

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection

Rule No.: Chapter ATPC 57, Wis. Adm. Code (Existing)

Relating to: Inedible Animal By-Products

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only):

N/A

2. Description of the objective of the rule:

The objectives of the proposed rule revision are to:

- a. Consider adding, expanding, clarifying, or eliminating definitions. Revising the definitions section could provide clarity to the terms that are vague, either by re-wording or providing examples. Adding definitions could also promote consistency between applicable state and federal rules. For example, the term “Disinfected” is not defined in the current rule but is a required step in the transportation of dead animals and should be defined for clarity. Methods of chemical disinfection are defined in 9 CFR 325.21. The term “Adulteration and Misbranding” is not defined in the current rule, but is defined in relation to animal food, in 21 CFR 589. Clarifying definitions of business types may allow business diversification and expansion. For example, clarifying the definition of a truck transfer station might allow currently unlicensed businesses to become licensed for sorting animal carcasses for delivery to businesses covered in this rule chapter, e.g. renderers, as well as doing their current deliveries to landfills and other businesses not covered in this rule chapter.
- b. Consider adding definitions and requirements for smooth integration with relevant federal regulations. Federal regulations govern interstate commerce, while state rules cover activities within Wisconsin. Some federal regulatory definitions might be included in the rule to ensure a consistent regulatory landscape for industry. For example, the Food and Drug Administration (FDA) defines “renderer” and “adulteration and misbranding.” The United States Department of Agriculture (USDA) defines “transportation and other transactions” concerning dead, disabled, dying, or diseased livestock. The USDA also spells out detailed requirements for transportation, labeling, and denaturing of carcass and carcass materials, whereas animal feed and its ingredients are regulated by the FDA. While the USDA and FDA regulations apply to interstate commerce, the ATPC 57 rule governs intrastate activities. The goal for revising definitions and requirements is to achieve uniformity across federal and state regulations.
- c. Consider updates and revisions to more specifically define existing general standards for facility construction, maintenance, equipment, sanitation, water supply, lighting, and record-keeping to ensure inedible byproducts made are suitable for intended use. For example, the current rule does not indicate how licensees are to verify that their water supply is potable and from a compliant source. The current rule is silent on lighting requirements to be met when ensuring a facility can be

operated safely or easily cleaned. The existing requirement for a self-draining floor does not indicate what types of drainage systems or floor materials are acceptable and prevent improper waste disposal. The Department will consider various effective dates for any requirements that are made more specific. Options could include various calendar dates, e.g. 1 year or 3 years from date of rule revision, or; an effective date coincident with licensing under a new owner.

- d. Consider adjusting language to include current and emerging business models, which have not been accounted for as the rule has not been updated since 2008. For example, dead animal collectors are prohibited from transporting animals except to specific types of businesses. The Department may consider adding additional types of locations where dead livestock may be transported.
- e. Consider clarifying language exempting biofuel producers from a grease processor licensing requirement. This exemption is arguably beyond the scope of the Department's licensing and regulatory authority.
- f. Review code citations to ensure references are current.
- g. Consider incorporating criticality ranking criteria for Department staff to use in identifying violations that pose a greater risk to human or animal health.
- h. Consider truck transfer licensing reciprocity with surrounding states in accordance with Wisconsin statute.
- i. Consider clarifying the way the Department identifies and documents operating deficiencies.
- j. Consider developing an efficient variance process by which an applicant or licensee may attain initial or renewed Department approval of alternative construction, equipment, processing or procedures that meet the public health and safety objectives of existing rule requirements.
- k. Update the Division name throughout the rule to reflect the name change that occurred in 2016.

3. Description of existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Department of Agriculture, Trade and Consumer Protection licenses and regulates inedible animal by-products pursuant to Wis. Stat. Ch. 95 and Wis. Admin. Code Ch. ATCP 57. Ch. ATCP 57 has not been significantly updated since November 2008. During the intervening time, the Code of Federal Regulations (CFR) has been updated to include federal regulations implementing the Food Safety Modernization Act (FSMA) and related to the production of animal food, and preventing the transmission of prions (causative agent of Bovine Spongiform Encephalopathy, a.k.a. BSE or "mad cow disease) in animal feeds.

Further, general changes to the rule are needed because it has not kept pace with changing technology and innovations in the businesses of rendering and processing of dead animals and their by-products.

The collection and transportation of dead, dying, disabled, or diseased livestock and other byproducts (such as grease) are changing as operators adopt new operational models not covered by the existing rule. Currently, these dead animal collectors are prohibited from transporting animals except to specific types of businesses. The Department may consider adding additional types of locations where dead livestock may be transported, in order to facilitate a more robust industry, so long as these additional locations are licensed

and adhere to all statutory and regulatory requirements intended to protect animal health and ensure clean operations.

The current rule contains an exemption from licensing for persons solely engaged in bio-fuel production. The materials produced by bio-fuel manufacturers often also include grease sold to brokers, who then market the grease for animal feed or other products for human and animal consumption. According to statute, this grease production should only be done under a license. The Department should consider revisions to the licensing requirements for these businesses in the rule.

Renderers from nearby states doing business in Wisconsin are required to hold a Wisconsin license when needing a transfer station for shipment of dead animals out of Wisconsin. The Department may consider how the out of state license might be given consideration in obtaining the Wisconsin license.

An undesirable alternative to updating the rule would be to continue as is, attempting to continue applying the existing rule to new methods, innovations, and trends not addressed or permitted under the existing rule. By continuing to regulate under the existing rule, the Department would be unable to address emerging threats and conditions and may be unnecessarily complicating the regulatory landscape for business operators.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

Subsection 95.72 (2), Stats., provides statutory authority for the licensing of businesses that collect or process dead animals as a renderer, animal food processor, grease processor, or collector. Subsection 95.72 (5), Stats., gives the Department specific rulemaking authority for the “collection, transportation, processing, rendering and disposal of dead animals, entrails and paunch materials, the slaughtering of animals for animal food processing or rendering, the location, construction and maintenance of all buildings, facilities and equipment used in collecting, slaughtering and processing operations, the sale or use of dead animal products as food for animals, the issuance of licenses or permits and other rules for the conduct of operations subject to a license under this section.”

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

The Department estimates that the work associated with developing and promulgating the proposed rule, including conducting advisory group meetings, will require approximately 0.10 FTE of staff time.

6. List with description of all entities that may be affected by the proposed rule:

Entities that may be affected by the proposed rule include:

- Dead Animal Collectors: Persons who collect and transport whole carcasses for delivery to a renderer, animal food processors, or fur farm operator.
- Renderers: Persons who apply heat to carcasses and carcass materials to produce byproducts for non-food use.
- Animal Food Processors: Persons who slaughter animals or process carcasses or carcass materials for use as animal feed.
- Grease Processors: Persons who take fully rendered products to produce grease or other products for non-food use.

- Carcass Dealers: Persons who sell, distribute, or broker for sale, carcasses or carcass materials.
- Fur Farm Operators, who purchase carcass materials to feed mink.
- Farmers: Farming operations may be affected by rule changes that lead to increases or decreases in the currently-limited number of animal food processors that pick up and dispose of dead animals. Service availability may affect costs charged to farmers.
- Retail Food Establishments, who may pay for removal of meat byproducts.
- Meat Establishments, who may pay for removal of carcasses and carcass materials.

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

Title 9 of the federal CFR contains regulations enforced by the USDA – Food Safety and Inspection Service. 9 CFR Part 325 addresses transportation and other transactions concerning dead, dying, disabled or diseased livestock, and parts of carcasses of livestock that have died otherwise than by slaughter. Importantly, these regulations apply to livestock that are legally “in commerce” as defined by USDA. As such they may not be applicable to all Wisconsin businesses handling carcasses and carcass materials. In addition, these federal regulations do not overlap requirements of ATPCP 57. 21 CFR contains applicable FDA regulations, namely Subchapter E. Animal Drugs, Feeds, and Related Products. Of particular relevance, 21 CFR Part 589 address substances prohibited from use in animal food or feed. The combination of USDA and FDA regulations (9 CFR Part 325 and 21 CFR Part 589, respectively) is intended to prevent the spread of Transmissible Spongiform Encephalopathies (TSE’s; caused by prions) via animal food or feed. There is little overlap of these regulatory requirements and those of ATPCP 57. Regulations implementing the FSMA address a broader range of hazards besides TSE-causing prions, and require animal food facilities to have a food safety plan in place that includes a hazard analysis, and the implementation of risk-based preventive controls to minimize or prevent those hazards identified as known or reasonably foreseeable. The FSMA requirements are found in 21 CFR Part 507 and generally do not overlap with requirements in ATPCP 57.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

The Department expects the proposed rule to have a positive impact on most stakeholders because it will give more flexibility in businesses meeting the rule requirements. For example, licensed businesses may become able to use alternative systems for collecting, stockpiling, and transporting carcasses and carcass materials under a revised rule. There may be some cost for licensing for certain, previously unlicensed, dead animal collection businesses, specifically if these operators will be required to hold a license in order to collect animals that move into the rendering, animal food processing realm. Pursuant to current requirements for licensing in Wis. Stat. s. 95.72 (2) (c), the cost would be \$100 per business per year. However, there would likely be only a small number of persons requiring such a license and the Department does not anticipate a significant fiscal impact from the proposed rule revisions. In these cases, the cost of licensing would likely be offset by the revenue gained from an expanded business model that allows for a range of animal carcass dispositions.

Some existing licensed businesses may incur facility upgrade costs if standards are made more specific. These costs are expected to range from small or moderate, e.g. conducting an annual water test or adding light fixtures, to more significant, e.g. repairing floor concrete or improving floor drainage.

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