



2025/328

20.2.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/328

of 19 February 2025

**amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council
as regards the approval of the negligible risk status for classical scrapie of Slovenia**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular Article 16 read in conjunction with Section A, point 2.2, first paragraph, of Chapter A of Annex VIII thereto,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. Article 15(1) of that Regulation provides, inter alia, that the placing on the market or, if need be, the export of bovine, ovine or caprine animals and their semen, embryos and ova are subject to the conditions laid down in Annex VIII thereto.
- (2) Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 contains, inter alia, the conditions which apply to the placing on the market of ovine and caprine animals and semen and embryos thereof. Point 2.1 of that Section concerns the case where a Member State considers that its territory or part of its territory poses a negligible risk of classical scrapie. In such case, the Member State concerned has to submit to the Commission appropriate supporting documentation demonstrating that the criteria laid down in that point are fulfilled. Point 2.2 of that Section states that the Commission may approve the negligible risk status for classical scrapie of the Member State or of the zone of the Member State. Point 2.2 of that Section also provides that the Member State is to notify the Commission of any change in the information submitted in accordance with point 2.1 thereof relating to that disease. In addition, point 2.3 of that Section lists the Member States whose negligible risk status for classical scrapie has been approved.
- (3) On 26 June 2023, Slovenia submitted an application to the Commission to be recognised as having a negligible risk status for classical scrapie. The Commission gave a favourable opinion on Slovenia's application with regard to the criteria laid down in Chapter A, Section A, point 2.1(a), (b), (d), (e) and (f) of Annex VIII to Regulation (EC) No 999/2001, but did not complete its assessment with regard to point 2.1(c) of that Section. On 29 February 2024, the Commission requested the scientific and technical assistance of the European Food Safety Authority (EFSA) to evaluate whether that Member State, in its application, demonstrated compliance with Section A, point 2.1(c) and point 2.2, of Chapter A of Annex VIII to Regulation (EC) No 999/2001.
- (4) On 21 October 2024, EFSA published a scientific report on the 'Evaluation of the application of Slovenia to be recognised as having a negligible risk of classical scrapie' ⁽²⁾ in response to the Commission's request (the EFSA report). The EFSA report concludes that, based on the diagnostic sensitivity provided by EFSA and the Joint Research Centre Institute for Reference Materials and Measurement (IRMM) for the screening diagnostic tests used by the competent authority of Slovenia to detect classical scrapie, and on the number and type of ovine and caprine animals tested for that purpose between 2016 and 2023, the overall sensitivity of the surveillance system applied to detect the disease is in line with the conditions set out in Section A, point 2.1(c), of Chapter A of Annex VIII to Regulation (EC) No 999/2001 for each of those seven years.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1, ELI: <http://data.europa.eu/eli/reg/2001/999/oj>.

⁽²⁾ <https://doi.org/10.2903/j.efsa.2024.9042>.

- (5) The EFSA report also concludes that, based on the testing sensitivity provided by the past evaluation of screening diagnostic tests by the EFSA and the IRMM, Slovenia's intentions concerning surveillance of classical scrapie in the future would continue to meet the requirements laid down in Section A, point 2.2, of Chapter A of Annex VIII to Regulation (EC) No 999/2001.
- (6) Taking into account the EFSA report and the favourable outcome of the Commission assessment of this application with the other criteria set out in Section A, point 2.1, of Chapter A of Annex VIII to Regulation (EC) No 999/2001, Slovenia should be listed as a Member State with a negligible risk of classical scrapie.
- (7) Section A, point 2.3, of Chapter A of Annex VIII to Regulation (EC) No 999/2001 should, therefore, be amended in order to add Slovenia to the list of Member States with a negligible risk status for classical scrapie.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex VIII to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex VIII to Regulation (EC) No 999/2001, in Chapter A, in Section A, point 2.3. is replaced by the following:

‘2.3. The Member States or zone of the Member State with a negligible risk for classical scrapie are the following:

- Austria
 - Czechia
 - Slovenia
 - Finland
 - Sweden.’
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