



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Ben Brancel, Secretary

DATE: March 16, 2016

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Division of Food Safety Administrator *Steve Ingham*

SUBJECT: ATCP 65-Milk and Milk Products; Final Rule

PRESENTED BY: Peter Haase

REQUESTED ACTION:

At the March 22, 2016, Board meeting, the Department of Agriculture, Trade and Consumer Protection ("Department") will ask the Board to approve a final draft rule (copy attached), ch. ATCP 65 (Milk and Milk Products.) The proposed rule consolidates chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants) and creates a new rule, ch. ATCP 65 (Milk and Milk Products.) The rule modifies and adopts provisions to ensure compliance with the most recent version of the Federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO). Although ATCP 60 and ATCP 80 are largely consistent with the PMO, Wisconsin's dairy farm and dairy plant rules must be revised periodically, as in this instance, to maintain that consistency. In addition, certain provisions have been modernized to account for technological advancements in the dairy industry. The final draft rule also indicates what provisions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by dairy plant operators.

SUMMARY:

Background

Wisconsin operates the nation's largest state dairy inspection program. Wisconsin has over 9,000 licensed milk producers, the largest number of any state, and ranks second nationally in milk production. Milk is shipped from each dairy farm to one of more than 400 licensed dairy plants in the state or to a licensed dairy plant in another state.

About 98% of the milk produced in Wisconsin is Grade "A." Grade "A" unpasteurized milk, along with pasteurized milk and certain other dairy products made from Grade "A" milk, can only be shipped across state and international boundaries if the production, transportation, processing, and regulatory oversight of these products are in accordance with the PMO. Wisconsin does not adopt the PMO directly, but has its own regulations for the dairy industry. These regulations must be at least as stringent, and consistent with, the PMO. The FDA revises the PMO every two years and the version of the PMO to which Wisconsin regulations are compared for compliance must be within two prior editions. This rule revision, which reflects changes found in

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the 2013 revision of the PMO, is essential for maintaining compliance with the PMO and for allowing Wisconsin farmers and dairy plant operators to ship their Grade "A" milk and milk products in interstate commerce.

Wisconsin's regulations also establish standards to ensure the quality of Grade "B" milk, which is milk used only to process non-Grade "A" milk products, such as butter, cheese, and ice cream. Wisconsin has over 1,000 Grade "B" licensed milk producers, about 13% of its total. Recommended standards for Grade "B" dairy farms are published by the United States Department of Agriculture (USDA). Wisconsin's regulations must be at least as stringent as the USDA standards to ensure access of Wisconsin Grade "B" milk products to international markets.

Wisconsin dairy farm and dairy plant regulations are currently found in chs. ATCP 60, "Dairy Farms" and ATCP 80, "Dairy Plants." The proposed rule repeals chs. ATCP 60 and 80 and consolidates and reorganizes these chapters into a new ch. ATCP 65, "Milk and Milk Products." Consolidation of these two rule chapters will eliminate numerous, and sometimes confusing, cross-references between the two chapters. In recent years, there has been increased interest in the operation of small dairy plants on the same site as the dairy farm supplying the milk. In the final draft rule, operators of these "farmstead" or "artisanal" dairy plants can now find most of the food safety- and quality-related rules affecting their business in one chapter, rather than two. The rule revises certain existing provisions and creates new provisions, as necessary, to ensure: 1) Wisconsin's Grade "A" and Grade "B" dairy sectors comply with the PMO and USDA standards, respectively, when they meet Wisconsin regulatory requirements; and 2) state regulations do not unnecessarily hinder technological advancement by Wisconsin's internationally recognized dairy industry.

Rule Content

Provisions from chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants) were renumbered, consolidated, and reorganized into one rule. Wording was changed throughout to provide greater clarity and modernize terms. For example, references to "milk haulers" were changed to "bulk milk weigher and samplers" to reflect the actual name of the license held by people who collect, sample, and transport milk. References to "inspectors" were changed to "division representatives" to reflect the broader range of staff, e.g., sanitarians, food scientists, regulatory specialists, who may conduct inspections. Subchapter, section, and subsection chapter titles were also revised throughout to more clearly reflect the content of the rule. The following is a summary of other notable changes made to the rule. A complete list of changes may be found as part of the plain language analysis in the hearing draft.

ATCP 65.01, Definitions.

In revising the rule, the Department:

- Added definitions for "abnormal milk," "aseptic processing and packaging system," "bulk tank unit," "facility," "grade A producer permit," and "qualified facility."

- Repealed and replaced definitions for “C-I-P equipment,” “C-I-P milking equipment,” and “C-I-P milk pipelines” with a definition of “C-I-P” which was numbered as 65.01 (9).
- Updated the definition for “dairy product” to be consistent with current statute.
- Replaced the term for “food safety division” with “division.”
- Expanded the definition for “Grade B milk” to clarify that Grade B milk is not processed into fluid milk for consumption; it is only used in the production of non-grade “A” dairy products.
- Broadened the definition for “equipment” to cover equipment used on dairy farms and in dairy plants.
- Repealed the definition from ATCP 65.01 (6) for “dairy plant” and replaced it with the definition from ATCP 80.01 (5) for “dairy plant.”
- Revised the definition of “milk” to be consistent with the PMO definition by including the phrases “practically free of colostrum, obtained by the complete milking of one or more healthy milking animals.”
- Expanded the definition “procure milk” to indicate that procured milk must be acquired directly from a licensed milk producer.
- Clarified that “sanitizers” shall be in compliance with 21 CFR part 178.1010 or otherwise approved by the division.
- Repealed the definitions “single-service utensil” and “single-service package” and replaced them with a definition for the term “single-service articles.”

ATCP 65.02, Milk producer license and permits; and fees.

ATCP 65.02 includes revised provisions that require a license for each milk producer, for each species of milk animal milked by a single milk producer, and each dairy farm operated by a milk producer at which milk is produced to be offered for sale. Previously, not all of these parameters were mentioned. The rule was also revised to clarify that a representative of the dairy plant may submit an application on behalf of a milk producer and that the dairy plant representative shall certify that both the dairy farm and milking operations comply with applicable requirements under the law. The rule now indicates that a licensed milk contractor (or the contractor’s representative), who procures milk but does not operate a dairy plant, may submit the milk producer license application and certify compliance. The rule allows no more than one milk producer to have a Grade “A” permit at a single dairy farm unless all of the milk shipped from that dairy farm is assigned to one bulk tank unit and each milk producer is licensed. The rule also describes conditions under which more than one Grade “A” milk producer permit may be held on one dairy farm. Finally, the rule adds the due date of April 30 for paying the annual license fee and indicates that milk producer license fees are non-refundable.

ATCP 65.04, Dairy plant licenses and permits; fees.

The rule clarifies that no dairy plant license is required for a farm manufacturing dairy products solely for the owner/operator, members of the farm household, or nonpaying farm guests or employees. It exempts licensed restaurants from a dairy plant license if they prepare or process commercially pasteurized dairy products. However, licensed restaurants are not allowed to package Grade "A" dairy products without holding a dairy plant license. The rule exempts retail food establishments licensed under s. 97.30, Stats., from the requirement to hold a dairy plant license if they process non-Grade "A" dairy products made from commercially pasteurized and packaged dairy products solely for retail sale. The rule does not modify dairy plant fees. It indicates that dairy plant license fees are non-refundable.

ATCP 65.08, Milkhouse.

ATCP 65.08 (2) prohibits locating milkhouse access driveways and doors such that animal waste could be tracked into the milkhouse.

ATCP 65.10, Dairy farm water supply.

ATCP 65.10 (3) was updated to require wells to comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Water Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.) ATCP 65.10 (5) (a) clarifies that if a milk producer has more than one well, water from each well shall be tested at least once every two years. This change brings the provision into conformance with the PMO.

ATCP 65.14, Milking and milk handling systems.

ATCP 65.14 (5) recognizes the increasing adoption of modernized milking systems by incorporating PMO requirements for automatic milking installations, or robotic milking systems.

ATCP 65.22, Farm premises.

ATCP 65.22 (5) (c) prohibits mixing or storage of human waste or septage with animal manure. This provision was added to prevent recurrence of observed situations in which transmission of human fecal pathogens via dairy farm facilities was clearly possible.

ATCP 65.23, Federal requirements.

ATCP 65.23 indicates which requirements of the FDA Preventive Controls – Human Food rule implementing FSMA must be met by Wisconsin-licensed dairy plants.

ATCP 65.24, Construction and maintenance.

ATCP 65.24 (1) (b) states that a written variance from a construction standard may only be issued for dairy plants that do not hold a Grade A permit, i.e., Grade "B" plants. The PMO does not allow construction variances for Grade "A" dairy plants. ATCP 65.24 (1) (c) also prohibits dairy plants from being directly connected to a milking barn, milking parlor, or animal housing area. This latter provision is intended to minimize transmission of pathogenic microorganisms into the dairy plant.

ATCP 65.24 (4) (a) revises a current exemption of overhead doors and electronic sliding doors in delivery areas from the requirement to be kept closed when not in use. The revised requirement excludes Grade "A" dairy plants from the exemption, while continuing to allow receiving stations and Grade "B" dairy plants to keep overhead and electronic sliding doors open when not in use. This change will bring Wisconsin's regulations in compliance with the PMO.

ATCP 65.24 (8), Dairy plant water supply.

ATCP 65.24 (8) contains a modified requirement that water used in dairy products must comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.)

ATCP 65.24 (8) (b) requires that water from a privately owned water system supplying a dairy plant shall be tested to ensure it meets safe drinking requirements under ch. NR 809 (Safe Drinking Water) after a repair or alteration. Finally, ATCP 65.24 (8) (h) was created to require Grade "A" dairy plants using water to flush pasteurized milk or milk products from their milk processing systems to use water that is of equivalent microbiological quality to pasteurized milk.

ATCP 65.28, Equipment and utensils.

ATCP 65.28 (7) (e) 5. was created to exempt dairy plants from having to clean certain reverse osmosis equipment after each day's use. ATCP 65.28 (7) (f) contains a modified requirement for a dairy plant operator to consult with FDA before seeking division approval of a proposal for alternative cleaning and sanitizing schedule for continuously operated equipment that comes in contact with Grade "A" products. This provision now conforms with the PMO.

ATCP 65.36, Receiving milk and dairy products.

ATCP 65.36 (3) indicates that a bulk milk tanker transporting Grade "A" milk may hold a Grade "A" permit issued by another state's regulatory agency. This change recognizes reciprocity requirements of the PMO and recent changes in ch. ATCP 82, Bulk Milk Collection, Sampling, and Transportation.

ATCP 65.40, Storing and handling milk and dairy products.

ATCP 65.40 (2) allows the division to authorize alternative temperature limits for storing milk and milk products.

ATCP 65.40 (2) (d) 7. exempts acid whey with at least a minimum specified percent titratable acidity or no more than a maximum specified pH from storage time and storage temperature requirements applicable to other dairy products. This change is in response to information presented by industry.

ATCP 65.41, Low-acid or acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage.

ATCP 65.41 (1) requires manufacturing of low-acid dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal canning regulations.

ATCP 65.41 (2) requires manufacturing of acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal regulations pertaining to acidified canned foods.

ATCP 65.42, Recall plan.

ATCP 65.42 requires dairy plants manufacturing or processing dairy products to have a written plan for identifying and recalling dairy products should a food recall become necessary, and describes the required contents of such a plan. This new requirement is consistent with the recall plan requirements in ch. ATCP 70 (Food Processing Plants) and ch. ATCP 88 (Eggs.) The new requirement does not apply to receiving stations or transfer stations.

ATCP 65.58, Pasteurization time and temperature.

ATCP 65.58 (1) requires that alternative methods of pasteurization of Grade "A" products be recognized by the FDA.

ATCP 65.72, Drug residue testing.

ATCP 65.72 (3) (c) was revised to indicate that a bulk load of milk must be agitated sufficiently to ensure that the sample taken for drug residue testing is representative of the bulk load of milk. Further revision allowed for Department approval of an alternative sampling methods that is not dependent on agitation to obtain a representative sample.

ATCP 65.72 (6) allows dairy plants to recover the cost of an entire bulk load of milk from a milk producer responsible for contaminating that load with milk adulterated with drug residues, or from the milk contractor from whom the milk was procured. The milk contractor may, in turn, recover the cost of the entire load from the milk producer responsible for contaminating that load with milk adulterated with drug residues.

ATCP 65.74, Milk and dairy products; quality standards.

ATCP 65.74 (2) (a) states that bacterial counts for nonfat dry milk shall not exceed 10,000 per gram. This provision is in conformance with the PMO.

ATCP 65.910, Inspection of dairy farms; general.

ATCP 65.910 (2) increases the inspection frequency for Grade "B" dairy farms from once every two years to once a year. This provision is made to ensure maintenance of adequate conditions on the Grade "B" dairy farms.

ATCP 65.912, Performance-based farm inspection.

ATCP 65.912 contains language which was modified to bring Wisconsin's performance-based farm inspection program in full compliance with Appendix P of the PMO. Specifically, the rule prohibits placing farms in categories requiring inspection once or twice per year under the program if they have been cited during the past year with any violation that presents an imminent health hazard. The rule also prohibits placing farms in a category requiring inspection once or twice per year if they have received a warning under ATCP 65.923 (1) during the past year. ATCP 65.923 (1) continues to require the division to issue a warning notice if an inspection finds a noncompliance with a key violation. However, the definition of a key violation was expanded to include instances when a farm receives one or more identical violations during two consecutive inspections, i.e., double debits. Finally, the rule prohibits placing farms in categories requiring inspection once or twice per year if the milk shipped from the farm was found to have had any drug residues during the past year.

ATCP 65.923, Drug residue violations; milk producer sanctions.

ATCP 65.923 requires the Department to issue a warning notice whenever a producer milk sample test result is confirmed positive for drug residue. Once a milk producer receives a warning notice for drug residues, the milk producer must implement a drug residue prevention program within 21 days of the effective date of the notice or the producer's Grade A permit will be suspended. If the drug residue prevention program is not completed within 45 days, the milk producer's license will be suspended. The rule already included this requirement, along with a penalty provision to be invoked if the producer has 3 drug residue violations within 12 months. These penalties are modified in the proposed rule and a penalty is created in ATCP 65.922 (4) for milk producers whose milk sample yields a confirmed positive test result for drug residue in a second separate 24-hour period within 12 months of the first violation. After the second offense, the proposed rule requires the license to be suspended for 5 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay a civil forfeiture or to discard one milk shipment; the milk producer must also complete participation in a drug residue prevention program and present a certificate of completion for the program within 180 days of receiving a warning letter. Milk producers whose milk sample yields a confirmed positive test result for drug residues in a third separate 24-hour period within 12 months of the first violation would have

their milk producer license suspended for 10 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay two civil forfeitures or to discard two milk shipments; the milk producer would also have to develop and implement a Department-approved drug residue program and present documentation indicating that this program has been implemented for at least 90 days.

ATCP 65.928, Right of hearing.

ATCP 65.928 (3) contains a revised requirement that the Department hold an informal hearing within 20 days, rather than 10 days, of receiving a hearing request. This change will bring the rule into compliance with ch. ATCP 1, Administrative Orders and Contested Cases.

ATCP 65.928 (4) is revised to eliminate the 10-day requirement for requesting a contested case hearing, in conformance with Subch. III, ch. 227, Stats., and s. ATCP 1.03 (3) (a) 1. It is also revised to add that a request for a contested case hearing must follow the requirements in s. ATCP 1.06.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

One objective of this proposed rule is to modernize current dairy farm and dairy plant inspection rules to ensure compliance with federal PMO requirements. The PMO establishes minimum standards for regulation of Grade "A" dairy farms and milk products. States must set standards equivalent to, or more stringent than, those in the PMO and each state's milk producers and dairy plants must meet these standards to be allowed to ship Grade "A" milk and milk products in interstate commerce. These rule changes will bring Wisconsin's dairy farm and dairy plant regulations into full accordance with the 2013 revision of the PMO.

Comparison with Rules in Adjacent States

Michigan, Minnesota, Iowa, and Illinois adopt the PMO as part of their Grade "A" dairy-related statutes and regulations and therefore enforce Grade "A" dairy regulations similar to those enforced by Wisconsin. None of the surrounding states have adopted performance-based farm inspection, as allowed by the PMO.

Public Hearing

The Department held five public hearings:

February 13, 2015	Mead Public Library, Sheboygan, Wisconsin
February 20, 2015	DATCP, Madison, Wisconsin
February 23, 2015	Menomonee Public Library, Menomonee, Wisconsin
February 24, 2015	North Central Technical College, Wausau, Wisconsin
January 14, 2016	DATCP, Madison, Wisconsin

A total of ten persons registered in the first four hearings. Following the initial four public hearings, the hearing record remained open until March 13, 2015, for additional written comments. The Department held an additional follow-up hearing ten months later on January 14, 2016, with written comments accepted through February 15, 2016, after further revising the rule in response to the comments received. A total of six persons registered in this latter hearing, including three who had also attended a 2015 hearing.

Written comments were obtained from sixteen individuals, four of whom commented in conjunction with both the 2015 and the 2016 hearings. Extensive written comments were received from the Department technical staff as the rule was revised in response to the 2015 and 2016 comments. Legislative Council Rules Clearinghouse comments were considered and appropriate revisions were made in the final draft. A summary of the comments received from individuals on the Department's technical staff may be found in Appendix A.

Changes from the Hearing Draft:

The Department made the following changes from the Hearing Draft:

Organization

Section ATCP 65.24 was added. This section identifies federal requirements related to the Preventive Controls for Human Foods (implementing FSMA) that must be met by dairy plants.

Section ATCP 65.41 was added. This section identifies federal requirements related to acidified canned foods and low-acid canned foods, that must be met by dairy plants.

The order of sections and section titles in Subchapters V and VI were changed to improve ease of reading.

Content

- The definition of "abnormal milk" was revised for consistency with the PMO.
- A definition for "automated milking installation" (AMI; robotic milking system) was added.
- The definition for "bulk tank unit" was condensed.
- The definition for "bulk transport container" was revised for clarity.
- The definition of "dairy plant" was re-formatted and broadened to include situations in which a milk contractor is treated the same as a traditional "brick and mortar" dairy plant.
- The definition of "dairy product" was revised to reflect statutory changes.
- Definitions for "facility" and "qualified facility," both of which are used in FSMA, were added.
- The definition for "milk component test" now acknowledges that a milk contractor may pay a producer based on component analysis.
- A definition for "milk contractor" was added.
- The definition for "milk quality test" now acknowledges that the price paid to a milk producer by a milk contractor may be influenced by quality test results.
- The definition for "milking animals" now includes camelid mammals.

- A definition for “receive milk from a milk producer” was added.
- The definition for “safe temperature” was revised to retain the original lower maximum temperature of 45°F.
- The definition of “sale” was deleted.
- The definition for “standard of identity” now includes citations of the federal regulation creating dairy product standards of identity.
- ATCP 65.02 (1) describing milk producer license requirements was reformatted for clarity.
- ATCP 65.02 (2) now includes a milk contractor as an entity that may submit a license application on behalf of a milk producer. Multiple subsequent provisions are revised to include a milk contractor as an entity that may perform functions also performed by a “brick and mortar” dairy plant.
- ATCP 65.02 (3) indicates that an automated milking installation must be reviewed and approved by the division before a milk producer license is issued.
- ATCP 65.02 (4) indicates that the milk producer license fee is non-refundable.
- ATCP 65.02 (12) was reformatted.
- ATCP 65.02 (19) and (20) were combined.
- ATCP 65.02 (21) was created to describe BTU requirements.
- ATCP 65.04 (1) was revised to reflect statutory changes related to the transfer of restaurant regulation to the Department. The exemption from a required dairy plant license for retail food establishments processing non-Grade A dairy products indicates that these products must be made from commercially pasteurized *and packaged* products.
- ATCP 65.04 (2) now indicates that the dairy plant license fee is non-refundable.
- ATCP 65.04 (7) now cites state regulations that must be followed if a dairy plant produces canned foods, seafood, or juice products. Additional product categories that trigger notification of the Department about operations have been added.
- ATCP 65.06 (4) more specifically defines what operations must be sufficiently illuminated.
- ATCP 65.06 (7) now contains a requirement about manure removal that was formerly in a “Note.”
- ATCP 65.06 (11) now includes drug administering devices in the list of items that should not be kept in a milkhouse unless intended or prescribed for use on dairy animals.
- ATCP 65.08 (2) now indicates that “Access to milkhouse” requirements apply to exterior access doors.
- ATCP 65.08(3) now includes requirements for ventilation and wash and rinse vats in an automated milking installation room. This subsection was updated to allow, with division approval, other methods for hand-drying instead of single-service towels in milkhouses and automated milking installation rooms.
- ATCP 65.08 (5) now indicates that washing machines and dryers, milk-replacement formula pasteurizers are not allowed in the milkhouse, per PMO requirements.
- ATCP 65.10 (8) was added to allow the limited use of water reclaimed from sources other than a heat exchanger.
- ATCP 65.14 (3) no longer requires pipeline supports to be floor-mounted.
- ATCP 65.14 (5) now includes detailed specific requirements for the milking equipment in automated milking installations.
- ATCP 65.16 (1) now includes specific distance requirements for clearance around a bulk tank.

- ATCP 65.16 (3) now includes provisions for division review of electronic bulk tank milk temperature monitoring records.
- ATCP 65.16 (4) bulk tank cooling capacity requirements were revised for consistency with the PMO.
- ATCP 65.18 (2) was revised to indicate that inflations contacting an unclean surface after milking an animal must be cleaned and sanitized before use in milking the next animal.
- ATCP 65.18 (3) now references regulatory standards for employee illness.
- ATCP 65.18 (4) has revised milk cooling requirements that are consistent with the PMO, and a provision setting time limits for the frozen storage of sheep milk before it is shipped to a dairy plant.
- ATCP 65.24 (1) provides additional details on how a dairy plant is to be separated from a milking barn, milking parlor or animal housing area.
- ATCP 65.24 (8) contains an added provision indicating who should obtain the water sample in a dairy plant producing both Grade "A" and non-Grade "A" products.
- ATCP 65.24 (9) contains an added provision for treatment of water reclaimed from membrane processing unpasteurized milk or unpasteurized dairy products to ensure safety.
- ATCP 65.26 (1) now references regulatory standards for employee illness.
- ATCP 65.26 (2) excludes medical alert necklaces worn under garments and secured by tape from the prohibition against jewelry.
- ATCP 65.28 (7) now describes allergen cross-contamination as an antecedent for mandatory cleaning and sanitizing of equipment and utensils. This subsection also lists additional food processing situations in which cleaning and sanitizing every 24 hours is not mandatory.
- ATCP 65.32 (3) contains added details on testing packaging materials for volatile organic compounds.
- ATCP 65.32 (4) contains added details about allowable manual capping processes. This addition achieves PMO compliance.
- ATCP 65.34 (2) and (3) have been combined.
- ATCP 65.36 (3) has been revised to reflect statutory elimination of the requirement for bulk milk tankers in Wisconsin to be licensed. This subsection also contains new language described requirements for an on-farm dairy plant receiving milk from the same farm.
- ATCP 65.36 (4) indicates that receiving of Grade "B" and Grade "A" milk need only be separated by rinsing, not by a full cleaning and sanitizing regime.
- ATCP 65.38 (1) creates the possibility that a means other than agitation could be approved by the division for ensuring a bulk milk sample is representative.
- ATCP 65.40 (2) is revised to indicate that production of cultured or acidified Grade "A" dairy products, or certain Grade "A" whey products is only exempt from cooling requirements if PMO process controls are followed. An additional exemption from cooling requirements is added for Grade "B" whey meeting certain processing criteria.
- ATCP 65.41 lists federal regulations that must be met in the production of low-acid canned dairy products and acidified canned dairy products.
- ATCP 65.42 (1) indicates that a mandated recall plan must cover all products produced at a dairy plant, even if some of the products are not dairy products. The subsection indicates that operators of receiving or transfer stations do not have to prepare a written recall plan.
- Record retention times listed in ATCP 65.44 (1) are now generally 2 years to be consistent with the Preventive Controls for Human Food regulations implementing FSMA.

- ATCP 65.54 (2) no longer allows the shipping in bulk of unpasteurized dairy products to a food processing plant. The Division is not convinced that enough industry and regulatory controls exist to allow this practice.
- ATCP 65.70 (5) contains milk temperature requirements updated to be internally consistent in this rule and consistent with the PMO.
- ATCP 65.72 (3) specifies that the milk producer's milk is offered for sale upon delivery at the dairy plant.
- ATCP 65.72 (3) indicates that other methods besides agitation, if approved by the division, can be used to ensure that sample of milk is representative. This subsection also clarifies that the sampling must be done before any of the milk is processed, and contains new requirements for testing of sheep milk which is frozen for later pooling and processing.
- ATCP 65.72 (6) now indicates that recovery of milk costs from the milk producer whose milk yielded a confirmed positive test result for drug residue and thereby contaminated a bulk load is optional, not mandatory.
- The table in ATCP 65.72 (11) is shorter due to the removal of drugs that are not allowed for use with lactating cattle or cattle in general.
- ATCP 65.74 (3) was revised to indicate that natural cheeses are not subject to the coliform limit requirement.
- ATCP 65.920 (3) now lists violations that can result in summary suspension of a milk producer's license. The violations were previously listed in a "Note."
- ATCP 65.922 contains revised penalties for a second and third drug residue violation within a year. These penalties are described above in the "Rule Content" section.

Next Steps

If the Board approves this final draft rule, the Department will transmit the final rule to the Governor for his written approval. After the Department receives written approval from the Governor, the Department will submit the rule to the Legislature for review by appropriate legislative committees. If the Legislature has no objections to the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

Appendix A – Comment Summary

Ch. ATCP 65, Dairy Farms and Dairy Plants

Rules Clearinghouse No. 14-073

DATCP Docket No. 13-R-06 and 13-R-13

**Public Hearing
February 13, 2015
Mead Public Library
Sheboygan, Wisconsin**

Name and Address of Contact Person	Support, Oppose or No position	Did the person speak?	Summary of comments
Jacqueline J. Papple 45 E. Scott Street Fond du Lac, Wisconsin 54935	No position	No	No comments

**Public Hearing
 February 20, 2015
 2811 Agriculture Drive
 Madison, Wisconsin**

Name and Address of Contact Person	Support, Oppose or No position	Did the person speak?	Summary of comments
John Holevoet 22 N. Carroll Street, Suite 101 Madison, WI 53703 Representing Dairy Business Association	Favor part and oppose part of the proposal	Yes	Expressed concern about new definition of "sale" and the implication for drug residue testing. Is there a shift of the practice of handling drug residue tests in direct load shipments? Also concerned about provision related to USDA repeat drug residue violator list and about threshold when drug residue would become a violation. USDA repeat residue violator list might not be best source.
David Cooper 4001 Nakoosa Trail, Suite 100 Madison, WI 53714 Representing FarmFirst Dairy Cooperative	Favor part and oppose part of the proposal	No	Expressed support for maintaining performance-based farm inspection program. Concerned about the drug residue tissues that may impact a producer's milk license.
David Ward 1 S. Pinckney Street, Suite 810 Madison, WI 53703 Representing Cooperative Network	Favor part and oppose part	Yes	Supportive of performance-based farm inspection, inspection frequency of grade B farms, temperature requirement exemptions for grade B whey and the fact that the rule does not change fees. Concerned about proposal to suspend milk producer license upon finding drug residue in slaughtered cattle. Specifically, concerned about definition of "dairy cow" used in USDA repeat residue violator list. If milk from that cattle never reaches the milk supply, should a milk producer be punished?
Kathryn Young Division of Food Safety Wisconsin Department of Ag, Trade and Consumer Protection 2811 Agriculture Drive Madison, WI 53708	No position on proposal	Yes	Request language be added that fees are not refundable. Brings rules in line with other Department divisions and would result in administrative savings.

<p>Representing the Department Paul Humphrey 6915 Old Sauk Ct. Madison, WI 53717 Representing Foremost Farms USA</p>	<p>Did not indicate</p>	<p>Yes</p>	<p>Add the word "exterior" in the AATCP 65.08 provision related to milk house access doors. Request the Department to consider the definition of "dairy cattle" under ATCP 65.923. Also consider whether penalties would apply to dairy producer locations or owners, since many owners own farms in multiple locations. Finally, he requested that the Department consider the potential impact of a 10 day license suspension on very large producers. It could result in a dairy plant losing as much as 10% of a dairy plant's capacity.</p>
<p>Norm Kedrowski 2617 Jefferson St Stevens Point, WI 54481 Representing Foremost Farms USA</p>	<p>Did not indicate</p>	<p>Yes</p>	<p>Reiterated the comments submitted by Paul Humphrey. Highlighted the potential economic impact of suspending a dairy farm license for 10 days from a large dairy farm. He noted the value of milk lost over a ten day period could be in excess of \$1 million. He also noted that milk is also already screened for drug residues. The penalty in the rule could result in dumping perfectly good milk.</p>
<p>Brian Dake PO Box 2135 Madison, WI 53701 Representing WIB Agri-Business Coalition</p>	<p>Generally, support the proposal</p>	<p>No</p>	<p>Still soliciting input from members.</p>
<p>Brad Legreid 8383 Greenway Blvd Middleton, WI 53562 Representing Wisconsin Dairy Products Association</p>	<p>Favor part and oppose part</p>	<p>Yes</p>	<p>Supportive of a lot of the changes. Believes ATCP 65.01 definition of 'safe temperature' conflicts with temperature requirements in ATCP 65.40. Suggested eliminating the second paragraph in ATCP 65.923 (3)(d) since there is no good definition of dairy cows related to this requirement. Also some larger farms may own several farms having a significant economic impact on larger producers. Suggested adding the word "exterior" regarding doors in ATCP 65.08(2). They want to make sure that Wisconsin continues to recognize permits and licenses issued by other states for milk trucks. They wondered why the definition of safe temperatures was changed to 41°F. Other comments</p>

			reiterated written comments submitted separately.
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Public Hearing
February 23, 2015
Menomonee Public Library
Menomonee, Wisconsin
No Attendees

Public Hearing
February 24, 2015
North Central Technical College
Wausau, Wisconsin

Name and Address of Contact Person	Support, Oppose or No position	Did the person speak?	Summary of comments
Andrew L. Johnson W7391 Chickadee Road Willard, WI 54493 Representing Grassland Dairy Products, Inc.	Favor part and oppose part of the proposal	Yes	Opposed the 10 day suspension provision in ATCP 65.923 and noted that milk is already tested for drug residues. Felt it was an unfair penalty for dairy farmers since beef farmers don't hold a similar license to be withheld if they are listed on the USDA repeat violator list. Discussed washers and dryers in milk houses. He stated that a recent Department meeting discussed the proper installation of washers and dryers in milk houses. He also noted that rating officers mark washers and dryers on a survey. He stated that he believed the rule should prohibit the practice of allowing washers and dryers in milk houses. He also felt that, in general, equipment installers should be certified and licensed. Suggested that there needs to be better definitions of potable vs. non-potable water. Is water that goes through a plate cooler potable or non-potable? He thought the rule should not allow water that's gone through a plate cooler also be used for first rinse of cleaning equipment. ATCP 65.154 (5)(c) that automatic milking installations treated as a milking parlor under the PMO. Requirements for AMI should then be carried over to other types of "parlors", specifically for continuous milking parlors. Requiring a curtain

			or door for a continuous milking parlor allows for access of rodents, dogs and cats and should be revised.
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**Public Hearing
 January 14, 2016
 DATCP Building
 Madison, Wisconsin**

Name and Address of Contact Person	Support, Oppose or No position	Did the person speak?	Summary of comments
David Cooper Farm First Dairy Cooperative 4001 Nakoosa Trail, Suite 100 Madison, WI 53714.	Favor the proposal and have questions	Yes	Opposed the requirement for raw milk transfer and receiving stations to have a written recall plan. Stated opinion that too much time was allowed for producers to take mandatory drug residue prevention course after a second violation within a year. Questioned definition of "shipment" of milk. Voiced several questions about drug residue testing. Questioned whether de-grading milk from grade A to grade B was a viable penalty in all parts of the state.
Ron Statz Scenic Central Milk Producers 106 9 th Street Prairie du Sac, WI 53578	Favor part and oppose part of the proposal.	No	
Brian Dake Wisconsin Independent Businesses 122 W. Washington Ave., #650 Madison, WI 53703	Favor the proposal.	No	
David Ward Cooperative Network 1 S. Pinckney Street Madison, WI 53703	Favor part and oppose part of the proposal.	Yes	Support continuation of Performance-Based Farm Inspection, and removal of provisions related to tissue drug-residue (+) results. Questioned whether receiving and transfer stations will have to write recall plan. Sought clarification of a "shipment".
Brad Legreid Wisconsin Dairy Products Asscn. 8383 Greenway Blvd. Middleton, WI 53562	Favor the proposal.	No.	
Bob Hagberg Land o' Lakes 4001 Lexington Ave. N Arden Hills, MN 55126	No position	No	

Written Comments

Person/Organization	Position/Comments
<p>Jordan Lamb DeWitt Ross and Stevens 2 East Mifflin Street, Suite 600, Madison, WI 53703 Comments on behalf of the Wisconsin Veterinary Medical Association</p>	<p>§ ATCP 65.72 (11)(b) includes drugs not legal for use in dairy cows or are not allowed to be used as suggested by the rule. There are other drugs that should be included on the list. § ATCP 65.923 lists two separate educational programs on page 173, lines 18-22, and page 176, lines 22-23, and one is named incorrectly. § ATCP 65.923. WVMA supports meaningful sanctions for people who violate drug residue limits.</p>
<p>David Ward Director of Government Relations and Dairy Cooperative Network 1 South Pinckney Street, Suite 810, Madison, WI 53703.</p>	<p>§ ATCP 65.923 (3) (b) and (d) establishes sanctions for milk producers whose milk tests positive for drug residues twice within 12 months. For producers who direct ship multiple loads of milk per day, one cow could result in a positive test on two or three different loads. Would this be considered one, two or three occurrences? If a producer owns more than one dairy operation and there are drug residue violations at different locations, do the violations go with the location or do they apply to the owner? §ATCP 65.923 (3) (d) comments are regarding sanctions for milk producers who are on the USDA repeat residue violator list. Is there a correlation between meat and milk residues? The rule does not define “dairy cattle”. Is it cows currently being milked, dry cows whose milk has not been shipped, bull calves that are a few days old or free martin heifers? There needs to be more specificity that carcasses in question come from a cow whose milk is being shipped. In both § ATCP 65.923 (3) (b) and (d), is it equitable to compare two violations in a 30 cow herd verses two violations in a 3,000 cow herd?</p>
<p>David Cooper General Manager FarmFirst Dairy Cooperative PO Box 14380 Madison, WI 53708</p>	<p>Appreciates efforts to align food safety regulations with the PMO. Supports inspection of grade B farms at least once every year. Appreciates the continuance of performance-based grade A dairy farm inspections. §ATCP 65.72 (6k) allows for a waiver of the requirement that dairy plants recover the value of bulk load from producers whose milk samples test positive for drug residue. It is important that this load is reported appropriately and to recognize that there are still costs associated with the load even if it is disposed of properly. The plant or milk hauler has to ensure the container is properly washed. Suggested that the rule say that the dairy plant operator “may charge the recover cost at their discretion of the bulk load of milk that has been properly rejected...” § ATCP 65.923 (3)(b) how would violations be counted in the case of a direct ship occurrence where one treated animal could result in contaminating multiple loads in one day? Would the violation be attached to the location of the farm (milk license) or to the owner of the farm? § ATCP 65.923 (3)(d). They disagree with the proposal to suspend a dairy farm license if a dairy producer has a tissue violation and is listed on the USDA repeat violators list. They note that a tissue violator reporting system doesn’t provide a snapshot of the current situation on the farm. The violators list includes Bob Veal and Dairy Cows. Would Bob Veal also be considered as part of the violation system? They note that the USDA list doesn’t distinguish between lactating and non-lactating dairy cows, animals presented for slaughter may not have been milked, suspending a license and dumping milk may not make sense since the violation may not have had anything to do with drug residues in the milk supply. Education about residues in the meat supply is warranted and already occurs if the producer plans to continue to offer meat for slaughter. Violations should not impact a producer’s milk license. They are confident that additional proposals will be made to improve testing protocols to strengthen the already</p>

Person/Organization	Position/Comments
	<p>existing milk safety system. They believe these methods will be better equipped to address the educational and milk supply safety than a license suspension that unduly destroys milk that is otherwise safe.</p>
<p>John Umhoefer Executive Director Wisconsin Cheese Makers Association 8030 Excelsior Drive, Suite 305 Madison, WI 53717</p>	<p>§ ATCP 65.01, Definitions. They offer suggestions for improving definitions. They state that the definition of bulk transport container seems redundant with the new definition for bulk milk tanker. They suggest using the term “milkhouse” instead of “milk house” in the definition for dairy farm. They wonder whether including operators of dairy plants outside of Wisconsin as a dairy plant operator inadvertently makes these out-of-state operators subject to inspections, fees, milk testing requirements, etc. of in-state operators? They believe the definition of “dairy product” may inadvertently imply that all products not identified in the Code of Federal Regulations (CFR) are not dairy products by definition. For example, cheese like feta, machego, pizza cheese, whey protein concentrate and other existing products are not noted in the CFR. This definition could hamper product development.</p> <p>“Safe temperature” should be 45° and not 41° to be consistent with the PMO and current industry practice.</p> <p>§ ATCP 65.02 is ambiguous as to whether the milk producer or dairy farm is licensed. WCMA proposes that a dairy farm shipping to more than one dairy plant procure its own milk producer licenses and pay its own reinspection fees since the dairy farm, in this case, is not “assigned” to a plant. They offer specific wording suggestions to accomplish this.</p> <p>§ ATCP 65.04 (1) (b) list of exemptions from § 97.20 (2) (e), Stats., and yet the list is missing two exemptions from the statutes. ATCP 65.04 (1)(b)(3) should be revised to give the Department some discretion as to when a retail establishment crosses a line and becomes an unlicensed dairy plant. For example, if a large retail food establishment starts producing a broad line of fresh cheese, it has become a cheese factory without a licensed cheesemaker or having to meet food safety requirements.</p> <p>§ ATCP 65.26 (2)(b) wording should be added that this paragraph also does not apply to medical alert necklaces worn under garments and secured by adhesive tape to undergarments to restrict movement.</p> <p>§ATCP 65.78 may need to be revised for clarity. Paragraphs mix milk quality and milk component testing language.</p> <p>§ ATCP 65.923 (3)(b) outlines sanctions for two drug residue violations within a 12 months. They would like the rule to be clearer about what a “license suspension” involves. Can a milk producer continue to ship milk to a dairy plant? Must the milk be dumped? They note that the definition of “sale” appears to move the liability for drug residue violations to when a milk tanker departs a farm. This is a significant change for farms that direct ship tankers to dairy plants. Currently, direct ship tankers may be tested at a dairy plant before a “sale” has occurred. If the tanker is found to be positive for drug residue, the drug residue result may be omitted from the producer’s record and the tanker disposed. In this way, no public safety concern exists and no violation has occurred. Under the proposal, a direct ship tanker would be punished if the load is found positive for residues while being tested at intake. A large dairy farm shipping multiple loads may incur more than one tanker load violation in a matter of hours. One animal could contaminate several tank loads. They also expressed concern about the severity of a 10 day license suspension.</p> <p>§ATCP 65.923 (3) (d) creates sanctions for milk producers that have been reported on the USDA repeat tissue residue violator list. WCMA members have expressed concern about the severity of this punishment. In addition, the term “dairy cattle” in the hearing draft is not clearly defined.</p>

Person/Organization	Position/Comments
	<p>WCMA would like to see a section devoted to the definition and description of variances in the regulations. They would like to see language defining, describing the process for seeking a variance, and a time frame for the Department to review and decide on proposed variances.</p> <p>WCMA also identified several portions of the proposed rule that they support.</p>
<p>Saputo Cheese Division One Overlook Point, Suite 300, Lincolnshire, IL. 60069.</p>	<p>§ ATCP 65.01(60) revises the definition of safe temperature to be 41°F for refrigerated potentially hazardous food. They state that the temperature should remain at 45°F to be consistent with the PMO. They stated that reducing the temperature to 41°F would be an economic hardship requiring additional cooling equipment and supplies, changes in manufacturing processes and procedures, and potential changes to product packaging. It would also be in direct conflict with the PMO and the CFR.</p> <p>They were concerned that § ATCP 65.01(61) will change the point of sale of raw milk from the dairy plant to the dairy farm. They note that this would have a significant effect on large dairy producers who direct ship milk. Specifically, it could mean that direct ship milk producers could acquire three drug residue occurrences in a single day. They felt that making the point of sale at the farm rather than at the dairy plant would mean that the milk would be tested on the farm, creating human safety and food safety concerns. They requested that the Department define sale to be at the dairy plant.</p>
<p>John Holevoet Director of Government Affairs Dairy Business Association P.O. Box 13505 Green Bay, WI 54307</p>	<p>§ATCP 65.01 (61) definition of the word “sale” is too broad and contrary to the common sense meaning of the words “sale” or “sold”. Most would consider a product sold when it has been offered and accepted. That is, something cannot be sold until it is bought. The definition of sale also runs contrary to the existing understanding of most dairy farm operators who view the sale of milk from direct ship tankers as occurring only after the tanker was tested and found to be free of drug residues. They noted that the definition in the rule is consistent with § 97.01 (15), Stats. They suggested removing the definition of “sale” or finding an alternative to the definition.</p> <p>The Dairy Business Association opposes adding the penalty included §ATCP 65.923(3)(b) for a second milk residue violation within a 12-month period. They state that the punishment is overly harsh, wasteful, and harmful. They suggest a proportional financial penalty based off the value of milk would make more sense. This would allow the farmer to continue to sell perfectly good milk instead of just wasting it.</p> <p>The Dairy Business Association also opposes the license suspension for producers outlined in §ATCP 65.923(3)(d). They noted several concerns, consistent with concerns raised by other commenters, citing a study that found no direct correlation between a past history of meat residues and ongoing issues with drug residues in milk, that the penalty is too severe, and procedural concerns about implementing the requirement. They said that a better solution would be to abandon the USDA list in favor of an independent metric, which would take into account the number of total animals culled by a producer when determining if punishment should result from meat residue incidents.</p>
<p>Clay Detlefsen Sr. VP- Environmental and Regulatory Affairs and Staff Counsel and Beth Briczinski, PhD, VP- Dairy Foods and Nutrition, National Milk Producers Federation</p>	<p>Expressed concern that the provisions contained in § ATCP 65.923 (3)(d) are based on a false premise and that preventing drug residues in milk is best managed at the national level. They noted that the FDA has submitted several proposals for the upcoming National Conference on Interstate Milk Shipments (NCIMS) that would modify industry’s current antibiotic testing protocols. They recommend that ATCP 65.923 (3) (d) be deleted.</p>

Person/Organization	Position/Comments
2101 Wilson Blvd., Suite 400, Arlington, VA 22201	
Brad Legreid Executive Director Wisconsin Dairy Products Association 8383 Greenway Blvd. Middleton, WI 53562	Comments asked why the temperature requirements were changed. Comments noted that they need time to react to a positive §ATCP 65.24 (8) (e). Suggested removing §ATCP 65.30 (3) because it is impossible to notify the Department of every change in C-I-P. Suggested that the requirement should be to validate that the wash is effective. Notes that the rule throughout refers to a “dairy plant operator” that deals directly with farmer requirements. Suggested that the rules should reflect the possibility of a co-op having those responsibilities even though they are not a “dairy plant” or the entity physically receiving the milk. One solution could be to add to the definition of “Dairy Plant Operator” in §ATCP 65.01 (13). Notes that sinks in dairy plants aren’t the same as sinks in retail and disagrees with the requirement for a 3 compartment sink in §ATCP 65.24 (11) (a) (2). Also noted that their brushes might not meet the definition of utensil found in §ATCP 65.01 (69).
Steve Stoner, Laura Traas, Jackie Owens, Bob Carrier, Pete Haase Division of Food Safety, Wisconsin Department of Ag, Trade and Consumer Protection, 2811 Agriculture Drive. Madison, WI 53708	Submitted several comments designed to address technical issues in the rule, make the rule more consistent with current practice either by adding provisions or deleting obsolete provisions and further improve the rule’s consistency with PMO requirements.
Christopher Maloney Chief Operating Officer Digested Organics 1515 Minthaven Road, Suite 105 Lake Forest, IL 60045	Submitted suggested language for stating how the process of reclaiming water from a heat exchanger, a compressor unit, or from other dairy farm systems or processes should work when the reclaimed water will be used for milkhouse and milking operations.
James Tostenson W925 County Road H Fremont, WI 54940	Submitted typographical suggestions. Asked about origins of requirements for custom processing; asked about origin of water potability requirements. Suggested that one provision exceeded Act 21 restrictions. Opposed proposal to increase frequency of grade B farm inspections. Suggested longer time allowance for correction of debits such as repairing a broken milkhouse wall.
David Ward and John Manske Cooperative Network 1 S. Pinckney Street Madison, WI 53703	Supported continuation of Performance-Based Farm Inspection, and removal of provisions related to tissue drug-residue (+) results. Questioned whether receiving and transfer stations will have to write recall plan. Sought clarification of the term “shipment” as used in the penalties for repeat drug residue violations..
John Holevoet Director of Government Affairs Dairy Business Association P.O. Box 13505 Green Bay, WI 54307	Reiterated earlier comments related to §ATCP 65.01 (61) definition of the word “sale” and its implications in the testing of direct-ship tankers of milk for drug residue. Opposed dumping of milk as a penalty for preceding drug residue violations. Opposed wording that may result in a direct-ship milk producer receiving a 2 nd and/or 3 rd drug residue violation in the same day. Had concerns about severity of penalties for 2 nd and 3 rd drug residue offenses.
Mike O’Brien Director of Member Services and Milk marketing,	Supported Mr. Holevoet’s comments.

Person/Organization	Position/Comments
Foremost Farms USA Baraboo, WI 53913	
John Umhoefer Executive Director Wisconsin Cheese Makers Association 8030 Excelsior Drive, Suite 305 Madison, WI 53717	<p>Offered improved definition for "dairy product".</p> <p>§ ATCP 65.02 is ambiguous as to whether the milk producer or dairy farm is licensed. WCMA proposes that a dairy farm shipping to more than one dairy plant procure its own milk producer licenses and pay its own reinspection fees since the dairy farm, in this case, is not "assigned" to a plant. Proposed removing volume and percentage limits associated with custom dairy processing. Questioned different time limits for a milk producer license-holder to be inactive, depending on species of milking animal. Questioned requirement that reclaimed water be heat-treated using a time/temperature combination at least as stringent as pasteurization of milk. Suggested language allowing for the possibility of other methods besides agitation for ensuring representative samples of milk are taken from a bulk milk tanker or bulk tank. Sought rationale for new record-retention-period requirements. Opposed the 20 day limit for the length of time that may elapse between a request for an informal hearing and the hearing itself. Requested that the rule allow a dairy plant to waive the cost recovery following discard of a bulk milk shipment that yielded a positive test result for drug residue. Sought clarification in the rule that the coliform limit does not apply to natural cheeses. Expressed concern that the rule could result in a direct-ship milk producer receiving a 2nd and/or 3rd drug residue violation in the same day. Sought clarity for what a "license suspension" involves. Opposed definition of "sale". With the proposed definition, a direct ship tanker would be punished if the load is found positive for residues while being tested at intake. A large dairy farm shipping multiple loads may incur more than one tanker load violation in a matter of hours. One animal could contaminate several tank loads. WCMA also identified several changes made to the hearing draft rule that they support.</p>

**PROPOSED ORDER
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION
ADOPTING RULES**

The Wisconsin department of agriculture, trade and consumer protection hereby proposes the following rule *to repeal* ATCP 60 and 80, *to amend* ATCP 77.01 (4m), 77.02 (1) (zd), 77.23 (1) (a) and (b) 2., 81.91 (1), 82.04 (1) (b) and (9)(b), 82.08 (3)(b), 82.10 (1)(a), and (6)(a), 82.12 (2m)(intro.) and (a), 82.12 (4) (c), 100.98 (2) (a) and (b), 100.982 (3) and (4) (f), and *to create* ATCP 65 and ATCP 65 Appendix *relating to* dairy farms and plants, and affecting small business.

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

This rule repeals chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants) and consolidates and reorganizes those rules into a newly created ATCP 65 (Milk and Milk Products.) Certain provisions have been revised to modernize dairy farm and dairy plant inspection rules. The rule thereby accommodates advances in dairying and ensures continued industry and regulatory compliance with the Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO) and federal guidelines for Grade "A" and Grade "B" milk and dairy products. The rule also indicates what provisions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by dairy plant operators.

Statutes Interpreted

Statutes Interpreted: ss. 97.20, Stats., "Dairy plants;" 97.22, Stats., "Milk producers;" 97.23, "Drug residues in milk;" and 97.24, Stats., "Milk products."

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.20 (4), 97.22 (8), and 97.24 (3), Stats.

Explanation of Statutory Authority

The Department has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. The Department also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The Department has specific authority, under s. 97.20 (4), Stats., to establish rules to regulate dairy plants and under s. 97.22 (8) to promulgate rules to regulate the operation of dairy farms by milk producers. The Department also has authority under 97.24 (3), Stats., to adopt rules ensuring compliance with the PMO.

Related Statutes and Rules

Wisconsin's dairy farms, dairy plants, and dairy products are governed by ch. 97, Stats. Section 97.20, Stats., "Dairy plants" and s. 97.22, Stats., "Milk producers," contain requirements related to milk producer and dairy plant licensing, milk procurement and reinspection fees, and Grade "A" permits. Section 97.23, Stats., "Drug residues in milk," allows a dairy plant to recover, from a milk producer, the monetary loss incurred when the plant rejects a milk shipment because it is adulterated with drug residues in milk from the producer's farm. Finally, s. 97.24, Stats., "Milk and milk products," includes Grade "A" requirements for milk and milk products and authorizes the Department to conduct surveys to verify conformance with the PMO's Grade "A" standards. Administrative rules spell out the requirements that must be met to ensure compliance with statutes. Dairy farm requirements are currently found in ch. ATCP 60 (Dairy Farms) and dairy plant requirements are currently found in ch. ATCP 80 (Dairy Plants.) These two chapters are consolidated in the proposed rule. Other chapters of administrative rules, governing milk and milk products, include ch. ATCP 77 (Laboratory Certification), ch. ATCP 81 (Cheese Grading, Packaging and Labeling), ch. ATCP 82 (Bulk Milk Collection, Sampling, and Transportation), ch. ATCP 83 (Dairy Product Advertising and Labeling), and ch. ATCP 85 (Butter Grading and Labeling.)

Plain Language Analysis

Wisconsin operates the nation's largest state dairy inspection program. As of November 27, 2015, Wisconsin had 9,976 licensed milk producers and ranked second nationally in milk production. Milk is shipped from each dairy farm to one of more than 400 licensed dairy plants in the state or to a licensed dairy plant in another state.

About 98% of the milk produced in Wisconsin is Grade "A." Grade "A" unpasteurized milk, along with pasteurized milk and certain other dairy products made from Grade "A" milk, can only be shipped across state and international boundaries if the production, transportation, processing, and regulatory oversight are in accordance with the PMO. Wisconsin does not adopt the PMO directly, but has its own regulations for the dairy industry. These regulations must be at least as stringent as, and consistent with, the PMO. The FDA revises the PMO every two years and the version of the PMO, to which Wisconsin regulations are compared for compliance, must be within two prior editions. This rule revision, which reflects changes found in the 2013 revision of the PMO, is essential for maintaining compliance with the PMO and for allowing Wisconsin farmers and dairy plant owners to ship their Grade "A" milk and milk products in interstate commerce.

Wisconsin's regulations also establish standards to ensure the quality of Grade "B" milk, which is milk used only to process non-Grade "A" milk products, such as butter, cheese, and ice cream. Wisconsin had 1,488 Grade "B" licensed milk producers, or 13% of its total, on November 27, 2015. Recommended standards for Grade "B" dairy farms are published by the United States Department of Agriculture (USDA). Wisconsin's regulations must be at least as stringent as the USDA standards to ensure access of Wisconsin Grade "B" milk products to international markets.

The majority of Grade "A" and Grade "B" dairy plants in Wisconsin will be subject to new federal regulations implementing FSMA and known as the Preventive Controls–Human Food rule. It is possible that future FDA policy will consider compliance with the PMO to be equivalent to compliance with the Preventive Controls–Human Food rule. Grade "B" dairy plants will be expected by the FDA to directly comply with the Preventive Controls–Human Foods rules. Wisconsin regulators operate within a nationally integrated system of food safety regulation. A key part of this integration is functional equivalence between state and federal regulations. In order to maintain state-federal integration and reduce confusion for industry over which rules must be followed, the proposed rule specifies the federal rules that must be followed by Wisconsin-licensed dairy plants.

Wisconsin dairy farm and dairy plant regulations are currently found in chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants.) The proposed rule repeals chs. ATCP 60 and 80 and consolidates and reorganizes these chapters into a new ch. ATCP 65 (Milk and Milk Products.) Consolidation of these two rule chapters will eliminate numerous, and sometimes confusing, cross-references between the two chapters. In recent years, there has been increased interest in the operation of small dairy plants on the same site as the dairy farm supplying the milk. The operators of these "farmstead" or "artisanal" dairy plants can now find most of the rules affecting their business in one chapter, rather than two. The rule revises certain existing provisions and creates new provisions, as necessary, to ensure: 1) Wisconsin's Grade "A" and Grade "B" dairy sectors comply with the applicable PMO, FSMA, and USDA requirements when they meet Wisconsin regulatory requirements, and 2) state regulations do not unnecessarily hinder technological advancement by Wisconsin's internationally recognized dairy industry.

Revisions to modernize dairy farm and dairy plant regulations.

The following describes specific revisions made in the proposed rule to modernize and consolidate Wisconsin's dairy farm and dairy plant regulations:

Revisions in General Terminology

Wording was changed throughout to provide greater clarity and modernize terms. For example, references to "milk haulers" were changed to "bulk milk weigher and samplers" to reflect the actual name of the license held by people who collect, sample, and transport milk. References to "inspectors" were changed to "division representatives" to reflect the broader range of staff, e.g., sanitarians, food scientists, and regulatory specialists, who may conduct inspections or investigations. References to "division" or "department" staff were also changed throughout to

more clearly align the rules with the roles and duties performed by each unit. For example, division representatives conduct inspections, while the department issues, suspends, and revokes licenses. Subchapter, section, and subsection chapter titles were also revised throughout to more clearly reflect the content of the rule.

ATCP 65.01, Definitions.

ATCP 65.01, as renumbered, includes the following revisions:

- Adds definitions for “abnormal milk,” “aseptic processing and packaging system,” “bulk tank unit,” “facility,” “grade A producer permit,” and “qualified facility.”
- Repeals and replaces definitions for “C-I-P equipment,” “C-I-P milking equipment,” and “C-I-P milk pipelines” with a definition of “C-I-P” and numbered this definition as 65.01 (9).
- Updates the definition for “dairy product” to be consistent with current statute.
- Replaces the term “food safety division” with “division.”
- Expands the definition for “grade B milk” to clarify that grade B milk is not processed into fluid milk for consumption; it is only used in the production of non-grade “A” dairy products.
- Broadens the definition for “equipment” to cover equipment used on dairy farms and in dairy plants.
- Repeals the definition from ATCP 60.01 (6) for “dairy plant” and replaces it with a modification of the definition from ATCP 80.01 (5) for “dairy plant.”
- Revises the definition of “milk” to be consistent with the PMO definition by including the phrase “practically free of colostrum, obtained by the complete milking of one or more healthy milking animals.”
- Revises the definition of “milk contractor” to indicate that a milk contractor can, while not operating an actual dairy plant, submit a milk producer license application on behalf of one or more milk producers and thereby certify that each milk producer’s dairy farm and milking operations comply with applicable requirements under this chapter.
- Expands the definition “procure milk” to clarify that procured milk must be acquired directly from a licensed milk producer.
- Clarifies that “sanitizers” shall be in compliance with 21 CFR part 178.1010 or otherwise approved by the division.
- Repeals the definitions for “single-service utensil” and “single-service package” and replaced them with a definition for “single-service articles.”

ATCP 65.02, Milk producer license and permits; and fees.

ATCP 65.02 is retitled from “Milk producer license; fees” to “Milk producer licenses and permits; fees.” This section is revised to consolidate all information about the milk producer license (required for Grade “A” and Grade “B” dairy farms), Grade “A” permits, and fees from ss. ATCP 60.02, 60.03, 60.04, and 60.05.

ATCP 65.02 (1) clarifies that a license is required for each milk producer, species of milk animal milked by a single milk producer, and dairy farm operated by a milk producer at which milk is produced and offered for sale. Previously, not all of these parameters were specifically mentioned.

ATCP 65.02 (2) is revised to clarify that a representative of the dairy plant or milk contractor may submit an application on behalf of a milk producer and that the dairy plant or milk contractor representative shall certify that both the dairy farm and milking operations comply with applicable requirements in this chapter.

ATCP 65.02 (4) (b) adds the due date of April 30 for paying the annual license fee.

ATCP 65.02 (4) (b) 2. specifies that the milk producer license fee is non-refundable.

ATCP 65.02 (8), “Milk produced for custom processing,” is created by consolidating existing requirements for custom processing a producer’s milk. Requirements for custom processing were not otherwise changed.

ATCP 65.02 (12) “Grade A permits at a single dairy farm operated by multiple dairy producers,” is added to describe conditions under which more than one Grade “A” milk producer permit may be held on one dairy farm.

ATCP 65.04, Dairy plant licenses and permits; fees.

ATCP 65.04 consolidates all dairy plant licensing and Grade “A” permit requirements, and fee information found in ss. ATCP 80.02, 80.04, and 80.06.

ATCP 65.04 (1) (b) 1. clarifies that no dairy plant license is required for a farm manufacturing dairy products solely for the owner/operator, members of the farm household, or nonpaying farm guests, or employees.

ATCP 65.04 (1) (b) 2. exempts appropriately licensed restaurants from a dairy plant license if they prepare or process dairy products made from commercially pasteurized dairy products. However, licensed restaurants are not allowed to package Grade “A” dairy products for retail sale without a dairy plant license.

ATCP 65.04 (1) (b) 3. exempts retail food establishments licensed under s. 97.30, Stats., from a dairy plant license if they process non-Grade “A” dairy products made from commercially pasteurized dairy products solely for retail sale at the establishment.

ATCP 65.04 (8) specifies that dairy plant license fees are non-refundable.

ATCP 65.08, Milkhouse.

ATCP 65.08 (2) is created to prohibit locating milkhouse access driveways and doors in such a way that animal waste could be tracked into the milkhouse.

ATCP 65.10, Dairy farm water supply.

ATCP 65.10 (3) is updated to require wells to comply with applicable requirements of chs. NR 810 (Requirements for the Operation and Maintenance of Public Water Systems), NR 811 (Requirements for the Operation and Design of Community Water Systems), and NR 812 (Well Construction and Pump Installation.)

ATCP 65.10 (5) (a) clarifies that if a milk producer has more than one well, water from each well shall be tested at least once every two years. This change brings the provision into conformance with the PMO.

ATCP 65.14, Milking and milk handling systems.

ATCP 65.14 (5) recognizes the increasing adoption of modernized milking systems by incorporating requirements for automatic milking installations, or robotic milking systems.

ATCP 65.16, Bulk tanks and bulk transport containers.

ATCP 65.16 (5) (f) creates requirements for the location of bulk transport containers which receive milk directly from the milking equipment, called "direct ship" milking.

ATCP 65.22, Farm premises.

ATCP 65.22 (6) (c) prohibits mixing or storing human waste or septage with animal manure. This provision was added to prevent recurrence of observed situations in which transmission of human fecal pathogens via dairy farm facilities was clearly possible.

ATCP 65.23, Federal requirements

ATCP 65.23 specifies which requirements of the federal Preventive Controls–Human Food rule must be met by Wisconsin-licensed dairy plants.

ATCP 65.24, Construction and maintenance.

ATCP 65.24 (1) (b) requires that a written variance from a construction standard may only be issued for dairy plants that do not hold a Grade A permit, i.e., Grade "B" plants. The PMO does not allow construction variances for Grade "A" dairy plants.

ATCP 65.24 (1) (c) prohibits dairy plants from being directly connected to a milking barn, milking parlor or other animal housing facility or area. This provision is intended to minimize transmission of pathogenic microorganisms into the dairy plant.

ATCP 65.24 (2) (e) is revised to clarify that floors in rooms used solely for the storage of dry ingredients or packaging materials need not have floor drains.

ATCP 65.24 (4) (a) currently exempts overhead and electronic sliding doors in delivery areas from the requirement that doors be kept closed when not in use. This requirement is revised to require Grade "A" dairy plants to keep overhead and sliding electronic doors closed when not in use. The new language will continue to allow receiving stations and Grade "B" dairy plants to keep overhead and electronic sliding doors open when not in use. This change will bring Wisconsin's regulations in compliance with the PMO.

ATCP 65.24 (8) is modified to require that water used in dairy products complies with applicable requirements in chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.)

ATCP 65.24 (8) (b) requires that water from a privately owned water system supplying a dairy plant shall be tested to ensure it meets microbiological standards under ch. NR 809 (Safe Drinking Water) after a repair or alteration. Testing is to be done by the operator of a Grade "B" plant while a division representative shall sample the water at a Grade "A" plant and have it tested. If a dairy plant is producing both Grade "A" and Grade "B" products, a division representative shall sample the water. If a water supply comes from multiple wells, the rule also requires that all wells be sampled and tested and that samples be taken upstream from any pressure tank or other water treatment equipment.

ATCP 65.24 (8) (h) is created to require Grade "A" dairy plants, using water to flush pasteurized milk or milk products from their milk processing systems, to use water that is of equivalent microbiological quality to pasteurized milk.

ATCP 65.28, Equipment and utensils.

ATCP 65.28 (7) (e) 5. is created to exempt dairy plants from having to clean certain reverse osmosis equipment after each day's use.

ATCP 65.28 (7) (f) is modified to require a dairy plant operator to consult with FDA before seeking division approval of a proposal for an alternative cleaning and sanitizing schedule for continuously operated equipment that comes in contact with Grade "A" products. This provision now conforms to the PMO.

ATCP 65.36, Receiving milk and dairy products.

ATCP 65.36 (3) is revised to clarify that a bulk milk tanker transporting Grade "A" milk may hold a Grade "A" permit issued by another state's regulatory agency. This change recognizes reciprocity requirements of the PMO and recent changes in ch. ATCP 82 (Bulk Milk Collection, Sampling, and Transportation.)

ATCP 65.38, Collecting milk samples.

ATCP 65.38 (1) is revised to indicate that all milk shipments received at a plant, including those received in a direct-ship tanker, must be sufficiently agitated to ensure that the mandatory sample taken is representative of the tanker contents.

ATCP 65.40, Storing and handling milk and dairy products.

ATCP 65.40 (2) (a) allows the division to authorize alternative temperature limits for storing non-Grade "A" milk and milk products.

ATCP 65.40 (2) (e) 7. exempts acid whey, with specified percent titratable acidity or pH, from storage time and storage temperature requirements applicable to other dairy products. This change is in response to information presented by industry.

ATCP 65.41, Low-acid or acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage.

ATCP 65.41 (1) requires manufacturing of low-acid dairy products, packaged in hermetically sealed containers for non-refrigerated storage, to be done in compliance with federal canning regulations.

ATCP 65.41 (2) requires manufacturing of acidified dairy products, packaged in hermetically sealed containers for non-refrigerated storage, to be done in compliance with federal regulations pertaining to acidified canned foods.

ATCP 65.42, Recall plan.

ATCP 65.42 requires dairy plants manufacturing or processing dairy products to have a written plan for identifying and recalling dairy products should a food recall become necessary, and describes the required contents of such a plan. This new requirement is consistent with the recall plan requirements in ch. ATCP 70 (Food Processing Plants), ch. ATCP 88 (Eggs), and federal requirements for facilities fully subject to the federal Preventive Controls – Human Food rule. This requirement does not apply to receiving stations or transfer stations.

ATCP 65.58, Pasteurization time and temperature.

ATCP 65.58 (1) requires that alternative methods of pasteurization of Grade "A" products be recognized by the FDA.

ATCP 65.72, Drug residue testing.

ATCP 65.72 (3) (c) is revised to indicate that a bulk load of milk must be agitated sufficiently to ensure that the sample taken for drug residue testing is representative of the bulk load of milk. Further revision allows for Department approval of an alternative sampling method that is not dependent on agitation to obtain a representative sample.

ATCP 65.72 (6) allows dairy plants to recover the cost of an entire bulk load of milk from a milk producer, responsible for contaminating that load with milk adulterated with drug residues, or from the milk contractor from whom the milk was procured. The milk contractor may, in turn, recover the cost of the entire load from the milk producer responsible for contaminating that load with milk adulterated with drug residues.

ATCP 65.74, Milk and dairy products; quality standards.

ATCP 65.74 (2) (a) is revised to state that bacterial counts for nonfat dry milk shall not exceed 10,000 per gram. This revision brings this provision into conformance with the PMO.

ATCP 65.910, Inspection of dairy farms; general.

ATCP 65.910 (2) increases the inspection frequency for Grade “B” dairy farms from once every two years to once a year. This provision is made to ensure maintenance of adequate conditions on the Grade “B” dairy farms.

ATCP 65.910 (3) is revised to be consistent with the PMO. The PMO does not allow a variance from a dairy farm standard for Grade “A” dairy farms.

ATCP 65.912, Performance-based farm inspection.

ATCP 65.912 is modified to bring Wisconsin’s performance-based farm inspection program into full compliance with Appendix P of the PMO. Specifically, the rule prohibits placing a farm in a category requiring inspection only once or twice per year under the program if the milk producer has been cited during the past year with any violation that presents an imminent health hazard. The rule also prohibits placing a farm in a category, requiring inspection only once or twice per year, if the milk producer has received a warning under s. ATCP 65.920(5) during the past year. ATCP 65.920(5) continues to require the division to issue a warning notice if an inspection finds a key violation. However, the definition of a key violation is expanded to include instances when a farm is cited for one or more identical violations during two consecutive inspections, *i.e.*, double debits. Finally, the rule prohibits placing a farm in a category requiring inspection only once or twice per year, if the milk shipped from the farm was found to have had any drug residues during the past year.

ATCP 65.920, Suspension or revocation of a Grade “A” producer permit or milk producer license.

ATCP 65.920 specifies the procedures for suspending or revoking a Grade “A” producer permit or milk producer license. Except for a summary suspension, it prohibits the department from suspending or revoking a milk producer’s license unless the secretary or the secretary’s designee orders the suspension. The Department must provide notice and opportunity for a hearing. Under ATCP 65.920 (3), the division may issue a summary suspension of a milk producer’s license under certain circumstances, including instances where the milk producer has refused an inspection or sampling authorized by law, and one or more specific conditions outlined in the

rule indicate the sale or shipment of milk from the farm poses an imminent hazard. ATCP 65.920 also outlines procedures for reinstating a Grade "A" permit or license, for suspending a Grade "A" milk producer permit and reinstatement of a Grade "A" milk producer permit.

ATCP 65.922, Enforcement actions taken in response to drug residue violations.

ATCP 65.922 requires the Department to issue a warning notice whenever a producer milk sample test result is confirmed positive for a drug residue. Once a milk producer receives a warning notice for drug residues, the milk producer must implement a drug residue prevention program within 21 days of the effective date of the notice or the producer's Grade "A" permit will be suspended. If the drug residue prevention program is not completed within 45 days of the effective date of the warning notice, the milk producer's license will be suspended. The rule already included this requirement and a penalty provision to be invoked if the producer has 3 drug residue violations within 12 months. These penalties are modified in the proposed rule and a penalty is created in sub. ATCP 65.922 (4) for milk producers whose milk sample yields a confirmed positive test result for drug residue in a second separate 24-hour period within 12 months of the first violation. After the second offense, the proposed rule requires the license to be suspended for 5 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay a civil forfeiture or to discard one milk shipment; the milk producer must also complete participation in a drug residue prevention program and present a certificate of completion for the program within 180 days of receiving a warning letter. Milk producers whose milk sample yields a confirmed positive test result for drug residues in a third separate 24-hour period within 12 months of the first violation would have their milk producer license suspended for 10 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay two civil forfeitures or to discard two milk shipments; the milk producer would also have to develop and implement a Department approved drug residue program and present documentation indicating that this program has been implemented for at least 90 days.

ATCP 65.928, Right of hearing.

ATCP 65.928 (3) is revised to require the department to hold an informal hearing within 20 days, rather than 10 days, of receiving a hearing request. This change will bring the rule into compliance with ch. ATCP 1 (Administrative Orders and Contested Cases.)

ATCP 65.928 (4) is revised to eliminate the 10-day requirement for requesting a contested case hearing, in conformance with Subch. III, ch. 227, Stats., and s. ATCP 1.03 (3) (a) 1. It is also revised to add that a request for a contested case hearing must follow the requirements in s. ATCP 1.06.

Appendix A: 3-A Sanitary Standards and Accepted Practices

Appendix A is updated to reflect 3-A Sanitary Standards and Accepted Practices effective on or before October 11, 2014.

Consolidating dairy farm and dairy plant regulations into one rule.

To minimize overlapping requirements and duplicative regulations, improve ease of use, and ensure consistent application of the rules, this rule revision consolidates and renumbers existing provisions from ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants) into the newly created ch. ATCP 65 (Milk and Milk Products.) The following describes how existing chapters were consolidated and renumbered into ch. ATCP 65. Subchapters, sections, and paragraphs were also retitled, as necessary, to maintain clarity.

Chapter ATCP 60, Dairy Farms

- ATCP 60.01, “Definitions,” are renumbered as follows:
 - ATCP 60.01 (1) and (1g) as ATCP 65.01 (6) and (7);
 - ATCP 60.01 (4) and (5) as ATCP 65.01 (10) and (11);
 - ATCP 60.01 (7) and (8) as ATCP 65.01 (13) and (15);
 - ATCP 60.01 (9) and (10) as ATCP 65.01 (18) and (16);
 - ATCP 60.01 (11) as ATCP 65.01 (23);
 - ATCP 60.01 (12) as ATCP 65.01 (26);
 - ATCP 60.01 (13) as ATCP 65.01 (30);
 - ATCP 60.01 (14) and (15) as ATCP 65.01 (31) and (34);
 - ATCP 60.01 (16) and (17) as ATCP 65.01 (35) and (38);
 - ATCP 60.01 (18) to (21) as ATCP 65.01 (42) to (46);
 - ATCP 60.01 (22) as ATCP 65.01 (40);
 - ATCP 60.01 (23) as ATCP 65.01 (51);
 - ATCP 60.01 (23m) as ATCP 65.01 (50);
 - ATCP 60.01 (23r) as ATCP 65.01 (56);
 - ATCP 60.01 (24) as ATCP 65.01 (63);
 - ATCP 60.01 (25) as ATCP 65.01 (66);
 - ATCP 60.01 (26) as ATCP 65.01 (67);
 - ATCP 60.01 (27) as ATCP 65.01 (69); and
 - ATCP 60.01 (29) as ATCP 65.01 (73).
- ATCP 60.02, “Milk producer license; fees,” is renumbered as ATCP 65.02 and remains largely unchanged except for the following:
 - ATCP 60.02 (2) (am), “Livestock premises registration,” has been incorporated into ATCP 65.02 (2)(a);
 - ATCP 60.02 (7) (b) and (c), “Producer shipping milk to more than one plant,” is largely deleted because it is duplicative of other provisions. Portions of ATCP 60.02 (7) (c) are renumbered as ATCP 65.02 (7);
 - ATCP 60.02 (7) (d), “Producer shipping milk to more than one plant,” was renumbered as ATCP 65.02 (8) and retitled “Milk produced for custom processing;”
 - ATCP 60.02 (8), “Temporary discontinuation of milk shipments,” is renumbered as ATCP 65.02 (9); and
 - ATCP 60.02 (9), “Dairy plant termination of milk producer,” is renumbered as ATCP 65.02 (10) and retitled, “Termination of a milk producer license.”

- ATCP 60.03 (1), "Grade "A" permit," is renumbered as ATCP 65.02 (11) and retitled "Grade A permit requirement."
- ATCP 60.03 (2) to (5) (a), "Grade "A" permit," is renumbered as ATCP 65.02 (13) to (16).
- ATCP 60.03 (5) (b), "Grade "A" permit" is renumbered as ATCP 65.02 (17).
- ATCP 60.03 (6), "Temporary discontinuation of milk shipments," is renumbered as ATCP 65.02 (18).
- ATCP 60.04 (1) and (2), "Reinspection fees" are renumbered as ATCP 65.02 (19).
- ATCP 60.05 (2), "Fee payment obligations; enforcement," is renumbered as ATCP 65.02 (20).
- ATCP 60.06. "Milking barn or parlor" is renumbered as ATCP 65.06.
- ATCP 60.07 (1) to (4), "Milkhouse," is renumbered as ATCP 65.08 (1) to (5).
- ATCP 60.08, "Water supply," is renumbered as ATCP 65.10, and retitled "Dairy farm water supply."
- ATCP 60.09, "Equipment and utensils," is renumbered as ATCP 65.12.
- ATCP 60.10, "Milking and milk handling systems," is renumbered as ATCP 65.14.
- ATCP 60.11 (1) to (4), "Bulk tanks and bulk transport containers," is renumbered as ATCP 65.16 (1) to (5).
- ATCP 60.12, "Milking procedure," is renumbered as ATCP 65.18.
- ATCP 60.13, "Abnormal milk; milking diseased animals," is renumbered as ATCP 65.20.
- ATCP 60.14, "Farm premises," is renumbered as ATCP 65.22.
- ATCP 60.15, "Milk quality standards," is renumbered as ATCP 65.70 and retitled "milk quality standards for milk collected from a dairy farm."
- ATCP 60.17 (1) to (3), "Collecting milk samples," is renumbered as ATCP 65.38 .
- ATCP 60.18 , "Bacteriological testing," is renumbered as ATCP 65.70 (2).
- ATCP 60.19 , "Drug residue testing," is renumbered as ATCP 65.72 .
- ATCP 60.20 , "Testing for somatic cells," is renumbered as ATCP 65.70 (4).
- ATCP 60.22, "Certified testers; test methods; reporting," is renumbered as ATCP 65.76 (2) to (4).
- ATCP 60.23, "Dairy plant operator to furnish producer milk samples to the department upon request," is renumbered as ATCP 65.78 (1) (e).
- ATCP 60.235, "Raw milk sales prohibited, exemptions," is renumbered as ATCP 65.52.
- ATCP 60.24, "Inspection of dairy farms; general," is renumbered as ATCP 65.910.
- ATCP 60.245 (1) to (4), "Performance-based Grade "A" dairy farm inspections," is renumbered as ATCP 65.912 (1) to (5).
- ATCP 60.25, "Suspension or revocation of milk producer license," is renumbered as ATCP 65.920.
- ATCP 60.26, "Suspension or revocation of grade A farm permit; general," is renumbered as ATCP 60.920 and retitled "Suspension or revocation of grade A producer permit or milk producer license."
- ATCP 60.27, "Violation of grade A milk quality standards; suspension of grade A farm permit by food division," is renumbered as ATCP 65.920.
- ATCP 60.275, "Drug residue violations; producer sanctions," is renumbered as ATCP 65.922 and retitled "Enforcement actions taken in response to drug residue violations."
- ATCP 60.28, "Violation of grade A farm standards; suspension of grade A farm permit by food division," is renumbered as ATCP 65.920.

- ATCP 60.29, "Suspension notice; requirements," is renumbered as ATCP 65.925.
- ATCP 60.30, "Holding orders; identification and disposal of adulterated milk," is renumbered as ATCP 65.927.
- ATCP 60.31, "Right of hearing," is renumbered as ATCP 65.928.

Chapter 80, Dairy Plants

- ATCP 80.01, "Definitions," are renumbered as follows:
 - ATCP 80.01 (1) as ATCP 65.01 (4);
 - ATCP 80.01 (1g) to (4) as ATCP 65.01 (7) to (9);
 - ATCP 80.01 (5) to (8) as ATCP 65.01 (12) to (15);
 - ATCP 80.01 (9) to (12) as ATCP 65.01 (18), (19), (21) and (22);
 - ATCP 80.01 (13) to (15) as ATCP 65.01 (24) to (26);
 - ATCP 80.01 (16) and (17) as ATCP 65.01 (28) and (29);
 - ATCP 80.01 (18) as ATCP 65.01 (31);
 - ATCP 80.01 (19) to (21) as ATCP 65.01 (35) to (37);
 - ATCP 80.01 (22), (23), and (23m) as ATCP 65.01 (40), (41), and (44);
 - ATCP 80.01 (24) to (31) as ATCP 65.01 (47) to (55);
 - ATCP 80.01 (32) to (33j) as ATCP 65.01 (57) and (60) to (62);
 - ATCP 80.01 (34), (35), and (36), and (39) as ATCP 65.01 (64), (66), (68) and (70); and
 - ATCP 80.01 (40) as ATCP 65.01 (71).
- ATCP 80.02 (1) to (8), "Dairy plant license," is renumbered as ATCP 65.04 (1) to (7).
- ATCP 80.04 (1) to (7), "Dairy plant fees," is renumbered as ATCP 65.04 (8) to (13).
- ATCP 80.06 (1) to (8), "Grade "A" dairy plant; permit," is renumbered as ATCP 65.04 (14) to (21).
- ATCP 80.08 (1) to (18), "Construction and maintenance," is renumbered as ATCP 65.24 (1) to (19).
- ATCP 80.10, "Personnel; sanitation standards," is renumbered as ATCP 65.26.
- ATCP 80.12, "Equipment and utensils," is renumbered as ATCP 65.28.
- ATCP 80.14, "C-I-P systems," is renumbered as ATCP 65.30.
- ATCP 80.16, "Dairy product packages," is ATCP 65.32.
- ATCP 80.18, "Sanitizers and sanitizing methods," is renumbered as ATCP 65.34.
- ATCP 80.20, "Receiving milk and dairy products," is renumbered as ATCP 65.36.
- ATCP 80.22, "Storing and handling milk and dairy products," is renumbered as ATCP 65.40.
- ATCP 80.24 (2), (3), and (3m), "Milk and dairy products; quality standards," is renumbered as ATCP 65.74 (1), (2), and (3) and ATCP 80.24 (1) is repealed.
- ATCP 80.26, "Milk quality testing," is renumbered as ATCP 65.76 and ATCP 65.84 (3)
- ATCP 80.28, "Persons authorized to perform milk quality tests," is renumbered as ATCP 65.76 (3) and ATCP 65.84 (1) and (2).
- ATCP 80.30, "Test samples," is renumbered as ATCP 65.78.
- ATCP 80.32, "Test methods," is renumbered as ATCP 65.76 (4) – (6) and ATCP 65.86 (1) and (2).
- ATCP 80.34, "Milk component testing devices," is renumbered as ATCP 65.86 (3).
- ATCP 80.36, "Milk quality test records and reports," is renumbered as ATCP 65.80.
- ATCP 80.38, "False samples, test results or reports," is renumbered as ATCP 65.82.

- ATCP 80.40 (1) and (2), “Definitions,” are renumbered as in ATCP 65.01 (32) and (33).
- ATCP 80.41, “Pasteurization required,” is renumbered as ATCP 65.54.
- ATCP 80.42, “Labeling pasteurized and unpasteurized products,” is renumbered as ATCP 65.56.
- ATCP 80.44, “Pasteurization time and temperature,” is renumbered as ATCP 65.58.
- ATCP 80.46, “Batch pasteurization,” is renumbered as ATCP 65.60.
- ATCP 80.48, “HTST and HHST pasteurization,” is renumbered as ATCP 65.62.
- ATCP 80.49, “Aseptic processing and packaging,” is renumbered as follows:
 - ATCP 80.49 (1), definition of “aseptic processing and packaging system” is moved to ATCP 65.01 (2); and
 - ATCP 80.49 (2) (a) and (b) are renumbered as ATCP 65.64 (1) and (2).
- ATCP 80.50, “Pasteurization records,” is renumbered as ATCP 65.66.
- ATCP 80.52, “Pasteurizer testing,” is renumbered as ATCP 65.68.
- ATCP 80.54, “Dairy plant records,” is renumbered as ATCP 65.44.
- ATCP 80.56, “Dairy plant reports to department,” is renumbered as ATCP 65.46.
- ATCP 80.58, “Confidential information,” is renumbered as ATCP 65.48.
- ATCP 80.60, “License suspension or revocation,” is renumbered as ATCP 65.926.
- ATCP 80.62, “Grade “A” dairy plant; compliance monitoring,” is renumbered as ATCP 65.930.
- ATCP 80.70, “Dairy product labeling,” is renumbered as ATCP 65.50.

Federal and Surrounding State Programs

Federal Programs

An important objective of this proposed rule is to modernize current dairy farm and dairy plant inspection rules to ensure compliance with federal PMO requirements. The PMO establishes minimum standards for regulation of Grade “A” dairy farms and milk products. States must set standards equivalent to, or more stringent than, those in the PMO and each state’s milk producers and dairy plants must meet these standards to be allowed to ship Grade “A” milk and milk products in interstate commerce. These rule changes will bring Wisconsin’s dairy farm and dairy plant regulations into further compliance with the 2013 revision of the PMO. An additional objective of this proposed rule is to ensure that Wisconsin-licensed dairy plants comply with applicable requirements of the federal Preventive Controls–Human Food rule implemented under FSMA.

Surrounding State Programs

Michigan, Minnesota, Iowa and Illinois adopt the PMO as part of their Grade “A” dairy-related statutes and regulations and therefore enforce Grade “A” dairy regulations similar to those enforced by Wisconsin. Unlike Wisconsin, none of the surrounding states have adopted performance-based farm inspection, as allowed by the PMO.

Data and Analytical Methodologies

The Department reviewed the 2011 and 2013 revisions of the PMO, federal regulations related to standards of identity, 3-A Sanitary Standards and Accepted Practices, results of an FDA audit of Wisconsin's Grade "A" dairy program, scientific data presented by the dairy industry, the Preventive Controls–Human Food rule implementing FSMA, and recent changes in Wisconsin statutes and rules to identify potential changes to the rule.

Standards Incorporated by Reference

Pursuant to s. 227.21, Stats., the Department requested and received permission from the Attorney General on March 23, 2015, to incorporate the following standards relating to milk and milk products into ATCP 65. A copy of these documents will be kept on file with the Department and the Legislative Reference Bureau.

"3-A Accepted Practices for the Design, Fabrication and Installation of Milking and Milk Handling Equipment," Number 606-05, 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D McLean, Virginia, 22101-3850, effective November 2002.

"3-A Sanitary Standards for Farm Milk Cooling and Holding Tanks," Number 13-11, 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D, McLean, VA 22101-3850, effective July 23, 2012.

"3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher Heat Shorter Time Pasteurizer Systems," Number 603-07, 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D McLean, Virginia, 22101-3850, effective November 21, 2005.

"Grade "A" Pasteurized Milk Ordinance (Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey—Supplement to the Grade "A" PMO)," Public Health Service, 2013 Revision.

Marshall, Robert T., "Standard Methods for the Examination of Dairy Products," American Public Health Association, 800 I Street, NW, Washington, D.C., 20001; 16th edition (1992).

"Official Laboratory Evaluation Forms (FDA-2400 Series)," Food and Drug Administration, US Department of Health and Human Services.
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>

"Official Methods of Analysis of AOAC International," AOAC International, 2275 Research Blvd., Rockville, Maryland, 20850. 18th edition (2005).

Wehr, Michael, "Standard Methods for the Examination of Dairy Products," American Public Health Association Inc., 800 I Street, NW, Washington, D.C., 20001; 17th edition (2004).

1 MILK AND MILK PRODUCTS

2 SUBCHAPTER I - DEFINITIONS AND GENERAL REQUIREMENTS

3 ATCP 65.01 Definitions

4 ATCP 65.02 Milk producer licenses and permits; fees

5 ATCP 65.04 Dairy plant licenses and permits; fees

6 SUBCHAPTER II -DAIRY FARMS

7 ATCP 65.06 Milking barn or parlor

8 ATCP 65.08 Milkhouse

9 ATCP 65.10 Dairy farm water supply

10 ATCP 65.12 Equipment and utensils

11 ATCP 65.14 Milking and milk handling systems

12 ATCP 65.16 Bulk tanks and bulk transport containers

13 ATCP 65.18 Milking procedure

14 ATCP 65.20 Abnormal milk; milking diseased animals

15 ATCP 65.22 Farm premises

16 SUBCHAPTER III -DAIRY PLANTS

17 ATCP 65.23 Federal requirements

18 ATCP 65.24 Construction and maintenance

19 ATCP 65.26 Personnel; sanitation standards

20 ATCP 65.28 Equipment and utensils

21 ATCP 65.30 C-I-P systems

22 ATCP 65.32 Dairy product packages

23 ATCP 65.34 Sanitizers and sanitizing methods

- 1 ATCP 65.36 Receiving milk and dairy products
- 2 ATCP 65.38 Collecting milk samples
- 3 ATCP 65.40 Storing and handling milk and dairy products
- 4 ATCP 65.41 Low-acid or acidified dairy products packaged in hermetically sealed containers
- 5 for non-refrigerated storage
- 6 ATCP 65.42 Recall plan
- 7 ATCP 65.44 Dairy plant records
- 8 ATCP 65.46 Dairy plant reports to department
- 9 ATCP 65.48 Confidential information
- 10 ATCP 65.50 Dairy product labeling
- 11 SUBCHAPTER IV - PASTEURIZATION
- 12 ATCP 65.52 Raw milk sales prohibited; exemptions
- 13 ATCP 65.54 Pasteurization required
- 14 ATCP 65.56 Labeling pasteurized and unpasteurized products
- 15 ATCP 65.58 Pasteurization time and temperature
- 16 ATCP 65.60 Batch pasteurization
- 17 ATCP 65.62 HTST and HHST pasteurization
- 18 ATCP 65.64 Aseptic processing and packaging
- 19 ATCP 65.66 Pasteurization records
- 20 ATCP 65.68 Pasteurizer testing
- 21 SUBCHAPTER V - SAFETY AND QUALITY STANDARDS
- 22 ATCP 65.70 Milk quality standards for milk collected from a dairy farm
- 23 ATCP 65.72 Drug residue testing

1 ATCP 65.74 Milk and dairy products; quality standards

2 ATCP 65.76 Milk quality testing

3 ATCP 65.78 Milk quality test samples

4 ATCP 65.80 Milk quality test records and reports

5 ATCP 65.82 False samples, test results or reports

6 ATCP 65.84 Milk component testing

7 ATCP 65.86 Milk component test methods

8 SUBCHAPTER VI - INSPECTION AND ENFORCEMENT

9 ATCP 65.910 Inspection of dairy farms; general

10 ATCP 65.912 Performance-based grade A dairy farm inspections

11 ATCP 65.920 Suspension or revocation of grade A producer permit or milk producer license

12 ATCP 65.922 Enforcement actions taken in response to drug residue violations

13 ATCP 65.925 Suspension notice; requirements

14 ATCP 65.926 Dairy plant license and grade A permit suspension or revocation.

15 ATCP 65.927 Holding orders; identification and disposal of adulterated milk

16 ATCP 65.928 Right of hearing

17 ATCP 65.930 Grade A dairy plants; compliance monitoring and inspection

18 SUBCHAPTER I

19 DEFINITIONS AND GENERAL REQUIREMENTS

20 **ATCP 65.01 Definitions.** In this chapter:

21 (1) "Abnormal milk" means milk that is visibly changed in color, odor, or texture, or milk
22 that contains chemical, medicinal or radioactive agents, which may be deleterious to human
23 health