**At the Farm:**

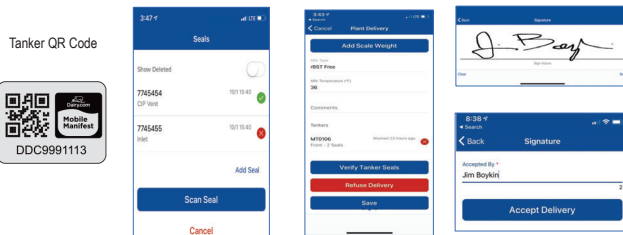
- Farm information captured by scanning tank QR Code
- Weights captured
- Sample information entered by barcode
- Producer's location confirmed

**Delivery:** As Hauler approaches scale an email is generated with PDF attachment of manifest

## Implementation approach

- DFA's Mountain Area was the first to begin testing functionality of the mobile manifest and dispatch solutions
  - Colorado fully transitioned to mobile manifest and dispatch in May 2019
  - Idaho and Utah implementation is currently in progress
- Other Areas are interested in utilizing these tools

## Plant delivery



Receiver will:

- Scan tanker QR code

Scan Tanker Seals to verify

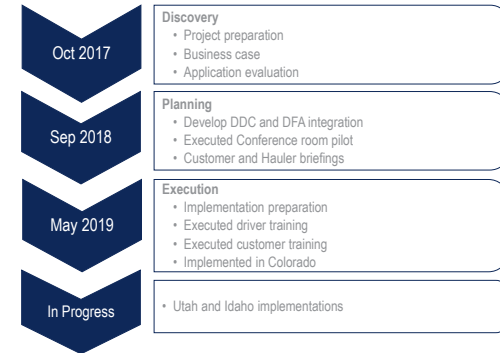
Enters:

- Temperature
- Enter load notes/comments

Accept Load:

- Signature

## Mountain Area project timeline



## Why dispatch?

- The dispatch solution enables DFA, its customers and haulers to gain visibility into milk supply schedules and plant demand schedules
- Provides automated communications with haulers and plants through electronic notifications
- Mobile Manifest integrates with the dispatch tool
  - Validates unique load numbers as they are entered
  - Provides visibility to load locations and status

## Current success rate

- Since implementation, over 93% of Colorado manifests have been successfully uploaded into the DFA SAP system
  - Manifests that contain errors are conveniently managed through an error screen
- Customers using the tool today have a high level of confidence and are pleased with the new processes



## New Tech in Dairy

Lowell T. Midla

Merck Animal Health

## Why?



<https://www.findfarmland.com/landscapes/articles/sold-on-the-cattle-business/>



<https://www.drovers.com/article/growing-cattle-breastlines-mean-more-stocker-opportunities>

<https://www.farmersweekly.co.za/animals/cattle-beef>

## The Whisper Digital Stethoscope



2

## So:

- “Pre-conditioning” / vaccination prior to move is the exception rather than the rule.
- More cattle than we’d like develop pneumonia.
- Diagnosing which animals need treatment vs. those who do not is a challenge.

5

## Whisper – The challenge:

As beef cattle move through the production cycle, both ownership and address typically changes.

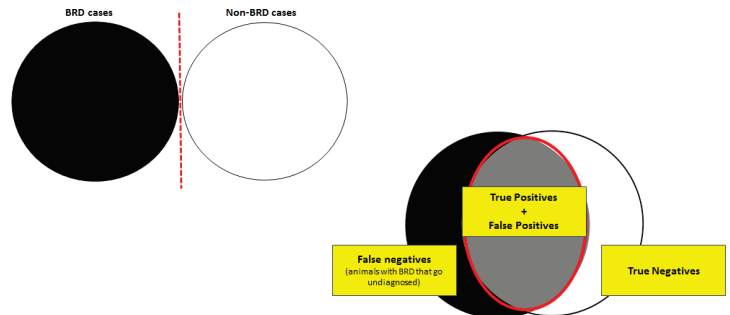
When this happens, cattle are susceptible to developing pneumonia.

(Layman’s term for pneumonia in cattle: “shipping fever”)



3

## Whisper – The diagnostic challenge:



6



## Solution:

### The Whisper Digital Stethoscope



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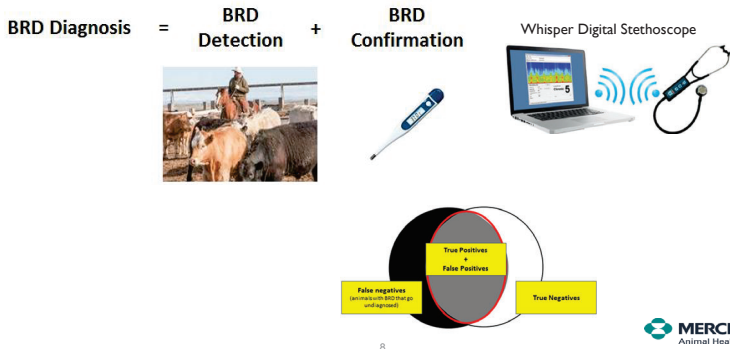
## Whisper Digital Stethoscope:

### Questions?



10

## Whisper – Better Pneumonia Diagnosis:



# SEQUIVITY™



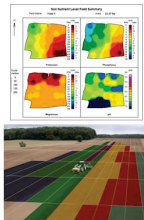
## Whisper – The point:

### Precision Agriculture

Row crop example:

- Variable rate application
  - Water
  - Seed
  - Fertilizer

Maximize yield  
Reduce input costs



### With Whisper:

- Increased sensitivity (potentially)
- Increased specificity
- Thus increased:

**Precision / Accuracy**

However... will need to “re-learn” for dairy calves.



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## How vaccines are made / approved:

- A “representative” sample of a bad bug is obtained.
  - Hopefully immunity to it will confer immunity to most strains.
- A vaccine is made.
- Vaccine is tested for safety and efficacy.
- Vaccine is approved.
- Vaccine becomes available.



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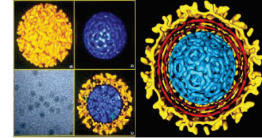
## Challenges associated with this approach:

- Must handle bad bugs in the lab.
- Several years from idea to release of commercial vaccine.
- Cost to get approval: high
- Must hope that you started with a strain that will result in immunity to many strains.
- Must hope that the strain that you started with will continue to confer immunity to many strains.
  - Influenza example.

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## A bit on how viruses work:

- A virus is a bit of RNA or DNA inside a shell.
- A virus cannot replicate by itself.
- A virus gets into a host cell and the host cell's machinery is tricked into making copies of the virus.
- Thus some folks do not consider a virus to be "alive".



## A bit on how vaccines work:



### "Modified Live" vaccines:

- Bad bug is modified so that it does not cause disease.
- Vaccine (made of modified bad bug) is administered to animal.
- Vaccine (modified bad bug) multiplies / reproduces for a brief period – until immune system recognizes it as foreign, mounts an immune response, and eliminates it.
- Animal's immune system now has memory of the "antigens" of that bug and can eliminate the bug if / when it sees it again.

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## How Sequivity works:

- A bad bug is isolated on a farm or at a diagnostic lab.
- Antigenic proteins from the sample are sequenced.
- An email is sent to Sequivity HQ with the protein sequence.
- RNA coding for that protein sequence (i.e. the antigen) is inserted into a viral particle that has been made unable to replicate.

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## A bit on how vaccines work:



### "Killed" vaccines:

- Bad bug is killed but not destroyed.
- Typically, an adjuvant is added.
- Vaccine (made of killed bad bug) is administered to animal.
- Vaccine "shows" the immune system an example of the bad bug.
- Animal's immune system now has memory of the "antigens" of that bug and can eliminate the bug if / when it sees it again.

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## How Sequivity works:

- Viral particle (containing RNA coding for antigen) is administered to animal.
- Dendritic cell captures the viral particle and travels to lymph node.
- Dendritic cell's machinery translates the RNA coding for the antigen of interest into a protein – that is, the dendritic cell manufactures the antigen.
- Dendritic cell then presents the antigen to both B-cells and T-cells thus evoking an immune response.

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## Why Sequivity is cool / useful / better:

- Speed – 8 to 12 weeks
- No handling of dangerous pathogens
- Agile – can address “this year’s strain”
- No adjuvant required
- Very safe
- Can update vaccine to protect against new strain



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## Mastitis:

### Mastitis Five Point Plan – 1970:

1. Treat and record clinical cases
  - Spontaneous cure rate ~ 2/3.
2. Post-milking teat disinfection
3. Total dry cow therapy
  - Very important in the demise of Strep ag
  - Very unlikely to contribute significantly to antimicrobial resistance
4. Cull chronic cases
5. Milking machine maintenance



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## Sequivity:

### Questions?



## Mastitis:

Between 1994 and 2001, isolation of Strep. agalactiae and Staph. aureus from milk samples submitted to the Wisconsin Veterinary Diagnostic Laboratory declined dramatically and gram-negative pathogens (or culture-negative results) have become the predominant results of milk samples obtained from cows experiencing clinical cases.

Ruegg 2017

Strep ag: 1. Tx Clinical, 2. PMTD, 3. TDCT, 4. Culling, 5. Machine maint  
Staph aureus: 1. Tx Clinical, 2. PMTD, 3. TDCT, 4. Culling, 5. Machine maint



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## Mastitis:

### Mastitis Five Point Plan ~1970:

1. Treat and record clinical cases
2. Post-milking teat disinfection
3. Total dry cow therapy
4. Cull chronic cases
5. Milking machine maintenance



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## Mastitis:

### 2019:

1. Treat and record clinical cases
  - Some farms no longer treating clinical cases.
2. Post-milking teat disinfection
3. Total dry cow therapy
  - Selective Dry Cow Therapy (SDCT)
4. Cull chronic cases
5. Milking machine maintenance



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## Mastitis:

- Potential Implications / Outcomes:
  - Not treating clinical cases:
    - Decreased Abx use?
    - More Strep ag?
    - Increased culling / herd turnover?
  - SDCT:
    - Decreased Abx use? (Increase during lactation?)
    - More Strep ag?
    - Increased SCC?



25

## Group housing / automatic feeders:

Table 2. Published research on the effects of social housing on feeding behavior and performance of calves

Treatment	Animals	Parameter	Effect of socialization	Reference
Individual; group (3 calves)	Bulls	BW	+	Andrighetto et al., 1999
Individual; group (6 calves)	Heifers and bulls	Solid feed intake	+	Babu et al., 2004
Individual; group (6 calves)	Heifers and bulls	ADG	+	Babu et al., 2009
Individual; group (6 calves)	Heifers and bulls	Solid feed intake	=	Babu et al., 2009
Individual; group (3 or 4 calves) <sup>2</sup>	Bulls	DMI	+	Bernal-Rigoli et al., 2012
Individual; group (3 or 4 calves) <sup>2</sup>	Bulls	BW	+	Bernal-Rigoli et al., 2012
Individual; group (3 or 4 calves) <sup>2</sup>	Bulls	ADG	+	Bernal-Rigoli et al., 2012
Individual; pairs	Heifers and bulls	Solid feed intake	=	Chua et al., 2002
Individual; pairs	Heifers and bulls	ADG	=	Chua et al., 2002
Individual; pairs	Bulls	Solid feed intake	+	Costa et al., 2015a
Individual; pairs	Bulls	ADG	+	Costa et al., 2015a
Individual; pairs	Heifers	Concentrate intake	+	de Paula Vieira et al., 2010
Individual; pairs	Heifers	ADG	=	de Paula Vieira et al., 2010
Individual; pairs <sup>3</sup>	Bulls	ADG	=	Hannison et al., 2005
Individual; group (4 calves) <sup>4</sup>	Bulls	Solid feed intake	+	Hepda et al., 2006
Individual; group (4 calves) <sup>4</sup>	Bulls	ADG	+	Hepda et al., 2006
Individual; pairs <sup>5</sup>	Heifers and bulls	Concentrate intake	+	Jensen et al., 2015
Individual; pairs <sup>5</sup>	Heifers and bulls	BW	+	Jensen et al., 2015
Individual; pairs <sup>5</sup>	Heifers	Solid feed intake	=	Pempek et al., 2013
Individual; pairs <sup>5</sup>	Heifers	ADG	=	Pempek et al., 2013
Individual; group (3 calves)	Heifers	Grass intake	+	Phillips, 2004
Individual; group (3 calves)	Heifers	BW gain	=	Phillips, 2004
Individual; group (3 calves)	Heifers and bulls	Final BW	=	Richard et al., 1988
Individual; group (3 calves)	Heifers and bulls	Concentrate intake	=	Richard et al., 1988
Individual; group (3 calves)	Heifers and bulls	Solid feed intake	+	Topik, 2007
Individual; group (3 calves)	Heifers and bulls	ADG	+	Topik, 2007
Individual; group (5 calves)	Bulls	Solid feed	=	Térré et al., 2006
Individual; group (5 calves)	Bulls	BW	=	Térré et al., 2006
Individual; group (6 calves)	Heifers and bulls	Solid feed intake	=	Warnick et al., 1977
Individual; group (6 calves)	Heifers and bulls	ADG	+	Warnick et al., 1977
Individual; group (4 calves)	Bulls	BW	+	Xiccato et al., 2002
Individual; group (4 calves)	Bulls	ADG	+	Xiccato et al., 2002

16 studies measured 31 outcomes: 19+ 13= 0- Coğa, von Keyserlingk, Weary JDS 2016



## Mastitis:

### Questions?



Photo stolen from: You Tube

26



## Group housing / automatic feeders:

### Midla's guesses / opinions:

- Since joining Merck, this is #1 requested farm visit
- # calves / pen to pay for machine vs. # calves / pen for health (also: # calves / nipple)
- Just like a pasteurizer, you don't just turn them on and forget about them
  - MONITOR TS out of nipple (not simple) (and bacteria count)
- Days to fill group / age range in group.
- Transition in when slightly older?
- Excellent management can overcome – LOOK AT THE CALVES!
- Mucosal (IN) vaccines

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## Group housing / automatic feeders:

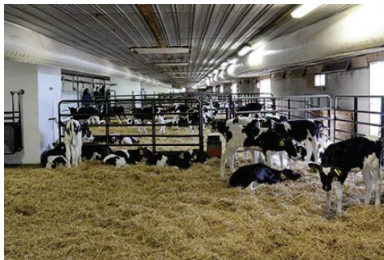


Photo stolen from: <https://dairystar.com/Content/Home/Home/Article/A-renovation-revitalizes-youngstock/80/254/14718>

27



## Group housing / automatic feeders:

### Questions?

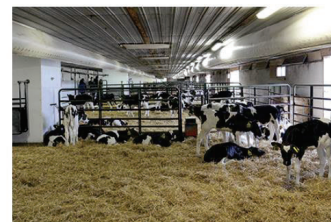


Photo stolen from: <https://dairystar.com/Content/Home/Home/Article/A-renovation-revitalizes-youngstock/80/254/14718>



## Dairy Cow Monitoring:

### Location of Technology:

- Ear
- Leg
- Neck
- Rumen
- Rump
- Vagina
- Milking unit- on claw, inflations, etc.
- In-line: between milking unit and bulk tank

Source: University of Kentucky – “Currently Available Precision Dairy Farming Technologies”



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## CRISPR-Cas9 / GE / GMOs:

FDA regulates GE animals under the “new animal drug” provisions of the Federal Food, Drug, and Cosmetic Act.



34

## Dairy Cow Monitoring:

### Location of Technology:

- Ear
- Leg
- Neck
- Rumen
- Rump
- Vagina
- Milking unit- on claw, inflations, etc.
- In-line: between milking unit and bulk tank

### Feedstuffs

### Merck completes Antelliq acquisition

Antelliq, specialist in emerging digital technology for livestock and companion animals, becomes operating unit within Merck Animal Health.

Apr 02, 2019

Source: University of Kentucky – “Currently Available Precision Dairy Farming Technologies”



32

## Other trends:

- Crossbreeding
  - Ho-Jo is great but then what?
  - What you want (size, components, fertility of Jersey; production of Holstein) vs. what you get
- Holstein component improvement (some herds are near 7 pounds)
- Breeding Dairy to beef
- Microbiome Research
- Big getting bigger



35

## Dairy Cow Monitoring:

### Parameter measured:

- Animal position/Location
  - Locates animals within a facility or pasture
- Body weight
- Feeding behavior
  - Duration and number of eating events
- Jaw movement / Chewing activity
- Rumination
- Rumen pH
- Lying / Standing behavior
- Lameness
- Cow activity
- Estrus / Standing heat
- Temperature

### Parameter measured:

- Fertility hormones
  - E.g. Progesterone – to predict estrus
- LDH (Lactate dehydrogenase) in milk
  - Proxy for mastitis
- Milk conductivity
  - Proxy for mastitis
- Somatic Cell Count
- Milk components (e.g. fat, protein)
- Milk flow
- Individual cow milking time
- Milk yield
- Vacuum in milk line

Source: University of Kentucky – “Currently Available Precision Dairy Farming Technologies”



## Any Questions?



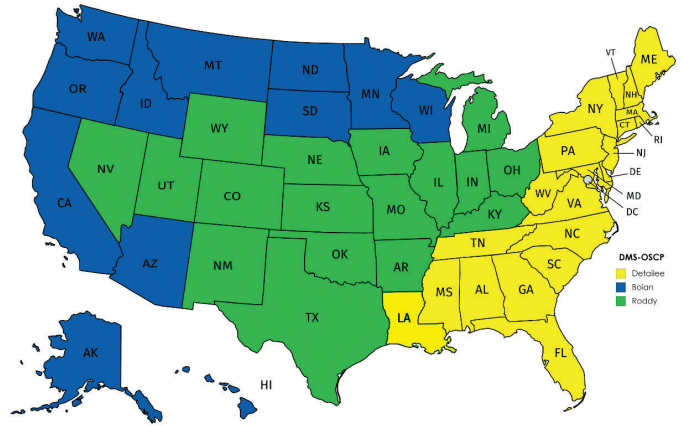
Lowell T. Midla

Lowell.Midla@Merck.com

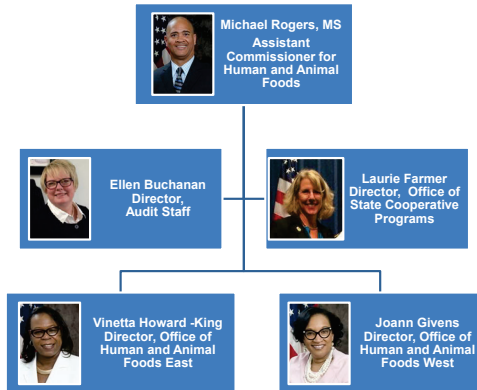


**NATIONAL ASSOCIATION OF DAIRY  
REGULATORY OFFICIALS  
MYSTIC, CT  
JULY 14-17, 2019**

**TIM RODDY  
OSCP  
DIVISION OF MILK SAFETY  
DIRECTOR BRANCH #2**



**Office of Human and  
Animal Food Operations**



**OSCP Milk Specialists  
State Assignments and Branches**

Milk Specialist	Assigned State	Manager	NEW Branch #
Griner	AL, FL, LA, MS, SC	Detailee	1
Mitchell	MD, VA, WV	Detailee	1
Pearce	DE, PA, NJ	Detailee	1
Willis	GA, NC, PR, TN	Detailee	1
Zick	CT, MA, ME, NH, NY, RI, VT	Detailee	1
Himebaugh	NM, UT, NV, WY, CO, TX	Roddy	2
Klug	IA, MO, NE, AR, OK, KS	Roddy	2
Oliver	IL, IN	Roddy	2
Pitts	OH, KY, MI	Roddy	2
Goldsmith	MN, ND, SD	Boian	3
Miller	CA, AZ, HI	Boian	3
Navarrete	OR, WA, AK, ID, MT	Boian	3
Torgerson	WI	Boian	3

**DMS Branches**

- Branch 1 (East)**  
Acting Director: Robert Altobelli  
States: AL, CT, DE, FL, GA, LA, MA, MD, ME, MS, NH, NJ, NY, NC, PA, PR, RI, SC, TN, VA, VT, WV
- Branch 2 (Central)**  
Director: Tim Roddy  
States: AR, CO, IA, IL, IN, KS, KY, MI, MO, NE, NM, NV, OH, OK, TX, UT, WY
- Branch 3 (West)**  
Director: Les Boian  
States: AK, AZ, CA, HI, ID, MN, MT, ND, OR, SD, WA, WI

**Milk Specialists Changes**

- Branch I (Eastern)  
– 2-3 New Hires
- Branch II (Central)  
– 2-3 New Hires
- Branch III (Western)  
– 2-3 New Hires
- Lezette Earhart retired in March 2019





### Grade "A" CHECK RATINGS FY 2018 (14 Milk Specialists)

BRANCH	BTU's	PLANTS	RS/TS	TOTAL	Single Service
I-(East)	53	29	7	89	15
II- (Central)	42	43	1	86	17
III (West)	17	40	7	64	17
<b>TOTALS</b>	<b>139</b>	<b>112</b>	<b>15</b>	<b>266</b>	<b>49</b>



### TOTAL ADVERSE ACTION RATES (%) -CHECK RATINGS

FY	PLANTS	RS/TS	BTU's	ALL
2018	10.7%	0.0%	18.0%	13.9%
2017	10.0%	9.1%	15.6%	13.2%
2016	8.6%	10.5%	22.5%	16.6%
2015	5.0%	0.0%	18.4%	12.6%
2014	6.8%	11.8%	16.7%	11.9%
2013	11.6%	16.7%	18.0%	15.2%
2012	6.6%	7.1%	20.4%	14.3%
2011	6.8%	0.0%	17.7%	12.7%
2010	6.7%	7.1%	9.6%	8.3%
2009	5.7%	6.3%	15.1%	11.1%



### Grade "A" CHECK RATINGS 2009-18

FY	PLANTS	RS/TS	BTU's	TOTAL
2018	112	15	139	266
2017	130	22	206	358
2016	151	19	227	397
2015	141	11	206	358
2014	147	17	156	320
2013	146	12	183	341
2012	151	14	206	371
2011	132	7	175	314
2010	134	14	177	325
2009	122	16	186	324



### Appendix T Training 2018

- Appendix T is accepted by FDA as equivalent to Title 21 CFR Part 117 for Grade "A" firms
- PMO-PC Cadre Assembled
- FD378 – Preventive Controls for Grade "A" Milk Plant Regulators
- Successful completion of this course meets FDA criteria for the Grade "A" PMO Preventive Controls Training for Regulatory Agencies.



### TOTAL WITHDRAWAL RATES (%) CHECK RATINGS

FY	PLANTS	RS/TS	BTU's	ALL
2018	5.4%	0.0%	.01%	2.2%
2017	4.6%	9.1%	3.9%	4.5%
2016	4.0%	5.3%	9.3%	7.1%
2015	3.5%	0.0%	6.8%	5.3%
2014	4.1%	5.9%	6.5%	5.3%
2013	3.4%	0.0%	3.3%	3.2%
2012	2.6%	7.1%	4.9%	4.0%
2011	1.5%	0.0%	6.9%	4.5%
2010	1.5%	0.0%	2.8%	2.2%
2009	3.3%	6.3%	4.8%	4.3%



### PC-PMO Regulatory Training

- FDA budgeted \$250,000 to fund states' travel
- Five classes conducted: Dallas, Chicago, Newport Beach, Washington D.C., and Denver
- 166 Total participants
  - Plant SROs (Plant)
  - State Program Managers
  - 3<sup>rd</sup> Party SROs and Managers
  - FDA Milk Safety Team Members (ORA/CFSAN)

## FDA Group Exercises

- Group exercise in Omaha, Nebraska at Prairie Farms and LaLa-U.S. firms the week of October 22, 2018
- Group exercise in Dallas, Texas at Dean Foods and Kroger firms the week of April 1, 2019



Special “Thank You” to the States and companies that participated in the exercises!

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## FDA Dairy Inspection Pilot

*“When it comes to the FDA’s milk inspection protocols, the agency is seeking additional ways to maximize state and federal resources and create greater efficiency through its obligations under the FDA Food Safety Modernization Act.”*

*“We believe there’s more opportunity for FDA and state regulators to better coordinate oversight efforts of the dairy industry, making the process more efficient while maintaining the high safety of the U.S. milk supply.”*

Dr. Scott Gottlieb, FDA Commissioner, November 1, 2017

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## Appendix T Inspections

- Start Date: December 1, 2018
- 40 Appendix T inspections conducted
- Action(s)
  - 3 Reinspections
  - Resulted from the absence of a Food Safety Plan or the firms lacking significant components of the Food Safety Plan.

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## Dairy Inspection Pilot

- Responding to multiple stakeholder groups:
  - Coordinate an approach to non Grade “A” PC and Grade “A” check ratings
  - Maximize Federal-State resources
  - Minimize burden of inspections on IMS-listed facilities
- Goal: Integration – not duplication – of food safety inspections

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## Top 5 Issues

- 1. Recall plans**  
Incomplete,
- 2. Hazard Analysis**  
Incomplete, missing, not all hazards identified, only one HA for entire plant with multiple different processes.
- 3. Plants using modified HACCP and SQF plans**  
Modeled to meet 3<sup>rd</sup> party audits.
- 4. Lack of Corrective Actions.**
- 5. Food Safety Plan not signed by most responsible individual.**

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## Dairy Inspection Pilot – Version 1.0

- What:
  - One combined visit from FDA
  - Simultaneous MS Check Rating with PC Inspection
  - Leverage expertise of combined visit
- When:
  - Fall 2018 (2 non-regulatory visits)

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## Stakeholder Listening Session

- Washington D.C. in December 2018
- Comments from mock inspections:
  - Simultaneous inspection was a burden on facility
  - Efficiencies were not being realized
- NCIMS, States, and Industry stakeholders asked FDA to reconsider pilot structure
  - Goal: single person, single regulatory activity
- FDA committed to explore new possibilities

## Appendix T/Limited Scope PC Combination

### Milk Specialist

Appendix T Audit with Activity to count as Limited Scope PC

## Dairy Inspection Pilot – Version 2.0

- An IMS-listed plant that solely manufactures Grade “A” dairy products and complies with the revised PMO would also comply with the PC rule (Appendix T audit only).
- FDA will pilot two approaches for dual-grade facilities:
  - Federal-State Partnership
  - Appendix T/Limited Scope PC Combination

## At the 2019 NCIMS Conference, Proposal JC-1 was unanimously passed by the Delegates.

- The NCIMS Liaison Committee was charged to work cooperatively with FDA to develop the pilot program which will be implemented by FDA and the participating States.
- The Committee will determine the eligibility criteria for pilot consideration, the types of non-Grade “A” products manufactured in dual-grade facilities that will be covered, the resource needs and potential hurdles likely to be encountered, and the metrics for evaluating success.

## Federal-State Partnership

### State Regulatory Agency

Grade “A” Inspection with Non-Grade “A” PC Inspection

### Milk Specialist

Appendix T Audit with Non-Grade “A” Audit (new\*)

## FDA Fully Supported JC-1

- Recognized that it demonstrated FDA’s strong commitment to develop the dairy pilot program.
- This option assures varied expertise and perspectives are considered.
- A complete report of the Pilot program will be shared with the 2021 NCIMS Conference.

## FDA Messages and Takeaways

- FDA recognizes the value and quality of work that the NCIMS program provides the FDA Milk Safety Program
- FDA will continue to support the NCIMS MOU and the integration of food safety through our Cooperative Programs

## FY2020 Dairy Seminars

**Eastern Seminar**  
 October 27<sup>th</sup> - 30<sup>th</sup>, 2019  
 in Madison, Wisconsin

**Western Seminar**  
 May 3<sup>rd</sup> - 6<sup>th</sup>, 2020  
 in San Antonio, Texas

## Next Steps

- FDA looks forward to the development and implementation of the new version of the Dairy Inspection Pilot with the NCIMS Liaison Committee.
- FDA will commit to open and transparent dialogue on the pilot with all stakeholders.

## Questions

## Projected Courses for FY2020

	Milk Courses	Location	Approximate Timeframe
FD371	Milk Pasteurization Controls and Tests	Nashville, TN	5/1/2020
FD371	Milk Pasteurization Controls and Tests	Omaha, NE	7/1/2020
FD372	Milk Plant Sanitation and Inspection	Albuquerque, NM	4/1/2020
FD372	Milk Plant Sanitation and Inspection	Buffalo, NY	8/1/2020
FD373	State Milk Laboratory Evaluation Officer (LEO)	Long Beach, CA	2/1/2020
FD374	Laboratory Examination of Dairy Products	Chicago, IL	3/1/2020
FD375	Dairy Farm Sanitation and Inspection	Palm Beach, FL	12/1/2019
FD375	Dairy Farm Sanitation and Inspection	Denver, CO	6/1/2020
FD378	Preventive Controls for Grade "A" Dairy Regulators	Seattle, WA	7/1/2020
FD577	Special Problems in Milk Protection	Austin, TX	2/1/2020

# Problem Solving with QualiTru.

BY: QUALITRU SAMPLING SYSTEMS



Why wouldn't we want all samples to be taken aseptically?



# Why do we sample?



Can this really agitate a 60,000lbs truck?

What is the best way to agitate a milk truck?



Is this the best method for collecting data from a producer, truck or plant?



How long do really have to agitate a bulk tank to get a true 'Representative Sample'?





The entire industry makes decisions based on the sample collected, why would we settle for inferior sampling methods?

## Sterile Collection Units



- ▶ Sterile Collection Bags
  - ▶ Sterilized (Gamma Irradiated)
  - ▶ 250ml, 2 Liter, & 7 Liter
- ▶ QualiTru Tru-Draw Single Sampler
  - ▶ Sterilized, ready to use
  - ▶ 2 oz.
- ▶ Sterile Syringes
  - ▶ 60cc & 140cc



## 7-Channel Septum

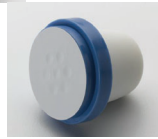


- ▶ Specifications
  - ▶ 250°F
  - ▶ 150 psi
  - ▶ 100 Hours
  - ▶ Cleaned in Place
- ▶ Specifications
  - ▶ 300°F
  - ▶ 50 psi
  - ▶ 100 Hours
  - ▶ Cleaned in Place



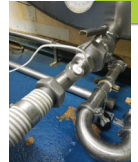
Standard 7 Channel Septa

High Temp. Septa



## Farm Applications

- ▶ Direct Load Sampling
- ▶ Silo/Bulk Tank Sampling
- ▶ Line Sampling
- ▶ Diagnostic Testing
- ▶ Tanker Truck Sampling



## Sanitary Ports

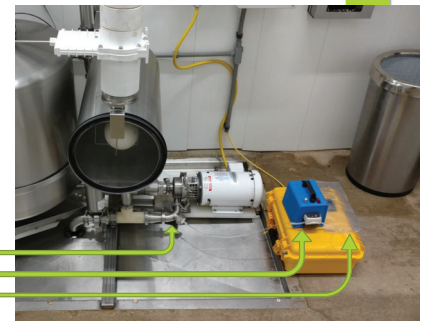


- ▶ Specifications
  - ▶ 316L Stainless Steel
  - ▶ 3A Certified
  - ▶ 32 RA
  - ▶ Tri-Clamp or Weld



## QualiTru Supplies for Pen Sampling

- ▶ 7 Port Stainless-Steel fitting as close to the receiver as possible
- ▶ Peristaltic Pump
- ▶ 2L Sterile Collection Bag



## Silo & Bulk Tank Sampling



## Side Truck Sampling

- ▶ Sample port accessible from the ground
- ▶ Ideal for safe & accurate antibiotic sampling in a receiving bay
- ▶ 10-15% increase in receiving bay efficiency observer.



## QualiTru Direct Load

- ▶ PMO approved.
- ▶ Piper
- ▶ Conflow



## Process Monitoring

- ▶ Validate & verify equipment meets specifications
- ▶ Post Pasteurization Monitoring



## Peristaltic Truck Loading.

- ▶ Removes the need for agitation.
- ▶ PMO approved.
- ▶ Produces the most representative sample obtainable.



## Peristaltic unload of Tankers Trucks

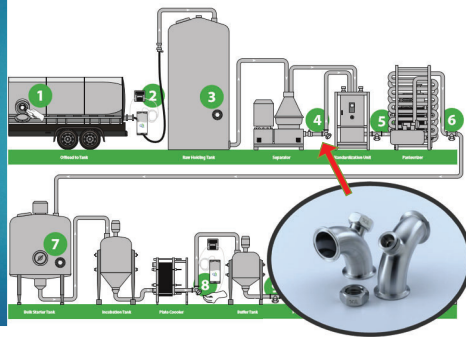
- ▶ True Representative sample without the need to agitate the truck, regardless of time between farm to plant.
- ▶ Study conducted saw .2-5 component variance with standard sampling methods, vs equal comparison of peristaltic loading of tanker.



Trying to locate a contamination.

- ▶ Diagnostic methodologies
- ▶ Tear down time dramatically reduced.

### DAIRY PROCESSORS - CULTURED APPLICATION SITES



I'M AN EXPERT



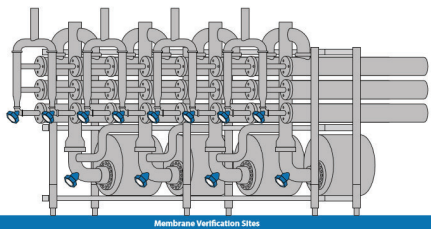
IN MY FIELD



Questions?

- ▶ Farm to plant applications and everything in between

### WHEY PROCESSING APPLICATION SITES



## FDA MI Acknowledgements

- ▶ FDA Memo M-I-12-4
- ▶ FDA Memo M-I-06-6
- ▶ FDA Memo M-I-06-12
- ▶ FDA Memo IMS-a-46
- ▶ FDA Memo M-I-16-17

# Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses

## USDA AMS Dairy Program Update



National Association of Dairy Regulatory Officials  
Groton, CT  
July 16, 2019

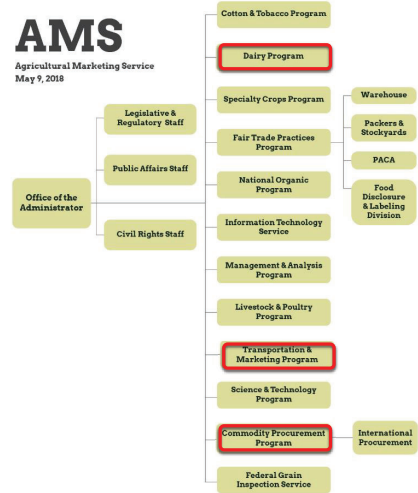
**USDA** United States  
Department of Agriculture

Chris Thompson, Acting Director,  
Dairy Grading and Standards Division

### Agricultural Marketing Service

## AMS

Agricultural Marketing Service  
May 9, 2018



### Agricultural Marketing Service

## Dairy farm data from NASS

### National Agricultural Statistics Service

Licensed Herd-operations with cow inventory.  
<https://downloads.usda.library.cornell.edu/usda-esmis/files/h989r321c/44558m869/j3860f20k/mkpr0319.pdf> (Please see page 18)

- The licensed dairy herd estimate is based on counts provided by state and other regulatory agencies.
- The data on farms with milk cows and milk sales is directly reported by farmers on the Ag Census.
- These two are totally separate and independent data sources.
- For further questions please contact NASS at [nass@nass.usda.gov](mailto:nass@nass.usda.gov)

### Agricultural Marketing Service

## Topics



Farm Bill



AMS Commodity Procurement



AMS Dairy Program Update  
• Dairy Grading and Standards

### Agricultural Marketing Service

## Florida example...

Year	State	CATTLE, COWS, MILK, LICENSED HERD - OPERATIONS WITH INVENTORY, AVG		Data Source	Operations with Milk sales	Data Source
		110	130			
2017	FLORIDA	110	130	State Data	143 CENSUS	119 CENSUS
2012	FLORIDA	110	130	State Data	143 CENSUS	119 CENSUS

According to Census Florida farms with milk cows and milk sales increased from 119 in 2012 to 143 in 2017

According NASS data for Florida Licensed Herd-operations with cow inventory decreased from 130 operations in 2012 to 110 operations in 2017.

Both data series are collected by USDA NASS. The sources and definitions are distinct.

### Agricultural Marketing Service

## 2018 Farm Bill

### Amendment to Class 1 Price Formula

- Specifies the Class I skim milk price will be the simple average of the two advanced pricing factors, plus \$0.74, plus the applicable adjusted Class I differential.

### Dairy Forward Pricing Program (extended 5 years)

- Producers voluntarily enter into price contracts with handlers for pooled milk within classes II, III and IV.
- Handlers pay farmers based on this contract instead of paying the minimum Federal order blend price for pooled milk.

## 2018 Farm Bill

### Fluid Milk Donation Program

- USDA is working to draft this rule which will be published in the Federal Register.
- Allows processors to claim reimbursements for a portion of the raw milk cost used to make donated fluid milk products.

### Dairy Margin Coverage (DMC)

- DMC replaces Margin Protection Program for Dairy (MPP-Dairy)
- Sign-up began in mid-June



## Commodity Procurement

### Section 32: Permanent appropriation created by Congress

Name derived from its authorization: Section 32 – August 24, 1935

The law specifies three “clauses” for the use of funds:

1. Encourage export of farm products through producer payments or other means;
2. Encourage the domestic consumption of farm products by diverting surpluses from normal channels or increasing their use by low-income groups; and
3. Re-establish farmers’ purchasing power by making payments to farmers.

## Transportation & Marketing Program

### Dairy Business Innovation Initiative

- Supports dairy businesses in the development, production, marketing and distribution of dairy products.
- Provides direct technical assistance and grants to dairy businesses, including niche dairy products, such as specialty cheese, or dairy products derived from the milk of a dairy animal, including cow, sheep and goat milk.
- Applications have been received...



## Commodity Procurement

### Section 32 - Dairy Commodity Purchases – Milk & Cheese



*“We’re so blessed to get milk from...the food bank...It’s such a rare gift.”*

- The purpose of Section 32 purchases of dairy products are to encourage the continued domestic consumption by diverting dairy products from the normal channels of trade and commerce and distributing them through food assistance programs.
- Beneficiaries of Section 32 are The National School Lunch Program and Domestic Food assistance Programs.

## Commodity Procurement



## Trade Mitigation

### Section 5 - Dairy Commodity Purchases

- The purpose of Section 5 purchases is to replace lost exports due to retaliatory tariffs placed on U.S. dairy products.
- Amounts of dairy products to be purchased are based on an economic analysis of the damage caused by tariffs imposed on these commodities by some U.S. trade partners

Butter      Fluid milk      Process Cheese      Natural American Cheese  
String Mozzarella



USDA Commodity Procurement Program Newsletter

USDA Agricultural Marketing Service sent this bulletin at 06/19/2019 03:04 PM EDT

[View as a webpage / Share](#)



Agricultural Marketing Service  
Commodity Procurement



Commodity Chronicles

We facilitate the marketing of 100% domestic agricultural products through the purchase of foods for international and domestic nutrition assistance programs...Feeding the hungry around the world.

Summer 2019

AMS Dairy Program

Federal Order Pricing Formula...

- Industry groups have assembled teams...
- USDA collaborating with UW to survey plants
- Survey results at end of summer available on website...



AMS Dairy Program



Dairy Grading and Standardization Division

Dairy Standardization Branch	Dairy Grading Branch
Policy Oriented and Program Development	Operations and Program Implementation
Domestic Dairy Standards & Spec. Development	Dairy Grading
International Standards Development, International Trade Items	Plant Surveys and Inspections
Model Requirements – Milk for Manufacturing	Dairy Equipment Review
Program reviews, liaison with other agencies	Dairy Export Certification
Collaborate with other Agencies	

AMS Dairy Program

California Federal Order 51



- Eight successful pools
- Utilized staff from other FMMOs
- New office late 2019 in Folsom, CA

Dairy Grading and Standards

Staffing Update

Acting Director/Standards Chief: Chris Thompson  
Dairy Grading Branch Chief: Terrance Jackson

Acting National Field Director: Michael Gunderson  
Assistant National Field Director: Darrell DeMont  
Administrative Officer: Mike Eichorst

Eastern Region: John Simpson  
Midwest: Wayne Still  
Western: Melissa Costa



## Dairy Grading and Standards

### Staffing Update

International Issues Analyst: John Kelly  
Dairy Products Marketing Specialist: Yvette Percell  
Quality Management System Project Mgr: Ashli Wheeler

Training Program Coordinator: John Gelsthorpe (September)  
Training Officer: TBA



## Dairy Grading and Standards

### Export Certificates

- Dairy export certificates
- Audit and review programs
- Liaison with other agencies



## Dairy Grading and Standards

### Future Openings

- National Field Director, National Field Office Lisle, IL
- Equipment Review Specialist, Location TBD
- Agricultural Commodity Grader (Program Coordinator) Location TBD
- Agricultural Commodity Graders (across US)



## Top U.S. Dairy Export Markets (2018)

#### By Volume:

1. Mexico
2. China
3. Philippines
4. Canada
5. Japan
6. South Korea
7. Indonesia
8. Vietnam
9. New Zealand
10. Malaysia

#### By Value

1. Mexico
2. Canada
3. China
4. South Korea
5. Japan
6. Philippines
7. Indonesia
8. Australia
9. Vietnam
10. Malaysia



## Dairy Grading and Standards

### Dairy Grading Program...

- Equipment Review
- Plant Survey
- Dairy Product Grading



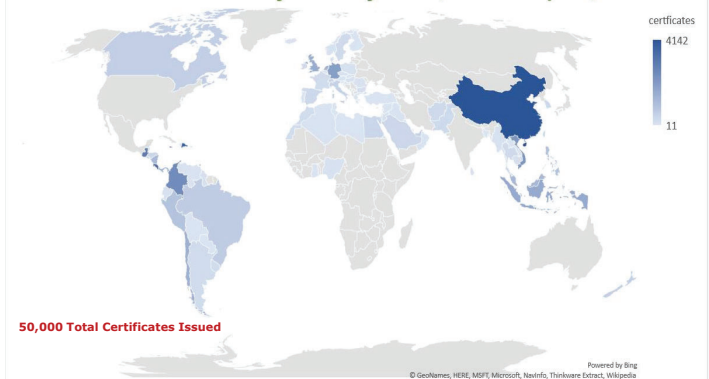
Training week of October 7, 2019



livesweetestemplations.blogspot.com

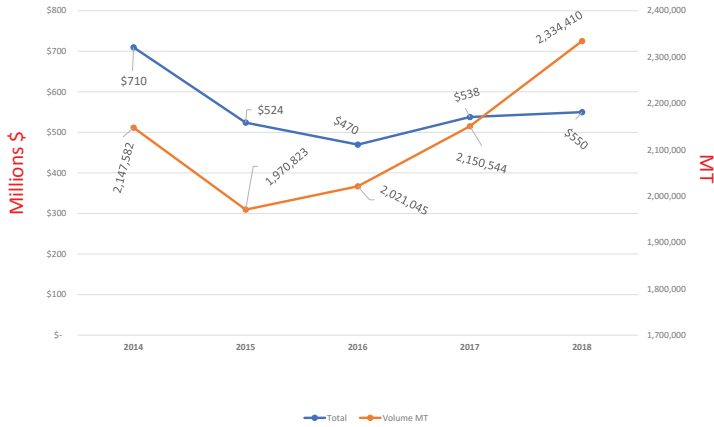
## Dairy Export Certificates

### Certificates Issued by Country Oct 1, 2017 - Sep 30, 2018



### Total Dairy Products Exports

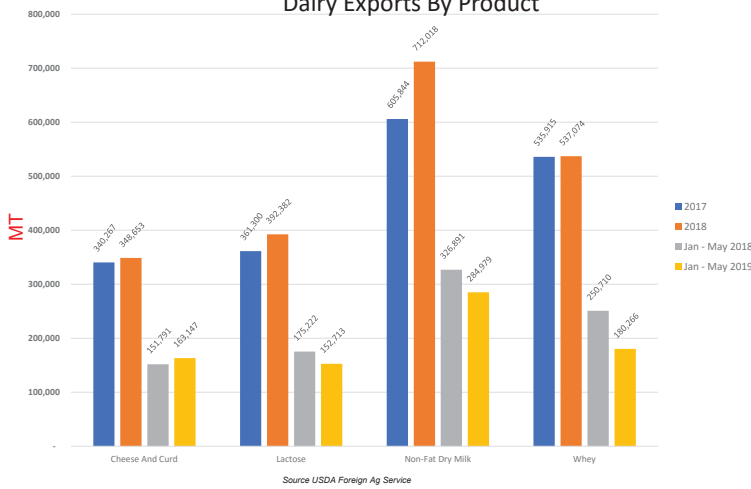
Source: USDA Foreign Ag Service



## Modernization of Grading & Standards



### Dairy Exports By Product



## Goal Alignment

### USDA Strategic Goals for FY 2018-2022

1. Ensure USDA programs are delivered efficiently, effectively, and with integrity and a focus on customer service.

### AMS Strategic Goals and Objectives

7. Review, modernize and improve the efficiency of AMS Grading Services  
Conduct a complete review of all AMS grading services and develop a plan of action to bring them up to date, improve efficiency and ensure that our grading services are meeting our customer needs in today's environment.

## Market Access: China

Firms must register with FDA Unified Registration and Listing System (FURLS)

Firms must successfully complete China Audit

AMS Dairy Grading audits

List updated quarterly, CNCA List

AMS Dairy Grading National Field Office  
Tel: 630-810-9999  
Email: DairyNFO@ams.usda.gov



## National Institute of Standards & Technology

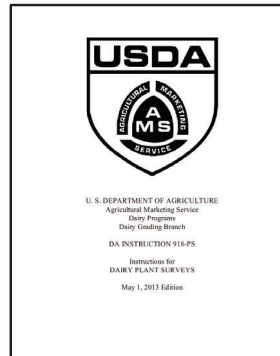
### Standards Coordination Office

DGSD & NIST Team: 6-month review....

- Comprehensive evaluation of Division programs and activities
- Consider options
- Employee involvement
- Outreach
- Recommendations

## Current priorities

- Key personnel
- Front facing documents
- Stakeholder engagement
  
- Seek informal comments this fall



## Thank you!



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