

# NOTICE OF PUBLIC RULEMAKING HEARING

### FOR AMENDMENTS TO

# Rules concerning the "Control and Eradication of Scrapie in Sheep and Goats" 8 CCR 1201-16

Notice is hereby given pursuant to § 24-4-103 C.R.S. that the Department of Agriculture will hold a public rulemaking hearing:

DATE: May 31, 2022 TIME: 1:00 pm

LOCATION: This hearing will be held via **Zoom** 

CALL INFORMATION: 1-253-215-8782

MEETING ID: 870 5981 5242 PASSCODE: 594532

In order to maintain a proper hearing record you are encouraged to pre-register by completing this <u>Google form</u>. If you do not have access to Google you may send your name and telephone number to <u>Jenifer.Gurr@state.co.us</u>
Pre-registration is not required to participate in the hearing.

The purposes of these proposed rule revisions is to incorporate changes as a result of the Department's Regulatory Efficiency Review Process, as well as to bring this rule into alignment with recent updates to federal rules and regulations pertaining to the importation of sheep and goats.

The statutory authority for these rules is § 35-50-105(3)(a), (c), (f), (h), and (p), C.R.S.

Any interested party may file written comment with the Commissioner's office prior to the hearing, or present at the aforementioned hearing written data, views or arguments. Emailed comments should be sent to the hearing officer at <a href="mailto:Jenifer.Gurr@state.co.us">Jenifer.Gurr@state.co.us</a>. A copy of the proposed rule is available on the Department of Agriculture's website at <a href="mailto:www.colorado.gov/ag">www.colorado.gov/ag</a> or may be obtained by calling 303-869-9002. The proposed rule shall be available for public inspection at the Colorado Department of Agriculture at 305 Interlocken Parkway, Broomfield, Colorado during regular business hours.



#### DEPARTMENT OF AGRICULTURE

**Animal Health Division** 

## CONTROL AND ERADICATION OF SCRAPIE IN SHEEP AND GOATS

8 CCR 1201-16

#### Part 1 Definitions

- 1.1. "Administrator" means The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.
- 1.24. "Animal" means a domestic sheep or goat.
- 1.32. "Animal and Plant Health Inspection Service (APHIS)" means the agency in the United States Department of Agriculture known as the Animal and Plant Health Inspection Service.
- 1.43. "Breeding animal" means a sexually intact sheep or goat of any age.
- 1.54. "Certificate of Veterinary Inspection (CVI)" means an official document issued by an accredited veterinarian at the point of origin of a shipment of livestock. The document shall include the date; the physical location of origin; the name and mailing address of the consignor; the physical location of the destination; the name and mailing address of the consignee; the age, sex, number, and breed of the livestock; sufficient identification marks, tags or other identification as may be approved by the State Veterinarian, to positively identify livestock; and the results of all required tests. Such document shall also include a statement verifying that the livestock identified on the document have been inspected and that they are free from clinical signs of any contagious, infectious, or communicable diseases and that the livestock do not originate from an area of quarantine, infestation, or infection. A certificate of veterinary inspection is valid for thirty (30) days after the date of issuance.
- 1.65. "Commuter agreement" means a form, approved by the Colorado State Veterinarian and the state veterinarian of the contiguous state, that establishes an agreement between Colorado and a contiguous state to enable livestock owners, managers, or operators to move livestock across state borders for grazing purposes and to return to the state of origin.
- 1.7. "Country mark" means a permanent mark identifying a sheep or goat to its country of origin.
- 1.86. "Exposed animal" means:
  - 1.86.1. Any animal that has been in the same flock at the same time as a scrapie-positive female animal, excluding limited contacts; or
  - 1.86.2. Any animal born in a flock after a scrapie-positive animal was born into that flock or lambed in that flock, if born before that flock completes the requirements of a flock plan; or
  - 1.86.3. Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambed, kidded, or aborted, or while a visible vaginal discharge was present, or that was commingled with any other scrapie-positive female animal for 24

hours or more, including during activities such as shows and sales or while in marketing channels; or

- 1.86.4. Any animal in a noncompliant flock.
- 1.97. "Feeder sheep and goats" means animals under 18 months of age not to be used for reproductive purposes and maintained for feeding and slaughter channels only.
- 1.<u>108</u>. "Flock" or "herd" means all animals maintained on any single premises, or multiple premises with animal movement or interchange between the premises.
- 1.119. "Flock plan" means a written flock management agreement signed by the owner of a flock, the accredited veterinarian who provides veterinary services for the owner, and a State or APHIS representative in which each signor agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal.
- 1.120. "Genetic tests for scrapie resistance" means DNA genotyping of sheep for genes associated with scrapie resistance at Codon 171 and may also include Codon 136. To be used in regulatory activities, all genetic tests must be collected by an accredited veterinarian or State or Federal animal health official, must occur at a laboratory approved for such purposes by the USDA, must be submitted on forms approved by the USDA and must be on animals identified with USDA approved methods. At present, no genetic test for scrapie resistance is valid for goats.
- 1.134. "Genetically resistant animal" means a sheep that tests RR or QR at Codon 171.
- 1.1<u>42</u>. "Genetically resistant to valine scrapie" means a sheep that tests AA at Codon 136. This does not apply to goats.
- 1.153. "Genetically susceptible genotype animal" means sheep that test QQ at Codon 171.
- 1.164. "Genetically susceptible to valine scrapie" means any sheep that tests VV or AV at Codon 136.
- 1.17 "Goat" means any animal of the genus Capra.
- 1.185. "High risk animal" means any goat or a genetically susceptible female sheep that is: (1) the progeny of a scrapie-positive dam; (2) born in the same flock during the same lambing season as progeny of a scrapie-positive dam; or (3) a scrapie susceptible animal that has been present in a flock and has been exposed to amniotic fluid of a scrapie positive dam. Any goat in an infected flock is considered a high risk animal.
- 1.196. "Infected flock" means any flock in which the State Veterinarian has determined that a scrapie positive female sheep has resided unless an epidemiological investigation conducted by the State Veterinarian or APHIS representative shows that the ewe did not lamb or abort in the flock. The USDA designation of a "source" flock shall be included in the infected flock definition for this regulation.
- 1.20. "Killed and completely destroyed" means killed or maintained under quarantine in a manner preventing disease spread until the animal is no longer living; and the remains have been disposed of in a manner preventing disease spread.

- 1.2147. "Limited contacts" means incidental contacts between animals from different flocks off the flock's premises such as at fairs, shows, exhibitions and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations.
- 1.22.48 "Live-animal screening test" means any test for the diagnosis of scrapie in a live animal that is approved by the USDA.
- 1.23.49 "Noncompliant flock" means:
  - 1.2349.1. Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so designated, or whose owner is not in compliance with either agreement;
  - 1.2319.2. Any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;
  - 1.2349.3. Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or
  - 1.2319.4. Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.
- 1.2<u>4.0</u> "Official identification" means an identification mark or device approved by APHIS for use in the Scrapie Eradication Program.
- 1.2<u>5.</u>4 "Official Test" means any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator of APHIS for that use and conducted either at an approved laboratory or at NVSL.
- 1.26.2 "Post Exposure Management and Monitoring Plan (PEMMP)" means a written agreement signed by the owner of a flock, any accredited veterinarian who provides veterinary services for the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the agreement to reduce the risk of the occurrence of scrapie and to monitor for the occurrence of scrapie in the flock for at least 5 years after the last high-risk or scrapie-positive animal is removed from the flock or after the last exposure of the flock to a scrapie-positive animal unless the monitoring time is otherwise specified by a State or APHIS representative. As part of a PEMMP, the flock owner must provide the facilities and personnel needed to carry out the required elements listed in the plan.
- 1.2<u>7</u>3. "Scrapie" means a non-febrile, transmissible, insidious, degenerative disease affecting the central nervous system, and is a transmissible spongiform encephalopathy (TSE) found in sheep and goats.
- 1.284. "Scrapie-positive" means an animal that has tested positive through an official test.
- 1.2<u>9.5</u> "Scrapie Eradication Program" means the cooperative State-Federal program administered by APHIS and Consistent States to control and eradicate scrapie.
- 1.30. "Sheep" means any animal of the genus Ovis.

- 1.3126. "State Veterinarian" means the veterinarian designated by the Commissioner of the Colorado Department of Agriculture as the director of the Division of Animal Health, Colorado Department of Agriculture.
- 1.3227. "Source Flock" means a flock in which a State or APHIS representative has determined that at least one animal in that flock was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less.
- 1.3328. "USDA" means the United States Department of Agriculture.
- 1.34.29 "Veterinary Services (VS)" means the division of APHIS charged with animal health activities within the United States.

# Part 2 Importation of Breeding Sheep and Goats into Colorado

- 2.1. Except as set forth in Parts 2.2. and 2.3., all breeding sheep and goats imported into Colorado, whether interstate or international, must be accompanied by a certificate of veterinary inspection (CVI) and an CDA-issued import permit. The accredited veterinarian who issues the CVI must obtain the import permit from the State Veterinarian. The accredited veterinarian issuing the CVI shall record the import permit number on the certificate.
- 2.2. No CVI or import permit is required for animals going directly to slaughter.
- 2.3. Animals entering Colorado from a state contiguous to Colorado without change in ownership and as a part of normal operating procedures may do so by acquiring a commuter agreement issued by the State Veterinarian.
- 2.4. CVIs for all breeding sheep and goats imported into Colorado must contain official identification for each animal. Official identification includes any of the following: 1) ear tags and/or microchips approved by the USDA for scrapie identification, 2) registration tattoos in goats when accompanied by a matching certificate of registration from a goat breed registration association, or 3) an APHIS assigned tattoo or tattoo for animals that cannot be ear tagged.
- 2.5. Sheep and goats imported from Canada or Mexico must have a permanent country mark and other official identification.

## Part 3 Sheep and Goat Transfer of Ownership or Exhibition

- 3.1. All breeding sheep and goats must be identified with official identification for purposes of transfer of ownership or for exhibition in Colorado.
- 3.2. All wether sheep and goats over 18 months of age must be identified with official identification for purposes of transfer of ownership or for exhibition in Colorado.

## Part 4 Infected Flocks Containing Animals with Scrapie

4.1. In any flock in which scrapie is diagnosed, the state veterinarian will conduct an investigation within 7 days upon receipt of notice of infection. The premises and all sheep and goats on the premises may be placed under quarantine by the State Veterinarian. For any premises, sheep or goats placed under quarantine, the owner of the flock must complete the following:

- 4.1.1. All sheep and goats must be identified with official identification and inventoried as to sex, age, breed and species.
- 4.1.2. An epidemiological tracing must be completed as to the origins of animals and the destination of animals moved from the flock; and USDA will determine a designation of infected or source flock within 15 days; and
- 4.1.3. A flock plan must be developed, signed by all parties, and approved by the State Veterinarian or his representative.
- 4.2. Any such quarantine will remain in effect until the animals are identified with the appropriate USDA approved methods, epidemiology is completed, and a flock plan has been developed and agreed upon and signed by all parties. The flock plan may be replaced with a PEMMP developed mutually by the owner, his veterinarian, and state or federal officials and approved by the State Veterinarian.
- 4.3 Flock plans for infected flocks within Colorado must be approved by the State Veterinarian prior to implementation. The flock plan must address, but is not limited to:
  - 4.3.1. Animal identification and record keeping;
  - 4.3.2. Disinfection and sanitary measures;
  - 4.3.3. Lambing or kidding management;
  - 4.3.4. The classification and disposition of affected and high-risk animals within the flock;
  - 4.3.5. Animal sales and movements of animals from the flock;
  - 4.3.6. Where appropriate, and as a part of a comprehensive flock management plan, approved live-animal screening tests and genetic tests for scrapie resistance will be used to evaluate the risk status of individual animals within the flock. Genetically susceptible genotype animals must be killed and destroyed or sent to a research facility. Flock plans may include breeding only with homozygous scrapie resistant rams for the duration of the flock plan; and
  - 4.3.7. At the discretion of the State Veterinarian, a second genotyping sample may be required at the owner's expense. If there is a discrepancy in test results indicating a QQ genotype, the animal will not be permitted entry into Colorado until the discrepancy is resolved with the approval of the USDA reference laboratory, the National Veterinary Service Laboratory (NVSL).
- 4.4 The flock plan will remain in effect until all scrapie susceptible animals have been removed from the flock. After all scrapie susceptible animals have been removed from the flock, and only homozygous scrapie resistant rams are used for breeding in the flock, the flock plan may be replaced with a PEMMP developed mutually by the owner, his veterinarian, and state or federal officials and approved by the State Veterinarian.

## Part 5 Exposed Animals

5.1. Any animal that originates from or had contact with a flock in which scrapie has been diagnosed and which animal is not considered high risk will be classified as an exposed animal. An owner of

- any exposed animal will be notified by the State Veterinarian with information regarding disposition of the exposed animal and any subsequent action required.
- 5.2. The State Veterinarian will conduct tracebacks of scrapie-positive animals and trace outs of highrisk and exposed animals and report any out-of-State traces to the appropriate State within 45 days of receipt of notification of a scrapie-positive animal.

#### Part 6. Livestock Markets

Any sale not specifically designated as a "feeder only sale" is classified as an "open sale," where all sexually intact animals presented, regardless of age, are considered breeding animals. Any "feeder" animal exempt from identification requirements may not be re-classified as a breeding animal (i.e., removed from feeding channels) without official identification showing its birth flock.

#### Part 7. Reserved

- Part 8. Statement of Basis, Specific Statutory Authority and Purpose
- 8.1. Adopted: February 10, 1999 Effective: March 30, 1999
- 8.2. Adopted October 30, 2002 Effective January 30, 2003

### STATEMENT OF BASIS AND PURPOSE

This rule is adopted by the Colorado State Agricultural Commission pursuant to Section 35-50-101, C.R.S. (1998).

The purposes of this rule are to define requirements for the importation into Colorado of breeding sheep and for public sheep and goat sales and define the procedures which will be applicable for scrapie infected, source and trace flocks.

### FACTUAL ISSUES ENCOUNTERED IN DEVELOPING THESE RULES.

Science has shown that scrapie transmission is primarily as result of a scrapie infected ewe's placenta and amniotic fluid at parturition taken in orally by a scrapie susceptible animal. Further, science has shown that a ewe with a resistant gene R at the 171 codon will not pass the scrapie infective agent when she was intentionally exposed to the infective agent.

The most promising strategy for the control and eradication of scrapie is the use of resistant genotype ram to assure that all progeny contains at least one resistant gene, regardless what the dam's genotype. Using homogeneous resistant rams RR in an infected or source flock will virtually eliminate scrapie transmission. Scrapie infected or source flocks that embrace the resistant genotype strategy as part of the flock plan should be permitted to sell animals that are either QR or RR genotype. However, it is important that all susceptible animals be restricted until eliminated from such flocks by euthanasia and disposal and that only homozygous resistant rams be used for breeding in such flocks, thus assuring that all progeny will be scrapie resistant and that the scrapie agent will not be introduced into other flocks through the movements of scrapie susceptible animals.

**Rule concept:** Sheep or goats originating from a scrapie infected or source flock both intra and interstate shall be allowed to sell in Colorado if the genotype is confirmed to be QR or RR at the 171 codon.

The seller of such sheep shall be responsible to have such sheep genotyped, but an accredited veterinarian or state or federal animal health official must have taken the specimen and submitted it to an official laboratory.

At the discretion of the State Veterinarian a second genotyping sample may be required at the owner's expense. If there is a discrepancy in test results indicating a QQ genotype, the animal shall not be sold in Colorado.

## 8.3. Adopted: August 30, 2006 – Effective: October 30, 2006

This rule is adopted by the Commissioner of Agriculture and approved by the Colorado State Agriculture Commission pursuant to Section 35-50-105(3), C.R.S. (2005).

The rule is designed to address the control and eradication of scrapie. Scrapie is a transmissible, degenerative disease affecting the central nervous system of sheep and goats. It is usually transmitted to a susceptible sheep at birth. Goat transmission is not understood as yet. This rule defines the requirements for importing breeding sheep and goats into Colorado, sets forth identification requirements for the transfer of ownership or the exhibition of sheep and goats, and establishes disease protocols for sheep and goat flocks/herds infected with scrapie. This rule is necessary to bring Colorado's standards into compliance with federal scrapie rules so that Colorado can be deemed to be a scrapie-compliant state. This in turn affects Colorado's ability to qualify for grants under various federal disease control programs and allows less stringent interstate movement. Genetic testing has shown that ewes with certain resistant genes will not transmit scrapie to their offspring. These genetic tests refer to both a gene type indicated by a capital letter ("R, Q, A or V") and to a marker or "codon" indicating the location on a strand of genetic material ("codon 171 or 136"). This rule sets forth the combinations of genotypes and codons that are used to determine an animal's susceptibility to scrapie infection. It is necessary to understand these terms in order to understand the scope of the rule. This rule uses these terms in order to track the federal program addressing scrapie control and eradication in sheep and goats.

Scrapie in sheep is transmitted primarily due to the oral ingestion by a susceptible animal of an infected ewe's placenta and amniotic fluid at birth. However, testing shows that a ewe with a resistant gene R at the 171 codon will not pass the scrapie infective agent after being intentionally exposed to the infective agent.

In addition, a gene at a second codon may be necessary to provide resistance to a "valine" strain of scrapie. The valine strain although uncommon at present, may be transmitted by a QR individual. Therefore, if valine strain is found, animals with the QR genotype at codon 171 must be tested at codon 136 and have AA to be classed as resistant animals. If they have AV at codon 136, they could be susceptible.

### 8.4. Adopted September 20, 2017 – Effective November 30, 2017

## Statutory Authority

This rule is amended and adopted pursuant to the Commissioner's authorities found at § 35-50-105(3)(a), (c), (f), (h), and (p), C.R.S.

## Purpose

The purpose of this rule-making is to update matters related to the requirements for importation into Colorado of breeding sheep and for public sheep and goat sales and to define the procedures that will be applicable for scrapie-infected source and trace flocks.

## Factual and Policy Issues

Language was updated to bring it into conformity with national disease prevention terms, definitions, and standards; the introduction section was deleted in order to bring this rule into conformity with other CDA rules; grammatical and syntactic changes were made to Part 1, including bringing the definitions into conformity with national disease prevention definitions; and language was removed that was formerly required on the CVI, this language is no longer required because facilities that have had positive scrapie animals are on a post exposure management program that would prohibit shipping of livestock from previously positive premises. Information was updated pertaining to identification for sheep intended for exhibition; and information related to flock plans was added in order to provide clarity for users of the rule with regard to the steps they must take once their premises are placed under quarantine and before any such quarantine will be released into either a flock plan or Post-Exposure Management and Monitoring Plan. Part 5 was removed and incorporated into Part 4 as there was a lot of overlap between these two Parts. The State Veterinarian can contact the owner of any scrapie exposed animals pertaining to the disposition of the exposed animals. Information was added about Livestock Markets; Part 7 was deleted; information regarding testing of infected flocks was moved to Part 4.3.6; and the rule has been renumbered to bring uniformity within the rule to its numbering convention.

## 8.5. Adopted June 8, 2022 - Effective July 30, 2022

## **Statutory Authority**

This rule is amended and adopted pursuant to the Commissioner's authorities found at § 35-50-105(3)(a), (c), (f), (h), and (p), C.R.S.

### Purpose

The revisions to these Rules incorporate changes as a result of the Department's Regulatory Efficiency Review Process, as well as to bring this rule into alignment with recent updates to federal rules and regulations pertaining to the importation of sheep and goats.

# Factual and Policy Issues

In 2021, USDA-APHIS revised its rule, "Importation of Sheep, Goats, and Certain Other Ruminants," effective January 3, 2022. Because Colorado is a scrapie-compliant state, the Department of Agriculture needed to update this rule set to comport its rule to USDA's 2021 amendments to maintain Colorado's compliance. USDA's revisions provided revised definitions and introduced new, key terms. This rule change updates language in the rule to bring it into conformity with national disease prevention terms, definitions, and standards, and it clarifies the identification requirements for Canada and Mexico-origin sheep and goats that are imported into Colorado.

## Specific Purpose of the Rulemaking

In Part 1.1 the reviewers added a definition for "administrator."

In Part 1.7, the reviewers added a definition for "country mark," which is a new term for this rule.

In Part 1.17 the reviewers added a definition for "goat."

In Part 1.30 the reviewers added a definition for "sheep."

In Part 2.1 additional language was added to clarify that all breeding sheep and goats imported into Colorado, whether interstate or international, must be accompanied by a CVI and CDA-issued import permit.

In Part 2.5 new language was added to require a permanent country mark and other official ID for all sheep and goats imported from Canada or Mexico.

In Part 3.2 new language was added to clarify that all wether sheep and goats over 18 months of age must be identified with official identification for purposes of transfer of ownership or for exhibition in Colorado.

In Part 4.1 additional language was added to clarify that the state veterinarian must conduct an investigation within seven days upon notice of a scrapie infection in a flock.

Part 4.1.2 was expanded to include language that the USDA will determine a designation of infected or source flock within 15 days.

A new Part 5.2 was added to stipulate that the State Veterinarian will conduct tracebacks of scrapie-positive animals and trace outs of high-risk and exposed animals and report any out-of-State traces to the appropriate State within 45 days of receipt of notification of a scrapie-positive animal.