

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

Date: February 3rd, 2021
Time: 9:00 AM – 11:30 AM
Location: Virtual Teams Meeting

Welcome and Introduction

Call to order:

Katie Tuchalski called meeting to order at 9:01 AM

Open meeting notice:

Kate Angeles stated the meeting is a public meeting. The open meeting notice has been posted.

Roll Call:

Members in attendance: Andy Johnson, Bob Wills, Katie Tuchalski, Gloria Joseph, Ben Shibler, Nelson Schrock, Helen Schmude, Jacquie Papple, Dean Hines, Daniel Smith, Shelly Mayer, Adam Brock, Megan Jensen, John Umhoefer, Debi Towns, Lisa Torkelson, and Mick Homb
Guests in Attendance: Alex O'Brien, Laura Traas, Tim Anderson, Steve Ingham, Norm Monsen, Jim Pikka, Pete Hesprich, Steve Stoner, Kate Angeles, Elmer Schmucker, Amy Millard, George Petrilli, Tyson Villarreal, Amandeep Dhillon, and Jennifer Wickman.
Members not in attendance include: Jeff Kirchberg, Tim Neubauer, Mark Frederixon, Tom Crave, James Baerwolf, and Jim Schwartz.

Approval of agenda:

No changes to the meeting agenda. The committee members will use the raise hand icon in Teams for voting or voice if member is joining in with audio only.

Approve previous meeting minutes:

No corrections to the previous meeting minutes for the DRAC November 4th, 2020 meeting. Meeting minutes were approved.

Public comments:

There were no public comments or input from the public.

Membership Updates:

Daniel Smith is replacing Mykel Wedig from Cooperative Network.

The committee reviewed the new member election in the DRAC Operational Guidelines and discussed when to seek nominations. The committee decided to vote for new nominations on the first meeting of the new year. Ben Shibler made a motion to open the vacant positions and have DATCP seek nominations. Shelly Meyer seconded the motion. The motion passed.

Andy Johnson is stepping down as co-chair but will still be participating in the committee as a member. Thank you, Andy, for your dedication and leadership as co-chair. Katie will continue as chair for 2021 and we will take nominations for chair(s) at the end of this year for the next term.

Subcommittee Update

Helen Schmude gave an update for the Raw Milk Cooling Temperature Sub-committee. The sub-committee looked at the discrepancies between ATCP 65, ATCP 82, and the PMO. The group discussed concerns when temperature deviations occur and what the difference is between raw milk that is received at 45°F to 50°F with a PC approach. DATCP is moving forward with a PC approach mindset. DATCP is allowing plants to have a validation study as proof that the milk is still quality milk when a temperature deviation may occur. DATCP will use 45°F as the benchmark temperature and will still follow ATCP 65. DATCP is more focused on temperature abuse trends vs. a one-time occurrence. The sub-committee did not have any recommendations for DATCP currently. The sub-committee discussed with CDR the need to create a validation study that could be shared with all dairy plants. By working with CDR, this would benefit smaller dairy plants that are not able to do a validation study.

The committee discussed the need to have a formal process to make this happen. There would need to be a leader designated and funding secured. Alex O'Brien is the point of contact with CDR. Alex is working on trying to find a quick test that would be reliable and available that can determine quality milk. A suggestion was made to contact Kathy Glass for help with a literature review (ComBase) type search. This may be a less expensive option.

The committee suggested the sub-committee determine some options for a potential study with CDR. The committee can then decide the best option and give Alex/Kathy more direction. Another idea was creating a checklist of what a plant needs to consider when setting up a validation study. There is a wide range of complexity in the dairy industry and a list may be more achievable for the sub-committee.

Gloria Joseph made a motion to have the sub-committee look at how to set-up a study/checklist template that creates a platform for plants to make good food safety decisions. Andy Johnson seconded the motion. Motion passed.

The raw milk cooling temperature sub-committee consists of Nelson Schrock, Helen Schmude (leader), Gloria Joseph, Lisa Torkelson, and Alex O'Brien.

Regulatory Update

Tim Anderson presented a regulatory update on the DATCP dairy program and the DATCP pandemic response (see **slides from DRAC February regulatory update 2-2021 presentation**). Tim introduced the new Dairy Supervisor (Mary Rollins), three new Dairy Technical Specialists (Ali Collins, Anne Hagopian, and Laurie Sippel), and two new Dairy Sanitarians (Nick Brost and Natasha Kowalchuk).

The Dairy Services Section has revised their pandemic response. The inspectors will still be wearing face coverings and conducting daily self-assessments for COVID symptoms. DATCP has been maintaining the Grade A program IMS listings. DATCP made a small request for FDA flexibility in December (about 18 farms) due to staff quarantine. Some of the revised safety measures is allowing overnight travel for staff. DATCP is minimizing the number of DATCP staff to 3 people at a plant. DATCP has removed the requirement that staff can only visit 1 plant per day. DATCP has been experimenting with headsets to communicate with each other during plant inspections. DATCP is looking into headsets that will work with a bump cap. DATCP did purchase one for the plant to use that can be sanitized. This will improve communication with social distancing.

Tim went through the Dairy Services Section Strategic 2021 Plan. In 2020, PC training was canceled due to COVID-19. We currently have 5 dairy staff in FD 254 training in January and February. After the course, the next steps are for staff to shadow a PC inspection and then lead a PC inspection, before being allowed to conduct inspections on their own. There will be up to 3 staff on each PC inspection. We currently have six plants that are inspected under the FDA manufactured foods contract. DATCP is looking to do non-contract “mock” PC inspections to help with staff training if any plants would like to partner with DATCP. DATCP will try to do a paper review remotely to help minimize inspection time in the plant.

DATCP is in the process of converting our old internal (Amanda) licensing database over to our new database (CRM). DATCP has already converted the haulers, tankers, and milk distributor licenses over to the new database. While switching over to the new database, DATCP is looking for process improvement steps. With the tanker licenses, the renewal was switch from every year to every two years and DATCP also reduced the paperwork and processing time. This year DATCP is working on farm and plant licensing and permitting. We will be issuing these licenses one more time out of the old Amanda database. With the new licensing database, there will be online applications and payments. It will also streamline notifications to field staff.

DATCP is working on document control and will be implementing a standard process. DATCP is updating all internal policies, procedure instructions, and guidance documents so they are fit for use by staff and industry. We are focusing on communication and consistency. Internally, we want to make sure all staff have the same current document. DATCP is involving all levels of staff and are taking a team approach with document control. All work units try to meet at least monthly. All units are focusing on training, joint inspections with supervisors or subject matter experts. All GovDelivery information that is shared to industry will also be shared with the staff. We have many ways to communicate with industry through this committee, GovDelivery, DATCP website, trainings, or direct communications with staff. We want feedback from industry. There is a customer survey link at the bottom of every DATCP email. DATCP appreciates those comments and takes the comments seriously. The more information and details that is provided with the survey comments helps us address the comment.

During our first DRAC meeting in 2019, licensing of farms and plants was identified as a topic DATCP needs to focus on. DATCP is focusing on the dairy plants license first. DATCP does not receive many new dairy plant licenses. DATCP will take a team approach (Sanitarians, SROs, and Specialists) and have the Specialist and Sanitarian inspect together. Part of the process will also include an approval of plans before the construction of the plant begins.

Tim discussed the status of the single farm pickup document. The document that was worked on by the committee, DATCP refers to as an interpretive memo. The next time the rule is open, the interpretive memo will be moved into the rule. Currently the document is still in our document review process. As soon as it is complete, DATCP will post the document to the DATCP website and send the document out via GovDelivery. DATCP will also email out the document directly to the committee and all dairy plants receiving milk.

After the presentation, one item that was raised was with the online renewal of licenses. The process requires a different email for each type of license. This causes the plant to not be able to sign into the online database to pay for each license. Another item that was raised is that the renewals do not have pricing listed and the plant needs to research to know the costs associated with the renewal.

The committee brought up concerns with the virtual food safety review and keeping trade secrets. If industry emails documents to DATCP, the documents become public records. Another option is setting up a virtual meeting with industry sharing their screen for the inspector to review their documents. There are sometimes certain documents that industry would share with DATCP but

not FDA. When DATCP comes in as both parties, there needs to be an awareness as to what needs to be redacted in reports to FDA.

Member Concerns

Helen Schmude discussed concerns with the 4-hour cooling rule. Certain cheeses cannot be cooled to 45°F in four hours. If the cheese cools too fast, the cheese can be ruined. Different types of cheese and different sizes of cheese have different cooling times. This applies more to semi-soft cheese than hard cheese.

ATCP 65 references to CFR 117 which allows for the PC approach. There is a learning curve with the PC approach. DATCP is working on being consistent. DATCP is still working on the process for plants validation studies. DATCP will not be approving any plant validations.

This problem may be more of a culture/inspection change instead of a rule change. The inspection staff needs to listen to why plants have a process. The comment was written in a way that portrayed the plant doing something incorrect. There needs to be more of an openness for inspectors to ask questions instead of stating the plant is not following the rule. DATCP will start adding PC updates for the committee.

Summary of Action Items and Person(s) Responsible

The next meeting will be Wednesday May 5th, 2021 from 9:00 am to 11:30 am.

The Raw Milk Cooling Temperatures Sub-committee will meet and look into how to set-up a study/checklist template that creates a platform to make good food safety decisions.

DATCP will seek nominations for vacant positions to be voted on at the next meeting.

Ben Shibler motioned to adjourn meeting. Dean Hines seconded. Motion passes.

Meeting Adjourned at 11:00 am