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REGULATORY UPDATE

I) Regulatory update

- 2) Single farm pick ups
- 3) FDA manufactured foods contract
- 4) Preventive control inspections

REGULATORY UPDATE

Staffing

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- Inspection numbers2020 recap
 - May, June and July farm inspection numbers

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- I- Multi-product Grader
- 2- Dairy Environmental Health Sanitarian positions
 I- Dairy Environmental Health Sanitarian Advanced

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PASTEURIZER FREQUENCY FOR PLANTS PARTICIPATING IN THE USDA GRADING PROGRAM • Dairy Technical Specialist staff are back to full staffing levels

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• Plants need to make a request to their DTS

2020 DAIRY SECTION INSPECTION NUMBERS 13,247 Farms • Grade A plants 204 Grade B plants 285 BMWS 1,559 Pasteurizer seals 600 Reseals 391 Surveys 173 • Lab surveys 116 A. W

MAY, JUNE AND JULY FARM INSPECTION NUMBERS

Farm inspection numbers are high in June and July
 Staff instructed to move some farms forward

CURRENT COVID MEASURES

Measures are being taken by staff:

- · Staff conduct daily self-assessments for symptoms.
- PPE shall be worn on all inspections; social distancing practiced when possible.
- Minimizing number of DATCP staff to 5 people at a plant.
- Removed the requirement that staff can visit only 1 plant per day.
- Virtual record and food safety plan reviews when possible.Staff are asked to call ahead for Grade B plants.
- Overnight travel is occurring as needed.

· Our response will continue to evolve as conditions change

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STATUS OF SINGLE FARM PICK UP

Need input from the committee. Our concerns are:

- 1) Balancing of milk not all plants are equipped to weigh and sample milk.
- 2) Clearing positive loads.
- 3) Lack of pick up weight information getting back to the farm

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FOLLOW UP ITEMS FROM THE FEBRUARY DRAC

FDA contract with Wisconsin

- Preventive Control inspections
- Food Safety Plans and Hazard Analysis

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DAIRY SECTION IN COMPLIANCE WITH REGULATORY PROGRAM STANDARDS

- Manufactured Food Regulatory Program Standards (2007)
 First State to be in full conformance in 2014
- Grade A Milk—Procedures Governing the Cooperative State-Public Health Service/FDA Program of the National Conference on Interstate Milk Shipments (NCIMS)
- ISO/IEC 17025:2005 Laboratory Standard

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DA CONTRACT WITH WISCONSIN

- We are part of an Integrated Food Safety System
- WI has been conducting inspections for FDA for more than a decade Only a small portion of inspections are done under contract.
 - Dairy facility numbers varies annually.
- Mutual reliance on Grade B facilities
 - FDA and WI accept our each other's contract inspections.
 - Goal is not to overlap or duplicate inspections.

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MUTUAL RELIANCE

"FDA also conducted a 12-month pilot project with the Wisconsin Department of Agriculture, Trade, and Consumer Protection to minimize duplication of inspectional work and improve collaboration and information sharing. The pilot covered inspections for dairy products and manufactured foods." – Food Safety Magazine April 27, 2021

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CONFUSION ABOUT FDA FOLLOWING UP ON WI REPORTS

- FDA has always had the authority to follow-up on WI inspection reports.
- FDA does notify the company indicating WI did an inspection.
- WI meets the FDA Manufactured Foods Regulatory Program Standards.
- WI conducts appropriate follow-up activities.
- + FDA Manufactured Foods won't follow-up on WI reports with additional compliance activities.

PREVENTIVE CONTROL INSPECTIONS

- FDA has rolled out the new process over the last 10 years
- Stepped implementation
- $\ensuremath{\mathsf{PC}}$ inspection process continues to evolve
- The FDA guidance document is still not complete
- Messages from MF and PMO have slight and nuanced differences

Goal is to have clear guidelines for industry and $\,$ DATCP staff on inspection process and what will be reviewed.

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PREVENTIVE CONTROLS IN 2021

- Five dairy staff in FD 254 training in January and February
 Prerequisite courses
- 2) Up to three staff will be on each PC inspection
- 3) Six plants will be inspected under the FDA manufactured foods contract
- 4) Additional non-contract PC inspections
- 5) Opportunity to partner for non-regulatory mock PC inspections

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PREVENTIVE CONTROLS - BUILDING CONSISTENCY

- FDA pre-requisites
- Including PCQI course
- FD254 (10 days)
- · Minimum of 2 joint inspections with a trained individual
- Joint inspections with FDA
- Participation in PC workgroupsReviewing FDA PC inspection reports
- Dairy Services Section PC work group

TEAM WORK TO IMPLEMENT PREVENTIVE CONTROLS Best practices I) Communication 2) Collaboration 3) Commitment

COLLABORATION

1) Dairy staff are asked to document their findings in the notes section

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- 2) Identify trends
- 3) Compare trends with FDA reports
- 4) Share trends with DRAC and Association partners
- 5) Collaborate on shared outcomes
- 6) Share general recommendations with dairy industry

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QUICK EXAMPLE- COOLING

- I) Has been identified on reports
- 2) FDA is also noting
- 3) We have shared observations with Associations and Academia
- 4) We have started the collaboration process



