

United States Comments

Terrestrial Animal Health Standards
Commission Report - September 2009

CHAPTER 14.9

SCRAPIE

Article 14.9,1 General Provisions

Text as presented:

Scrapie ~~is~~ does not ~~considered to~~ pose a risk to human health.

Retain original text:

Scrapie is not considered to pose a risk to human health.

Rationale: No data has been published that supports the proposed change.

Article 14.9.1. General provisions

General comment: The United States recommends that semen donor requirements remain in place.

14.9.1.1 Text as presented:

- a. semen collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

Proposed alternative text:

- a. ~~semen collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;~~

Maintain donor requirements in article 14.9.8 and update 4.5.3.1.g to replace reference to 14.9.6 with 14.9.8.

Rationale:

While the literature supports minimizing the requirements for semen with respect to scrapie transmission risk (Sarradin, et al., 2008; Palmer, 1957); this very limited data on lack of infectivity in semen is inadequate to support the use of semen from animals known to be infected with scrapie, exhibiting clinical signs associated with scrapie or that are likely to be infected with scrapie. The limited number of studies and the lack of diversity of scrapie “strains” evaluated make it appropriate to utilize additional layers to mitigate risk with respect to the donor animal that are not described in Chapter 4.5 or 4.6.

Also, Chapter 4.5 referred to in the proposed text, in section 4.5.3.1.g, reads “If the animals do not originate from a scrapie free country or zone as defined in Article 14.9.3., the animals should comply with Article 14.9.6.” Article 14.9.6 in the draft refers to animals for breeding and rearing not semen.

Article 14.9.3. Scrapie free country or zone

General comment: The United States, as expressed in our comments to the October 2008 draft of this chapter, continues to have concerns with the recommendations of this article. Specifically, limiting surveillance criteria to only sampling sheep and goats with “wasting conditions” will miss scrapie-affected animals. This approach was tried in the United States and clearly failed to detect scrapie cases at a rate higher than sampling cull sheep that did not have a wasting condition (Lynn et al 2007, Unpublished USDA data).

14.9.3.2.b Text as presented:

b. for at least 7 years, a sufficient number of representative mature ~~culled~~ sheep and goats over 18 months of age culled and/or dead on farm have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.1% out of the total number of all chronic wasting conditions in the population of sheep and goats older than 18 months of age and no *case* of scrapie has been reported during this period; it is assumed that the occurrence rate of chronic wasting conditions within the population of sheep and goats older than 18 months of age is at least 1% ~~(under study)~~; or

Proposed alternative text:

b. for at least 7 years, a sufficient number of representative mature ~~culled~~ sheep and goats over 18 months of age culled and/or dead on farm have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.01% or a comparable detection level is achieved through targeted surveillance of higher risk populations within a country out of the total number of all chronic wasting conditions in the population of sheep and goats older than 18 months of age and no *case* of scrapie has been reported during this period; ~~it is assumed that the occurrence rate of chronic wasting conditions within the population of sheep and goats older than 18 months of age is at least 1% (under study)~~; or

Rationale: The OIE-recommended population to be sampled will effectively miss detecting many cases of the disease. The proposed text of Article 14.9.3 paragraph 4b, as written, calls for surveillance at “...a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.1% out of the total number of all **chronic wasting conditions** in the population of sheep and goats older than 18 months of age...”. When this strategy is applied, it results in sheep and goats over 5 years of age being preferentially selected for sampling. Since the majority of sheep and goats infected by classical scrapie die before 5 years of age (Wineland et. al. 1998), this sampling strategy will result in a lower ability to detect scrapie than sampling the same number of animals from the overall cull population (Lynn et. al. 2007, Unpublished USDA data). The United States recommends either sampling at the level required to detect a prevalence rate exceeding 0.01% in the overall cull population or establishing a point system based on the relative prevalence within risk groups that would achieve a similar sensitivity level as was done for BSE.

14.9.3.4 Text as presented:

4. introductions of sheep and goats or their ~~semen or~~ their embryos/oocytes from countries or ~~zones~~ not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., ~~14.9.8.~~ or 14.9.9., as relevant.

Proposed alternative text:

4. introductions of sheep and goats or their semen or their embryos/oocytes from countries or ~~zones~~ not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., 14.9.8. or 14.9.9., as relevant.

Rationale: While the literature supports minimizing the requirements for semen with respect to scrapie transmission risk (Sarradin, et al., 2008; Palmer, 1957); the very limited data on lack of infectivity in semen is inadequate to support the use of semen from animals known to be infected with scrapie, exhibiting clinical signs associated with scrapie or that are likely to be infected with scrapie. The limited number of studies and the lack of diversity of scrapie “strains” evaluated make it appropriate to utilize additional layers to mitigate risk with respect to the donor animal that are not described in Chapter 4.5 or 4.6.

Article 14.9.4. Scrapie free compartment**14.9.4.3 Text as presented:**

3. introductions of sheep and goats are allowed only from accredited free establishments;

Proposed alternative text:

3. introductions of sheep and goats are allowed only from accredited free establishments or free countries;

Rationale: Introductions of animals from free countries should also be allowed and this change should be made in 14.9.5.2.c also for consistency.

Article 14.9.5. Scrapie free establishment**Text as presented:**

e. sheep and goat semen introduced into the establishment should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

Proposed alternative text:

e. semen donors should comply with article 14.9.8;

Rationale: The requirements of Chapter 4.5 and 4.6 are primarily intended to address conditions other than scrapie and would unduly restrict the ability of flock owners to obtain new genetic material.

Article 14.9.8. Recommendations for importation from countries or zones not considered free from scrapie for semen of sheep and goats

14.9.8. Text as presented:

Section was deleted in the draft

Proposed alternative text:

Recommendations for importation from countries or zones not considered free from scrapie for semen of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

- a) are permanently identified, to enable trace back to their *establishment of origin*;
- b) have not tested positive for scrapie and are not known to be scrapie exposed susceptible animals;
- c) showed no clinical sign of scrapie at the time of semen collection;

2. the semen was collected, processed and stored in conformity with the relevant provisions of Chapter 4.5 and 4.6.

Rationale: While the literature supports minimizing the requirements for semen with respect to scrapie transmission risk (Sarradin, et al., 2008; Palmer, 1957); the very limited data on lack of infectivity in semen is inadequate to support the use of semen from animals known to be infected with scrapie, exhibiting clinical signs associated with scrapie or that are likely to be infected with scrapie. The limited number of studies and the lack of diversity of scrapie “strains” evaluated make it appropriate to utilize additional layers to mitigate risk with respect to the donor animal that are not described in Chapter 4.5 or 4.6.

Also, Chapter 4.5 referred to in the proposed text, in section 4.5.3.1.g, reads “If the animals do not originate from a scrapie free country or zone as defined in Article 14.9.3., the animals should comply with Article 14.9.6.” Article 14.9.6 in the draft refers to animals for breeding and rearing not semen and should be changed to 14.9.8.

Article 14.9.15. Requirements to declare a country or zone historically free from scrapie

14.9.15.b. Text as presented:

b. a formal programme of targeted *surveillance* and monitoring, which includes clinical suspects, animals dead on farm and aged sheep and goats, can be documented as having been in place for at least 10 years; and

Proposed alternative text:

b. a formal programme of targeted *surveillance* and monitoring, which includes clinical suspects, and mature sheep and goats over 18 months of age culled and/or dead on farm ~~animals dead on farm and aged sheep and goats~~, can be documented as having been in place for at least 10 years; and

Rationale: For conformity with 14.9.3.2.b. Use of the word “aged” is not precise and suggests that older animals should be preferentially sampled, when for classical scrapie the highest prevalence is found in animals that are 2-4 years of age.

References Cited

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