STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
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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 slaughered (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

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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

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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 aginst 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	18. Contact Phone Number
Cindy Klug, Director-Bureau of Meat Safety and Inspection	608 224-4729

This document can be made available in alternate formats to individuals with disabilities upon request.

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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