DATCP Docket No. 13-R-07
Rules Clearinghouse No. 14-024

ORDER OF THE WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION ADOPTING RULES

The Wisconsin department of agriculture, trade and consumer protection hereby adopts the following rule ***to renumber*** ATCP 55.02 (1), ***to amend*** ATCP 55.07(6) and (7)(f) and ***to create*** ATCP 55.02 (1) and 55.07(6) (d) and (Note); ***relating to*** drug residues in animals for human food, and affecting small business.

Analysis Prepared by the Department of Agriculture, Trade and Consumer Protection

The Department of Agriculture, Trade and Consumer Protection (DATCP) adopts this rule revision for ch. ATCP 55, Wis. Adm. Code, specifying corrective actions that must be imposed by state-licensed meat establishments on certain livestock producers before the establishment operator accepts animals from the producer for slaughter. The required corrective actions apply to livestock producers who on two or more occasions during the past year submit animals to be slaughtered at a state or federally inspected meat establishment, which yield carcasses testing positive for any illegal drug residue.

Statutes Interpreted

Statute Interpreted: s. 97.42, Stats.

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), and 97.42 (4) Stats.

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The department has specific authority to promulgate rules related to compulsory inspection of animals, poultry and carcasses under s. 97.42 (4), Stats., which allows the department to establish rules related to the inspections before and after slaughter of all animals and poultry killed or dressed for human consumption at any establishment.

Related Statutes and Rules

Wisconsin's state meat and poultry inspection program is governed by ch. 97, Stats. (Food Regulation), including s. 97.42, Stats. (Compulsory inspection of animals, poultry and carcasses). Chapter ATCP 55 interprets and implements ch. 97, Stats., as it relates to Meat and Meat Food Products.

State meat and poultry inspection programs operate under a cooperative agreement with the USDA's Food Safety and Inspection Service (FSIS) to provide inspection services to small and very small meat establishments. State meat and poultry inspection programs were established by the Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968, which amended the Federal Meat Inspection Act (FMIA) to create 21 USC 661 and the Poultry Products Inspection Act (PPIA) to create 21 USC 454. Section 11015 of Title XI of the Food, Conservation, and Energy Act of 2008 (the 2008 "Farm Bill"), enacted on June 18, 2008, amended FMIA and PPIA to establish a new voluntary program that allows certain selected state-inspected meat establishments to sell their products in interstate commerce.

Title 9, Animal and Animal Products, of the Code of Federal Regulations (CFR) interprets and implements the federal FMIA and PPIA. Section 97.42 (4m), Stats., and ch. ATCP 55 adopt certain relevant sections of Title 9 that establish slaughter and processing standards for meat and meat products.

Plain Language Analysis

Medications are important for maintaining healthy livestock. However, if medications are not carefully managed, illegal drug residues may remain in animals submitted for slaughter. Residues of medications in meat, particularly antibiotics and anti-inflammatory agents, can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The anti-inflammatory drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as those needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by USDA-FSIS to check the published Residue Repeat Violators list. The list identifies livestock producers whose animals have yielded carcasses which had positive tissue drug residue test results at two or more times in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture industry is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

Currently ATCP 55 (Meat and meat food products) addresses the production of meat and meat food products starting with the submission of an animal for slaughter for human consumption and, by reference, adopts United States Department of Agriculture regulations prohibiting the

slaughter of "downer" (non-ambulatory) cattle for human food or feed destined for bovine animals.

Current rules prohibit slaughter of a food animal for human consumption or submission of a food animal for slaughter if the person knows or has reason to know the animal is diseased or injured. This rule further prohibits someone from slaughtering or submitting for slaughter a food animal for human consumption if they know or have reason to believe that the animal will yield an adulterated carcass. The rule adopts the definition for adulterated, as applied to a carcass, which is already contained in federal regulations pertaining to slaughter operations. According to this definition, a carcass containing violative drug residues is considered adulterated. The rule then clarifies that the slaughter of animals presented by producers who have been included on the USDA Residue Repeat Violator List for Use by Livestock Markets and Establishments is not prohibited if the producer provides written evidence that they have completed a course on proper administration of animal medications. The department will approve an acceptable course or courses. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The rule also revises ATCP 55.07 (7), which requires a person who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. This rule revises the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the date of delivery, the delivery method, and the withdrawal time following delivery of all drugs provided as treatments or feed additives has complied with a veterinarian's prescription or the manufacturer's recommendations (over-the-counter drugs). This revision acknowledges that some drugs may require a longer withdrawal time than 30 days, and that withdrawal time may differ according to the method by which the drug is delivered to the animal.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Meat and poultry establishment operators must develop a plan to monitor and document that each of these key steps is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected establishment operators are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues.

One approach for minimizing drug residue risks is for slaughter facility operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is a potential indicator of whether an animal may have a drug residue problem, federal plants are expected to consult the federal Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. This list is compiled as part of the National Residue Program (NRP) at FSIS, which has collected data on

drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

State meat inspection programs operate under a cooperative agreement with the USDA-FSIS. Under this agreement, state meat inspection programs are required to adopt regulations that are "at least equal to" federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the "same as" federal meat inspection regulations.

The rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. It will enhance the effectiveness of oversight by requiring an additional educational corrective action that would be required of the producer by the slaughter facility operator well before federal regulatory action is needed.

Comparison with Rules in Adjacent States

Michigan currently does not operate a state meat and poultry inspection program and all meat processed for wholesale in Michigan is federally-inspected by USDA. Illinois' state meat inspection program includes USDA's Federal-State Cooperative program (formerly known as the "Talmadge-Aiken" program). Under this program, state inspectors conduct federal inspections. Minnesota and Iowa operate state meat inspection programs. All processors of meat and meat products, whether operating under state meat-inspection programs or under the USDA program, are expected to minimize the risk associated with drug residues and are expected, but not required in regulation, to consult the USDA's Residue Repeat Violator List for use by Livestock Markets and Establishments before accepting animals for slaughter. The approach in this rule revision is innovative and goes beyond requirements in neighboring states which operate state meat inspection programs. Although enforcement of the provisions in the rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

Summary of Factual Data and Analytical Methodologies

These rule changes were developed after careful analysis of federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. The department consulted with a large livestock medication and veterinary services company, and with the Wisconsin Veterinary Medical Association before developing the rule. Both entities supported the intent of the rule.

Effect on Small Business

This rule change is anticipated to have little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the

USDA Residue Repeat Violators List and, if a producer is on the list, determine whether the mandatory corrective action has been taken. Since very few livestock producers from Wisconsin and neighboring states are on this list, the rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarian. There will be a slight short-term negative economic impact on livestock producers who must attend a course and improve documentation of animal medications as a result of the rule. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian. To the extent that the rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility rate payers.

DATCP Contact

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Where and When Comments May Be Submitted

Questions and comments related to this this rule may be directed to:

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Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

SECTION 1. ATCP 55.02 (1) is renumbered as ATCP 55.02 (1m).

SECTION 2. ATCP 55.02 (1) is created to read:

(1) "Adulterated" has the meaning given in 9 CFR 301.2 (2) (i).

SECTION 3. ATCP 55.07 (6) (intro.) is amended to read:

ATCP 55.07 (6) (intro.) ~~DISEASED OR~~ ANIMALS THAT ARE DISEASED, INJURED ~~ANIMALS~~, OR WILL YIELD AN ADULTERATED CARCASS; GENERAL. No person may slaughter a food animal for human consumption, or submit a food animal for slaughter for human consumption, if the person knows or has reason to know that the animal is diseased ~~or~~, injured, or will yield an adulterated carcass. This subsection does not prohibit any of the following:

SECTION 4. ATCP 55.07 (6) (d) is created to read:

(d) The slaughter of an animal presented by a producer listed in the U.S. department of Agriculture Residue Repeat Violator List for Use by Livestock Markets and Establishments if the producer, in collaboration with a licensed veterinarian, provides to the department written evidence of enrollment and completion of a course on proper administration of animal medications, approved by the department. Certification of course enrollment and completion shall be provided on a form prescribed by the department. Enrollment in the course shall occur not more than 30 days after the producer is listed on the U.S. department of agriculture Residue Repeat Violator List for Use by Livestock Markets and Establishments, and completion of the course shall occur not more than 180 days after enrollment.

SECTION 5. ATCP 55.07(6)(Note) is created to read:

Note: The U.S. department of Agriculture Residue Repeat Violator List for Use by Livestock Markets and Establishments may be accessed at the following website: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry and selecting the link to the USDA Residue Repeat Violator List for Use by Livestock Markets and Establishments.

SECTION 3. ATCP 55.07(7) (f) is amended to read:

ATCP 55.07(7) (f) ~~All drugs administered to the animal as treatments or feed additives within 30 days prior to the slaughter submission date, and the last date each drug was administered~~ The date(s) of delivery, the delivery method, and the withdrawal time following

delivery of all drugs as treatments or feed additives have complied with manufacturer's recommendations, or complied with a licensed veterinarian's prescription, including a prescription for an extra-label use of an over-the-counter drug.

SECTION 4. **EFFECTIVE DATE.** This rule takes effect on the first day of the month following publication in the Wisconsin administrative register, as provided under s. 227.22(2)(intro.).

Dated this _____day of _____, 2015.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary