EXPLANATORY MEMORANDUM TO

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (AMENDMENT) (ENGLAND) REGULATIONS 2025

2025 No. 249

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Baroness Hayman, Parliamentary Under-Secretary of State at the Department for Environment, Food and Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

2.2 Louise Leighton-McTague, Deputy Director for Exotic and Endemic Disease Control, at the Department for Environment, Food and Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Nieves Bottomley at the Department for Environment, Food and Rural Affairs Telephone: 020 8026 3797 or email: TSEgeneralmailbox@defra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument is being made to remove a requirement for farms that have had a confirmed case of atypical scrapie to be subject to intensified monitoring for two years. Scrapie is a fatal neurological disease that occurs in sheep and goats. The disease is notifiable.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is in England only.

5. Policy Context

What is being done and why?

5.1 Scrapie is a disease affecting sheep and goats. Assimilated Regulation 999/2001 previously required that where a case of atypical scrapie is confirmed on a farm, intensive monitoring must be carried out for a period of two years. This instrument removes that requirement, reducing the regulatory burden for the farmers affected. The requirement is no longer considered proportionate, does not reflect the latest

scientific knowledge, creates a burden for the farmers affected, and is resource-intensive for the Animal and Plant Health Agency (APHA). Its removal maintains the level of protection of animal and human health provided by Regulation 999/2001.

What was the previous policy, how is this different?

5.2 Assimilated Regulation 999/2001 required that farms with a confirmed case of atypical scrapie were intensively monitored for two years. Scrapie affects sheep and goats. While classical scrapie is contagious, there is no evidence that atypical scrapie is transmitted between animals. This instrument does not amend the controls that are put in place when a case of classical scrapie is confirmed.

5.3 The requirement for intensified monitoring meant that animals over 18 months going for slaughter had to be sent to designated abattoirs to be sampled and tested for scrapie. Animals aged over 18 months which died or were killed on the farm were also tested. Atypical scrapie usually affects animals older than 5 years. The two-year monitoring period was reset if a further case of atypical scrapie was confirmed.

5.4 The assimilated Regulation did not impose movement restrictions and the testing requirement did not apply to any sheep or goat moved to a different farm. Unlike BSE, there is no evidence that scrapie is zoonotic and it is not considered a public health risk.

5.5 Until 2013, farms with a confirmed case of atypical scrapie were also subject to movement restrictions for two years. This requirement was removed following a scientific report in 2011 that concluded that it is probable that atypical scrapie is non-contagious; there is currently no evidence of transmission between animals. At the time, the decision was taken to maintain the monitoring of holdings with an atypical scrapie case to gather more scientific evidence. A 2021 study of atypical scrapie cases in 22 countries supported the conclusions of the 2011 report.

5.6 Modelling work undertaken by APHA concluded that the number of atypical scrapie cases expected to be missed if the intensified monitoring was stopped was low relative to the number of atypical cases detected as part of its ongoing general active surveillance programme. It was estimated that removing the requirement in Great Britain would mean detecting one fewer atypical scrapie case every 3 years, compared to an average of 10 atypical scrapie cases in sheep confirmed annually through active surveillance.

5.7 This requirement is therefore not proportionate, and its removal maintains the level of protection of human and animal health provided by the Regulation.

6. Legislative and Legal Context

How has the law changed?

6.1 Assimilated Regulation 999/2001 has been amended to remove the requirement in Annex 7, Chapter B to monitor holdings in England that have had a case of atypical scrapie. This requirement is effectively imposed in three separate passages in Chapter B, all of which are removed by regulation 2 of this instrument.

Why was this approach taken to change the law?

6.2 The requirement was set out in legislation and was mandatory; therefore, legislation was required to remove it. The provisions in question form a minor and discrete part of the Regulation, such that amendment was preferable to re-making the instrument.

7. Consultation

Summary of consultation outcome and methodology

7.1 Article 23 of assimilated Regulation 999/2001 provides for the appropriate authority, in this case the Secretary of State for Environment, Food and Rural Affairs, to amend the Annexes to the Regulation after taking appropriate advice on any question which could have an impact on public health. Article 24(9)(b) of the same Regulation requires the appropriate authority to consult (i) such bodies or persons as appear to the appropriate authority to be representative of the interests likely to be substantially affected by the regulations and (ii) such other bodies or persons as the appropriate authority considers appropriate.

7.2 The Food Standards Agency (FSA) was consulted on the amendment. It is content that the change maintains the level of protection of human and animal health in line with the latest scientific evidence.

7.3 A targeted stakeholder consultation was undertaken in May 2024, summarising the proposed changes to be made by this instrument and inviting comments. It was targeted at industry representatives of sheep and goat farmers, markets and abattoirs, and local authorities' representatives.

7.4 At the close of consultation, Defra had received 7 responses. All responses supported the proposed change to remove the requirement to monitor farms that had an atypical scrapie case.

8. Applicable Guidance

8.1 Guidance to farmers is published on the gov.uk website and includes information on what happens when scrapie is confirmed in a holding. This guidance will be updated at the time the instrument comes into effect. The guidance is available online.[1]

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because its provisions are deregulatory and reduce business and government costs. The removal of the monitoring requirement is estimated to benefit an average of ten farms per year in England. These farms will benefit from a wider choice of abattoirs to take eligible animals to slaughter, with reduced travel time and costs, and from the removal of the requirement to test eligible animals that die or are killed on farm. The government benefits from official veterinarians not having to monitor these holdings and the reduced costs from fewer tests (estimated at under £5k per year in England).

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is deregulatory.

9.3 The legislation impacts small or micro businesses.

9.4 This instrument does not exempt small and micro businesses from the requirements of regulation because its provisions are deregulatory and reduce business costs.

9.5 The impact on the public sector is limited and reduces the administrative burden.

[1] https://www.gov.uk/guidance/scrapie

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is through the course of normal departmental business.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Baroness Hayman has made the following statement:

"In my view the inclusion of a review provision is not appropriate as it would be disproportionate when taking into account the economic impact of the regulatory provisions on the qualifying activity".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Parliamentary Under-Secretary of State has made the following statement regarding Human Rights:

"In my view the provisions of the Transmissible Spongiform Encephalopathies (Amendment) (England) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").