



# **Update on regulatory activities on TSE in the EU**

**Joint workshop of EURLs for TSE and AP**  
**Rome, Italy – 13-15 May 2024**

## Review of activities

### ➤ ***Management of TSE issues at SANTE level***

### ➤ ***Recent regulatory activities***

- ☐ Negligible risk status for classical scrapie
- ☐ Regulatory adjustments: Feed ban/Scrapie
- ☐ Breeding programmes

### ➤ ***Future regulatory activities***

- ☐ Impact of new WOAHA Chapter on BSE
- ☐ New request for recognition of negligible risk status for CS

# Management of TSE issues at SANTE level



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# SANTE news

## Transfer of the TSE file to SANTE G2



# Recent regulatory activities

# Negligible risk status for CS

## Recognition of CZ negligible risk status for CS

- Czechia submitted an application to the Commission to be recognised as having a negligible risk status for classical scrapie
- Initial favourable assessment by the Commission in 2022 complemented by a favourable EFSA assessment in 2023
- Addition of CZ to the list of MS with a negligible risk status of classical scrapie

**Status:** Published in the first quarter 2024 (R2024/877)

# Regulatory adjustments

## Feed ban

- Minor adjustments in Annex IV to Regulation 999/2001 required:
  - Correction of mistakes in the act adopted in August 2021
  - Reflection of the notion of end point developed for organic fertilisers / soil improvers in the framework of the ABP legislation

## Scrapie

- Regulation 2020/772 recognised in the legislation that the alleles K222, D146 and S146 are associated to resistance to CS in goats. But the 2020 adjustments failed to fully align measures in goats vs sheep, on movements to holdings with a scrapie status and imports

**Status:** Published in the first quarter 2024 (R2024/887)

# Breeding programmes

## Reporting obligations

- Member States may introduce breeding programmes to select for resistance to TSE in their ovine populations (Article 6a of R999/2001)
- Member States which introduce breeding programmes are required to submit reports to the Commission on a yearly basis
- Simplification of reporting requirements for Member States by moving from a systematic annual reporting to a reporting when there is a clear need, namely when changes have been made to the breeding programmes

**Status:** Published in the first quarter 2024 (R2024/918)



# Future regulatory issues

# New WOAHA (ex-OIE) Code on BSE

- **Status:**

- Discussions launched in 2018
- Last EU position provided to WOAHA in April 2023
- Revised chapters 11.4 and 1.8 **adopted** at the 2023 WOAHA General Assembly

- **Next steps:** to be discussed at next TSE working group

- Need to review monitoring rules for BSE?
- Need to review safety rules for ruminant gelatine and collagen other than from hides and skins (on-going work at EFSA level)?

# New request for recognition of negligible risk status for CS

- **Slovenia** submitted an application to the Commission to be recognised as having a negligible risk status for classical scrapie
- Initial favourable assessment by the Commission in 2023

**Status**: Requested scientific and technical assistance to EFSA (report to be expected by October 2024)

**Next steps**: Formal amendment of the list if favourable outcome (End 2024)

# WOAH Code on scrapie

- Decision of the WOAH Code Commission to launch a revision in 2023
- **Status**: EU comments supporting the revision in December 2023
- **Next steps**: To be clarified by WOAH



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**Thanks for  
your  
attention**