

**DEPARTMENT OF AGRICULTURE, TRADE, AND CONSUMER PROTECTION  
(DATCP)  
DAIRY RULES ADVISORY COMMITTEE (DRAC)  
MEETING MINUTES**

**Date:** May 5, 2021  
**Time:** 9:00 AM – 11:00 AM  
**Location:** Virtual Teams Meeting

**Welcome and Introduction**

**Call to order:**

Katie Tuchalski called meeting to order at 9:00 AM

**Open meeting notice:**

Katie Tuchalski stated the meeting is a public meeting. The open meeting notice has been posted.

**Roll Call:**

Members in attendance: Andy Johnson, Katie Tuchalski, Jessica Hansen, Gloria Joseph, Jeff Kirchberg, Ben Shibler, Nelson Schrock, Helen Schmude, Jacquie Papple, Dean Hines, Daniel Smith, Shelly Mayer, Adam Brock, Tim Neubauer, Megan Jensen, John Umhoefer, and Mick Homb

Guests in Attendance: Laura Traas, Tim Anderson, Steve Ingham, Norm Monsen, Kara Kasten-Olson, Jim Pikka, Pete Hesprich, Steve Stoner, Kate Angeles, Amy Millard, George Petrilli, Tyson Villarreal, Mary Rollins.

Members not in attendance include: Bob Wills, Lisa Torkelson, Mark Frederixon, Tom Crave, Debi Towns, James Baerwolf, and Jim Schwartz.

**Approval of agenda:**

It was asked to change the order of the DATCP presentations. First will be the DATCP Update presentation; followed by the DATCP Preventative Control Inspections presentation, and then the DATCP Dairy Plant Licensing presentation. The agenda was amended and approved. The committee members will use the raise hand icon in Teams for voting or voice if a member is joining in with audio only.

**Approve previous meeting minutes:**

No corrections to the previous meeting minutes for the DRAC February 3<sup>rd</sup>, 2021 meeting. Meeting minutes were approved.

**Public comments:**

There were no public comments or input from the public.

**Membership Updates:**

The committee welcomed new member Jessica Hansen. Last meeting the committee discussed seeking nominations for vacant positions. The DRAC Operational Guidelines (Membership A.k) allows for replacements. Katie Tuchalski reached out to Milk Specialty Global to see if the company would like to have a replacement for their position. Jessica will be the replacement for Milk Specialties Global for the remainder of the term.

## Subcommittee Update

Helen Schmude gave an update for the Raw Milk Cooling Temperature Sub-committee. The sub-committee met on April 1<sup>st</sup>, 2021. Helen reached out to Alex O'Brien and Kathy Glass from CDR. CDR was not able to provide the ComBase study yet but will hopefully have the study completed by Friday May 7<sup>th</sup>. CDR will send the study for the sub-committee to review. Once reviewed, the sub-committee will present the study to the committee.

The sub-committee wanted to know if raw milk received at temperatures slightly above 45.0°F under certain circumstances would be safe to receive into the plant. The sub-committee wanted to look at any adverse effects that would happen if the raw milk were above 45.0°F. The ComBase predictive model shows the time it takes for growth of enterotoxin-forming pathogens when temperatures are between 48°F to 51°F. CDR will be putting together a formal document with this information. The sub-committee also discussed a checklist with quality measurements of milk. CDR is willing to put something together but the sub-committee is unsure if that will be put into the formal document.

DATCP would accept the ComBase study with sources cited for industry to use as a science-based tool to show that receiving milk outside 45.0°F may be safe.

This study will be helpful with industry that has more of a preventive control approach. Industry will need to understand what verifications need to be in place to accept raw milk above 45.0°F. Mary Rollins presentation will cover more on this topic. The sub-committee will need to meet again to review the final CDR document and will present the document to the committee at the next meeting.

## DATCP Regulatory Update

Tim Anderson presented a regulatory update on the DATCP dairy program (**see slides from DATCP Update 5-2021 presentation**). DATCP currently has four vacant positions in the dairy section. The vacant positions include: one Multi-product Grader position, two Dairy Environmental Health Sanitarian positions, and one Dairy Environmental Health Sanitarian-Advanced position. There will be one more retirement coming soon. The Dairy Technical Specialist (DTS) staff are back to full staffing levels. Plants participating in the USDA grading program that need a pasteurizer to be timed/sealed biannually are encouraged to make a request to their Dairy Technical Specialist.

Tim reviewed DATCP's 2020 inspection numbers. Pasteurizer and reseals increased from 2019. DATCP's dairy team deserves a lot of credit for getting numerous inspections done while dealing with COVID-19 safety issues, which included only inspecting one facility a day. Farm inspection numbers are high in June and July due to staff going back into the field and focusing on farm inspections in 2020. To spread the farm inspections out, the staff has been instructed to inspect some farms a month early. DATCP can do farm inspection early but can't perform them late.

Tim discussed the current COVID measures being taken by the Dairy Services Section. The inspectors will still be wearing face coverings with social distancing when possible and conducting daily self-assessments for COVID symptoms. DATCP is allowing overnight travel for staff. DATCP is minimizing the number of DATCP staff to 5 people at a plant. Staff are asked to call ahead for Grade B plants. DATCP has removed the requirement that staff can only

visit 1 plant per day. DATCP is still encouraging virtual record and food safety plan reviews when possible.

Tim went through the status of the DNR single farm pick-up proposal. During internal discussions, a few items came up that DATCP would like some discussion and feedback from the committee on. It was decided to move the discussion to the Member Concerns portion of the meeting.

1. With producers that may have milk being transported to multiple dairy plants, who is responsible for making sure a dairy plant is capable of weighing and/or agitating the load? Not all dairy plants are equipped to handle the weighing and sampling of the milk. Is the responsibility on the hauler, field representative, or other?
2. If a farm does not have a drip sampler, how does the farm obtain a clearing sample after a positive load has been found? Would DATCP need to require a drip sampler with a meter-based weight device on the farm?
3. How much separation is happening in the silo (i.e. Skim/Cream) and how does that affect the farmer getting paid for components?
4. Is there an issue with pick-up weights getting back to the farm?

At the last meeting, a concern was brought up with FDA contract inspections with Wisconsin. In 2014, Wisconsin was the first state to be in full conformance with the Manufactured Food Regulatory Program Standards. Wisconsin has been a part of the FDA inspections for 10 years. With the FDA contract, the dairy section does Grade A and Grade B plant inspections. Only a small portion of our inspections are done under the contract. The contract inspections numbers vary year to year and depends on FDA's schedule. DATCP has 25 facilities to inspect this year and last year DATCP did between 75-80 inspections. Part of the contract is for DATCP to share the inspections with FDA and FDA to share inspections with us. These contract inspections apply overall and are not just the Dairy program. DATCP tries not to overlap or duplicate these inspections. DATCP will pull an inspection back if FDA will be coming in. DATCP meets with a FDA liaison every month. During one of these meetings, the liaison brought to our attention their quote about our mutual reliance in Food Safety Magazine.

There has been some confusion about FDA follow-ups on Wisconsin's inspection reports. FDA has always had the authority to follow-up on Wisconsin's contract inspection. FDA will notify the company by email indicating that Wisconsin did the initial inspection. There is some concern from industry that FDA will take regulatory action based on Wisconsin's inspection reports. If DATCP submitted for a re-inspection, FDA would discuss with DATCP before the re-inspection occurs. DATCP would perform the re-inspection. Thus far, FDA has not ever stepped in for a re-inspection.

Tim updated the committee about DATCP's preventive control (PC) inspections. FDA has been rolling out this new process over the last 10 years with step by step implementation. The FDA guidance document is still not complete. There are slight differences between Manufactured Foods standards and the PMO. DATCP's PC inspections are continually evolving. DATCP's goal is to have clear guidelines for industry and DATCP staff on the inspection process and what will be reviewed during these inspections. DATCP started 4 years ago having sanitarians go through the ten-day PC course (FD 254 training). The sanitarians need pre-requisite courses (including PCQI course) before taking the FD 254 training. Five dairy staff have completed FD 254 training in January and February 2021. After the course, the inspector needs a minimum of 2 joint inspections with a trained individual. DATCP has also been doing joint inspections with FDA. There has been up to three staff during each PC inspection and we currently have six plants that are being inspected under the FDA manufactured foods contract. DATCP has had some non-contract plants volunteer for PC inspections to help refine the process. DATCP has a work group with all PC trained staff to review the last two FDA PC inspections for consistency and discuss

best practices. This group discussed the CDR ComBase study with citations and decided the report would be acceptable for industry to use. DATCP is committed to working with industry and this committee as we move towards the PC inspections. DATCP will continue to work on communication, collaboration, and commitment as we implement the PC inspections. Dairy staff are being asked to document their findings in the notes section. This will help identify trends and compare trends with FDA reports. This will allow DATCP to share these trends with DRAC and other association partners. DATCP and industry can collaborate on shared outcomes and share general recommendations with the dairy industry. An example of this is a cooling trend that DATCP is identifying on reports and FDA is also noting. DATCP has shared these observations with associations and academia and has started the collaboration process. The DRAC sub-committee has made a lot of progress on this trend as well.

Question: If a load had a temperature of 45.1°F, can a plant receive that raw milk as Grade A?

DATCP: If the plant has a food safety plan and occasionally gets a load that comes in slightly over 45.0°F, the plan needs to document the corrective action and address the problem. The PMO Appendix T allows for documenting corrective actions. The PC approach allows plants the flexibility to accept the load or not. Some plants may choose not to take the PC approach and just reject the load.

### **Preventive Control Inspection Presentation**

Mary Rollins presented on DATCP's preventive controls inspections (**see slides from DATCP Preventive Controls Inspections 5-2021 presentation**). Mary started with explaining some background information. Preventive control inspections are conducted per Wisconsin's contract with FDA. DATCP updated ATCP 65 to include 21 CFR 117 regulations. DATCP has updated our inspection reports to meet FDA needs and requirements. For consistency for the sanitarians, DATCP's inspection reports will be the same for contract inspections or regular DATCP inspections. The preventative control inspections will be conducted by at least two staff members. Having two DATCP inspectors will help with reviewing paperwork and bouncing ideas off each other. DATCP can have copies of the Food Safety Plan, Hazard Analysis, and Preventive Controls but will leave copies at the plant once the inspection is complete. Having copies during the inspection makes it easier to compare, review, and take notes.

Mary discussed feedback from previous preventative control inspections. The most time-consuming part of the inspection is reviewing the hazard plan. We are seeing inconsistency or missing information with the hazard analysis. For the hazard analysis, 21 CFR 117.120 (b) requires the identification of hazards. The first step is to use the FDA guide to determine what hazards are associated with the process: Table 1A is for Biological Hazards; 2A- Chemical Hazards; and 3A- Process Hazards. Mary went through an example of hazards associated with unsalted butter as an ingredient for cream. The next step is to evaluate the process controls. The plant needs to have a written evaluation of every single hazard identified. It needs to be determined whether a PC is needed. If a hazard is eliminated, the reason needs to be documented as to why the hazard was eliminated (i.e. cross contact allergen). If a process control can be applied at a point or step in the food production process to prevent/eliminate/reduce the hazard to an acceptable level, that should be classified as a preventive control. DATCP is not going to be an expert on every product.

Question: Does it matter if a hazard is in the correct category?

DATCP: An inspector might ask more questions if they are not seeing a certain type of hazard addressed. DATCP is not concerned with how the plan is laid out.

Question: How is DATCP enforcing these findings?

DATCP: Most plants have the basics of PMO Appendix T. We have only had one plant that did not have a food safety plan. DATCP is taking a slow educational approach unless the item is a food safety issue. Most items will be written as a note for the plant to consider.

### **Dairy Plant License Program**

Tyson Villarreal presented on DATCP's dairy plant license program (**see slides from DATCP Dairy Plant Licensing Process 5-2021 presentation**). Tyson reviewed DATCP's role when licensing a new dairy plant. DATCP will supply a licensing application, process the application, and conduct the licensing inspection to issue or deny the application. DATCP is not a business advisor, process authority, or equipment engineer. When asking DATCP to consult on certain items, this puts DATCP in a difficult situation and outside of our role. DATCP encourages new plants to use the resources available to them. The DATCP Dairy Services website has a lot of resources available to industry along with DATCP contact information.

The licensing process starts online. Once received, the licensing specialist will forward the license application materials and assist the operator with the submission process. The operator will complete the application, dairy plant questionnaire, construction plans (if applicable). The operator will need to mail all the documents with the licensing fee to the DATCP lock box. Once DATCP receives the documents and processes them, the appropriate staff will be notified which includes the dairy supervisor, dairy sanitarian, and dairy technical specialist (DTS). The Milk Sanitation Rating Officer (MSRO) will also be notified if the plant needs to be an IMS listed facility. The DTS will complete the plan review within 30 days.

Before the licensing inspection, the application materials and DTS plan review needs to be complete. The sanitarian will contact the operator to schedule the licensing inspection within 40 days after receipt of a completed application. The licensing inspection will be performed by the assigned dairy sanitarian, DTS and MSRO (if needed). If the facility and processes meet ATCP 65 requirements, a dairy plant license will be issued. If the ATCP 65 requirements are not satisfactory, the license will be denied, and the application process restarts.

New licensing concerns were brought up at the initial DRAC meeting and DATCP wanted to share our new data management system and get a baseline with industry.

### **Member Concerns**

The committee discussed the items DATCP brought up about the single farm pick-up proposal. The first item was issues with a farm moving multiple loads to different dairy plants and the dairy plant not being able to weigh or agitate the load. Tim Neubauer indicated it should be the milk hauler's responsibility to determine if the plant can agitate/weigh the load. There may be some milk haulers who are do not researching this ahead of time and unloading incorrectly. This may be a communication issue with haulers or haulers are unaware of the requirements.

Question: Are drip samplers approved to use for Appendix N samples? We have concerns about the chain of custody being broken down with these types of samplers.

DATCP: The Laboratory Evaluation Officers have started a discussion about the use of these drip samplers. The PMO and ATCP 65 do not specify who can take an Appendix N sample. Some plants have an approved Bulk Milk Weigher and Sampler take the sample and test the sample. DATCP will start looking into a policy for this.

A suggestion was made to take a final sample from the silo before processing as a control. Laura Traas noted that suggestion.

The committee decided to have the single farm pick-up sub-committee meet again to address the issue of clearing a producer that had a positive drug residue load. DATCP has already seen a few issues in the field with this scenario.

The 3<sup>rd</sup> item of discussion was getting the weight of the load back to the farmer. The committee agreed that it should be the responsibility of the hauler to get the information back to the farmer.

An additional concern was brought up about if any rules exists with cleaning the milk hose. Some haulers are not able to wash their milk hoses out at the plant. If the hose is not washed out at the plant, it doesn't get cleaned. DATCP will follow-up with the Dairy Technical Specialists with this concern.

### **Summary of Action Items and Person(s) Responsible**

The next meeting will be Tuesday August 10<sup>th</sup>, 2021 from 9:00 am to 11:00 am.

The Raw Milk Cooling Temperatures Sub-committee will meet and review CDR's ComBase study.

The Single Farm Pick-up Sub-committee will meet again to address the issue of producer clearing samples that was brought forth by DATCP during the meeting.

Tim Neubauer motioned to adjourn meeting. Adam Brock seconded. Motion passes.

Meeting Adjourned at 11:01 am