

MARYLAND REGISTER

Proposed Action on Regulations

Comparison to Federal Standards Submission and Response

Name: Iva Benson
Agency: Department of Agriculture
Address: 50 Harry S. Truman Parkway, Suite 303
State: MD
Zip: 21401
Phone: 410-841-5829
Email: iva.benson@maryland.gov

In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

COMAR Codification: 15.11.18.1-.08

Corresponding Federal Standard:

9 Code of Federal Regulations Part 54 and 79.

Discussion/Justification:

The proposed action updates existing health regulations governing goats and sheep to address Scrapie, a contagious degenerative disease, so that the State's rules meet new federal standards. The proposed action will enable Maryland to retain its status as a "Scrapie consistent state," and reap all the benefits that this status entails, such as ensuring the most favorable treatment possible for Maryland sheep and goat producers in any market.

TO BE COMPLETED BY DBED

- Agree

-Disagree

Comments:

Commerce believes the Department of Agriculture has the appropriate subject matter expertise in this policy area and trusts their assertion the regulation is not more restrictive/stringent than corresponding federal regulations

Name: Jennifer Cox

Date: 3/4/2016

-Submit to Governor's Office

Governor's Office Response

Comments:

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	03/04/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 4/1/2016

2. COMAR Codification

Title Subtitle Chapter Regulation

15 11 18 1-.08

3. Name of Promulgating Authority

Department of Agriculture

4. Name of Regulations Coordinator

Iva Benson

Telephone Number

410-841-5829

Mailing Address

50 Harry S. Truman Parkway, Suite 303

City State Zip Code

Annapolis MD 21401

Email

iva.benson@maryland.gov

5. Name of Person to Call About this Document

Dr. Michael Radebaugh

Telephone No.

410-841-5810

Email Address

michael.radebaugh@maryland.gov

6. Check applicable items:

New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: .

X- Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

32: 19 Md. R 1588 2005
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes **X-** No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Craig Nielsen, Assistant Attorney General, (telephone #410-841-5883) on February 22, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Joseph Bartenfelder

Title

Secretary

Telephone No.

410-841-5884

Date

February 22, 2016

Title 15
DEPARTMENT OF AGRICULTURE

Subtitle 11 ANIMAL HEALTH

15.11.18 Eradication of Scrapie in Maryland

Authority: Agriculture Article, §§3-101, 3-105, and 3-108, Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Agriculture proposes to repeal existing regulations .01 - .08 under COMAR 15.11 Chapter 18 "Eradication of Scrapie in Maryland" and adopt new regulations .01 - .12 under COMAR 15.11 with new Chapter 18 "Requirements for Sheep and Goats for the Eradication of Scrapie".

Statement of Purpose

The purpose of this action is to update existing health regulations governing sheep and goats to address Scrapie so that they meet new federal standards. Scrapie is a contagious, degenerate disease of sheep and goats. The proposed action will enable Maryland to retain its status as a "Scrapie consistent state," and reap all the benefits that this status entails, such as ensuring the most favorable treatment possible for Maryland sheep and goat producers in any market. If adopted, sheep and goat producers will be able to continue to ship their livestock without further testing as required by federal regulations.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact.

Updated Maryland regulations will have a positive economic impact on the Maryland sheep and goat livestock industry because the State will keep its status as a "Scrapie consistent state," enabling producers to continue enjoying the free movement of their livestock in any market. In addition, the proposed Scrapie regulations will further Maryland's effort to completely eradicate Scrapie in this State, which also adds economic value to this industry.

II. Types of Economic Impact.

Revenue (R+/R-)

Expenditure (E+/E-)

Magnitude

A. On issuing agency:	NONE	Unknown
B. On other State agencies:	NONE	
C. On local governments:	NONE	

Benefit (+)	Magnitude
Cost (-)	

D. On regulated industries or trade groups: (+)		Unknown
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public: (+)		Unknown

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The cost to MDA to enforce the proposed Scrapie regulations will be covered with existing Animal Health general funding.

D. With the implementation of the proposed Scrapie regulations, Maryland will retain its status as a "Scrapie consistent state," and reap all the benefits that this status entails, such as ensuring the most favorable treatment possible for Maryland sheep and goat producers in any market. Sheep and goat producers will benefit from a reduction in Scrapie disease incidence. Therefore, there will be an overall increase in value to Maryland's sheep and goat industries.

F. The proposed Scrapie regulations will lead to the eradication of Scrapie in Maryland. The public will benefit by knowing that Maryland sheep and goats products are free of this disease.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Dr. Michael Radebaugh, State Veterinarian, Animal Health Program, 50 Harry S. Truman Parkway, Annapolis, Maryland 21401, or call 410-841-5810, or email to michael.radebaugh, or fax to 410-841-5999. Comments will be accepted through February 22, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

General funds.

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See attached

G. Small Business Worksheet:

SMALL BUSINESS ANALYSIS WORKSHEET

1a. Intended Beneficiaries.

1b. Intended Beneficiaries: Households.

1c. Intended Beneficiaries: Businesses.

Sheep and goat producers

2a. Other Direct or Indirect Impacts: Adverse.

None

2b. Other Direct or Indirect Impacts: Positive.

Increase value of sheep and goats

3. Long-Term Impacts.

Planned eradication of Scrapie in Maryland

4. Estimates of Economic Impact.

A. Cost of providing goods and services.

B. Effect on the workforce.

C. Effect on the cost of housing.

D. Efficiency in production and marketing.

Less disease and dying animals, less condemnations of product

E. Capital investment, taxation, competition and economic development.

F. Consumer choice.

Attached Document:

Title 15 DEPARTMENT OF AGRICULTURE

Subtitle 11 ANIMAL HEALTH

Chapter 18 Requirements for Sheep and Goats for the Eradication of Scrapie

Authority: Agriculture Article, §§3-101, 3-105, and 3-108, Annotated Code of Maryland

.01 Purpose.

The purpose of this chapter is to explain State animal health requirements for sheep and goats entering or moving within Maryland to prevent the introduction or spread of scrapie, a fatal, degenerative disease. The control and prevention of this disease is a joint effort by the Maryland Department of Agriculture and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. The requirements of this chapter qualify Maryland to be classified as a scrapie consistent state under 9 CFR, Part 79. Scrapie consistent status not only enhances the well-being of the State's sheep and goat industry by protecting against scrapie but also helps ensure the most favorable treatment possible for Maryland sheep and goat producers in any market. Sheep and goat producers desiring to participate in the U.S. Scrapie Free Flock Certification Program shall follow the requirements for certification found in 9 CFR, Part 54 and 79.

.02 Definitions.

A. In this chapter the following terms have the meanings indicated.

B. Terms Defined.

(1) "Animal" means a sheep or a goat.

(2) "Administrator" means an employee of USDA, APHIS-VS authorized to administer the National Scrapie Eradication Program.

(3) "APHIS-VS" means the Animal and Plant Health Inspection Service, Veterinary Services unit of the U.S. Department of Agriculture.

(4) "Approved tagging site" means a site approved by the Department or APHIS-VS that tags and records all animals according to 9 CFR 86, the Animal Disease Traceability Rule.

(5) "Department" means the Maryland Department of Agriculture.

(6) "DSE" means a designated scrapie epidemiologist with knowledge of scrapie who is selected by the Administrator and the Department to coordinate and evaluate the scrapie eradication program.

(7) "Exposed animal" means an animal that:

(a) Has been in a flock or an enclosure off the premises of the flock with a scrapie positive animal;

(b) Resides in a non-compliant flock; or

(c) 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.

(8) "High risk animal" means any one of the following:

(a) A genetically susceptible exposed animal including embryos;

(b) A female offspring of a scrapie-positive female animal including embryos;

- (c) A suspect animal; or
- (d) Any animal including embryos that the Administrator determines to be high risk based on the epidemiology of the flock.
- (9) "Immediate Slaughter" means a process where a goat or sheep is sold or transferred for slaughter and is moved with an owner-hauler statement to a restricted slaughter facility for processing within 72 hours of a sale or transfer or entry into Maryland.
- (10) "Interstate Certificate of Veterinary Inspection" or "ICVI" means a certificate for interstate movement of animals completed by an issuing veterinarian, or a State or federal veterinarian.
- (11) "Issuing Veterinarian" means an accredited veterinarian approved by the Department and APHIS-VS to issue an ICVI.
- (12) "Low risk exposed animal" means any one of the following:
- (a) The animal was exposed to a positive animal that was not born in the flock and did not lamb in the flock or lamb in an enclosure where the exposed animal resided;
- (b) The exposed animal is male and was not born in the infected or source flock; or
- (c) The exposed animal is a castrated male; or
- (d) The exposed animal, as determined by the Administrator and State representative, is unlikely to be infected with scrapie.
- (13) "Official Identification" means an identification mark or device approved by the Department and APHIS-VS that identifies an animal and is used in accordance with APHIS-VS program standards, including:
- (a) A U.S. Department of Agriculture approved scrapie ear tag, provided that the tag is placed:
- (i) In the animal's ear (left ear recommended); or
- (ii) If the animal is earless and moving for immediate slaughter or to a terminal feedlot as defined in 9 CFR 79, on a durable neck strap placed around the animal's neck;
- (b) An electronic implanted device as defined by the U.S. Department of Agriculture under 9 CFR 79.2;
- (c) Legible registry tattoos issued by a registry that has agreed to cooperate with APHIS-VS in tracing scrapie positive, suspect, and exposed animals, provided the tattoo is placed:
- (i) In the animal's ears in the location required by the registry; or
- (ii) If the animal is earless, on the animal's tail web.
- (14) "Owner" means the owner of the flock of origin or an agent of the owner.
- (15) "Owner-hauler statement" or "owner-shipper statement" means a document that is generated by the owner, signed by the owner or hauler, documenting an animal's movement to a approved tagging site or a restricted livestock facility approved by the Department, and that, at a minimum, includes:
- (a) The name, address, and telephone number of the owner and, if different, the hauler;
- (b) The address and scrapie flock identification number of the flock of origin;
- (c) The name and address of the destination of the shipment;
- (d) A description of the species, breed, number, sex, and age of the animals shipped;
- (e) A complete listing of all animals by official identification; and
- (f) The date of the shipment.
- (16) "Restricted livestock facility" means an auction market approved by the Department that maintains animals to be sold or transferred for immediate slaughter in separate enclosures from other animals.
- (17) "Scrapie" means a fatal degenerative disease, classified as transmissible spongiform encephalopathy, affecting the central nervous system of sheep and goats.
- (18) "Scrapie consistent state" means a state that meets the scrapie control requirements provided in 9 CFR 79.6.
- (19) "Scrapie exposed flock" means a flock:
- (a) That the DSE has designated as:
- (i) An infected flock; or
- (ii) A source flock that has completed a flock plan and has retained a female genetically susceptible exposed animal; or
- (b) A flock under investigation:
- (i) That has retained a female genetically susceptible exposed animal or suspect animal; or
- (ii) Whose owner declines genotyping and live-animal or post-mortem scrapie testing required by APHIS-VS or the Department
- (c) Any flock for which a Post Exposure Monitoring and Management Plan is required by APHIS-VS or the Department that is not in compliance with the conditions of that plan.
- (20) "Scrapie positive animal" means an animal that is diagnosed with scrapie by an authorized laboratory approved by APHIS-VS.
- (21) "Scrapie suspect animal" means an animal suspected of having scrapie by an accredited veterinarian, the Department, or by a veterinary medical officer of USDA.
- (22) "Waybill" means a document from an approved tagging site, a restricted livestock facility, or a licensed livestock dealer that documents an animal's sale from such location to a farm, an authorized slaughter facility, or other location approved by the Department, and that, at a minimum, includes:
- (a) The name, address, and telephone number of the issuing party;

- (b) *The date of sale and the date of movement;*
- (c) *The name and address of the destination of the animal shipment;*
- (d) *A description of the species, breed, age, sex, and number; and*
- (e) *A complete listing of the individual official identification of each animal, which may include any use of glue-on back tags for animals destined for slaughter.*

.03 Official Identification Requirements.

A. Except as provided by §B of this regulation, for any animal entering or moving within Maryland, an animal owner shall:

- (1) *Ensure that the animal has an official identification; and*
- (2) *Keep and maintain a record of each animal's official identification for five years in a manner that will allow the Department to trace the animal to its flock of origin or a new owner, if sold or transferred.*

B. *Exceptions to Official Identification Requirement. The official identification requirements of this regulation do not apply for an animal:*

- (1) *That never leaves the premise of birth and has not commingled with animals originating outside the premise of birth;*
- (2) *Less than 18 months of age that has not lambed, is not pregnant, and is moving for immediate slaughter; or*
- (3) *Born in or entering Maryland and moving directly for sale to an approved tagging site, provided the animal is accompanied with an owner-hauler statement.*

.04 Requirements for Sheep and Goats Entering Maryland.

A. *General Requirements.*

(1) *Except for an animal moving to immediate slaughter, a person may not import an animal into Maryland unless the animal originates from a flock in a scrapie-consistent state or from a flock enrolled in the Scrapie Flock Certification Program as defined by 9 CFR 54.*

(2) *Exposed Animals. A person may not move a high or low risk exposed animal into Maryland without the Department's written approval.*

(3) *ICVI Requirement.*

(a) *Except as provided by §B of this regulation, for any animal entering Maryland, the hauler or person responsible for the animal shall ensure that each animal is accompanied with an ICVI.*

(b) *The owner shall provide the issuing veterinarian the following information for completing the ICVI:*

- (i) *Complete addresses of the flock or premise of origin and destination;*
- (ii) *The species, breed, sex and official scrapie identification of each animal; and*
- (iii) *Any document certifying the scrapie status of the flock.*

(c) *The issuing veterinarian shall include the following information in the ICVI:*

- (i) *The date of inspection;*
- (ii) *The date that the ICVI is issued;*
- (iii) *The scrapie premise or flock identification number(s); and*
- (iv) *Any other statement pertaining to the scrapie status of the flock if required under 9 CFR 79.3 and 79.5, certifying the known scrapie status of the flock.*

(d) *After completing the ICVI, the issuing veterinarian shall forward a copy to the chief animal health official of the state of destination within 7 days of issuance and keep a copy of it for a minimum of 5 years.*

(e) *An ICVI is invalid 30 days after issuance.*

B. *Exceptions to ICVI Requirement. An ICVI is not required for an animal moving into this State for immediate slaughter provided that the animal is accompanied with an owner-hauler statement.*

.05 Requirements for Moving Sheep and Goats within Maryland.

A. *Except as proved in Regulation .03B, an owner or hauler may move an animal within Maryland only if the animal is officially identified.*

B. *When an animal is moved within Maryland, the seller and new owner shall keep a record of the transaction for a minimum of 5 years on an owner-hauler statement or other document approved by the Department that provides for traceability as required by 9 CFR 86.*

C. *When an owner or hauler moves an animal within Maryland to an approved tagging site, the owner or hauler shall ensure that the animal is accompanied with a properly completed owner-hauler statement.*

D. *When an owner or hauler moves an animal within Maryland from an approved tagging site or a restricted livestock facility to a farm in Maryland, the owner or hauler shall ensure that the animal is officially identified and accompanied with a waybill.*

.06 Requirements for Moving Sheep and Goats for Immediate Slaughter.

A. *When selling or transferring animals for immediate slaughter:*

- (1) *The owner shall note on the owner-hauler statement and waybill that the animal is being sold for "immediate slaughter only"; and*

(2) The owner, dealer, market operator or hauler shall insure that the animal is delivered to the slaughter facility for processing within 72 hours of the animal's sale or transfer.

B. A person may not remove an animal from immediate slaughter:

(1) Without an ICVI or other document approved by the Department that has been signed by a State or federal official;
or

(2) If prohibited by 9 CFR 79.

C. Animals in slaughter channels as defined by 9 CFR 79 may only be removed from slaughter channels as provided in 9 CFR 79.

.07 Movement of High Risk Animal or Low Risk Exposed Animals.

A. The Department with the concurrence of the Administrator may re-designate high risk exposed animals as low risk exposed animals based on either the scrapie type involved or the epidemiology of the flock.

B. A person may not move any of the following high risk exposed animals into or within Maryland without prior written approval from the Department:

(1) An animal that originates from a state that:

(a) Is not a scrapie consistent state as provided in 9 CFR 79.6, as determined by APHIS-VS; or

(b) Originates from any flock or area under any animal movement restriction resulting from the presence or suspected presence of scrapie infection;

(2) A sexually intact genetically susceptible exposed animal;

(3) An animal that is scrapie suspect or scrapie positive; or

(4) An animal that is considered to be a high risk animal for scrapie as determined by the Department, APHIS-VS or by the chief animal health official of any state, territory, the District of Columbia, or any other official of a political subdivision recognized by the Department.

.08 Reporting Scrapie-Tested, Scrapie-Suspect, or Scrapie-Positive Animals.

A. If a clinically suspicious animal or test suspect is found, the flock owner or flock veterinarian is responsible for notifying the Department or the district office of APHIS-VS within 24 hours.

B. The accredited veterinarian or APHIS-VS authorized laboratory that conducts a scrapie test is responsible for notifying the Department of the test results within 24 hours when a test-positive scrapie animal is found. The Department shall immediately notify the district APHIS-VS office of the positive finding.

.09 Management of Scrapie-Suspect or Scrapie-Positive Animals and their Flocks.

A. If a clinical or other scrapie-suspect animal is reported by an owner, a veterinarian, or any other person, the following action shall be taken:

(1) The Department shall place the scrapie-suspect animal and the flock under a hold order until the actual status of the animal is determined;

(2) A State or federal animal health official shall officially identify the suspect animal and the entire flock;

(3) The owner of the animal shall allow the Department to collect and submit tissues for diagnostic testing and scrapie genetic susceptibility testing from all animals in the flock to an authorized laboratory to conduct scrapie testing; and

(4) If the suspect animal is euthanized or dies, the Department shall ensure that appropriate tissues are collected for scrapie testing and that the carcass is completely destroyed by one of the following means:

(a) Proper disposal by the owner on the owner's premises; or

(b) Disposal of the carcass by the owner at a Department approved facility.

B. When a scrapie-positive animal is identified by an official test, the following action shall be taken:

(1) The Department shall place the scrapie-positive animal and the flock under a hold order or other appropriate restriction until:

(a) An epidemiologic investigation is complete and the status of each animal in the flock is determined;

(b) The high risk animals die or are euthanized or removed to an approved research facility; and

(c) The lambing or kidding areas are cleaned and disinfected;

(2) A DSE, or any other appropriate official designated by the Department and APHIS-VS, shall conduct the epidemiologic investigation for scrapie;

(3) A State or federal animal health official shall officially identify the positive animal and entire flock;

(4) The owner of the animal shall allow a State or federal animal health official to collect and submit tissues for diagnostic testing from all animals in the flock to a laboratory authorized by APHIS-VS to conduct scrapie testing or scrapie genetic susceptibility testing; and

(5) If an animal is euthanized or dies, the Department shall ensure that appropriate tissues are collected for scrapie testing and that the carcass is completely destroyed by one of the following means:

(a) Proper disposal by the owner on the owner's premises; or

(b) Disposal of the carcass by the owner at a Department approved facility.

.10 Management of Flocks that Have Received Exposed or High-Risk Animals.

A. When a flock of sheep or goats is determined by State or federal animal health official to have received a scrapie-exposed or high-risk animal, the following steps shall be taken:

(1) The flock owner shall be contacted by a State or federal veterinary medical officer;

(2) The State or federal animal health officer shall place the scrapie-exposed or high risk animal and the entire flock under a hold order until the status of the flock is determined;

(3) A State or federal animal health official shall officially identify the exposed or high risk animal and the entire flock; and

(4) A DSE or a designated veterinary medical officer of the Department or APHIS-VS shall determine the status of animals within the flock by identifying the high-risk and exposed animals and restricting the movement of any animal that is determined to be high risk.

B. The flock owner shall allow a State or federal animal health official to officially identify the animals and to collect and submit animal tissues for diagnostic testing from all animals in the flock to a laboratory authorized by APHIS to conduct scrapie testing or scrapie genetic susceptibility testing. The owner shall report immediately to a State or federal animal health official if an exposed or high-risk animal dies or is in danger of dying.

C. If an animal in the flock is euthanized or dies, the appropriate State or APHIS-VS official shall ensure that appropriate tissues are collected for scrapie testing and that the carcass is completely destroyed by one of the following means:

(1) Proper disposal by the owner on the owner's premises; or

(2) A disposal of the carcass by the owner at a Department approved facility.

.11 APHIS-VS Requirements.

In addition to the requirements of this chapter, the owner of a sheep or goat shall comply with APHIS-VS requirements as provided by 9 CFR Parts 54 and 79.

.12 Non-Compliance.

A. A person who violates this chapter is subject to an administrative fine up to \$10,000 as provided in COMAR 15.11.19.

B. In addition to any administrative penalty, any person who violates this chapter is guilty of a misdemeanor, and is subject to fine or imprisonment as provided by Agriculture Article, §§ 12-101 and 12-102, Maryland Annotated Code.