

CHAPTER 14.9.

SCRAPIE

EU position

The EU can only support the adoption of the modified chapter if its comments in article 14.9.3 point a)ii) and b) are taken on board.

The EU also wishes its other comments inserted in the text below to be taken into account.

Article 14.9.1.

General provisions and safe commodities

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.

Scrapie ~~is~~ does is not ~~considered to~~ 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* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats derived, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*:
 - a) semen collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6. in vivo derived sheep embryos handled in accordance with Chapter 4.7 of this Terrestrial Code;

EU comment

The EU thanks the OIE to take its previous comment as regards semen into account. However the EFSA opinion published on 6 January 2010 (Scientific Opinion on Risk of transmission of TSEs via semen and embryo transfer in small ruminants, EFSA Journal 2010;7(1):1429) concludes that the risk of TSE transmission associated with semen and embryos collected from Classical Scrapie incubating sheep and goats ranges from negligible to low. Based on this opinion, it is not possible to consider that in vivo derived sheep embryos do not represent any risk as regards scrapie transmission. Therefore the Community proposes to delete Article 14.9.1, point 1)a entirely.

b) *meat* (excluding materials as referred to in Article 14.9.12.);

b)c) hides and skins;

~~e~~)gelatine;

EU comment

The EU can only support the inclusion of gelatine prepared exclusively from hides or skins.

~~e~~)collagen prepared from hides or skins;

~~e~~) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

EU comment

The EU can only support the inclusion of tallow if no commodities referred to in article 14.9.12 have been used for its production.

~~e~~) dicalcium phosphate (with no trace of protein or fat);

~~e~~) 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 sheep and goat populations of the *exporting country, zone or compartment*.

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

Article 14.9.2.

Determination of the scrapie status of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone, compartment or establishment* 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) importation or introduction of sheep and goats or their ~~semen or~~ **semen, in vivo derived goat embryos or their in vitro processed sheep and goat** embryos/oocytes potentially infected with scrapie;

EU comment

Following the publication of the EFSA opinion of 6 January 2010, the Community proposes to modify Article 14.9.2 point 1)a as follows in order to include all types of embryos: " importation or introduction of sheep and goats or their semen or their embryos/oocytes potentially infected with scrapie;"

- b) extent of knowledge of the population structure and husbandry practices of sheep and goats;
 - c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;
 - d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;
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 sheep and goats showing clinical signs compatible with scrapie;
 - d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;
 - 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 are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding 7 years;

AND

2. one of the following conditions should be met:
 - a) the country or the *zone* have demonstrated historical freedom as follows: taking into account the recommendations in Articles 14.9.14. and 14.9.15. (under study); or
 - i) scrapie has been notifiable for at least 25 years; and
 - ii) a formal programme of targeted *surveillance* and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and

EU position

The EU can only support the adoption of the chapter if in Article 14.9.3 point 2)a)ii, the words "statistically valid" are inserted between "a formal programme of" and "targeted surveillance".

- iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
 - either scrapie has never been reported; or
 - no case of scrapie has been reported for at least 25 years.
- b) for at least 7 years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of representative mature culled sheep and goats over 18 months of age, representative of slaughtered, culled and/or found dead on farm, have been tested

annually, to provide a 95% level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.01% 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

EU position

The EU can only support the adoption of the chapter if the prevalence rate for detecting scrapie is maintained at 0.1%. Indeed, the rationale for the change in the target population is to enhance the probability of finding cases, there is no justification for a lower prevalence rate.

- c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

EU comment

Experience within the EU pointed out the risk of cross-contamination through feed of other mammalian origin.

The EU proposes to modify Article 14.9.3, point 3 as follows: “the feeding to sheep and goats of meat-and-bone or greaves of ruminant origin as been banned and effectively enforced through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, in the whole country for at least 7 years”

This comment also applies to Article 14.9.5 point 1) d and 14.9.9 point 1)d.

AND

4. introductions of sheep and goats or their semen or their semen, in vivo derived goat embryos or their in vitro processed sheep and goat 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.~~ 14.9.8. or 14.9.9., as relevant.

EU comment

Following the publication of the EFSA opinion of 6 January 2010, the EU proposes to modify Article 14.9.2 point 4 as follows in order to include all types of embryos: "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."

Article 14.9.4.

Compartment free from sScrapie free compartment

To qualify as a A compartment free from scrapie, may be considered free from scrapie if the following conditions are fulfilled all sheep and goats in a compartment should be certified by the Veterinary Authority as satisfying the following requirements:

1. all establishments within the *compartment* are free from scrapie according to Article 14.9.5.;

2. all establishments within the compartment are managed under a common biosecurity plan protecting them from introduction of scrapie, and the compartment has been approved by the Veterinary Authority in accordance with Chapters 4.3. and 4.4.;
3. introductions of sheep and goats are allowed only from accredited free establishments or free countries;

EU comment

The EU proposes to refer only to "free establishments" insofar as the term "accredited" has never been defined.

Furthermore, the EU proposes that sheep of ARR/ARR genotype can be introduced as well even if they come from establishments which are not free.

4. introductions of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes are allowed either from accredited free establishments or in accordance with Article 14.9.9.;

EU comment

Following the publication of the EFSA opinion of 6 January 2010, the EU proposes to modify Article 14.9.4 point 4 as follows in order to include all types of embryos: "introductions of sheep and goat embryos/oocytes are allowed either from scrapie free establishments or in accordance with Article 14.9.9."

5. sheep and goat semen should be introduced into the compartment should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6. in accordance with Article 14.9.8.;
6. sheep and goats in the compartment should have no direct or indirect contact, including shared grazing, with sheep or goats from establishments not within the compartment.

~~One or more establishments may be considered eligible for accreditation as a scrapie free compartment if:~~

1. ~~in the country or zone where the establishments are situated, the following conditions are fulfilled:~~
 - a. ~~the disease is compulsorily notifiable;~~
 - b. ~~an awareness, 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 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 establishments the following conditions have been complied with for at least 7 years:~~
 - a. ~~sheep and goats are 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 maintained;~~
 - c. ~~introductions of sheep and goats are allowed only from free establishments of an equal or higher stage in the process of accreditation; however, rams and bucks complying with the provisions in point 1 of Article 14.9.8. may also be introduced;~~

- d. ~~an Official Veterinarian inspects sheep and goats in the establishments and audits the records at least once a year;~~
 - e. ~~no case of scrapie has been reported;~~
 - f. ~~sheep and goats of the establishments should have no direct or indirect contact, including shared grazing, with sheep or goats from establishments of a lower status;~~
 - g. ~~all culled sheep and goats over 18 months of age are inspected by an Official Veterinarian, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a laboratory for scrapie. The selection of the sheep and goats to be tested should be made by the Official Veterinarian. 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).~~
3. ~~cattle, water buffalo and wood bison in a compartment free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the compartment has been approved by the Veterinary Authority in accordance with Chapters 4.3. and 4.4.~~

Article 14.9.5.

Scrapie free establishment

~~To qualify as free from scrapie, an establishment of sheep and goats may be considered eligible for accreditation as a scrapie free establishment if should satisfy the following requirements:~~

1. in the country or zone where the establishment is situated, the following conditions are fulfilled:
 - a) the disease is compulsorily notifiable;
 - b) an awareness, surveillance and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are ~~slaughtered~~ **killed** and completely destroyed;

EU comment

For the sake of clarity, the EU proposes to simplify point c) as follows: "all affected sheep and goats are completely destroyed".

The same remark applies for Article 14.9.7 point 1c), Article 14.9.9 point 1c) and Article 14.9.12 point 2a)iii).

- d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country **for at least 7 years**;
 - 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 are 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 maintained;

- c) introductions of sheep and goats are allowed only from free *establishments* or establishments at an equal or higher stage in the process of accreditation;

EU comment

The EU proposes that sheep of ARR/ARR genotype can be introduced as well even if they come from establishments which are not free.

Furthermore, the EU proposes to use the word "qualification" instead of "accreditation" and invites OIE to provide some clarifications and guidance on the different steps of the qualification process foreseen in order to have a harmonised application in establishments which are not yet qualified as free.

- d) introduction of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos /oocytes should comply with Article 14.9.9.;

EU comment

Following the publication of the EFSA opinion of 6 January 2010, the EU proposes to keep the last version of Article 14.9.5 point 2)d in order to include all types of embryos: "introduction of sheep and goat embryos/oocytes should comply with Article 14.9.9.;"

- e) sheep and goat semen should be introduced into the *establishment* should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6. in accordance with Article 14.9.8.;
- df) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;
- eg) no *case* of scrapie has been reported;
- fh) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;
- gi) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. 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*).

EU comment

The EU invites OIE to clarify which population of sheep and goats is concerned by the term "culled".

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 an *establishment* free from scrapie as described in Article 14.9.5.

OR

In cases where the animals do not come from an *establishment* free from scrapie as described in Article 14.9.5., the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.

EU comment

The EU proposes that sheep of ARR/ARR genotype can be imported even if they come from establishments which are not free and proposes to add the following alternative condition:

"OR

In cases where the animals are sheep and do not come from an establishment free from scrapie as described in Article 14.9.5, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals are of ARR/ARR genotype. "

This comment also applies to Article 14.9.9 point 2.

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) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are **slaughtered killed** 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. 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;
 - 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 provisions of Chapter 4.5. and Chapter 4.6.~~

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. the donor animals:
 - a) are permanently identified to enable trace back to their *establishment* of origin;
 - b) showed no clinical sign of scrapie at the time of semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie for *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes of sheep and goats

EU comment

Following the publication of the EFSA opinion of 6 January 2010, the EU thinks that no distinction should be made between the different types of embryos and proposes not to modify the introductory phrase of Article 14.9.9.

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) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are **slaughtered killed** and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;
2. the donor animals either have been kept since birth in a free *establishment*, 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 Chapters 4.7., **4.8. and 4.9.**, as relevant.

Article 14.9.10.

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

for milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

EU comment

In view of the proven transmissibility of classical scrapie through milk and due to the risk of cross-contamination between cattle feed and small ruminant feed, protective measures in relation to milk and milk products coming from classical scrapie infected flocks should be extended to all ruminant feeds.

The EU proposes the following wording:

"for milk and milk products of sheep or goat origin intended for use in feeding of ruminants"

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

Article 14.9.11.

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 14.9.12.

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

EU comment

The EU would like to know what scientific basis allows considering adrenal gland, pancreas and liver as non safe commodities.

Furthermore, the EU would like to inform the OIE that EFSA has been recently mandated to reassess the risk posed by small ruminant tissues as regards TSEs. The final opinion of EFSA is expected by the end of 2010.

1. these commodities should not be traded for use in ruminant feeds;
2. for purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
 - ~~1a)~~ in the country or *zone*:
 - Ai) the *disease* is compulsorily notifiable;
 - Bii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - eiii) affected sheep and goats are **slaughtered** **killed** and completely destroyed;
 - 2b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

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*.

~~Article 14.9.14.~~**Principles for declaring a country or zone historically free from scrapie**

~~Articles 14.9.14. and 14.9.15. 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 14.9.15.~~**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:~~

- ~~1. scrapie has been notifiable for at least 25 years; and~~
- ~~2. 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~~
- ~~3. the presence of a range of scrapie susceptible genotypes in this sheep population can be documented; and~~
- ~~4. appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and~~
 - ~~a) either scrapie has never been reported; or~~
 - ~~b) no *case* of scrapie has been reported for at least 25 years.~~

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