



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
Secretary-designee Randy Romanski

DATE: April 29, 2021

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Randy Romanski, Secretary
Steve Ingham, Division of Food and Recreational Safety Administrator

SUBJECT: ATCP 57, Inedible Animal By-Products

PRESENTED BY: Steve Ingham

REQUESTED ACTION:

At the May 13, 2021, Board meeting, the Department will request approval of a scope statement for revision of ch. ATCP 57 (Inedible Animal By-Products). Chapter 95 in statute authorizes DATCP to promulgate rules relating to renderers, animal food processors, grease processors, dead animal collectors, and carcass dealers that are licensed or registered by the Department. ATCP 57 describes requirements for licensing or registration, facilities and practices at these businesses, transporting and denaturing carcasses and carcass materials, and labeling processed products. The rule also spells out several prohibitions related to uses of processed inedible animal by-products.

SUMMARY:

DATCP licenses renderers, animal food processors, grease processors, and dead animal collectors, and registers carcass dealers under authority of ch. 95 of the Wisconsin Statutes. The activities regulated by ch. ATCP 57 serve an overlooked but essential part of the animal agriculture sector. It is essential that these activities are done in a way that does not create a public nuisance, degrade the environment, or inadvertently transmit animal diseases such as Bovine Spongiform Encephalopathy (BSE or “mad cow disease”). Rules for these businesses are spelled out in ch. ATCP 57.

Chapter 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 BSE) in animal feeds. Further, the rule has not kept pace with changing technology, innovations, and operational models. For example, dead animal collectors are currently prohibited from transporting animals except to specific types of businesses. The addition of other types of licensed locations to which dead livestock may be transported may provide further business opportunities.

On February 19, 2021, the Governor approved a Scope Statement allowing consideration of revising ATCP 57. The Department held a virtual preliminary public hearing on the Scope Statement March 15, 2021, and had an

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open comment period from to March 15 through March 29, 2021. Eleven people attended the hearing. One company sent several representatives to the hearing, submitted five pages of written comments, which is attached.

Board approval of the Scope Statement will allow the Division of Food and Recreational Safety to begin preparing a hearing draft of ATCP 57. The comments received at the preliminary public hearing will be considered in the preparation of the hearing draft.

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STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection

Rule No.: Chapter ATCP 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 ATCP 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:

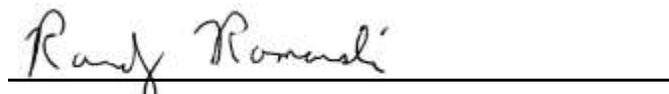
Title 9 of the federal CFR contains regulations enforced by the USDA – Food Safety and Inspection Service. 9 CFR Part 325 addresses transportation and other transactions concerning dead, dying, disabled or diseased livestock, and parts of carcasses of livestock that have died otherwise than by slaughter. 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 ATCP 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 ATCP 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 ATCP 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.

Contact Person: Steve Ingham, Administrator, Division of Food and Recreational Safety; (608) 224-4701



Randy Romanski
Secretary-designee
Department of Agriculture, Trade and Consumer Protection

Date: January 11, 2021

March 26, 2021

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Re/Attn: Statement of Scope for Proposed Rule Revision of Chapter ATCP 57

Dear Ms. Jeidy,

Darling Ingredients Inc. ("Darling") appreciates this opportunity to submit comments in response to the Statement of Scope as the Department of Agriculture, Trade and Consumer Protection ("DATCP") considers revisions to Chapter ATCP 57 of the Wisconsin Administrative Code relating to Inedible Animal By-Products.

Darling is a global company, with operations on five continents, that develops and produces sustainable natural ingredients from edible and inedible bio-nutrients to create a wide range of ingredients and customized specialty solutions for customers in the food, pet food, pharmaceutical, feed, industrial, bioenergy and fertilizer industries. In the United States, Darling is a leading provider of rendering, used cooking oil and bakery residual recycling and recovery solutions to the food industry and operates more than 120 processing and transfer facilities. Rendering facilities in Berlin, WI; Clinton, IA and Blue Earth, MN and truck transfer stations located in Eau Claire, WI and Hazel Green, WI provide animal mortality and slaughter byproduct collection and rendering services in Wisconsin.

The rendering industry, including Darling, is heavily regulated by various state and federal agencies. The Food and Drug Administration (FDA) regulates finished rendered products that are used in animal food. Key regulations FDA enforces include, but are not limited to, 21 CFR §589.2000 and §589.2001 (BSE feed rules); 21 CFR Part 507 (the Food Safety Modernization Act or FSMA); 21 CFR §§1.900 through 1.934 (Sanitary Transportation of Human and Animal Food). In addition, state agencies such as the Agrichemical Resource Management Division of DACTA, also regulate rendered products used in feed or in fertilizer, which are the two primary uses for animal proteins, such as meat and bone meal. Rendering facilities are required to register with the Food Safety Inspection Service (FSIS), which verifies the food defense plans for rendering facilities to insure that condemned meat and meat byproducts are rendered so they cannot re-enter the human food chain. The Animal and Plant Health Inspection Service (APHIS) relies on rendering facilities for help in disease surveillance as well as disease control.

Because Darling must comply with all these different federal and state agencies, we ask the DATCP to avoid being prescriptive as the proposed rule revisions are developed. Such a non-prescriptive approach allows industry to develop policies, practices and safeguards that best fit the facility and business culture of the company as it complies with the various regulations. The FDA was nonprescriptive

in its FSMA regulations. The same procedures developed for a facility to comply with FSMA may also comply with state food safety regulations if the DACTP takes a similar approach.

Statement of Scope part 2 a

In the Statement of Scope, the DATCP stated it is considering adding, expanding, clarifying or eliminating definitions. We agree that defining important terms used in regulations is critical to be sure the regulated industry and regulatory staff each understand what is required. Some specific examples include:

- The term "disinfectant" is used as a specific example of a term that is not defined in the current Inedible Animal By-Products rule. Darling agrees this term should be defined, but we encourage the DATCP to avoid prescribing specific disinfectants or limiting allowable disinfectants to those listed in 9 CFR 325.21. Other disinfectants already in use by the industry are effective at sanitizing trailers used to transport raw animal byproducts and dead animal remains. Additionally, at times APHIS may require renderers to use specific disinfectants to help prevent the spread of infectious diseases that may be present in an area or region.
- Darling also agrees the term "*truck transfer station*" should be more clearly defined to separate the regulatory standards for *truck transfer stations* from rendering facilities and grease processors. *Truck transfer stations* are especially important to renderers that run routes to collect livestock that die on farms. Renderers use such *transfer stations* to extend the reach of the rendering plant and to improve raw material collection efficiency. *Truck transfer stations* we use in Wisconsin do not process, grind, cook, decant, separate, hold and/or store raw material. Instead they are primarily used to consolidate raw material loads from the small trucks used to run raw material routes over to large trucks, which transport the raw material to the rendering plant where it is sorted, ground, cooked, fat and solids separated and the finished rendered products stored. In some cases, a *truck transfer station* will also have one or more tanks dedicated to finished rendered animal fat or yellow grease produced by the rendering plant linked to the station. Such tanks are separate from the raw material receiving and transfer areas and hold only finished fat that will be distributed to individual farms for use in animal food. The finished fat is transported from the rendering plant or distribution tank in truck tankers dedicated for finished product transport and distribution.

The only employees at these *truck transfer stations* are the truck drivers. We typically have only two drivers at a site just long enough to transfer loads, which takes only two or three hours each day. The *transfer station* will be vacant and idle for the rest of the day, so to be cost effective, stations will have minimal facilities and only essential utilities. Therefore, *truck transfer stations* should not be held to the same standard as a rendering plant that receives animal remains from several different *transfer stations* as well as

animal byproducts, fat and bone. A rendering plant will receive and process several million pounds of animal byproducts and animal remains each week.

The FDA recognizes that raw materials for rendering, such as dead animal remains and animal byproducts, which may be laden with microbial pathogens and have begun decomposing, should not be held to the same sanitation standards as finished rendered products.¹ FDA does not consider such raw materials to be adulterated during transport because the materials are destined to be further processed at the rendering plant and the hazards controlled. *Transfer stations* are an extension of the raw material collection and, in some cases, finished fat distribution system. When raw materials enter the facility, the same raw material leaves the facility. The only difference is the size of the truck coming in compared to the one going out. The *truck transfer station* is not intended to control biological hazards or affect chemical or physical contaminants. The rendering plant is the point of control and if such hazards cannot be controlled, the material cannot be used in animal feed and the rendering plant will dispose of the material. Thus, *truck transfer stations* have a very different function compared to rendering or grease plants and should not have to meet the same standards and requirements expected of these processing facilities.

- The definition used for grease in ATCP 57.01(16), which excludes any fat or oil used to cook food, is potentially in conflict with the definition for yellow grease adopted in 2018 by both the FDA and the Association of American Feed Control Officials (AAFCO). According to AAFCO, the feed ingredient **Yellow Grease, Feed Grade** is rendered fat from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation.

Statement of Scope part 2 b

Darling agrees with the goal for revising definitions and requirements to achieve uniformity across federal and state regulations. The FSMA was a sweeping food safety legislation that shifted the FDA's regulatory philosophy from reactionary to preventive. Now that the FDA has implemented most of the planned regulations under FSMA, it makes sense to review state food safety regulations. We suggest, however, that consistency across state and federal regulations may be more important than uniformity.

Statement of Scope part 2 c

This section of the Statement of Scope proposes updating and revising current general standards for facility construction, maintenance, equipment, sanitation, water supply, lighting and record keeping. We would like to remind the DATCP that the FDA addresses these areas as

¹ Preamble to 21 CFR Parts 1 and 11. Sanitary Transportation of Human and Animal Food; Final Rule. Federal Register April 6, 2016. Volume 81 (Number 66): Page 20128

prerequisite programs or CGMPs in 21 CFR §§ 507.17 through 507.25. We also request the DATCP be cognizant of the cost associated with making capital improvements or changes to existing rendering facilities as the FDA did in Draft Guidance regarding requirements for plant size, construction and design²: “We do not expect existing plants to be redesigned and reconstructed to meet the requirements in 21 CFR § 507.17(b). Maintenance, repair, retrofitting or other changes to the existing facility, equipment or plant procedures may be used to meet the requirements”. The Darling facilities that service Wisconsin are in compliance with 21 CFR § 507.17(b) and other applicable parts of 21 CFR Part 507.

We also ask that the DATCP change the record retention requirement for Renderers in ATCP 57.10(12)(b) from 3 years to 2 years. The FDA requires that records pertaining to BSE safeguards be kept for 2 years after the date they were prepared. The FSMA record retention requirement for animal food, in 21 CFR § 507.208, is also 2 years after the date the records are prepared. Retaining records for 3 years or longer is required only to support the status of a qualified facility or records that relate to the general adequacy of equipment or processes used at the facility. Harmonizing the record retention requirement in ATCP 57.10 with FDA requirements will avoid confusion for renderers operating in the state.

Statement of Scope part 2 e

We believe grease processors, renderers and/or processors of used cooking oil collected from restaurants and food service establishments are important sources of feedstock to biodiesel producers. In addition, biofuel producers should be regulated by sections within the DATCP if the biodiesel producer sells crude glycerin for use in animal food. Crude glycerin is a byproduct of biodiesel production. Because it was being used in animal food, the FDA and AAFCO adopted **Biodiesel-Derived Glycerin** as a feed ingredient in 2016. Biodiesel-derived glycerin must be derived from sources of fatty acids compliant with the term “feed grade” and, if animal fat of ruminant origin is used, the fat cannot contain more than 0.15% insoluble impurities. Darling believes that only facilities that are registered with the FDA are eligible to make feed grade fat or other feed grade products such as biodiesel-derived glycerin.

Summary

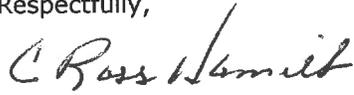
Darling supports the DATCP proposed review and revision of the Inedible Animal Byproducts rule. We especially support standards for *truck transfer facilities* that are different from and less demanding than standards for rendering or grease processing facilities. We agree with the need to have consistency between state and federal regulations. The FDA made a landmark shift with preventive food safety regulations under FSMA. The FDA has already addressed a number of areas identified in 21 CFR Part 507, especially in Subpart B which

² Guidance for Industry #235. Current Good Manufacturing Practice Requirements for Food For Animals. Draft Guidance. August 2016. Page 15.

addresses the CGMPs. We hope the DATCP will follow the FDAs lead in preparing state regulations that are consistent rather than in conflict with federal regulations.

Darling appreciates the opportunity to submit these comments and looks forward to reviewing the proposed regulations when they are available.

Respectfully,

A handwritten signature in black ink that reads "C. Ross Hamilton".

C. Ross Hamilton, Ph.D.

Vice president Government Affairs, Technology and Biosecurity

- Cc: Mr. Rick Elrod, Executive Vice President
Mr. Mike Molini, Senior Vice President, Midwest
Mr. William Fosdick, Regional Vice President
Mr. Scott Krueger, General Manager
Mr. Guy Murphy, General Manager