

## Summary of Proposed Changes to 9 CFR Parts 54 and 79

(September 4, 2015)

### Overview

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is proposing changes to its existing scrapie regulations. Scrapie is a degenerative and eventually fatal prion disease of sheep and goats, and APHIS regulations help prevent its spread and support its eventual eradication.

This is a synopsis of the proposed rule and should not be considered definitive. Please read the entire proposed rule <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127> to review all the proposed changes as well as APHIS' reasons for the proposed changes. Also, please read the draft "Scrapie Program Standards, Volume 1: National Scrapie Eradication Program" which is also posted at the link above. The rule proposes to:

1. Remove the low-risk commercial goat exemption and treat sheep and goats the same with respect to official identification requirements, the only differences are the allowed state exemptions which have not been changed.
2. Simplify the way the identification and movement requirements are presented and clarify the requirements. Also, adds tag replacement and use requirements from the ADT rule. Recommend reading proposed §79.2 and 79.3 in their entirety.
3. Add "Free" to "Scrapie Flock Certification Program" to read "Scrapie Free Flock Certification Program"
4. Change the **noncompliant** definition so that it now reads:

**Noncompliant flock.** (1) Any source, infected, **or exposed flock or flock under investigation** 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;

(2) Any exposed flock **or flock under investigation** 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;

(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

- (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.
5. Remove concept of “separate contemporary lambing group”.
  6. Change certificate to **Interstate Certificate of Veterinary Inspection (ICVI)**. See proposed § 79.5 for ICVI requirements. Adds requirement for breeding animals that official genotype be included on the ICVI if known.
  7. Change definition of flock sire to read:  
Flock sire. A sexually intact male animal that has produced offspring in the preceding 12 months or that was used for breeding during the current breeding cycle.
  8. Change definition of scrapie positive animal to add ELISA

**Scrapie-positive animal.** An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with this chapter, through:

- (1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;
  - (2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry, **and/or ELISA**, and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a **given method or combination of methods** has been approved by the Administrator for use on that tissue;
  - (3) Bioassay;
  - (4) Scrapie associated fibrils (SAF) detected by electron microscopy; or
  - (5) Any other test method approved by the Administrator in accordance with §54.10 of this chapter.
9. Add the concept of “classification or reclassification investigation” and moves details for conducting them to the APHIS website in the program standards. See proposed § 79.4 and the draft program standards for more information.

**Classification or reclassification investigation.** An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or

animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4 of this chapter, official genotype test results, exposure risk, scrapie type involved, and/or results of official scrapie testing on live or dead animals

10. Changes definition of **destroy**, removes slaughter option for indemnified animals

**Destroyed.** Euthanized and the carcass disposed of by means authorized by the Administrator that will prevent its use as feed or food, or moved to a quarantined research facility if the movement has been approved by the Administrator.

11. Change exposed animal definition:

- a. Adds embryo explicitly
- b. Sets criteria for setting date of infection
- c. Adds concept of further designation based on genotype and exposure risk.

**Exposed animal.** Any animal or embryo that: (1) Has been in a flock or in an enclosure off the premises of the flock with a scrapie-positive female animal, (2) resides in a noncompliant flock, or (3) has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal(s) will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4.

12. Redefine exposed flock (divides old definition into Flock Under Investigation and Exposed Flock and references redesignation section:

**Exposed flock.** (1) Any flock that was designated an infected or source flock that has completed a flock plan and that retained a female genetically susceptible exposed animal; (2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or (3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP. A flock will no longer be an exposed flock if it is redesignated in accordance with § 79.4 of this chapter.

**Flock under investigation.** Any flock in which an APHIS or State representative has determined that a scrapie-suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided. A flock will no longer be a flock under investigation if it is redesignated in accordance with § 79.4 of this chapter.

13. Add definitions for genetically less susceptible exposed sheep, genetically resistant exposed sheep, genetically resistant sheep, genetically susceptible animal, and genetically susceptible exposed animal.

**Genetically less susceptible exposed sheep.** Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible where Q represents any genotype other than R at codon 171; or

(2) An exposed sheep or sheep embryo of genotype AV QR, unless it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which AV QR sheep are not less susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

**Genetically resistant exposed sheep.** Any exposed sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

**Genetically resistant sheep.** Any sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR sheep.

**Genetically susceptible animal.** Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, or sheep or sheep embryo of undetermined genotype where Q represents any genotype other than R at codon 171.

**Genetically susceptible exposed animal.** Excluding low-risk exposed animals, any exposed animal or embryo that is also:

(1) A genetically susceptible animal.

(2) A sheep or sheep embryo of genotype AV QR that is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by

valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

(3) A sheep or sheep embryo of genotype AA QR that is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible where Q represents any genotype other than R at codon 171; or

(4) A sheep or sheep embryo of genotype RR that is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

14. **High-risk animal redefined** as. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk based on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4 of this chapter.

This in concert with the new low-risk exposed animal definition below gives a lot of flexibility in handling infected/source flocks and exposed animals minimizing the need to revise the regulations as scientific knowledge increases. It also allows APHIS to not restrict animals exposed to Nor98-like scrapie and to at some point if warranted by new scientific evidence establish a genetic based approach for goats.

**Low-risk exposed animal.** Any exposed animal to which the DSE has determined one or more of the following applies:

(1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;

(2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;

(3) The exposed animal is male and was not born in an infected or source flock;

(4) The exposed animal is a castrated male;

(5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or,

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of scrapie transmission.

15. Change the first paragraph of the **suspect animal** definition to read:

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: (i) Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; (ii) behavioral abnormalities; (iii) significant weight loss despite retention of appetite or in an animal with adequate dentition; (iv) increased sensitivity to noise and sudden movement; (v) tremors; (vi) star gazing; (vii) head pressing; (viii) bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; (ix) repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; (x) abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or (xi) other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4 of this chapter.

16. Add definition of **tamper-resistant sampling kit** and changes definition of **Official genotype test** to allow sampling using an APHIS approved tamper evident eartag for official genotyping. Note: APHIS is not aware of tamper-evident versions of these devices being commercially available.

17. Add definition of **owner/hauler statement** in place of previous owner statement.

**Owner/hauler statement.** A signed written statement by the owner or hauler that includes:

(1) The name, address, and phone number of the owner and, if different, the hauler;

(2) The date the animals were moved;

(3) The flock identification number or PIN assigned to the flock or premises of the animals;

(4) If moving individually unidentified animals, the group/lot identification number and any information required to officially identify the animals;

(5) The number of animals;

(6) The species, breed, and class of animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; and

(7) The name and address of point of origin, if different from the owner's address, and the destination.

18. Add definition:

**Restricted animal sale or restricted livestock facility.** A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels and are sold in lots that consist entirely of animals sold for slaughter only or a livestock facility at which all animals are in slaughter channels and where the sale or facility manager maintains a copy of, or maintains a record of, the information from, the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

19. Tighten up **slaughter channels** through revised definition and requirement for an owner hauler statement and addition of §79.3(g).

**Slaughter channels.** Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service or under State inspection that the Food Safety and Inspection Service has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot. Any animal sold at an unrestricted sale is not in slaughter channels. Animals in slaughter channels must be **accompanied by an owner/hauler statement** completed in accordance with § 79.3(g) of this chapter. Animals in slaughter channels may not be held in the same enclosure with sexually intact animals from another flock of origin that are not in slaughter channels. When selling animals that do not meet the requirements to move as breeding animals, **owners must note on the bill of sale that the animals are sold only for slaughter.**

79.3(g) Animals moved to slaughter. Once an animal enters slaughter channels the animal may not be removed from slaughter channels. An animal is in slaughter channels if it was sold through a restricted animal sale, resided in a terminal feedlot, was sold with a bill of sale marked for slaughter only, was identified with an identification device or tattoo marked "slaughter only" or "MEAT" or was moved in a manner not permitted for other classes of animals. Animals in slaughter channels may move either directly to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service or under State inspection that the Food Safety and Inspection Service has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an

individual for immediate slaughter for personal use, to a terminal feedlot, or may move indirectly to such a destination through a restricted animal sale or restricted livestock facility. Once an animal has entered slaughter channels it may only be officially identified with an official blue eartag marked with the words "Meat" or "Slaughter Only" or an ear tattoo reading "Meat." Animals in slaughter channels must be accompanied by an owner/hauler statement indicating the owner's name and address; the name and address of the person or livestock facility from which and where they were acquired, if different from the owner; the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which they are being moved, and a statement that the animals are in slaughter channels. A copy of the owner/hauler statement must be provided to the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which the animals are moved. Any bill of sale regarding the animals must indicate that the animals were sold for slaughter only.

20. Revises **Terminal feedlot** definition by revising paragraph 1 to include removal of organic material before use by other sheep or goats, by adding paragraph 2, and revising paragraph 3 (now 4) to increase the record retention requirement to 5 years and reiterate that the owner hauler statement or the information contained therein must be retained:

**Terminal feedlot.** (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized to perform this function where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.



(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2 of this chapter, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

21. In the indemnity sections proposed § 54.3 adds:

a. Prohibitions:

No indemnity will be paid for any animal, or the progeny of any animal, that has been moved or handled by the owner in violation of the requirements of the Animal Health Protection Act or the regulations promulgated thereunder. No indemnity will be paid for an animal added to the premises while a flock is under investigation or while it is an infected or source flock other than natural additions. No indemnity will be paid for natural additions born more than 60 days after the owner is notified they are eligible for indemnity unless the Administrator makes a determination that the dam could not be removed within the allowed time as a result of conditions outside the control of the owner. No indemnity will be paid unless the owner has signed and is in compliance with the requirements of a flock plan or PEMMP as described in § 54.8.

b. Allows partial indemnity if cleaning and disinfection cannot be completed due weather or other factors outside the control of the owner make immediate disinfection impractical.

c. Moves specific instructions for calculating indemnity to the program standards which includes specific language on late gestation and early lambing premiums as well as allows for the use of available price reports rather than specifying particular ones, which may become unavailable. See proposed § 54.6 and draft program standards for details.

22. Add language stating that APHIS may pay full disposal costs for indemnified animals

23. Add use of an EPA approved product should one be approved or new exempted products

24. Update section § 54.8 Requirements for flocks under investigation and flocks subject to flock plans and post-exposure management and monitoring plans (PEMMPs)

a. Reorganized and reworded for clarity

b. Adds flocks under investigation to the requirements for official identification

c. Requires official identification on all animals in a flock under a flock plan or PEMMP

d. Specifically allows APHIS to establish policies for retention of high-risk animals.

e. Gives more flexibility on when a PEMMP will be used

25. Update section § 54.10 Program approval of tests for scrapie

a. Adds information on appeals

b. Moves test use guidelines to the APHIS website. See draft program standards for details.

26. Update section § 54.11 Approval of laboratories to run official scrapie tests and official genotype tests
- a. Adds ability for NVSL to waive tissue retention times in an SOP
  - b. Adds additional information on appeals
  - c. Adds that NVSL may recoup costs associated with laboratory approval from the approved laboratories
27. Change low-risk commercial sheep to low-risk commercial flock to include goats, but limits this exception to animals moving for slaughter
28. Require submission of tagging records by individuals who tag animals for others such as markets and veterinarians through a website or by other mutually agreed methods.
29. Revise information required to be maintained about animal dispositions/acquisitions and records of animals tagged. Remove requirement to record tags that are on animals when acquired unless an ICVI is required.
30. Add meeting surveillance targets as a requirement for remaining a consistent state and requires States to conduct of facilitate surveillance in State inspected mature sheep and goat slaughter establishments (see proposed § 79.6).
31. Simplify the requirements for inconsistent states and includes the option to use genotyping for movement of breeding sheep in addition to enrollment in SFCP (see proposed § 79.3(j)).
32. Move the Consistent State List to the website in the program standards and provides for notice and comment for changing the list. Specifically the definition is changed to read:

Consistent State. (1) A State that the Administrator has determined conducts an active State scrapie control program that meets the requirements of §79.6 or effectively enforces a State-designed plan that the Administrator determines is at least as effective in controlling scrapie as the requirements of § 79.6.

(2) A list of Consistent States can be found on the Internet at <http://www.aphis.usda.gov/animal-health/scrapie>.

(3) When the Administrator determines that a State should be added to or removed from the list of Consistent States, APHIS will publish a notice in the Federal Register advising the public of the Administrator's determination, providing the reasons for that determination, and soliciting public comments. After considering any comments we receive, APHIS will publish a second notice either advising the public that the Administrator has decided to add or remove the State from the list of Consistent States or notifying the public that the Administrator has

decided not to make any changes to the list of Consistent States, depending on the information presented in the comments.

33. Add/revise definitions for **flock identification (ID) number**, **Premises identification number (PIN)** and **group/lot number**

**Flock identification (ID) number.** A nationally unique number assigned by a State or Federal animal health authority to a group of animals that are managed as a unit on one or more premises and are under the same ownership. The flock ID number must begin with the State postal abbreviation, must have no more than nine alphanumeric characters, and must not contain the characters "I", "O", or "Q" other than as part of the State postal abbreviation or another standardized format authorized by the administrator and issued through the National Scrapie Database. Flock identification numbers will be linked in the National Scrapie Database to one or more PINs and may be used in conjunction with an animal number unique within the flock to provide a unique official identification number for an animal, or may be used in conjunction with the date and a sequence number to provide a GIN for a group of animals when group identification is permitted.

**Premises identification number (PIN).** This term has the meaning set forth in § 86.1 of this subchapter. APHIS may also maintain historical and/or State premises numbers and link them to the premises identification number in records and databases. Such secondary or historical numbers are typically the State's two-letter postal abbreviation followed by a number assigned by the State.

**Group/lot identification number (GIN).** The identification number used to uniquely identify a unit of animals that is managed together as one group. The format of the GIN may be either as defined in § 71.1 of this chapter, or the flock identification number followed by a six-digit representation of the date on which the group or lot of animals was assembled (MM/DD/YY). If more than one group is created on the same date a sequential number will be added to the end of the GIN. If a flock identification number is used, the flock identification number, date, and sequential number will be separated by hyphens.

34. Revise definitions of **Animal identification number (AIN)**, **Officially identified**, **Official identification device or method** and **Official Eartag** for clarity to specific the use of devices approved and distributed in accordance the scrapie rules and methods approved for use in sheep and goats by APHIS.

35. Explicitly allows an appeal of designation decisions see proposed § 79.4(c)(3). Draft rules of practice may be found in the draft program standards.

36. Prohibit transferring official eartags without the permission of APHIS or the State or applying official sheep and goat tags to animals other than sheep or goats. See proposed § 79.2 (b)(5)(d&e)

37. Provide for eartagging compliance agreements. See proposed § 79.3 (k).
38. Allow APHIS through the program standards or other web posting to establish the requirements for official identification devices and methods including:
- a. Establishing allowed colors and limiting certain colors to certain uses. For example only “slaughter only” official sheep and goat eartags can be blue and all “slaughter only” official sheep and goat eartags must be blue. Specifies that yellow metal official tags will be used for permanently exposed animals and that red metal official tags will be used for animals that have tested positive for scrapie.
  - b. Requirements for use of tattoos. Proposed changes:
    - i. Not allowed as a sole means of official identification on animals in slaughter channels or moving through livestock markets
    - ii. Registry tattoos must be issued by a registry that has agreed to cooperate with APHIS in tracing scrapie positive and exposed animals or the registry tattoo prefix must be provide to APHIS for entry into the National Scrapie Database.
  - c. Requirements for use of electronic implants. Proposed changes:
    - i. Not allowed as a sole means of official identification on animals in slaughter channels or moving through livestock markets
    - ii. If used as the sole form of official identification must be tattooed with “E” for implants in the ear or “ET” for implants in the tail
    - iii. If used in an unregistered animal must also be tattooed with the flock identification number.
  - d. Specifies that eartags must be placed in the ear.

See the draft program standards ([link](#)) or the extract of materials ([link](#)) referred to in the proposed rule as available on the web for more detailed information.