

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection

Rule No.: Chs. ATCP 70, 55, 65, 71, and 75 (existing)

Relating to: Food Processing Plants and Food Processing Provisions in Related Administrative Rules

1. Description of the objective of the rule:

This proposed revision of ch. ATCP 70, relating to food processing plants, will update Wisconsin's food processing standards, including incorporating, as necessary, new federal requirements designed to improve the nation's food safety system, updating certain sections and references related to food processing in retail food establishments, and make other changes, as necessary, to modernize Wisconsin's standards for food processing. The rule revision will examine provisions related to food processing found in chs. ATCP 55 (Meat and Meat Food Products), ATCP 65 (Milk and Milk Products), ATCP 71 (Food Warehouses and Milk Distributors), and ATCP 75 (Retail Food Establishments) to determine whether, and to what extent, these rules should also be revised.

Wisconsin is a national leader in food processing, serving as a home to many nationally recognized food manufacturing companies. According to the National Agricultural Statistics Service, industrial sales from food processing total \$67.8 billion each year and provides 259,600 jobs in Wisconsin. The Department of Agriculture, Trade and Consumer Protection ("Department") currently licenses over 2,000 food processing plants.

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:

Background - Chapter ATCP 70 establishes standards for all types of food processing and food wholesaling or distribution in Wisconsin except dairy plants and meat and poultry processing plants, which are covered under separate administrative rule chapters. Among other provisions, ch. ATCP 70 establishes requirements and standards for food processing plant licensing, construction and maintenance, personnel, equipment and utensils, safe water supply, food ingredients, food packaging and labeling, recall planning, along with specific requirements for canning and bottling facilities, fish processing plants and molluscan shellfish plants. Chapter ATCP 70 also sets the standards by which retail food establishments, primarily grocery stores and restaurants, may do a limited amount of wholesaling or distribution of non-meat or poultry and dairy products.

Chapter ATCP 70 must be both comprehensive enough to be applicable to a broad range of products, yet specific enough to provide useful guidance at the production level to both industry and regulators. The rule must also be consistent with the regulations of surrounding states and federal government regulations, primarily those of the United States Department of Agriculture ("USDA") and the Food and Drug Administration ("FDA"), in order to provide a level playing field for businesses operating in the State of Wisconsin and other states, to facilitate interstate sales of Wisconsin products.

Chapter ATCP 70 was renamed and published in 1989, but has been updated and revised frequently since then in order to keep pace with industry changes. The proposed rule revision will ensure ch. ATCP 70

remains current with changing federal requirements and emerging issues. Similar updates to modernize food safety rules have already been made to other administrative rules, including: (1) ch. ATCP 55, to reflect new USDA requirements and concerns about drug residues in livestock presented for slaughter; (2) ch. ATCP 65, to incorporate federal requirements promulgated under the federal Food Safety Modernization Act (FSMA) and changes made to the federal Pasteurized Milk Ordinance (PMO), which serves as the basis for all states' rules governing grade "A" dairy products shipped across state lines; (3) ch. ATCP 71, to clarify the range of activities that can be conducted in a food warehouse without the operator being required to obtain an additional food processing plant license; and (4) ch. ATCP 75, to incorporate the latest science-based and consensus best-practice requirements added to the FDA's Model Food Code.

Policy Proposals – The Department proposes incorporating by reference provisions of federal regulations that implement FSMA. Multiple subparts of *21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Human Food* dealing with preventive food safety systems have already been referenced in chs. ATCP 65 and 71. Since the majority of Wisconsin food facilities subject to this federal rule are licensed as food processing plants, similar referencing must be done in ch. ATCP 70. This revision will ensure that requirements for Wisconsin-licensed food processing plants not subject to the federal rule are also clearly stated.

The FDA recently updated *21 CFR 110, Current Good Manufacturing, Packing, and or Holding Human Food* as a subpart of *21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Human Food*. This subpart contains basic requirements related to food processing facilities, personnel, equipment and controls. The Department proposes to make any necessary reference to this subpart and / or other revisions to harmonize Wisconsin food processing plant regulations with these federal requirements.

The Department's Division of Food Safety was recently merged with the Department of Health Services' ("DHS") Food Safety and Recreational Licensing unit to form the Division of Food and Recreational Safety ("DFRS"). The merger transferred responsibility for inspecting restaurants to the Department from DHS, thereby consolidating responsibility for inspection of all retail food establishments in one agency. The Department will review and update ch. ATCP 70 to ensure the rule reconciles provisions related to food processing in retail food establishments, as necessary, to meet the newly expanded mission of DFRS.

Food businesses are increasingly likely to perform combinations of activities previously addressed by the two different agencies or by multiple rule chapters under one agency. To the extent possible, the Department proposes to clarify which license is required and which requirements are in effect for businesses conducting specific food activities. This will avoid unnecessary licensing and regulatory burdens.

The rule revision will also review and update ch. ATCP 70, as necessary, to ensure the rule is properly integrated with requirements found in recently adopted revisions to administrative rules for maple syrup and eggs, as well as with requirements for other types of specialty foods such as dairy and meat.

Other specific topics the Department plans to review and address, as necessary, during this revision include:

- Requirements for commissaries that supply food to vending machines and micro-markets. Modernization of definitions and criteria related to the use of chemical sanitizing compounds to sanitize surfaces in food processing plants.
- Updating the list of extended-run food processing activities for which daily cleaning and sanitizing are unnecessary.

- Specifying a food processing plant operator's responsibilities for evaluating whether cleaning and sanitizing are necessary after a processing line stoppage.
- Clarification of requirements for filing and obtaining process-authority approval of processes used in making acidified or low-acid canned foods.
- Updating, if necessary, of chemical and microbiological standards and Department approvals associated with ingredient, operations, and reclaimed water used in food processing plants.
- Clarification of finished product sampling and analysis requirements for bottling establishments.
- Updating raw material and ingredient recordkeeping requirements to be consistent with federal regulations and industry best practices.
- Updating requirements for food processing plants to prevent allergen cross-contact during food processing activities.
- Updating definitions, licensing requirements and exemptions, as well as processing and labeling requirements associated with processing of fish and molluscan shellfish.
- Reconciliation of inadvertently conflicting definitions and requirements.
- Corollary revisions to ATCP 55 (Meat and Meat Food Products), ATCP 65 (Milk and Milk Products), ATCP 71 (Food Warehouses and Milk Distributors), and ATCP 75 (Retail Food Establishments), as needed and only to the extent these administrative rules address food processing requirements.
- Examination of whether, and to what extent, ATCP 70 and ATCP 55 should be modified to accommodate federal rules that went into effect in March, 2016, and transferred authority for the inspection of Siluriformes fish, including catfish, from FDA to USDA.

As part of this comprehensive review, the Department may review and revise other provisions related to food processing, as authorized in ss. 93.09, 97.09 (4), or 97.29 (5), Stats., for food processing plants; s. 97.24 (3), Stats., for dairy products; s. 97.27 (5), Stats., for food warehouses; s. 97.30 (5), Stats., for retail food establishments; and s. 97.42 (4), Stats., for meat establishments; or as otherwise authorized by statute as necessary to update Wisconsin's food processing requirements.

Policy Alternatives -This rule revision is essential for ensuring Wisconsin's food processing industry stays current with prevailing industry practices for protecting public health and ensure Wisconsin's businesses are not subject to unique and outdated regulations. It will maintain consistency with federal requirements, and requirements in other states, and provide a level-playing field for Wisconsin businesses. It will protect public health and safety through implementation of current food safety practices.

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

The statutory authority for this rule revision includes ss. 93.07 (1), 93.09, 97.09 (4), and 97.29 (5), Stats., related to food processing plants. The applicable text of these statutes is set further below. The Department has similar rulemaking authority to revise other administrative rule chapters that may also include food processing provisions. This rulemaking authority includes, but is not limited to, s. 97.24, Stats. (Milk and milk products), s. 97.27, Stats. (Food warehouses), s. 97.30, Stats. (Retail food establishments), and s. 97.42, Stats. (Compulsory inspection of livestock or poultry, and meat or poultry products).

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

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.

93.09 Standards and regulations. (1) The department, after public hearing, may establish standards for the grade of food products and farm products and for receptacles therefor and may prescribe regulations governing the marks or tags which may be required upon food products or farm products or upon receptacles therefor, for the purpose of showing the name, address or serial number of the person producing or marketing the product or receptacle, the grade of the product or receptacle, the quality, quantity, type, variety, size, weight, dimensions or shape of the product or the quality, type, size, weight, content, dimensions or shape of the receptacle.

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. (5) RULE MAKING. The department may promulgate rules to establish the fees, required under sub. (3) (a) or (c) or to govern the operation of food processing plants. Rules may include standards for the construction and maintenance of facilities; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; food handling and storage; sanitary production and processing; and food sources and food labeling.

97.24 Milk and milk products

(3) RULES. The department, in consultation with the department of health services, shall issue rules governing the production, transportation, processing, pasteurization, handling, identity, sampling, examination, labeling and sale of milk and fluid milk products; the inspection of dairy herds, dairy farms and dairy plants; the issuing and revocation of permits to milk producers and milk haulers, and of licenses to dairy plants and milk distributors

97.27 Food warehouses

(5) RULE MAKING. The department may promulgate rules to establish the fees required under sub. (3) or to govern the sanitary operation of food warehouses. Rules may include any of the following:

- (a) Standards for the construction and maintenance of food storage facilities.
- (b) Standards for the storage, identification and handling of food.
- (c) Record-keeping requirements to show the length of time that food is kept in storage.
- (d) Freezing and temperature requirements applicable to frozen-food warehouses, frozen-food locker plants and cold-storage warehouses.

97.30 Retail food establishments.

(5) RULE MAKING. The department may promulgate rules to establish the fees required under sub. (3) or to govern the operation of retail food establishments. Rules may include standards for the construction and maintenance of facilities; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; food handling, display and storage; and food sources and food labeling.

97.42 Compulsory inspection of livestock or poultry, and meat or poultry products.

(4) RULES. The department may issue reasonable rules requiring or prescribing any of the following:

(g) Specifications and standards for location, construction, operation, facilities, equipment, and sanitation for any premises, establishment, or mobile facility where slaughter or processing is

carried on, including custom slaughtering of livestock or poultry and custom or retail processing of meat or poultry products.

(h) Conditions of sanitation under which meat or poultry products shall be stored, transported, or otherwise handled by any person engaged in the business of buying, selling, freezing, storing, transporting, or processing meat or poultry products.

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 :

The Department estimates that it will use approximately 0.20 FTE staff to develop this rule, including 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. The Department 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 food processors who produce products other than meat, poultry, or dairy for wholesale. It will also affect persons who produce a limited amount of food products, other than meat, poultry, or dairy, at retail establishments for wholesale. The rule specifically applies to persons who do canning, both of low-acid and acidified foods, bottling of water, juice, tree products, and other beverages and food products, fish and molluscan shellfish processors, and persons performing these operations in establishments licensed under different administrative rules, yet are still bound by the requirements of ATCP 70. The rule could also help those producers market their product in interstate and international commerce and could help Wisconsin's food processors develop and market new products.

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 :

Food Safety Modernization Act -- FSMA (P.L. 111-353) was signed into law on January 4, 2011 as a comprehensive reform of the food safety system. According to FDA, FSMA addressed five major components of the food safety system, including requiring FDA to develop comprehensive, prevention-based controls across the food supply to prevent food safety problems and allowing FDA to apply inspection in a risk-based manner and adopt innovative inspection approaches. It provided new mechanisms for ensuring the safety of imported foods. FSMA also gave FDA mandatory recall authority and expanded FDA's authority to detain food that is potentially in violation of the law and to suspend a food facility's registration. Finally, it established tools for strengthening collaboration between federal, state and local governments by directing FDA to improve training of state and local officials.

FDA has finalized several rules to implement FSMA. Most significantly for this proposed rule revision is *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR 117)*, which replaces *Current Good Manufacturing, Packing, and or Holding Human Food (21 CFR 110)*. 21 CFR 117 requires certain food manufacturing facilities to develop a written food safety plan to implement a risk-based preventive control system, which includes a hazard analysis to identify potential food safety hazards and preventive control systems to minimize or eliminate hazards. This rule revision will examine 21 CFR 117 to determine the extent to which establishments covered by ch. ATCP 70 are required to comply with these federal regulations and to incorporate requirements into ch. ATCP 70 as appropriate.

21 CFR 117 also replaced certain requirements previously found in 21 CFR 110 not related to FSMA requirements. This rule revision will also evaluate ch. ATCP 70 to ensure it accurately reflects these updated guidance and requirements for Good Manufacturing Practices, Equipment and Utensil

requirements, Structure and Grounds requirements, and Processing Controls as they are currently contained in 21 CFR 117.

Inspection of Siluriformes Fish -- In December 2015, USDA issued new regulations for inspection of Siluriformes fish, including catfish. The 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA) to include “catfish” as an amenable species under the FMIA, transferring responsibility for inspecting catfish from FDA to USDA. The 2014 Farm Bill further expanded the type of fish to be inspected by USDA to all fish of the order Siluriformes, which includes catfish among other types of fish.

Prior to the transfer, U.S. catfish processors, exporters, and importers had been subject to FDA’s seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 123) and requirements under the Food, Drug, and Cosmetic (FD&C) Act (76 FR 10437). Wisconsin-licensed fish processors also must comply with FDA’s seafood HACCP regulations as cited in ATCP 70 and 71. FDA’s regulations on current good manufacturing practices (21 CFR 110) and on recordkeeping and registration requirements (21 CFR part 1, subparts H and J) also applied. Imported fish and fish products were required to come from a country with an active memorandum of understanding with FDA that ensured the product was in compliance with an equivalent foreign inspection system and that the importer had written verification that fish and fish products were processed in accordance with FDA regulations. The new USDA regulations, which went into effect March 1, 2016, adapted existing meat inspection regulations to the inspection of Siluriformes fish, with a few modifications to accommodate the difference between fish and meat.

Although the new regulations transfer responsibility from FDA to USDA, the Department has been notified that inspection of Siluriformes fish will not become a component of the state’s meat inspection program, which is operated under a cooperative agreement with USDA. Nonetheless, Wisconsin plans to examine the new federal regulations to determine whether, and to what extent, Wisconsin’s food processing rules require modification to accommodate the new rules for inspection of fish of the order Siluriformes.

7. Anticipated economic impact

The Department expects the proposed rule to have only a minimal economic impact on Wisconsin’s food processing industry. Chapter ATCP 70 is an existing rule, and the focus of opening it is not to add to its scope, but to update it, reconcile it with existing rules, and clarify its provisions.

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