

Guideline for drafting a dossier for the recognition of a Member State or zones of a Member State with a negligible risk of classical scrapie

Version 6 – presented at the Standing Committee of 6 October 2022

The present document provides some information on the data and documents that could be provided in the dossier to be submitted to the Commission according to Annex VIII, Chapter A, Section A, point 2.1 to Regulation (EC) No 999/2001.

Regulatory provision (Annex VIII, Chapter A, Section A, <u>point 2.1</u> to Regulation (EC) No 999/2001)	Comment / suggested documentation
(a) a risk assessment has been conducted, and it has demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any risk identified. This risk assessment shall identify all potential factors for classical scrapie occurrence and their historic perspective, in particular the:	<p>Use article 2.1.3 and 2.1.4 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH) as a guide for conducting the risk assessment.</p> <p>Include date of last known case of classical scrapie.</p>
(i) importation or introduction of ovine and caprine animals or their semen and embryos potentially infected with classical scrapie;	<ul style="list-style-type: none"> • Documentation including tables describing origin and volume of introductions through import and trade for the past seven years. • Documentation including tables describing the purpose of imported and traded ovine and caprine animals: breeding, fattening, slaughter, other. • Documentation on specific rules for the movement of imported and traded ovine and caprine animals or their semen and embryos within the country, if any. • If applicable, reference to specific rules of an approved National Control Programme for Classical Scrapie. • Information on any other relevant measures taken to prevent the risk of introducing classical scrapie into the Member State or zone, via the movement of ovine and caprine animals or their semen and embryos.
(ii) extent of knowledge of the population structure and husbandry practices of ovine and caprine animals;	<ul style="list-style-type: none"> • Documentation describing the ovine and caprine industry in the country: number of sheep and goats older than 18 months of age, numbers and location of farms, average size of holdings, etc.
(iii) feeding practices, including consumption of meat-and-bone meal or greaves derived from ruminants;	<ul style="list-style-type: none"> • Documentation to support claims that meat-and-bone meal, greaves or feedstuffs containing either meat-and-bone meal or greaves have not been imported during the past seven years.

<p>(iv) importation of milk and milk products of ovine and caprine animals origin intended for use in feeding of ovine and caprine animals;</p>	<ul style="list-style-type: none"> • Documentation describing origin and volume of introductions through import and trade for the past seven years.
<p>(b) for a period of at least seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;</p>	<ul style="list-style-type: none"> • What were the date and content of a possible national legal act making notification of TSE suspects compulsory? • Documentation indicating if and when an awareness programme was instituted and its continuous application and geographical coverage. • Documentation on the number and occupation of persons who have participated in the awareness programme (veterinarians, producers, workers at auctions, slaughterhouses, etc.). • Documentation of materials used in the awareness programme (the manual, supportive documents, or other teaching materials). • What guidance is given to veterinarians, producers, workers at auctions, slaughterhouses, etc. in terms of the criteria that would initiate the investigation of an animal as a TSE suspect? Have these criteria evolved over time? • What are the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspect? • Number of ovine and caprine animals annually tested as TSE suspects and results.
<p>(c) for a period of at least seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95 percent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 percent and no case of classical scrapie has been reported during that period;</p>	<ul style="list-style-type: none"> • Documentation explaining the monitoring system of classical scrapie and its evolution overtime. • Documentation explaining how the animals to be tested are chosen. • Number of ovine and caprine animals over 18 months age tested annually in each target group. • Documentation to support claims that the numbers were sufficient to meet the requirement. <p><u>Concerning the calculations to support demonstration of the requirement:</u></p> <ul style="list-style-type: none"> - 2 different testing streams should be considered when providing raw data: "animals slaughtered for human consumption" and "animals NOT slaughtered for human consumption". Animals culled for destruction being a negligible testing stream in Member States applying for the status, any test in that stream should be pooled with the tests in "animals NOT slaughtered for

	<p>human consumption".</p> <p>Also data should be provided for sheep and goats separately.</p> <ul style="list-style-type: none"> - For the final calculation in a given year, the data for both testing streams and both species may be pooled together. - The requirement must be verified for each year separately. - For the calculation it is recommended to use a scenario-tree modelling, similar to that used by EFSA in its 2015 scientific reports on the evaluation of the application of Sweden/Finland to be recognised as having a negligible risk of classical scrapie¹, assuming that the sensitivity of the surveillance system is equivalent to the diagnostic sensitivity provided by the past evaluations of screening diagnostic tests by the EFSA and the Joint Research Centre Institute for Reference Materials and Measurement (IRMM) (see Appendix B of the EFSA scientific reports).
<p>(d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole Member State for a period of at least seven years;</p>	<ul style="list-style-type: none"> • Documentation on prohibitions concerning animal feeding during the previous seven-year period at least within the territory of the Member State. • Documentation on the measures taken to control cross-contamination of feedstuffs with meat-and-bone meal, greaves and processed animal protein (PAP) including the risk of cross-contamination during production, transport, storage and feeding. • Documentation, in the form of the following table 1, on the audit findings in rendering plants and feed mills processing material, related to the prohibition of the feeding to farm animals of meat-and-bone meal, greaves and processed animal protein (PAP). • Documentation, in the form of the following table 2, on the audit findings in farms keeping ovine and/or caprine animals, related to the prohibition of the feeding to farm animals of meat-and-bone meal, greaves and processed animal protein (PAP). • Documentation, in the form of the following table 3, on each plant with an infraction mentioned in table 1, specifying the type of infraction and the method of resolution.

¹ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4292/epdf> and <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4293/epdf>

	<ul style="list-style-type: none"> • Documentation, in the form of the following table 4, on each farm with an infraction mentioned in table 2, specifying the type of infraction and the method of resolution. • Documentation explaining why, in light of the findings displayed in the tables 1 to 4, it is considered that there has been no significant exposure of ovine and caprine animals to the TSE agent through consumption of meat-and-bone meal, greaves and processed animal protein (PAP).
<p>(e) introductions from other Member States of ovine and caprine animals and semen and embryos thereof are carried out in accordance with point 4.1.(b) or point 4.2.;</p>	<ul style="list-style-type: none"> • Documentation on scrapie-related specific controls / audits on introduction of ovine and caprine animals and semen and embryos thereof from other Member States. <p><u>Concerning the requirement that live sheep and goats for all intended uses except immediate slaughter moved from other Member States be introduced only from holdings with a negligible risk of classical scrapie, or Member States or zone of a Member State with a negligible risk of classical scrapie, or be sheep of ARR/ARR prion protein genotype or be goats carrying at least one of the K222, D146 or S146 alleles:</u></p> <ul style="list-style-type: none"> • Similar to the requirement of Article 14.8.3 of the WOAH Terrestrial Animal Health Code, this requirement does not need to be complied with for the preceding seven years, but needs to be complied with from the date at which the Member State / zone of a Member State has officially been granted the status of Member State / zone of a Member State with negligible risk of classical scrapie. This is ensured by point 4.1.(b) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 itself. • Therefore, for the original application, there is no obligation to demonstrate that this requirement has been applied or is already being applied. Furthermore, having an approved National Control Programme for Classical Scrapie is not a mandatory prerequisite for applying for the status of Member State or zone of a Member State with a negligible risk of classical scrapie.
<p>(f) introductions from third countries of ovine and caprine animals and semen and embryos thereof are carried out in accordance with Chapter E or Chapter H of Annex IX.</p>	<ul style="list-style-type: none"> • Documentation on specific scrapie-related controls / audits on imports of ovine and caprine animals and semen and embryos thereof from third countries.

Regulatory provision (Annex VIII, Chapter A, Section A, <u>point 2.2</u> to Regulation (EC) No 999/2001)	Comment / suggested documentation
<p>...</p> <p>The Member State is to notify the Commission of any change in the information submitted according to point 2.1. relating to the disease.</p> <p>...</p>	<p>The consequence of this provision is that the Member State must keep on testing yearly enough small ruminants to be able to demonstrate over the years that compliance with point 2.1(c) particularly is maintained.</p> <p>Provide information on the future testing regime to be applied after the Member State is granted the negligible risk status.</p>

Table 1

Year (information should be provided for each of the last 7 years at least)	Type of plant (renderer or feed mill)	Number of plants	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

Table 2

Year (information should be provided for each of the last 7 years at least)	Type of farm	Number of farms inspected	Total number of visual inspections in (A)	Total number of farms in (A) with infractions	Total number of inspected farms in (A) with sampling	Total number of farms in (B) with positive test results
		(A)			(B)	
Year 1	Ruminants only					
	Ruminant and monogastric animals					
Year 2, etc.	Ruminants only					
	Ruminant and monogastric animals					

Table 3

Year (information should be provided for each of the last 7 years at least)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3, etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Renderer				
	Feed mill				

Table 4

Year (information should be provided for each of the last 7 years at least)	Type of farm	Farm ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Ruminants only	ID 1			
		ID 2			
		ID 3, etc.			
	Ruminant and monogastric animals	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Ruminants only				
	Ruminant and monogastric animals				