

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Ch. ATCP 80, Wis. Adm. Code (Existing)

Relating to: Dairy plants, and affecting small business.

1. Description of the objective of the rule:

The department proposes a comprehensive review and revision of ATCP 80 relating to the food safety oversight of dairy plants in Wisconsin. The objective of this proposed rule is to modernize current dairy plant inspection rules in order to ensure compliance with federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), accommodate advances in manufacturing dairy products, and continue ensuring the safety and quality of Wisconsin dairy products. The department will also determine whether and the extent to which revisions are needed to harmonize Wisconsin regulations with federal risk-based preventive controls regulations implemented under the Food Safety Modernization Act.

2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:

Wisconsin has more than 400 licensed dairy plants. Grade A dairy plants produce pasteurized fluid milk and milk products such as cottage cheese, cream and yogurt made using Grade A milk from Grade A dairy farms. Grade A milk and milk products must be processed in accordance with standards in the FDA's PMO and are thereby eligible for interstate commerce. The PMO is a guidance document and ATCP 80 is in substantial compliance with it. Ninety-eight percent of the milk produced in Wisconsin is Grade A. Ch. ATCP 80 (Dairy Plants) is a comprehensive rule designed to address the specific challenges of manufacturing milk and dairy products and ensuring that these products are high-quality and safe to consume. ATCP 80 establishes milk bacteriological and compositional quality standards, sets pasteurization requirements, requires milk testing to measure whether these standards are met, and establishes procedures for testing milk and recording results. ATCP 80 also requires dairy plants to keep records of information needed to monitor the safety of their products, and ensure proper financial reporting. The rule also establishes inspection and enforcement requirements, including a requirement that Grade A plants be periodically audited against federal sanitation compliance standards. Finally, ATCP 80 includes labeling requirements for dairy products not sold for human food or animal feed.

Grade B dairy plants make products not covered under the PMO such as butter, ice cream and cheese. Grade B products may be made from either Grade A or Grade B milk. Grade B milk comes from farms that have less stringent bacteriological requirements and are inspected less frequently.

FDA revises the PMO every two years. The current ATCP 80 rules, although largely in compliance with the PMO, must be revised periodically to maintain the needed consistency with the latest version of the PMO and to adapt to new innovations in the dairy industry. For example, the most recently adopted PMO contains new requirements related to aseptic processing and packaging of dairy products which have not been incorporated in ATCP 80.

The department will consider a variety of potential rule changes which mainly, but not exclusively, involve maintaining consistency with the PMO, and relate to topics such as: the statutory definition of a dairy product; delineation of financial responsibilities for milk contractors and dairy plant operators; equipment and facility standards; evaluation of a plant's water supply; microbiological standards for different products; limits for operating a pasteurizer after a seal has been broken; and variance procedures.

As part of its overall review of Ch. ATCP 80, the department will explore provisions consistent with impending federal regulations (implemented under the Food Safety Modernization Act) that require food processing plants to conduct a hazard analysis and develop a risk-based system of preventive controls. The department may propose rule changes addressing this topic, as needed.

Policy Alternatives. FDA revises the PMO every two years and the department must periodically revise ATCP 80 to ensure substantial compliance with the PMO. If the department does not alter the current rule, the rule may not remain consistent with the PMO which could eventually lead to problems when the FDA audits the Wisconsin dairy inspection program for compliance. A failing regulatory audit score could jeopardize the ability of Wisconsin dairy producers and plants to participate in the Grade "A" program and to maintain Wisconsin's reputation as the Dairy State. Current regulations may not be adequate for addressing emerging food safety issues related to dairy processing.

3. Statutory authority for the rule (including the statutory citation and language): Statutory Authority: ss. 93.07 (1), 97.09 (4), and 97.20 (4), Stats.

93.07 Department duties. It shall be the duty of the department:

(1) REGULATIONS. To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, which regulations shall have the force of law.

97.09 Rules.

(4) The department may, by rule, establish and enforce standards governing the production, processing, packaging, labeling, transportation, storage, handling, display, sale, including retail sale, and distribution of foods that are needed to protect the public from the sale of adulterated or misbranded foods.

97.20 Dairy plants.

(4) **RULE MAKING.** The department may promulgate rules to establish the fees required under sub. (2) (c) to (2) (w) or to govern the operation of dairy plants. The rules may include standards for the safety, wholesomeness and quality of dairy products; the construction, maintenance and sanitary operation of dairy plants; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; storage and handling of milk and fluid milk products; pasteurization and processing procedures; sampling and testing; and reports and record keeping. The rules may also set forth duties of dairy plants to inspect dairy farms, collect and test producer milk samples and make reports to the department.”

4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:

DATCP estimates that it will use approximately 0.20 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, holding public hearings and communicating with affected stakeholders. DATCP will use existing staff to develop this rule.

5. Description of all entities that may be impacted by the rule:

Dairy plant operators will benefit from increased consistency of Wisconsin regulations with the PMO.

6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:

The proposed rule makes ATCP 80 more consistent with the PMO. Although compliance with the PMO is technically a voluntary effort by state regulatory agencies, Wisconsin is periodically evaluated by the FDA for compliance with the PMO. Failure to pass the FDA audit would jeopardize the state's interstate and international dairy industry.

7. Anticipated economic impact

This rule change is anticipated to have no negative impact, but a positive economic impact for Wisconsin's dairy industry. In many respects, it will make Wisconsin's regulations consistent with practices in other states, including those elsewhere in the Upper Midwest which adopt the latest version of the PMO by reference. The rule will not modify fees or have an economic impact on local governmental units or public utility taxpayers.

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Secretary

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