STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Chs. ATCP 88, 70, 71 and 75 Wis. Adm. Code (Existing)

Relating to: Egg grading, handling, packaging, labeling and retail sales

1. Description of the objective of the rule:

This proposed rule would modify ATCP 88, Wis. Adm. Code, related to egg grading, handling and labeling, thereby addressing concerns related to the viability of small agricultural operations, assurance of accurate egg marketing, and protection of public health. This revision may also modify ATCP 70, Food Processing Plants, ATCP 71, Food Warehouses, and ATCP 75, Retail Food Establishments, as needed to adopt appropriate provisions related to egg packaging and retail sales of eggs. The proposed rule would help businesses by clarifying licensing and inspection requirements, as well as safety, and sanitation requirements applying to the collection, cleaning, grading, packaging, and distribution of eggs. In particular, the proposed rule would: define licensing, facility and temperature-control requirements; remove obsolete provisions in the existing rule; provide explanatory text to improve rule clarity; and, modernize requirements to ensure consistency with existing federal and state egg safety regulations.

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:

History and background. Egg production is important to Wisconsin's agricultural economy. Wisconsin ranks 18th in the nation in egg production, producing 1.37 billion eggs each year. Wisconsin also ranks first in the nation in the number of farms producing organic eggs, a market that saw a 39 percent increase for Wisconsin farmers between 2008 and 2011.

Frequent phone and e-mail inquiries to DATCP indicate that ATCP 88 should be revised to clarify licensing and inspection requirements, particularly for egg producers who sell eggs at farmers' markets. In order to sell eggs at a farmers' market, an egg producer must hold the retail food establishment license required for selling processed items at retail. The retail food establishment regulations (ATCP 75) require foods sold at retail to be obtained from approved sources that comply with law. This requirement is interpreted to mean that washing and packing of eggs for retail sale must be done in a licensed food processing plant (under ATCP 70). However, this requirement is not clearly stated in statute or administrative rules and should therefore be clarified.

The existing Chapter ATCP 88 (Egg Grading, Handling and Labeling), created in 1996, consolidated and replaced an earlier version of Chapters ATCP 88 (Egg Grade and Quality Standards) and 89 (Eggs, Unfair Practices; which was repealed). The intent of consolidating egg-related rules is sound and will only be strengthened by the proposed rule. ATCP 88 should

be revised to reflect the needs of egg processors, including the need to clarify jurisdictional boundaries between state regulations and new federal rules related to flock management, sanitation, microbiological testing, and evolving food safety concerns related to eggs in general (e.g. transovarian infection of eggs with *Salmonella enteritidis*).

Proposed policies. One goal of the rule revision is to clarify existing requirements. For example, the proposed rule will explicitly state licensing requirements, and contain explanatory text added to improve the understanding of requirements associated with operating an egg processor (e.g. requirements related to wash water temperature, prohibiting the freezing of shell eggs and minimizing condensation). The proposed rule would also include modernized sections to replace obsolete or confusing language (e.g. out-of-print citations, unclear differentiation between mechanical and visual egg-evaluation systems), and more comprehensive requirements, replacing those that are only partially stated in ATCP 88 (e.g., control of domestic animals is mentioned in ATCP 88, but other pest control is addressed in ATCP 70) or are unclear (use of the undefined term "average ambient temperature"), making the rule difficult for producers to understand.

Working closely with industry representatives, DATCP will also explore whether specific facility, sanitation, and temperature-control requirements for eggs during post-collection handling, cleaning, grading, packaging, and distribution in the rule should be revised. DATCP will examine both federal regulations and egg-related regulations in force in other states to identify potential approaches that could be integrated into Wisconsin's egg rule to reduce health risks associated with egg processing and sales licensed by the department. DATCP will strive to ensure that any provision incorporated into a proposed rule is scale-appropriate and does not conflict or overlap with federal regulations generally applying to producers who sell eggs from egg-laying flocks of more than 3,000 birds. The consequences of flock infection, exacerbated by poor sanitation or temperature control, in these operations could have important public health implications. The department plans to continue to exempt licensing for eggs sold on the premises where the eggs are produced directly to household consumers and will evaluate options for licensing and inspection of egg producers selling their eggs directly to consumers at farmers' markets.

Policy Alternatives. If the department does not alter the current rules, there will continue to be confusion about licensing, facility, sanitation, and temperature-control requirements for the collection, cleaning, grading, packing, distribution, and off-farm sale of eggs. To the extent that sanitation and refrigeration are inadequate because of obsolete or unclear regulations, the risk of contaminated eggs causing salmonellosis increases.

3. Statutory authority for the rule (including the statutory citation and language):

Sections 93.07 (1), 97.09 (4), 97.29(1)(g) and 97.30(1)(b)(c), 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.

97.29 Food processing plants.

(1) Definitions. In this section:
(g) "Food processing" means the manufacture or preparation of food for sale through the process of canning, extracting, fermenting, distilling, pickling, freezing, baking, drying, smoking, grinding, cutting, mixing, coating, stuffing, packing, bottling or packaging, or through any other treatment or preservation process. "Food processing" includes the activities of a bakery, confectionary or bottling establishment, and also includes the receipt and salvaging of distressed food for sale or use as food. "Food processing" does not include any of the following:
8. Any other activity exempted by the department by rule.

97.30 Retail food establishments.

(1) Definitions. In this section:
(b) *Exemptions.* 1. A license is not required under this section for any of the following:
c. A retail food establishment which is exempted from licensing by the department by rule. If a restaurant or other establishment for which a permit has been issued under s. 254.64 is incidentally engaged in operating a retail food establishment at the same location, the department may exempt by rule the restaurant or establishment from licensing under this section. Rules under this subd. 1. c. shall conform to a memorandum of understanding between the department and the department of health services, under which the department of health services agrees to inspect the retail food establishment operations on behalf of 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 0.50 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, coordinating advisory committee meetings, holding public hearings and communicating with affected persons and groups. DATCP will use existing staff to develop this rule.

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

This rule will affect Wisconsin egg processors who sell eggs at locations other than where the eggs were produced. It will provide clear guidance for persons seeking to begin an egg business.

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:

In general, rules designed to ensure egg safety and consistent egg quality cover activities that include ensuring the health of a flock and sanitation at the farm; egg grading, sanitation, temperature control, packaging and labeling at egg processing facilities; and safe transportation, handling and storage of eggs for the retail sale. Federal egg regulations consist of a patchwork of rules involving several agencies that are each responsible for different portions in the continuum of activities designed to promote egg safety and consistent egg quality. One objective of this rulemaking process will be to more clearly differentiate Wisconsin's role from the jurisdiction of federal agencies in regulating egg packaging and sales.

Federal Egg Regulations

The Egg Products Inspection Act (Title 21 USC, Chapter 15) authorized USDA to create regulations (7 CFR Part 57) for egg processing operations. Egg processing operations generally make products other than shell eggs, such as pasteurized whole eggs and dried egg whites. Additional USDA regulations created under this act authorize at least yearly inspection of hatcheries and at least quarterly inspection of businesses that pack shell eggs for the ultimate consumer. As part of these inspections, USDA assures that egg packages are labeled "Keep Refrigerated" and stored at 45°F or less. For eggs moving in interstate or foreign commerce, federal law and regulations pre-empt state law and regulations relating to temperature control, quality or grade, condition, weight or quantity. A voluntary egg grading service is administered by USDA, using essentially the same egg grading standards currently contained in ATCP 88. Regulations governing the voluntary grading of shell eggs are found in Title 7, Part 56 of the Code of Federal Regulations.

Under the Federal Food, Drug and Cosmetic Act (Title 21 USC, Chapter 9), and the Public Health Service Act (Title 42 USC, Chapter 264), the FDA has enacted egg safety regulations that apply to shell egg producers (21 CFR 118) with 3,000 or more laying hens at a particular farm who are not selling all of the eggs directly to consumers. These regulations require egg producers to register with FDA and to develop a written *Salmonella enteritidis* prevention plan for each farm. The plan must address procurement of chicks, environmental testing, cleaning and disinfection, biosecurity, pest control, and egg refrigeration. The regulations also require testing of eggs for *Salmonella enteritidis*.

Federal and State Regulatory Roles

Various federal agencies regulate egg quality and safety. Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for activities related to disease control in flocks of laying hens; the Agricultural Marketing Service (AMS) is responsible for quality grading for shell eggs and the Shell Egg Surveillance program, which ensures eggs for sale meet Grade B or better standards; and the Food Safety and Inspection Service (FSIS) is responsible for inspecting egg products sold in interstate commerce and re-inspecting imported egg products. The U.S. Food and Drug Administration (FDA), on the other hand, is responsible for ensuring sanitation and safety control measures at the farm, monitoring safe handling and good manufacturing practices in shell egg packaging plants that do not use USDA's shell egg grading

service and for issuing recalls involving shell eggs or egg products inspected by either FDA or USDA.

State and local agencies typically are responsible for working in cooperation with FDA to inspect shell egg packaging plants that do not use USDA's shell egg grading service and for inspecting retail food establishments. Wisconsin currently regulates voluntary egg grading in plants that do not use USDA's shell egg grading service, egg packaging and warehouse activities, and retail sales of eggs.

7. Anticipated economic impact

DATCP expects the proposed rule to have only a positive economic impact statewide and locally. The rule revision is expected to assist both new and existing egg production businesses by clarifying licensing and inspection requirements. Since most egg businesses that wash, pack or sell eggs are already licensed and inspected, rule revisions are expected to result in no or minimal costs to these establishments. The rule will not increase licensing fees for egg washing, packaging or sales and the department will continue to exempt from licensing eggs sold directly to a household consumer on the premises where the eggs are produced. The expected rule revisions will have no economic impact on local governmental units or public utility taxpayers.

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