

Terrestrial Animal Health Standards Commission Report

October 2008

CHAPTER 14.9

SCRAPIE

Article 14.9.1.

General provisions

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

~~The recommendations in the present Chapter are not intended, or sufficient, to manage the risks associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.~~

Scrapie is not considered to pose a risk to human health. The recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The Chapter does not cover so-called 'atypical' scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

1. When authorising import or transit of the following commodities and any products made from these commodities and containing no other tissues from small ruminants, Veterinary Authorities should not require any scrapie-related conditions, regardless of the scrapie risk status of the small ruminant populations of the exporting country, zone or compartment.
 - a) meat (excluding materials as referred to in Article 14.9.11.);
 - b) semen;
 - c) hides and skins;
 - d) gelatine;
 - e) collagen prepared from hides or skins;
 - f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - g) dicalcium phosphate (with no trace of protein or fat);

h) wool or fibre.

2. When authorising import or transit of other commodities listed in this Chapter, Veterinary Authorities should require the conditions prescribed in this Chapter relevant to the scrapie risk status of the small ruminant populations of the exporting country, zone or compartment.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.9.2.

The scrapie status of the sheep and goat populations of a country, ~~a zone or an establishment~~ compartment ~~can~~ should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:
 - ~~a) epidemiological situation concerning all animal transmissible spongiform encephalopathies (TSE) in the country, zone or establishment;~~
 - ~~b) importation or introduction of small ruminants sheep and goats or their embryos/oocytes potentially infected with scrapie;~~
 - ~~e) extent of knowledge of the population structure and husbandry practices of sheep and goats in the country ~~or~~ zone or compartment;~~
 - ~~e) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;~~
 - ~~e) importation of *meat-and-bone meal* or *greaves* potentially contaminated with an animal TSE or feedstuffs containing either;~~
 - ~~f) the origin and use of ruminant carcasses (including fallen stock), by products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;~~
2. an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;
3. a *surveillance* and monitoring system including the following:
 - a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;
 - b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
 - c) compulsory notification and clinical investigation of ~~all~~ sheep and goats showing clinical signs compatible with scrapie;
 - d) examination, in accordance with the *Terrestrial Manual*, in an ~~approved~~ *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie ~~taking into account the recommendations in Chapter X.X. (under~~

~~study~~);

- e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any *risk* identified;

AND EITHER

2. one of the following conditions should be met:

- a) the country or the *zone* have demonstrated historical freedom taking into account the recommendations in Articles 14.9.13. and 14.9.14.;or,

OR

3. ~~for at least 7 years, a *surveillance* and monitoring system as referred to in Article 14.9.2. has been in place, and no *case* of scrapie has been reported during this period;~~

OR

- 4.b) for at least 7 years, a sufficient number of investigations has been carried out 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 (~~under study~~) 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%; or,

OR

- 5.c) all ~~*establishments*~~ *compartments* containing sheep or goats have been accredited free as described in Article 14.9.4.;

AND

63. the feeding to sheep and goats of ~~*meat-and-bone meal* or *greaves*~~ potentially contaminated with an animal TSE of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

74. introductions of sheep and goats, ~~semen and~~ 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.

~~For maintenance of country or zone free status, the investigations referred to in point 4 above should be repeated every 7 years.~~

Article 14.9.4.

Scrapie free ~~establishment~~ compartment

An *establishment* may be considered eligible for accreditation as a scrapie free ~~establishment~~ compartment if:

1. in the country or ~~zone~~ where the *establishment* is situated, the following conditions are fulfilled:
 - a) the *disease* is compulsorily notifiable;
 - b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are slaughtered and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin ~~potentially contaminated with an animal TSE~~ has been banned and effectively enforced in the whole country;
 - e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
2. in the *establishment* the following conditions have been complied with for at least 7 years:
 - a) sheep and goats should be permanently identified and records maintained, to enable trace back to their *establishment* of birth;
 - b) records of movements of sheep and goats in and out of the *establishment* are ~~established and~~ maintained;
 - c) introductions of ~~animals~~ sheep and goats are allowed only from ~~establishments~~ free country, zone or compartment of an equal or higher stage in the process of accreditation; however, ~~rams and bucks complying with the provisions in point 2 of Article 14.9.8. may also be introduced;~~
 - d) an *Official Veterinarian* inspects sheep and goats in the *establishment* and audits the records at least once a year;
 - e) no *case* of scrapie has been reported;
 - f) sheep and goats of the *establishment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;
 - g) all culled ~~animals~~ sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting neurological or wasting signs are tested in a *laboratory* for scrapie. The selection of the ~~animals~~ sheep and goats to be tested should be made by the *Official Veterinarian*. ~~Animals~~ Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

~~Article 14.9.5.~~**Recommendations on safe commodities**

Regardless of the scrapie status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of *meat* (excluding materials as referred to in Article 14.9.11.), *milk, milk products*, wool and its derivatives, hides and skins, tallow, derivatives made from this tallow and dicalcium phosphate originating from sheep and goats.

Article 14.9.6.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals come from a ~~zone or~~ an establishment compartment free from scrapie as described in ~~Article 14.9.3. and in~~ Article 14.9.4.

Article 14.9.7.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for slaughter

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

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are slaughtered and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

~~Article 14.9.8.~~**~~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. in the country or *zone*:~~
 - ~~a) the *disease* is compulsorily notifiable;~~
 - ~~b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;~~
 - ~~c) affected sheep and goats are slaughtered and completely destroyed;~~

- d) ~~the feeding of sheep and goats with *meat and bone meal* or *greaves* potentially contaminated with an animal TSE has been banned and effectively enforced in the whole country;~~
2. ~~the donor animals:~~
 - a) ~~are permanently identified, to enable trace back to their *establishment* of origin;~~
 - b) ~~have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;~~
 - e) ~~showed no clinical sign of scrapie at the time of semen collection;~~
 3. ~~the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.~~

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie for embryos/oocytes of sheep and goats

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

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are slaughtered and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin ~~potentially contaminated with animal TSE~~ has been banned and effectively enforced in the whole country;
2. the donor animals either have been kept since birth in a free *compartment*, or meet the following conditions:
 - a) are permanently identified, to enable trace back to their *establishment* of origin;
 - b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;
 - c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7.

Article 14.9.9.bis

Recommendations for importation from countries or zones not considered free from scrapie

for milk and milk products intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the milk and milk products come from scrapie free compartments.

Article 14.9.10.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.11.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

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

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are slaughtered and completely destroyed;
2. the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.12.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or ~~establishment~~ *compartment*.

Article 14.9.13.

Principles for declaring a country or zone historically free from scrapie

Articles 14.9.13. and 14.9.14. outline principles for declaring a country or *zone* free from scrapie.

An essential prerequisite to provide the guarantees required for the recognition of freedom from *disease/infection* is that the *Veterinary Services* of the Member comply with the provisions of Chapter 3.1. on evaluation of *Veterinary Services*, and, if relevant, with the provisions of Chapter 4.3. on zoning and compartmentalisation.

The provisions of the above-mentioned articles are based on the principles developed in Chapter 1.4. and the following premises:

1. the sheep population of the country or *zone* includes a range of genotypes known to be susceptible to scrapie;
2. the *Veterinary Services* have the competence, capacity and mandate to investigate, diagnose and report scrapie, if present;
3. the absence of scrapie over a long period of time can be substantiated by effective *disease* investigation and reporting by the *Veterinary Services* of an OIE Member.

Article 14.9.14.

Requirements to declare a country or zone historically free from scrapie

A country or *zone* may be recognised free from scrapie without having applied the requirements of Article 14.9.3. when:

- a) scrapie has been notifiable for at least 25 years; and
- b) a formal programme of targeted *surveillance* and monitoring can be documented as having been in place for at least 10 years; and
- c) the presence of a range of scrapie susceptible genotypes in this sheep population can be documented; and
- d) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
 - i) either scrapie has never been reported; or
 - ii) no *case* of scrapie has been reported for at least 25 years.