



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Ben Brancel, Secretary

DATE: December 3, 2014

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Division of Food Safety Administrator *Steve Ingham*

SUBJECT: ATCP 55-Meat and Meat Food Products; Final Draft Rule

PRESENTED BY: Steve Ingham

REQUESTED ACTION:

At the December 17, 2014 Board meeting, the department will ask the DATCP Board to approve a final draft rule modifying ch. ATCP 55, Meat and Meat Food Products. The Board approved an earlier version of this rule at its July 23, 2014 meeting, but a stakeholder identified an inadvertent error in the proposed rule text and commented on potential confusion that could result from another part of the text. We appreciate the input from the stakeholder and have addressed both issues in this revised final draft rule.

We corrected a citation for the Code of Federal Regulation (CFR) definition of "adulterated." The previous version of the rule used a citation from an outdated version of the CFR found on the Government Printing Office website. The current version of the CFR had a different numbering system which made the citation incorrect. We have updated the rule to use the correct citation.

The stakeholder comment identified, in ATCP 55.07(6)(intro.), an ambiguity as to whether the term "adulterated", for which the CFR definition was cited, applied to a carcass or a live animal before slaughter. The stakeholder stated that the term applies to the carcass and, after further review, we agree. The rule text now clearly indicates that an animal which yields an adulterated carcass cannot be presented for slaughter. The intent of the rule is not altered by this change; the rule still specifies corrective actions that state-licensed meat establishments must impose 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 a calendar year submit animals to be slaughtered at a state- or federally inspected meat establishment, which yield carcasses testing positive for any illegal drug residue.

SUMMARY:

Background

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-

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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 the United States Department of Agriculture - Food Safety and Inspection Service (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 is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

Rule Content

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. The rule will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know 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 from producers 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 a course or courses which are acceptable. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The rule also revises ATCP 55.07, 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. The proposed rule will revise 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 to the animal as treatments or feed additives have complied with a veterinarian's prescription or the manufacturer's recommendations (over-the-counter drugs). This revision acknowledges that some drugs may require a withdrawal time longer than 30 days and that withdrawal time 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. Establishment operators must develop a plan to monitor and document that each key step is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected establishments 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 abattoir 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 establishment operators are expected, but not required, 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 proposed 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 abattoir 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; all meat processed in Michigan for wholesale 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 the USDA program, are expected to minimize the risk associated with drug residues and to consult the USDA's Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. The approach proposed 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 proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

Effect on Small Business

This rule change is anticipated to have very 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 proposed 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 veterinarians. 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 proposed 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 proposed 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.

Small Business Regulatory Review Report

The Small Business Regulatory Review Board did not issue a report on this rule.

Public Hearings

DATCP held three hearings at the following locations:

April 22, 2014	Madison, Wisconsin
April 23, 2014	Eau Claire, Wisconsin
April 25, 2014	Green Bay, Wisconsin

Following the public hearing, the hearing record remained open until May 9, 2014 for additional written comments. One person representing the Cooperative Network attended the hearings. The Cooperative Network did not take a position on the proposal. We received written comments from the Wisconsin Veterinary Medical Association expressing support for the rule and suggesting language changes to clarify rule requirements.

Changes from the Hearing Draft

We made all of the changes suggested by the Legislative Council Rules Clearinghouse. Both the Legislative Council Rules Clearinghouse and the Wisconsin Veterinary Medical Association (WVMA) suggested revisions

to the language defining adulteration. In response to the WVMA comments we added, by reference, the USDA definition of “adulterated” (with the citation corrected in this presentation to the Board) and separated the prohibition against presenting adulterated animals for slaughter and the corrective action required for producers who are on the USDA Residue Repeat Violators List. Subsequent to the July 23, 2014 Board meeting, the rule text has been clarified to indicate that the prohibition is against presentation of an animal which will yield an adulterated carcass. We also broadened the list of information required from the producer when he/she presents a diseased or injured for slaughter. The additional language reflects the complexity of FDA requirements for drug withdrawal times before slaughter. In response to a suggestion from the WVMA that the course required as a corrective action after repeat drug residue violations be completed within 180 days of the producer’s name appearing on the list, we modified the language to require that the course be started within 30 days after the producer’s name appeared on the list, and be completed within 180 days after being started. We also adopted a WVMA suggestion to require that all drugs used to treat a diseased or injured animal presented for slaughter be certified either as administered as prescribed by a licensed veterinarian or as recommended on the manufacturer’s label (for over-the-counter medications).

Next Steps

If the Board approves this final draft rule, the department will transmit the rule to the Governor for his written approval. After DATCP receives written approval from the Governor, DATCP will submit the rule to the Legislature for review by appropriate legislative committees. If the Legislature has no objections to the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

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

- 1 The Wisconsin department of agriculture, trade and consumer protection hereby proposes the
2 following rule *to renumber* ATCP 55.02 (1), *to amend* ATCP 55.07(6) and (7)(f) and *to create*
3 ATCP 55.02 (1) and 55.07(6) (d) and (Note); *relating to* drug residues in animals for human
4 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) proposes a 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. The proposed rule will further prohibit 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. The proposed rule will revise 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

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Summary of Factual Data and Analytical Methodologies

Proposed 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 proposed 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 proposed 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 proposed 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 proposed 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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Madison, WI 53708-8911
Telephone: (608) 224-4729 E-Mail: Cindy.Klug@Wisconsin.gov

Where and When Comments May Be Submitted

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

Cindy Klug, Director
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Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4711
E-Mail: Cindy.Klug@Wisconsin.gov

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.

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- 1 SECTION 1. ATCP 55.02 (1) is renumbered as ATCP 55.02 (1m).
- 2 SECTION 2. ATCP 55.02 (1) is created to read:
- 3 (1) "Adulterated" has the meaning given in 9 CFR 301.2 (2) (i).

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

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

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

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

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

18 **Note:** The U.S. department of Agriculture Residue Repeat Violator List for Use by
19 Livestock Markets and Establishments may be accessed at the following website:
20 [http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry)
21 [reports/chemistry/residue-chemistry](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
22 Violator List for Use by Livestock Markets and Establishments.

23
24 SECTION 3. ATCP 55.07(7) (f) is amended to read:

25 ATCP 55.07(7) (f) ~~All drugs administered to the animal as treatments or feed additives~~
26 ~~within 30 days prior to the slaughter submission date, and the last date each drug was~~

1 administered The date(s) of delivery, the delivery method, and the withdrawal time following
2 delivery of all drugs as treatments or feed additives have complied with manufacturer's
3 recommendations, or complied with a licensed veterinarian's prescription, including a
4 prescription for an extra-label use of an over-the-counter drug.

5 SECTION 4. **EFFECTIVE DATE.** This rule takes effect on the first day of the month
6 following publication in the Wisconsin administrative register, as provided under s.
7 227.22(2)(intro.).

8

Dated this _____ day of _____, 2014.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Final Regulatory Flexibility Analysis

Rule Subject: Drug Residues in Meat and Meat Products
Adm. Code Reference: ATCP 55
Rules Clearinghouse #: 14-024
DATCP Docket #: 13-R-07

Rule Summary

The proposed rule will specify 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 state- or federally-inspected meat establishments, which yielded carcasses testing positive for any illegal drug residue.

Medications are important for maintaining healthy livestock. However, drug residues may remain in animals submitted for slaughter if illegal drugs have been administered or the appropriate withdrawal time between drug administration and slaughter has not been observed. Residues of medications, particularly antibiotics and anti-inflammatory agents, in meat 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 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 the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators List. The list identifies livestock producers whose animals 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 residue in livestock and meat products.

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. The proposed rule will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know that the animal will yield an adulterated carcass. The rule adopts a definition of adulterated that, as applied to a carcass, is already contained in federal regulations pertaining to slaughter

operations. By this definition, a carcass containing any illegal drug residue is adulterated. The rule specifies that animals from producers included on the USDA Residue Repeat Violator List for Use by Livestock Markets and Establishments can only be slaughtered 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 proposed rule also revises ATCP 55.07, 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. The proposed rule will revise 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 to the animal as treatments or feed additives have complied with a veterinarian's prescription or the manufacturer's recommendations (over-the-counter drugs). This revision acknowledges that some drugs may require a withdrawal time longer than 30 days and that withdrawal time may differ according to the method by which the drug is delivered to the animal.

Small Businesses Affected

State-inspected meat establishment operators who accept livestock for slaughter, and livestock producers listed on USDA's Residue Repeat Violator list, who submit their animals for slaughter at state meat establishments, will be affected by this rule. This proposed rule is anticipated to have a very slight 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 the 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 proposed 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 minor short-term negative economic impact on a small number of livestock producers listed on the USDA's Residue Repeat Violator list who, under the proposed rule, would be required to attend a workshop and improve documentation of the use of animal medications. To the extent that the proposed 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 taxpayers.

Reporting, Bookkeeping and other Procedures

The proposed rule would require state-licensed meat establishment operators who slaughter livestock to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. The proposed rule would

require a producer who is listed to provide written evidence to a meat establishment operator that they have completed a course on proper administration of animal medications before the state-licensed meat establishment may accept animals for slaughter from that producer.

Professional Skills Required

The proposed rule does not require any new professional skills by small businesses. However, livestock producers included on USDA's Residue Repeat Violator list who wish to submit their animals for slaughter must complete a course on proper administration of animal medications. Completion of the approved course will require the involvement of the livestock producer's veterinarian.

Accommodation for Small Business

State meat inspection programs only regulate small businesses. State meat inspection programs operate under a cooperative agreement under USDA's authority and must meet federal "at least equal to" requirements. No special accommodation may be made for small businesses to meet the requirements of this proposed rule. However, the rule is expected only have an appreciable impact on meat establishments interacting with a small number of livestock producers. The rule will affect this small number of livestock producers, but it will benefit small state-inspected meat establishments by further ensuring that the livestock they accept for slaughter is free of drug residues.

Conclusion

Given the potential health risks associated with drug residues in animals for human food, consumers, meat establishment operators, and livestock producers will all benefit from a mandatory procedure for reducing the likelihood that the human food supply contains animals from producers who have been listed for repeated tissue drug-residue violations.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this 2nd day of December, 2014.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Steven C. Ingham
Steven C. Ingham, Administrator,
Division of Food Safety

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

ATCP 55-Meat and Meat Food Products

3. Subject

Drug residues in meat and meat products

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

102

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses (if checked, complete Attachment A)

8. Would implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

The proposed rule will specify corrective actions state-licensed meat establishments must impose on certain livestock producers before the establishment operator accepts animals from the producers for slaughter. The required corrective actions apply to livestock producers who on two or more occasions during the past year submitted animals to be slaughtered at state- or federally-inspected meat establishments, which yielded carcasses testing positive for any illegal drug residue.

Medications are important for maintaining healthy livestock. However, if drug delivery and withdrawal time requirements are not carefully followed, 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 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.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

The rule will have little impact on state inspected meat establishments at which livestock are slaughtered (about 100 establishments), and will have a slight impact on a very small number of livestock producers and veterinarians.

11. Identify the local governmental units that participated in the development of this EIA.

Local governmental units are not impacted by this rule change and did not participate in the development of this EIA.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

State-Inspected Meat Establishments: Current rules prohibit submission for slaughter of a food animal for human consumption if the person submitting the animal knows or has reason to know the animal is diseased or injured. This rule change will further prohibit someone from slaughtering or submitting for slaughter a food animal for human

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

consumption if they know that the animal will yield an adulterated carcass, with a carcass containing illegal drug residues defined as adulterated. The rule change then clarifies that the slaughter of animals from producers 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 a course or courses which are acceptable. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian. This rule change is anticipated to have little impact on operators of meat establishment at which livestock are slaughtered, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List.

Livestock Producers: Under the rule change, livestock producers who are listed on the USDA Residue Repeat Violator List will be required to complete a course on the proper administration of animal medications and present written documentation of their course completion before submitting animals for human consumption for slaughter at a state-inspected meat establishment. Very few livestock producers from Wisconsin and neighboring states are on this list and this rule change will have no impact on the majority of livestock producers who follow proper procedures for the administration of animal medications. Livestock producers who take a course in proper administration of animal medications will have to bear costs associated with the course presentation (likely a registration fee to cover expenses incurred by the course presenters) and time away from their regular work. We characterize this impact as slight.

Veterinarians: Successful completion of a course in proper administration of animal medications by a producer will require the involvement of the livestock producer's veterinarian. This involvement will require a time commitment by a very small number of veterinarians. We characterize this impact as slight.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The rule change will benefit state inspected meat establishments, all of whom are small businesses, by clarifying procedures they must follow in the event that a producer on the Repeat Residue Violators List submits a food animal for slaughter. Implementing these mandatory procedures will further decrease the likelihood that animals with illegal drug residues enter the human food chain, and will protect consumer trust in meat from Wisconsin-inspected establishments. The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations. It adds an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action would normally be taken. The rule change will help livestock producers who are on the USDA Residue Repeat Violators List improve their practices for administering animal medications and avoid future problems. If the rule is not implemented, there is a chance that producers on the Repeat Residue Violators List would present animals containing illegal residues to unknowing meat establishment operators. Although this scenario is unlikely, the economic importance of the meat industry in Wisconsin is high enough that prudent steps should be taken to make illegal drug residues in meat even more unlikely to occur.

14. Long Range Implications of Implementing the Rule

To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, the rule change will have a positive long-term economic impact on Wisconsin's meat industry.

15. Compare With Approaches Being Used by Federal Government

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. Plants must develop a plan to monitor and document that each key step is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected plants 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 abattoir 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

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

have a drug residue problem, federal plants are expected, but not required, to consult the federal Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. The list is compiled by 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. Federal action against residue repeat violators is generally not taken unless the US Food and Drug Administration investigates, issues a warning letter and, upon further violations, obtains an injunction against the livestock producer. This process is cumbersome, lengthy, and does not happen often.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations, and it will enhance the effectiveness of oversight by requiring an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action is needed.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Michigan currently does not operate a state meat and poultry inspection program and all meat processed in Michigan for wholesale 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 the USDA program, are expected to minimize the risk associated with drug residues and to consult the USDA's Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. The approach proposed 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 proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

17. Contact Name Cindy Klug, Director-Bureau of Meat Safety and Inspection	18. Contact Phone Number 608 224-4729
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ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

This proposed rule 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. However, meat establishments are already expected to review the list before accepting animals for slaughter. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed 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 a small number of livestock producers listed on the USDA's Residue Repeat Violator list who, under the proposed rule, would be required to attend a course and improve documentation of the use of animal medications. The primary economic impact for these producers would be the registration cost for the course and time away from their farm duties. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian.

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

To determine the potential impact on small businesses, DATCP requested input from a meat processors professional organization, and the Wisconsin Veterinary Medical Association.

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

The rule is expected to only have an appreciable impact on meat establishments interacting with the small number of livestock producers on the USDA Residue Repeat Violators List. The rule will affect this small number of livestock producers, but it will benefit small state-inspected meat establishments by further ensuring that the livestock they accept for slaughter is free of drug residues. Under the proposed rule, DATCP must approve the course on proper administration of animal medications that livestock producers on the Repeat Residue Violators List would be required to attend before they can submit animals for slaughter at a state-inspected meat establishment. In evaluating course(s) for approval, the DATCP will carefully balance the effectiveness of the learning activities in the course with the number and duration (and thus economic impact) of these learning activities to ensure that an undue economic burden is not placed on course attendees.

5. Describe the Rule's Enforcement Provisions

Enforcement of the rule will occur as part of normal meat establishment regulatory activities. Typically, noncompliance with regulatory requirements results in a Noncompliance Report (NR). Upon receiving an NR, the establishment operator takes corrective actions, which are described to the Meat Safety Inspector. In cases of noncompliance related to suspected drug residues, carcasses may be retained for testing. Non-violative carcasses would be released for further processing and/or sale. Violative carcasses would be condemned in accordance with normal procedures.

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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