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SCIENTIFIC OPINION

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Possible alignment of the EU BSE surveillance with the new WOAH provisions

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The European Commission requested the assessment of the capacity of the surveillance provisions of the World Organization for Animal Health (WOAH) to detect bovine spongiform encephalopathy (BSE) cases (C-, H- and L-type) in the European Union (EU) and to propose if any current EU surveillance provisions should be kept. The WOAH provisions stipulate that BSE surveillance should target animals on the BSE clinical spectrum and require the implementation of standardised clinical protocols for selecting animals for testing. Based on expert judgement of retrospective clinical data, between 5% and 49% of the 55 BSE cases detected in the EU & UK since 2015 would have been selected for testing by the WOAH surveillance. Assuming the current EU surveillance, a back-calculation model predicted a very low number of BSE cases detected for the period 2025–2029: 0.0196 for C-BSE, 10.94 for H-BSE and 9.13 for L-BSE. As no classical BSE (C-BSE) cases are expected, the application of the WOAH provisions would primarily impact the detection of atypical BSE (H-BSE and L-BSE), with an estimated detection over the next 5 years of between zero and five H-BSE cases and between zero and four L-BSE cases. Supplementing the WOAH provisions with systematic testing of fallen stock (with or without emergency slaughter) with increased age threshold of 60 or 72 months would achieve a detection capability close to current EU levels. This approach would enable the documentation of the effectiveness of BSE control measures, provide scientific assurance that the decline in C-BSE is sustained and allow atypical BSE trends to be monitored reliably while maintaining the sensitivity required to detect any re-emergence of C-BSE. Finally, this would contribute to risk mitigation by triggering immediate statutory control measures when cases are detected. Modifications of EU surveillance requirements should consider any potential adjustments to other available BSE control measures.

KEYWORDS

BSE, cattle, EU, surveillance, WOAH

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SUMMARY

The European Food Safety Authority (EFSA) was asked by the European Commission to deliver a scientific opinion by 31 March 2026 on (i) the assessment of the capacity of the surveillance provisions recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code in terms of detection of potential BSE cases (C-, H- and L-type) in the case of the EU situation; and (ii) to propose if any current EU surveillance provisions should be kept, beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code, considered necessary and proportionate, with critical justification of their added value in ensuring the detection of potential BSE cases (C-, H- and L-type) and of BSE risk mitigation measures in the current EU epidemiological situation.

The first part of the Term of Reference (ToR) was addressed by conducting a retrospective assessment by expert judgement of the clinical records of the cases detected in the EU and UK since 2015. The probability of detection was judged individually by experts and compiled in a best-case scenario (cases deemed by some experts as being selected for testing under the WOAH surveillance), and a worst-case scenario including only those records unanimously selected for testing. The outcome was an estimation of the percentage of BSE cases (C, H and L) that were likely to be targeted by the WOAH surveillance. A validated and previously applied back-calculation model was used in order to estimate the population prevalence of BSE in the EU in 2024 and the number of cases detected by EU surveillance in the future. The model was applied to predict the number of cases detected by the WOAH baseline under the two scenarios and was further applied to estimate the number of future cases expected to be detected by the current EU provisions if the age threshold for testing was increased. For the second part of the ToR, a comparative analysis of the relevant articles of the WOAH terrestrial code and the EU legislation was conducted with a narrative description of the objectives of surveillance, the testing groups and criteria for selection of animals for testing, including the legal statutes, and the identification of commonalities and differences of the two surveillance frameworks, as identified by the experts of the working group. A number of additional components to the WOAH surveillance provisions were developed and the estimation of the number of cases detected by the surveillance schemes that combine WOAH surveillance with the additional components was produced.

The absence of pathognomonic clinical signs of BSE poses a significant challenge to the sensitivity of surveillance systems that rely on clinical recognition. Early clinical signs may be very subtle or non-specific. More reliable signs can sometimes be elicited by experienced clinicians in certain settings, but such data would be unavailable retrospectively for dead or recumbent animals. According to the new WOAH provisions, only the animals that lie on the clinical spectrum of BSE should be targeted for BSE surveillance, and this requires the implementation of standardised, precise clinical protocols for selecting animals for testing. The implementation of a surveillance system targeting only animals within the BSE clinical spectrum represents a fundamental paradigm shift in the model of surveillance and presents challenges that may compromise its effectiveness.

None of the BSE cases detected in the EU in the last 10 years have been reported as a clinically suspect, emphasising the low sensitivity of the current clinical surveillance in the EU. Of the 55 cases confirmed in the EU and UK in the last 10 years, 28 (51%) had as the final decision 'NO' (it would not have been selected for testing by WOAH); three cases (5%) had 'YES' (it would have been selected for testing by WOAH); and 24 (44%) cases resulted in 'NO AGREEMENT'. Under the worst-case scenario, 5% would have been selected for testing by the WOAH surveillance system, and under the best-case scenario, 49% would have been selected. There was variability in the judgements regarding the capability of clinical surveillance to target these cases, mostly due to the limited amount and the quality of the clinical data available.

An exponential decline was observed during 2008–2024 in the estimated population prevalence of C-BSE, with an annual rate of decline of 38.3% (95% CI: 34.2%–43.4%), while neither temporal decline nor increase was observed in the population prevalence of either H-type or L-type BSE over the same period. The number of cases predicted by the model as detected by current EU surveillance over the next 5 years (2025–2029) was 0.0196 C-BSE cases, 10.94 H-BSE cases and 9.13 L-type cases, assuming continuation of the annual trend detection for each BSE type and the same number of animals tested annually as in 2024. Most of these cases are expected in fallen stock, with no cases expected as clinical suspects. Applying the criteria of the retrospective assessment, the estimated number of cases detected by the WOAH surveillance in EU over the next 5 years (2025–2029) is between 0.0011, 0.58 and 0.45 cases (worst-case scenario) and 0.0096, 5.26 and 4.09 cases (best-case scenario) for C-, H- and L-BSE, respectively. Therefore, as no C-BSE cases are estimated to be detected over the next 5 years, the WOAH surveillance recommendations would primarily impact the capability to detect the atypical BSE cases (H- and L-type) predicted during this period, resulting in an estimated detection of between zero and five H-BSE cases and between zero and four L-BSE cases. However, this reduced detection capability will also decrease the likelihood of detecting new cases associated with any future re-emergence of classical BSE.

The commonalities of the EU and WOAH surveillance provisions are that they are both risk-based systems and they share definitions for disease status and clinical suspects. Key differences include the objective and type of surveillance, the case selection principles, the definition of the surveillance streams and the age and clinical status of animals to be tested. The new WOAH system is designed to meet different objectives than those historically defined by the EU. The objective of the WOAH surveillance is the detection of cases, whereas the current EU surveillance objectives include prevalence monitoring and trend analysis. In light of the historical context within the EU, the current epidemiological situation and the associated uncertainties regarding BSE strain variants, the potential objectives identified for future BSE surveillance in the EU that could be achieved by keeping some of the current EU provisions are the ability to document the continuing effectiveness of BSE control measures; the monitoring of residual BARB C-BSE cases or any re-emergence of C-BSE; the ability to detect changes in patterns of atypical BSE (H & L strains); the contribution to risk mitigation by triggering the removal of BSE cases and their disposal as high-risk animal by-products.

To achieve the proposed surveillance objectives, maintenance of testing within at least the fallen stock (FS) stream would be the minimum additional surveillance component capable of detecting BSE cases with sufficient sensitivity. Of the current EU surveillance streams, the additional components proposed are the systematic testing of either FS alone or both FS and emergency slaughtered (ES) surveillance streams, increasing the age threshold to 60 or 72 months. These additional components would enable the detection of a high proportion of the BSE cases expected to be detected by the current system (between 94.9% and 97.8% with age limit at 60 months, and between 89.3% and 96.9% with age limit at 72 months, depending on the BSE type), while reducing the testing by 34.3% or 51%, respectively. Assuming compliance with the new WOAH provisions constitutes the baseline, its combination with the additional proposed measures would significantly exceed the WOAH baseline and would achieve a detection capability close to current EU levels. This approach would imply discontinuing testing in all other EU active surveillance streams currently in place as well as in the ES and/or FS streams for animals aged between 48 and 60 or 72 months. Maintaining the active surveillance streams of FS or FS + ES from the current EU provisions would offset the uncertainty surrounding the expected capability of the WOAH baseline, as this would dramatically reduce the difference between the best- and worst-case scenarios.

The detection capability of the proposed surveillance framework would ensure continuity in epidemiological trend analysis, providing scientific assurance that the decline in classical BSE (C-BSE) is sustained, while maintaining the sensitivity required to detect potential re-emergence of the disease. This approach would enable the detection of BSE-infected bovines in the preclinical phase and the early identification of disease trends, thus allowing to fulfil the proposed objectives, such as documenting in a consistent manner the continuing effectiveness of control measures, reliably monitoring atypical BSE trends and contributing to mitigate the risk of exposure to BSE infectivity. Additional benefits of the proposed surveillance framework include mitigating the impact of a potential low reporting rate for bovines that lie on the BSE clinical spectrum, while also contributing to the maintenance of laboratory proficiency and to monitoring the biological variability of BSE strains.

It is recommended the additional testing of high-risk cattle population (i.e. fallen stock, emergency slaughter over 60 or 72 months) in the EU and that any modifications to surveillance protocols should consider any potential adjustments to the other BSE control measures.

1 | INTRODUCTION

1.1 | Background and Terms of Reference AS provided by the requestor

Request for a scientific opinion on the potential BSE risk of alignment of the BSE monitoring requirements laid down in Regulation (EC) no 999/2001 with the revised WOAH code Chapter 11.4.

1.1.1 | Background

Regulation (EC) No 999/2001[1] of the European Parliament and of the Council lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs). In particular, Article 6 and Annex III, Chapter A, laid down the Bovine spongiform encephalopathy (BSE) monitoring requirements to be implemented by the EU. Since its adoption in 2001, the Regulation has been amended several times to reflect the evolution of the epidemiological situation and scientific knowledge in the EU. It was established in response to the BSE epidemic of the late 1990s and early 2000s and introduced strict 'monitoring' requirements based on a combination of active and passive surveillance, including mandatory testing as described in Article 6, of:

- all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;
- all bovine animals above 30 months of age slaughtered normally for human consumption;
- all bovine animals above 24 months of age not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir (fallen stock).

This surveillance system played a critical role in enabling early detection of cases and assessing the effectiveness of key control measures such as the feed ban and specified risk material (SRM) removal.

However, given the significantly improved BSE epidemiological situation in the European Union (EU) and other regions of the world, and the negligible risk status across almost all EU Member States and World Organisation for Animal Health (WOAH) Member Countries, it may no longer be adapted or proportionate to the risk.

In May 2023, motivated notably by the epidemiological situation, WOAH adopted an updated version of Chapter 11.4 of its Terrestrial Animal Health Code.[2] The revised Chapter states in Article 11.4.20, that 'the objective of BSE surveillance is to detect occurrence of BSE within the bovine population' and recommends doing so by focusing on 'all animals that show signs of the clinical spectrum of BSE'. The WOAH standards, following the advice of the ad hoc expert groups and specialist commissions, thus prioritise targeted clinical surveillance over a generalised testing approach.

In this regard, the BSE monitoring requirements of Regulation (EC) No 999/2001 may lead, for the Member States competent authorities, to surveillance obligations that are disproportionate to the actual risk, while at the same time creating unnecessary costs and operational burdens, with no added value for public health or animal health.

In this context, and with a view to the necessary assessment of the need to revise Regulation (EC) No 999/2001, the Commission requests a scientific opinion from EFSA on the alignment of EU surveillance requirements with the revised Chapter 11.4 of the WOAH Terrestrial Code. The aim is to support the design of a science-based, risk-proportionate surveillance system appropriate to the current epidemiological situation in the EU.

1.1.2 | Terms of Reference (ToR)

In light of the above, given the current epidemiological situation in the EU and taking into account the data from the current surveillance system in the EU, EFSA is requested:

– to assess the capacity of the surveillance provisions recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code in terms of detection of potential BSE cases (C-, H-, and L-type) in the case of the EU situation;
– to propose if any current EU surveillance provisions should be kept, beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code, considered necessary and proportionate, with critical justification of their added value in ensuring the detection of potential BSE cases (C-, H-, and L-type) and of BSE risk mitigation measures in the current EU epidemiological situation.

[1]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 ELI: http://data.europa.eu/eli/reg/2001/999/2025-03-12.

[2]Terrestrial Animal Health Codes, Chapter 11.4. Bovine Spongiform Encephalopathy https://www.woah.org/en/what-we-do/standards/codes-and-manuals/.

1.2 | Interpretation of the Terms of Reference

Article 11.4.20 of the revised WOAH Terrestrial Code and the WOAH guidelines for its implementation by Member States (MSs) establish a new system for targeted BSE surveillance, focusing on animals within the identified BSE clinical spectrum (classical, L-type and H-type BSE). This surveillance identifies four groups of animals that should be reported and investigated for a BSE diagnosis. However, there are no specific prescriptions that specify which or how many animals should be targeted, as this may depend on local factors such as bovine population and distribution and husbandry systems. Member states are individually responsible for implementing such provisions.

Point 3 of Article 11.4.20 of WOAH's Terrestrial Animal Health Code describes the raft of supporting activities needed to ensure the effectiveness of a BSE surveillance system targeting animals using clinical surveillance. Point 3 lists (inter alia) ongoing awareness, training programmes, the fact that BSE is a notifiable disease and laboratory testing capabilities. The consideration of these supporting activities and challenges to the implementation of the WOAH BSE surveillance provisions are outside the scope of this Scientific Opinion; however, they are considered briefly (see Section 3.3) due to their importance.

In the absence of a specific EU implementation of the WOAH Article 11.4.20, the capacity of the revised WOAH surveillance system to detect BSE cases in the EU will be assessed by referring to the definitions set out in Article 11.4.20, Point 2 of the revised Terrestrial Code.

The capacity of the WOAH surveillance system to detect potential cases will be assessed in terms of its capability to detect BSE cases, compared to the current EU system. Therefore, this risk assessment will focus on the relative capability of the WOAH and EU BSE surveillance systems in detecting BSE cases, rather than their absolute sensitivity.

A BSE case is defined in the current Regulation (EC) No 999/2001 as an animal that has tested positive by the current BSE testing protocols regardless of how the animal was initially identified (systematic testing or clinical suspicion). The population of interest in this assessment is the proportion of BSE-infected animals in which the disease-specific prion protein in the target tissues of the central nervous system can be detected by the current BSE testing protocols.

In the analysis of the surveillance data, the EU will be considered as a single epidemiological unit. For that purpose, surveillance data will be aggregated from all or part of the 28 Member States (MS, EU28) until 2021 or 27 MS (EU27) + the United Kingdom (in respect of Northern Ireland (XI)) from 2022[3], respectively, depending on their availability. This assessment is carried out based on the assumption that the current EU BSE controls with respect to SRM and the feed ban are, and will remain, in place. In particular, the modelling predictions reflect the current EU control framework and their validity is based on the implementation of the SRM and feed ban as in the last 20 years.

The 'necessity and proportionality' of maintaining any existing EU provisions beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code will be based only on the analysis of the current BSE epidemiological situation in the EU with the view to fulfilling the objectives of the BSE surveillance and not based on any economic analysis or feasibility study of its implementation. Thus, the added value of maintenance of any of the existing EU provisions or any additional proposed components will be based on their capability to detect BSE cases compared with the WOAH provisions. Early and reliable detection, enabling the timely activation of the removal and destruction of BSE cases and at risk cohorts by statutory control measures, will be considered as the main risk mitigation measure of surveillance.

1.3 | Historical context of BSE in the EU

There are three different forms, or strains, of BSE in bovines: classical BSE (C-BSE), H-type atypical BSE (H-BSE) and L-type atypical BSE (L-BSE).

C-BSE was the first BSE strain to be identified, in the United Kingdom in 1986 (Wells et al., 1987), and was responsible for the large-scale epidemic of BSE in Europe. Epidemiological investigations identified ruminant-derived meat and bone meal (MBM) used as a supplement in concentrate feed as the common source of infection that recirculated the C-BSE agent in the cattle population (Wilesmith et al., 1988). C-BSE is zoonotic and causes variant Creutzfeldt–Jakob disease (vCJD) in humans. The main measures to successfully prevent infection in cattle and protect humans from BSE exposure were the ban on MBM in livestock feed and the removal of SRM from the food chain.

H- and L-BSE were later discovered through active monitoring programmes (Biacabe et al., 2004; Casalone et al., 2004). These atypical BSE strains are sporadically detected in cattle, usually over 8 years old, and their origin is still unclear. H- and L-BSE are less well characterised than C-BSE, although their ability to transmit within and between species has been demonstrated experimentally. Their zoonotic potential is uncertain.

In 1990, Commission Decision 90/134/EEC added BSE to the list of notifiable diseases. From then and until 2001, Member States were only required to carry out passive surveillance (through mandatory reporting of clinical suspects). In 2001, Regulation (EC) 999/2001 (TSE Regulation) established a compulsory surveillance programme whereby *'each Member State*

[3]In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Windsor Framework in conjunction with Annex 2 to that Framework, for the purposes of this scientific opinion, references to Member States include the United Kingdom in respect of Northern Ireland.

has to carry out an annual monitoring programme for TSEs based on passive and active surveillance in accordance with Annex III. If available for the animal species, that programme shall include a screening procedure using rapid tests'.[4]

'The monitoring programme provides a reliable insight into the prevalence and evolution of TSEs in the Member States and at the same time ensures that no BSE cases are being slaughtered for human consumption'.[5]

The categories of bovine animals to be submitted for BSE testing are defined in the TSE Regulation and are based on a combination of age (age limits have been changed over time) and surveillance target groups. Point 1a of Article 6 states that '*the annual monitoring programme referred to in paragraph 1 shall cover as a minimum the following subpopulations:*

a. *all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;*
b. *all bovine animals above 30 months of age slaughtered normally for human consumption;*
c. *all bovine animals above 24 months of age not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir (fallen stock)'*.

Over time, multiple amendments to the TSE regulation resulted in changes to the requirement to target all surveillance streams and to the minimum age of the animals selected for testing, including a derogation (Commission Implementing Decision 2013/76/EU) to discontinue testing of animals slaughtered normally for human consumption. The testing regime applied in 2024 by each MS of the EU is shown in Appendix C (Table C.1).

The monitoring of trends, the evolution of the epidemic and the assessment of the impact of control measures were at the forefront of maintaining compulsory comprehensive active surveillance of cattle during the last 25 years. This approach was prioritised because reliance on notification and testing of animals showing BSE-like signs proved insufficient for monitoring trends and detecting cases in countries where the disease had not yet been identified (Bird, 2003; Doherr et al., 2001).

A constant decline in the total number of detected C-BSE cases has been recorded in the EU MSs since the establishment of compulsory surveillance in the EU in 2001. Since 2008, surveillance in the EU has allowed the analysis of the surveillance data to identify prevalence trends of not only C-BSE, but also of the H and L types.

In terms of the trend of the BSE epidemic in Europe, the analysis conducted in 2012 by EFSA (EFSA, 2012) concluded that 'the $\log_{10}$ transformed annual BSE prevalence and incidence in the EU17 and in the EU8 show a statistically significant decreasing trend … during the last 11 years and 8 years in the EU17 and the EU8, respectively'. Equally, '*epidemiological data reported by the EU MSs indicate that over the last years the number of detected Atypical BSE cases did not show any trend and that Atypical BSE cases were mainly identified in the fallen stock and healthy slaughtered animals older than 8 years of age*'.

The formal trend analysis of the incidence of BSE included in the EFSA's EU summary report on TSE (EFSA, 2017) consistently revealed a statistically significant decrease in the proportion of C-BSE cases (per 1,000,000 tests) adjusted by target group, from 68.4 in 2007 to 1 in 2016 ($\beta = 0.4$, $p < 0.0001$), with no significant trend upwards or downwards in the two atypical BSE forms (H-BSE: $\beta = 0.0003$, $p = 0.99$; L-BSE: $\beta = 0.04$, $p = 0.54$). Time-series analyses carried out over the period 2008–2017 showed a significant decreasing trend in the proportion of C-BSE cases per tested animals (annual relative risk = 0.62, i.e. an annual decrease of 38%; $p < 0.0001$), whereas no significant trend for the two atypical BSE forms was found (H-BSE: annual RR = 0.99, $p = 0.85$; L-BSE: annual RR = 1.04, $p = 0.51$) (EFSA, 2018). This pattern was consistent in the analyses of the following 5 years (EFSA, 2019, 2020, 2021, 2022, 2023, 2024).

The decreasing trend in the proportion of C-BSE cases per tested animals is a consequence of the implementation of the BSE control measures. As a result, C-BSE has become a rare disease in the EU. The number of detected C-BSE cases has declined since 2001.

The last case in a current EU MS was confirmed by France in 2016. Since then, the UK has reported single cases of C-BSE in 2018, 2021 and 2024.

Atypical L-type and H-type BSE remained stable over the years, with an incidence between 0 and 6 cases per million tested (EFSA, 2025). The relatively constant number of atypical cases detected by surveillance, comprising between 1 and 11 per year, contrasts sharply with the epidemic dynamics previously observed for classical BSE.

1.4 | Current surveillance streams in the EU legislation

The Regulation (EC) 999/2001 establishes the bovine animals to be tested for BSE. They can be grouped in six different surveillance streams:

1. Emergency slaughtered animals (ES): bovine animals sent for emergency slaughter, i.e. otherwise healthy animals that have suffered an accident that prevented their transport to the slaughterhouse for welfare reasons. Using the authorisation provided in Commission Decision 2009/719/EC, most Member States increased the age threshold for the emergency slaughtered sub-population to 48 months.

[4]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 ELI: http://data.europa.eu/eli/reg/2001/999/2025-03-12n
[5]https://food.ec.europa.eu/food-safety/biological-safety/food-borne-diseases-zoonoses/control-tses_en.

2. Animals with observations at ante-mortem inspection (AM): animals that have undergone an ante-mortem inspection with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004 (2). Using the authorisation provided in Commission Decision 2009/719/EC, most Member States increased the age threshold for the ante-mortem sub-population to 48 months.
3. Fallen stock (FS): animals not slaughtered for human consumption that have died or been killed on the farm, during transport or in an abattoir. Using the authorisation provided in Commission Decision 2009/719/EC, most Member States increased the age threshold for the fallen stock sub-population to 48 months.
4. Healthy slaughtered animals (HS): bovine animals slaughtered for human consumption. Commission Implementing Decision 2013/76/EU (amending Decision 2009/719/EC) resulted in the reduction or discontinuation of the testing of this surveillance stream in many Member States.
5. Clinical suspects (SU): Bovine animals of any age displaying behavioural or clinical signs consistent with BSE.
6. Animals culled under BSE eradication measures (EM), namely, cohort and progeny animals. Cohort as defined in Point 2(b), Annex I of Regulation (EC) 999/2001 means a group of bovine animals which includes both:

   (i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and
   (ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;

Progeny refers to animals born within a period of 2 years prior to, or after, the clinical onset of the disease of a confirmed female case (Point 1(a), Annex VII).

According to Annex VII Chapter B, the measures laid down in Article 13(1)(c) shall comprise at least, in the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a) (progeny and cohorts); however, the Member State may decide:

– not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
– to defer the killing and destruction of animals of the cohort referred in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

These mutually exclusive surveillance streams contribute differently to the overall ability of surveillance to detect cases.

2 | DATA AND METHODOLOGIES

2.1 | Data

The following datasets have been used in the different analyses in this opinion.

2.1.1 | Background information

The description of the new WOAH surveillance system was obtained from the Terrestrial Animal Health Code, the reports of the WOAH Scientific Commission for Animal Diseases and the reports of the WOAH's ad hoc group on bovine spongiform encephalopathy risk assessment and surveillance. The description of BSE surveillance in the EU was extracted from Regulation (EC) No 999/2001, as amended. The description of the clinical signs of BSE was extracted from the WOAH's Guidelines for targeted BSE surveillance, the WOAH Terrestrial manual and targeted scientific literature.

2.1.2 | Surveillance data EU

Data submitted to EFSA since 2018 were extracted from the EFSA's data warehouse and aggregated for the different analyses conducted in this scientific opinion. The data items included are those spelled out in Annex III of Regulation (EC) No 999/2001. The data prior to 2018 were extracted from the reports on the monitoring of ruminants for the presence of transmissible spongiform encephalopathies (TSE) in the EU, published by the European Commission since 2001.

Since 1 January 2016, EFSA has analysed the data referred to in Part I, Chapter B.I of Regulation (EC) No 999/2001. Each year, by the end of November, it publishes a summary report on trends and sources of TSEs in the EU, based on information from the previous calendar year. General information on BSE, such as case numbers by surveillance stream and by country, was drawn from these annual EU reports on TSE surveillance.

2.1.3 | Clinical data for BSE in the EU

Submission of clinical data from BSE cases by MSs is not required by Regulation (EC) No 999/2001. To gather information relating to this area, EFSA asked reporting countries to submit voluntarily a clinical and epidemiological description of the BSE cases detected as complementary information. These descriptions have been included in the annual summary reports and presented in tabular format. The information collected since 2015 was used to conduct the retrospective assessment of the BSE cases in Section 3.4.

The clinical data were collated together with BSE type, age (in months) at detection, reporting country, year of reporting and surveillance stream. The cases included in this elicitation were all the BSE cases (C, L and H types) reported by EU MSs between 2015 and 2025 and included epidemiological and clinical data. Data on the cases reported by the UK after Brexit were obtained from the UK TSE statistics website and the publicly available epidemiological reports.[6]

2.1.4 | Model parameters

The parameterisation of the model and the input data were obtained from previous EFSA opinions and reports and from scientific literature. Data on the total number of cattle tested and number of positive tests for BSE (by type) were extracted from the European Commission and EFSA TSE summary reports and were totalled across the EU27 for each surveillance stream between 2008 and 2024.

The winbugs model code to run back-calculation model to infer infection prevalence in EU27 by BSE type can be found in the following link https://doi.org/10.5281/zenodo.19183565.

2.2 | Methodologies

The following assessment questions (AQs) and sub-assessment questions (SAQs) were formulated to address the ToR:

- AQ1: to assess the capacity of the surveillance provisions recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code in terms of detection of potential BSE cases (C-, H and L-type) in the case of the EU situation.
  - SAQ1.1: What is the number of BSE cases (C, H and L) confirmed in the EU since 2015 that might have been missed, assuming the WOAH system had been implemented, without any specific implementation protocol?
  - SAQ1.2: What is the current (2025) prevalence of BSE (C, H and L) in the EU?
  - SAQ1.3: What could be the number of BSE cases (C, H and L) detected in the EU assuming the WOAH system had been implemented, without any specific implementation protocol, in the next 5 years by surveillance stream?
- AQ2: to propose if any current EU surveillance provisions should be kept, beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code, considered necessary and proportionate, with critical justification of their added value in ensuring the detection of potential BSE cases (C-, H- and L-type) and of BSE risk mitigation measures in the current EU epidemiological situation.
  - SAQ2.1: How do the new surveillance provisions under Article 11.4.20 of the WOAH Terrestrial Animal Health Code compare with the current EU surveillance provisions under Regulation (EC) 999/2001?
  - SAQ2.2: What could be additional components to the WOAH surveillance provisions appropriate for the EU surveillance under the current epidemiological situation?
  - SAQ 2.3: What could be the number of BSE cases (C, H and L) detected in the EU in the next 5 years under the components selected in SAQ 2.2 that are additional to the WOAH surveillance provisions?

The original protocol including the approaches and the methodology to address the SAQ can be found in Annex A.[7] Details of the methods applied to answer each SAQ and the diversions from the protocol are described below.

2.2.1 | SAQ1.1 Retrospective assessment of the cases detected in the EU since 2015

Before presenting the retrospective assessment aimed at addressing the first sub-assessment question, it was deemed appropriate to reflect on and elaborate on aspects considered relevant to understand the assessments conducted from this point onwards. First, the reasons why the clinical diagnosis of BSE is particularly challenging are discussed. Second, a thorough description of the new article in the BSE chapter of the Terrestrial Animal Health Code is included, presenting the

[6] https://www.gov.uk/government/publications/cattle-tse-surveillance-statistics BSE in Scotland: epidemiology report, 2018, BSE in England: epidemiology report 2021, BSE in Scotland: epidemiology report 2024.

[7] Annex 1 is available under the Supporting Information section on the online version of the scientific output.

rationale behind the changes approved in 2023 after reviewing the reports of the ad hoc group on BSE surveillance and of the Scientific Commission of the organisation. Third, the supporting activities and challenges to clinical BSE surveillance are mentioned. These three aspects are presented in Sections 3.1–3.3, respectively.

In order to answer SAQ1.1, a retrospective assessment of the cases detected in the EU since 2015 was conducted. The clinical data, as described in Section 2.1.3, may be inaccurate and/or incomplete. However, it was considered the only available approach to provide an evidence-based judgement of the capability of the WOAH provisions to select actual BSE cases for testing. The retrospective clinical data were evaluated according to the criteria defined in Article 11.4.20 of the WOAH Terrestrial Code (points 2a–2d) and the associated WOAH guidelines. The experts participating in the assessment based their grading on a veterinary understanding of clinical presentations, balancing the data with expert knowledge of recording practices. The clinical data were reviewed by six members of the working group (WG) who individually categorised cases into five groups: 'NO' (it would not have been selected for testing by WOAH); 'YES' (it would have been selected for testing by WOAH); 'Probably NO' (probably it would not have been selected for testing by WOAH); 'Probably YES' (probably it would have been selected for testing by WOAH); and 'I do not know'. Additional comments were provided to explain the rationale of the answers. The individual judgements were not shared until they were presented in an ad hoc session, during which the justification for the choices was discussed.

The outcome was an estimation of percentage of BSE cases (C, H and L) that were likely to be targeted by the WOAH surveillance. The results are presented as two distinct percentages: (I) the percentage based on consensus (unanimous agreement) and (II) the percentage for which there was no agreement.

The initial aim was to reach a consensus on a YES or NO for each case. However, this was not possible for a number of cases. For each case, the individual judgements were collated into a summary category reflecting the distribution of the individual choices. Eventually, three summary categories were considered:

- **NO**: 'NO' AND/OR 'Probably NO' AND NOT ('I do not know' OR 'YES' OR 'Probably YES').
- **YES**: 'YES' AND/OR 'Probably YES' AND NOT ('I do not know' OR 'NO' OR 'Probably NO').
- **NO AGREEMENT**: all those not compliant with the previous two, i.e. if there was at least one discrepant answer or 'I do not know'.

To further analyse cases that resulted in 'NO AGREEMENT,' a Consensus Bias Score was utilised to quantify the underlying leanings of the expert panel. Each qualitative judgement was assigned a numerical value: YES: +2, Probably YES: +1, I do not know: 0, Probably NO: -1, NO: –2. The total Bias Score for each case was calculated by summing the values of all individual expert judgements. Higher absolute scores indicate a stronger group trend towards either selection for testing under the WOAH protocol (positive values) or not (negative values), despite lacking consensus.

2.2.2 | SAQ1.2 estimation of the current (2024) prevalence of BSE (C, H and L) and prediction of cases detected in the EU (2025–2029)

The estimation of the population prevalence of BSE in the EU in 2024 was conducted via a back-calculation model, accounting for the long incubation period of the disease and including multiple surveillance streams. Additionally, the model was applied to estimate the number of cases detected by EU surveillance in the future. The model was further applied to estimate the number of future cases that might be expected to be detected if the age threshold for testing was increased (SAQ2.2 and SAQ2.3).

The age of clinical onset of C-BSE, with a peak between 5 and 6 years for C-BSE (Arnold & Wilesmith, 2004), follows a long preclinical phase during much of which no disease-specific markers can be identified (Arnold et al., 2007). The age of onset is older for atypical BSE (Adkin et al., 2012). This means that the majority of infected animals are slaughtered or die before showing any clinical signs or detectable evidence of infection. Consequently, only a minority of infected animals are ever detected by surveillance, and the true number of infected animals in the total population is much higher than the number of BSE positives, especially as infected animals are only likely detectable late in the incubation period (Arnold et al., 2007). Although the population of interest is the proportion of BSE-infected animals that can be detected by the current BSE testing protocols, in order to predict these cases for future years, it is necessary to estimate the prevalence of infection in the population. To overcome this, back-calculation models that account for the long incubation period have been developed for BSE (Anderson et al., 1996; Arnold & Wilesmith, 2003, 2004). While these models have been adapted to include multiple surveillance streams (Arnold & Wilesmith, 2003; Donnelly et al., 2002) and used to inform surveillance in the EU (Adkin et al., 2012), they are birth-cohort based (Arnold & Wilesmith, 2004). For the purposes of addressing the terms of reference of the mandate and future surveillance, it was considered more relevant to focus on a model that considered the prevalence in the overall population. Therefore, previously developed back-calculation models for scrapie (Arnold et al., 2024; Arnold & Ortiz-Pelaez, 2014), which are similar to models for BSE but without the need for age-specific data on testing, were adapted to infer population prevalence and trends of BSE in the EU.

Data on the total number of cattle tested and number of positive tests for BSE (by type) were totalled across the EU27 for each surveillance stream between 2008 and 2024. The existing six surveillance streams were consolidated into four. Emergency slaughter (ES) and clinical signs at ante-mortem inspection (AM) were merged, as Member States appeared to vary in their interpretation of these streams. Additionally, the eradication measures stream (EM) was merged with the fallen stock (FS) stream because the EM stream now has minimal impact and was not considered in forward projections. The following four resulting streams were inspected with the model:

- detected in the fallen stock/eradication measures (FS/EM) stream, with probability denoted P_{FS};
- detected in the emergency slaughter/ante-mortem inspection (ES/AM) stream, with probability denoted P_{ESd};
- detected as a clinical suspect (SU, passive surveillance) with probability denoted P_C;
- detected in the healthy slaughter (HS) stream, with probability denoted P_{HS}.

It was assumed that the number of detected cattle in year *j* in each of the four streams followed a binomial distribution with parameters *p* given by P_{FS}, P_C, P_{HS}, P_{ES} and *n* given by the number of animals tested in each stream for FS/EM, HS and ES/AM and the size of the cattle population for SU. The calculation of P_{FS}, P_C, P_{HS} and P_{ES} is described below using the notation in Table 1.

Probability of detection in fallen stock

There were two possible ways that an animal could end up as a fallen stock positive at age *a:* (i) it reached clinical onset without being identified by the farmer and died of BSE, and (ii) it died on farm for reasons unrelated to BSE and happened to be infected with BSE. Probability (i) is the product of the probability the animal is infected (θ) (Table 1), the probability of surviving to age *a (S(a))*, and that the animal reached clinical onset and was not reported (denoted by 1-(e.g. due to lack of farmer awareness of how to spot the clinical signs of BSE)). Probability (ii) is the product of the probability that the animal is infected (θ), the proportion of animals of age *a* that are found dead on farm *(=*$\omega_{FS}(a)$ *(S(a) − S(a + 1)))*, and the probability that an infected animal of age *a* will be detected by the diagnostic test (which depends on the sensitivity of the test (ψ)). We also allow for the potential that subclinical cattle may be at higher risk of slaughter due to an effect of BSE on their production traits, so that cattle end up in the fallen stock/clinical stream with probability 1 − *K*, and in the healthy slaughter stream with probability *K*. Therefore, the probability of being detected as a fallen stock positive in year *j* is given by:

$$P_{FS}(j) = \sum_a \theta_j (1-K)\left\{ S(a)(1-\rho)f(a) + \omega_{FS}(a)(S(a) - S(a+1)) \int_a^\infty f(x)\psi(x-a)dx \right\},$$

where θ_j is the risk of infection in year *j* and ψ(t) is the probability that the diagnostic test will detect an infected animal *t* months before clinical onset, and the summation is over all ages tested in the fallen stock in year *j*.

Probability of detection in emergency slaughter/ante-mortem inspection

Given the similar levels of prevalence observed in the emergency slaughter/clinical signs at ante-mortem inspection to those observed in fallen stock, we assume similarly that many of the animals observed in those streams are clinical suspects that have been missed by passive surveillance, and hence

$$P_{ES}(j) = \sum_a \theta_j (1-K)\left\{ S(a)(1-\rho)f(a) + \omega_{ES}(a)(S(a) - S(a+1)) \int_a^\infty f(x)\psi(x-a)dx \right\},$$

where $\omega_{ES}(a)(S(a) - S(a+1))$ is the proportion of animals of age *a* that enter the ES/AM stream, and the summation is over the ages of animals tested in the ES stream.

Probability of detection as a clinical suspect

The probability that an animal would end up as a clinical suspect in year *j* was given by

$$P_C(j) = \sum_a \theta_j (1-K)\rho S(a) f(a),$$

where the summation is over the entire possible age range of cattle. To account for possible changes over time in the baseline infection prevalence, models were fitted where it was (i) allowed to vary independently each year and (ii) where the risk of infection in year *t*, varied each year according to an exponentially, following an earlier study which demonstrated an exponential decline in C-BSE in the EU (Arnold et al., 2017), i.e. $\theta_t = \alpha \exp(-\beta t)$, where α represented the prevalence in 2008, and β the exponential rate of annual change.

Probability of detection in healthy slaughter

The probability that an animal would be detected as a healthy slaughter positive was given by the product of the risk of infection, the proportion of animals of age *a* that are sent for slaughter (i.e. do not die on farm) $\omega_{HS}(a)$ *(S(a) − S(a + 1))*, and the likelihood that an infected animal of age *a* will be detected by the diagnostic test. Therefore, the probability of an infected animal being detected in the healthy slaughter stream in year *j* is given by:

$$P_{HS}(j) = \theta_j \sum_a K \left\{ \omega_{HS}(a)(S(a) - S(a+1)) \int_a^{\infty} f(x)\psi(x-a)dx \right\}$$

where the summation is over the ages of animals tested in the HS stream in year *j*.

Fitting the model to data

The fitting of the model to the observed EU27 BSE data was performed in WinBUGS 3.1, using a burn-in of 5000 iterations followed by 5000 iterations of the model. Inspection of the history of each parameter and the Gelman–Rubin statistic (Brooks & Gelman, 1998) were used to check convergence. As part of the Bayesian modelling process, prior distributions were required for the unknown parameters that represented what was known about them prior to the model fitting. For the models fitted to atypical BSE, all parameters (reporting rate of clinical suspects, differential survivorship (K), annual prevalence (α, β)) were given minimally informative beta distributed priors with both parameters set to 1 (uniform distribution between 0 and 1). For C-BSE, the parameters determining the initial prevalence and exponential trend (α, β) were given normally distributed priors, with mean 1×10^{-6} (and constrained to be between 0 and 1) and variance 10, and a gamma distribution with both parameters equal to 0.01 for β. WinBUGS code for the model can be found in the following link https://doi.org/10.5281/zenodo.19183565.

TABLE 1 List of model parameters used in a Bayesian model to infer the true prevalence of BSE infection (classical and atypical types) in the European Union (EU27) from passive and active surveillance data.

Parameter	Description	Value	Source
F	Incubation period distribution	Lognormal (2.07, 0.29) – C type	Adkin et al. (2012)
		Lognormal (2.56, 0.243) – H/L-type	Adkin et al. (2012)
$S(a)$	Probability of cattle survival until age a	Data from EU25 used to generate probability of survival to 1,2,3 years, etc.	Adkin et al. (2012)
$\omega_{FS}(a)$ $\omega_{HS}(a)$ $\omega_{ES}(a)$	Proportion of cattle that enter FS/HS/ES, respectively, at age a	Data calculated from EU25, averaged 2002–2008	Adkin et al. (2012)
$\psi(t)$	Sensitivity of diagnostic test t months prior to clinical onset	Based on estimated incubation period and experimental data for C-BSE	Arnold et al. (2007)
P	Reporting rate of cattle with clinical BSE	Estimated by model	N/A
K	Probability that BSE-infected cattle end up in healthy slaughter stream	Estimated by model	N/A
θ_t	Baseline risk of BSE-infection by year t	Estimated by model	N/A

Key uncertainties

- The incubation period of H- and L-type BSE was derived using age of onset data and assuming infection close to birth. If cattle do not become infected with atypical BSE until they are older, then the incubation period would be shorter than estimated, and this would result in much lower numbers of animals infected. However, it would not affect predictions of future cases.
- The sensitivity of the diagnostic tests for detected H- and L-type BSE is based on estimates obtained for C-BSE. If the sensitivity of the tests differed for H- and L-type BSE, this would also impact the estimated number of infected animals, but not predictions of future cases.

Expected future cases in EU by surveillance stream

The expected number of future C-BSE cases in each surveillance stream (FS, ES/AM, HS, SU) was calculated by projecting forward the estimated prevalence trend by 5 years. The expected number of H-BSE and L-BSE cases was estimated by calculating a yearly infection prevalence (with beta (1,1) prior) and taking 10,000 bootstrap samples from the resulting 17 annual prevalence estimates 2008–2024. The impact of increasing the age of testing, useful to address SAQ2.2, was also looked at by removing animals from yearly age groups from FS, ES/AM as appropriate, covering the range 60–120 months in 12-month intervals and assuming the numbers tested in each stream remain the same as the number tested in 2024.

2.2.3 | SAQ1.3 Estimation of the BSE cases detected by the WOAH system in the next 5 years

The capability of a surveillance system that implements the new WOAH provisions was addressed by considering (i) the plausible detection rate of clinical animals from the clinical reports of historic cases of BSE assessed against the WOAH provisions as in the retrospective assessment of the EU cases (SAQ 1.1) and (ii) the number of cases that could be detected under current EU provisions (forward prediction of the back-calculation model as in SAQ 1.2).

The outputs from SAQ 1.2 provided the total estimated number of EU cases detected in the next 5 years. The WOAH rate of detection was then applied using two scenarios: a best-case scenario, in which the rate of detection referred to historic reports that were judged as being selected for testing or where disagreement was found (categories 'YES' and 'No agreement', see Section 2.2.1); and a worst-case scenario including only those records unanimously selected for testing ('YES'). The results of this estimation were referred to in the opinion as the WOAH baseline, which represents the estimated capability of the surveillance provisions recommended in Article 11.4.20 of the WOAH Terrestrial Code, without specific implementation protocols in place, to detect the estimated BSE cases (C-, H- and L-) in the next 5 years in the EU.

2.2.4 | SAQ2.1 comparison of the WOAH and EU surveillance systems

Comparative analysis of the relevant articles of the WOAH terrestrial code and guidelines and the EU legislation. This was structured in two parts:

- A narrative description of the previous and new surveillance provisions of the WOAH terrestrial Animal Health Code was conducted, along with the surveillance requirements in the EU according to the TSE regulation, focused on the objectives of surveillance, the testing groups and criteria for selection of animals for testing, including the legal statutes that drive surveillance.
- The identification of commonalities and differences of the two surveillance frameworks, as identified by the experts of the working group.

One of the approaches listed for SAQ2.1 described in the protocol is the expert judgement on the relevance of the objectives of the EU surveillance in 2025. For that purpose, further analysis of the potential objectives that future surveillance in the EU could fulfil was conducted, based on the current epidemiological situation of the three strains of the disease, the outputs of the model and the uncertainties associated with key issues like the origin of the atypical strains, their zoonotic potential and the confirmation of C-BSE cases still in Europe.

2.2.5 | SAQ2.2 Additional components to the WOAH surveillance provisions adequate/appropriate for the EU surveillance

The definition of additional components to the WOAH surveillance provisions, with supporting justification of surveillance in the EU and departing from the current obligations of Regulation (EC) 999/2001, was based on different supporting data:

- the description of the EU surveillance streams contributing the most to the BSE (C, H and L) caseload in the EU, excluding clinical suspects already included in the WOAH baseline;
- the ages of positive animals detected between 2015 and 2024, broken down by BSE-type and surveillance stream in order to inform the adjustment of the age threshold;
- the determination of the relative risk of BSE (C, H and L) in the different surveillance streams using as a baseline the healthy slaughter to identify the most suitable options;
- the back-calculation model and its prediction of the number of FS/ES cases that are expected as the age threshold increases;
- the capability of the WOAH baseline to detect cases as in SAQ1.3;
- the potential objectives that the EU surveillance should fulfil in the next years.

The number of tests required for different additional components (surveillance streams and age thresholds) based on 2024 data was also considered, assuming consistent testing distribution over the next 5 years, while comparing scenarios based on the detection capability versus the percentage reduction in testing. These figures have been used as a proxy for the surveillance burden when comparing different additional components, and they are not intended to represent costs.

2.2.6 | SAQ 2.3 estimation of the number of BSE cases detected in the EU in the next 5 years under the selected components additional to the WOAH surveillance provisions

Two outputs of previous SAQ were applied to answer this one: the prediction of the number of cases detected by the WOAH baseline, as in SAQ1.3, and the estimation of the detected cases of the additional components of surveillance by the

model, as described in SAQ 2.2. An additional output not included in the protocol was the number of tests done if the additional components were applied, and the percentage of test reduction using the 2024 throughput as baseline. Another consideration is the added value of these additional components to fulfil the potential objectives of the future BSE surveillance in the EU, as described in SAQ2.2.

The estimation of the number of cases detected by the surveillance schemes that combine WOAH surveillance with the additional components was conducted as follows: for each proposed scenario, the prediction of the number of cases detected by the WOAH baseline was added to the estimated detection capability of the additional component. Because some of the cases expected to be detected by the additional components – those with an appropriate clinical history – would instead be detected under WOAH surveillance streams, the detection capability of WOAH was subtracted from the estimated capability of the additional component, applying the percentages of the best-case scenario (BCS) and the worst-case scenario (WCS).

3 | ASSESSMENT

3.1 | Clinical diagnosis of BSE

All previous and existing EU and WOAH BSE surveillance systems have required, and still mandate, the reporting and submission of any BSE clinical suspects (regardless of age), but it is clear from historical data that this approach alone would have missed a substantial proportion of the infected animals that have been identified through alternative surveillance streams (see Section 3.3).

All TSEs, which include classical and atypical BSE strains, have long, asymptomatic incubation periods. In cattle, these range from 2 to more than 10 years for classical BSE based on age at presentation of naturally occurring cases throughout the epidemic and experimental oral challenge studies (Konold et al., 2012). For atypical BSE, incubation periods of up to 2 years were derived from experimental intracerebral challenge (for summary see EFSA, 2014), but no data are available following oral challenge or for naturally occurring disease. The diagnostic hallmark of these diseases, the accumulation of the abnormal protein PrP^{Sc} in the brainstems of affected animals, can be detected through post-mortem testing in affected animals up to 12 months (or more) prior to any detectable clinical abnormality. Animals in this phase of the disease will not be detected through surveillance that relies on the detection of clinical signs, but BSE infectivity will be present increasingly in SRM tissues during this preclinical phase (Arnold et al., 2012).

The WOAH's Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[8] gives an overall description of the clinical signs of BSE based on published analyses of both cases of naturally occurring disease and animals that have been experimentally challenged. The manual confirms that there are no pathognomonic clinical signs for BSE. This is clear from the literature on this topic, whether based on retrospective analysis of reported clinical signs in BSE suspects in the field (Konold et al., 2006; Saegerman et al., 2004), direct observation of natural disease (Braun et al., 1998; Konold et al., 2004) or the systematic longitudinal study of experimentally induced disease (Balkema-Buschmann et al., 2011; Konold et al., 2010, 2012, 2014; Lombardi et al., 2008). Early clinical signs may be very subtle, such as a change from normal behaviour (e.g. a quiet animal becoming more aggressive or a normally assertive animal becoming more timid), or very non-specific signs such as a loss of body condition or a drop in milk yield. These signs may lead to an animal being sent for slaughter for management or economic reasons, with no suspicion of BSE.

While the more reliable clinical signs, such as hypersensitivity to touch/sound/startling, can be elicited via standardised methods (Konold et al., 2004), they are not always present, and conducting such tests may not be practical/feasible in some settings. Effective use of elicited responses also requires the clinician to have knowledge and practical experience of the methods and a good understanding of the range of normal responses in various environmental settings. Such data would be unavailable retrospectively for animals found dead. Ataxia or paresis may also be unnoticed prior to an animal falling and experiencing other injuries, which might then mask the original cause of the fall. The ability to obtain a comprehensive picture of the preceding clinical condition of a recumbent or found dead animal will vary greatly depending on the circumstances (e.g. after transit, in an extensive farming system). Hence, the lack of pathognomonic clinical signs for BSE presents substantial challenges to both the sensitivity and specificity of a surveillance system that relies solely on the identification of clinical signs by either the livestock keeper/handler or the private veterinarian and an understanding of their relevance for case selection.

As an illustration, a study was carried out in France at the time of the BSE epidemic in 2000, comparing the rapid tests carried out on fallen stock and emergency slaughter animals with clinical surveillance when both surveillance systems were in force at the same time and in the same area (Calavas et al., 2001). The analysis indicated that clinical surveillance had a sensitivity of approximately 25% relative to rapid diagnostic testing, showing the lack of sensitivity of clinical surveillance. However, within 6 months of the experiment, the awareness of the veterinarians improved (Morignat et al., 2002) and the ratio detected by surveillance versus detected by the tests increased, indicating that increased awareness improved the sensitivity of the clinical surveillance.

[8] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/.

3.2 | The former and the new WOAH surveillance system

Prior to the 2023 revision of the Terrestrial Code, the WOAH surveillance[9] used a point-based system to prioritise higher risk groups and to improve detection efficiency.

The system allocated points to the sampling of the following four subpopulations/surveillance streams: healthy slaughter, fallen stock, casualty slaughter and clinical suspects. The number of 'points' generated by each tested animal depended on the subpopulation and the animal's age category. Testing higher risk animals (i.e. older animals, fallen stock, animals from casualty slaughter and clinical suspects) yielded more points because BSE was more likely to be detected in these subpopulations. The points reflect the likelihood of detecting BSE cases in a particular subpopulation within a certain age class, as estimated by the BSE-survE model (Prattley et al., 2007). The point values for samples collected under the WOAH's previous BSE surveillance programme (by surveillance stream and year) are displayed in Table 2. The clinical suspect subpopulation was assigned a point value several orders of magnitude greater than the other surveillance streams.

The system was designed to ensure that countries or zones conducted sufficient surveillance to detect BSE at or above a given design prevalence (e.g. one case per 100,000 adult cattle) with a specified confidence level (95%) within their adult cattle populations. To reach its surveillance target, a country had to accumulate points over a period of up to 7 years. The points target for a country depended on the size of its adult bovine population.

TABLE 2 Surveillance sub-populations and points assigned to them, as per WOAH terrestrial code prior to 2023.

Age	Routine (healthy) slaughter	Fallen stock	Casualty slaughter	Clinical suspects
≥ 1 year and < 2 years	0.01	0.2	0.4	N/A
≥ 2 years and < 4 years (young adult)	0.1	0.2	0.4	260
≥ 4 years and < 7 years (middle adult)	0.2	0.9	1.6	750
≥ 7 years and < 9 years (middle adult)	0.1	0.4	0.7	220
≥ 9 years	0.0	0.1	0.2	45

The rationale for reviewing the surveillance provisions of the WOAH arose from the reflections and lessons learned after the long-term implementation of the previous surveillance system, as explained in the report of the meeting of the OIE ad hoc group on BSE surveillance (OIE, 2018). In summary:

- *'Surveillance has emerged as a significant roadblock for some low and middle-income Members in attaining an official BSE-risk status.*
- *The clinical suspect surveillance subpopulation is assigned a much higher point value than the other surveillance subpopulations. In an attempt to maximise the number of accumulated surveillance points, some Members have claimed more animals as clinical suspects than would appear to be reasonably justified.*
- *Historically, stratification into four subpopulations was based on European experiences; with point values based on age and subpopulation. While such an approach might be suitable for those Members where cattle are intensively reared and subjected to regular observation, in more extensive systems where cattle are not monitored closely, it may be difficult to stratify cattle into these streams. Situations would inevitably arise where an animal might be considered to be a clinical suspect … Under such circumstances assigning an animal to a particular surveillance subpopulation is highly dependent on when it was first observed in the continuum of a progression from clinical suspect to downer to fallen stock.*
- *It is apparent that Members with small cattle populations continue to struggle to reach their surveillance points target.*
- *The implementation of the current*[10] *surveillance provisions with a focus on achieving and maintaining a surveillance points target can be extremely costly. An important objective in defining surveillance requirements is to ensure that they are both achievable and implemented to the extent that is reasonably necessary without imposing an undue burden on Members'.*

The previous WOAH approach was intended to be active and passive, using statistically based methods to detect BSE at a predetermined design prevalence and confidence, while also allowing trends to be observed over time. The new system, as described in the following paragraphs, changes the approach to a clinically based one which focuses on case-based reporting and emphasises awareness without numeric testing targets.

According to the new provisions of the BSE chapter of the WOAH Terrestrial Animal Health Code, *'the BSE-risk status of a country would be determined from a detailed consideration of comprehensively documented risk assessment (entry assessment, exposure assessment, consequence assessment, and risk estimation)'*. The ad hoc WG stated that, consequently, *'surveillance should always have played a secondary role in evaluating the BSE-risk status of a country. The primary focus should be on a transparently documented and comprehensive risk assessment that includes a detailed evaluation of husbandry and farming practices*

[9] https://rr-europe.woah.org/en/news/new-terrestrial-codes-available-for-download-in-pdf/.
[10] Pre-2023.

as well as the continuous and effective implementation of relevant mitigation measures with the ongoing results of a surveillance program taken into account'.

As a result, '*a baseline level of surveillance should continue with the focus being on cattle identified with a clinical syndrome consistent with BSE (refractory to treatment, displaying progressive behavioural changes or neurological signs). This would include animals on a continuum of a progression from clinical suspect to downer to fallen stock with an appropriate supporting history*'.

These new principles were transposed after consultation and internal procedures into the new BSE chapter approved by the General Assembly of the WOAH in May 2023. The objective of the new WOAH surveillance provision is '*the detection of the occurrence of BSE in the bovine population*'. As stated in Point 2 of Article 11.4.20 of the WOAH Terrestrial Animal Health Code,[11] '*the animals that lie on the clinical spectrum of BSE should be targeted for BSE surveillance and the following animals should be reported and followed up with appropriate laboratory testing in accordance with the Terrestrial Manual to accurately confirm or rule out the presence of BSE agents, including discrimination between atypical and classical BSE strains':*

a. *those displaying progressive clinical signs suggestive of BSE mentioned in point 1*[12] *that are refractory to treatment, and where the clinical presentation cannot be attributed to other common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes);*
b. *those showing behavioural or neurological signs at ante-mortem inspection at slaughterhouses/abattoirs;*
c. *those unable to rise or walk without assistance, with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of recumbency);*
d. *those found dead (fallen stock), with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of death).*

Point 3 of Article 11.4.20 states that '*The credibility of the surveillance programme is supported by:*

a. *ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock, including bovine breeders, owners and keepers, veterinarians, transporters and slaughterhouse/abattoir workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;*
b. *the fact that BSE is a notifiable disease throughout the whole territory;*
c. *appropriate laboratory testing in accordance with the Terrestrial Manual;*
d. *robust, documented, evaluation procedures and protocols for:*

- *the definition of the target population for BSE surveillance,*
- *the reporting of bovines described in points 2a) to 2d),*
- *the determination of animals to be subjected to laboratory testing,*
- *the collection and submission of samples for laboratory testing,*
- *the follow-up epidemiological investigations for BSE positive findings'.*

The new WOAH provisions specify the categories of bovine animals that should be subject to BSE testing, but it does not indicate which specific animals should be tested. The responsibility now lies with each Member Country to design a surveillance system compatible with their livestock population and their husbandry and industry practices that can identify, select and test the animals that meet the WOAH requirements.

Article 1.8 of the Terrestrial Animal Health Code sets out general principles in relation to the information that Member Countries should provide in support of their application for official recognition of risk status for BSE.

In Point 2 of Article 1.8.5, there are key aspects that member countries should include in their applications:

'[…].

b) Describe the supportive measures in place for targeting animals that show signs of the clinical spectrum of BSE and for reporting of animals described in points (2a) to (2d) of Article 11.4.20, such as incentives, compensations or penalties.
c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including bovine breeders, owners and keepers, veterinarians, transporters, and workers at livestock markets, auctions and slaughterhouses/abattoirs in terms of the criteria for reporting. What mechanisms are in place to ensure that these guidelines reach those stakeholders?'

Point 4 of Article 1.8.5 acknowledges the difficulty of detecting appropriate candidates for surveillance in countries that have never confirmed a case of BSE. Therefore, the guidelines support a risk-based approach, in which the efforts should be aimed at increasing the capacity for targeting animals within the clinical spectrum. '*Given that the incidence of BSE is likely to*

[11] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/.

be very low in Member Countries, it is important that surveillance efforts focus on subsets of the bovine population where disease is more likely to be detected'.

Point 4 then explains how a surveillance programme should be designed and implemented to meet these requirements: is '*Considering that BSE is a progressive disease and that animals to be included in the surveillance programme may arise at the farm, the slaughterhouse/abattoir, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification of animals showing signs of the clinical spectrum of BSE (*e.g. *by the breeder, owner or keeper, animal handler, veterinarian*, etc.*); (2) the criteria to determine which of these animals need to be reported and tested for BSE; (3) the collection and submission of samples for testing in a laboratory; and (4) a follow-up epidemiological investigation for BSE positive findings*.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

a. *List the common bovine disorders with clinical signs compatible with BSE in the country or zone. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group*.
b. *Describe the procedures and protocols in place for reporting animals described in points (2a) to (2d) of Article 11.4.20. For example, these procedures and protocols may include the steps that a breeder, owner or keeper may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock*.
c. *Describe the procedures and protocols in place for the investigation of reported animals. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the herd are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock*.
d. *Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition*.
e. *Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the bovine identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from*.
f. *Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results'*.
g. *Provide a summary table for each of the preceding 8 years of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points (2a) to (2d) of Article 11.4.20)*.

3.3 | Supporting activities and challenges to clinical BSE surveillance

The potential change from a combined framework of passive and active BSE surveillance to a strategy targeting only animals within the BSE clinical spectrum, as proposed in the revised WOAH provisions, represents a fundamental paradigm shift in the model of surveillance.

WOAH in Point 3 of Article 11.4.20 of the Terrestrial Animal Health Code describes the raft of supporting activities needed to ensure the effectiveness of a BSE surveillance system targeting animals using clinical surveillance. Point 3 lists ongoing awareness, training programmes, the fact that BSE is a notifiable disease and laboratory testing capabilities. It also refers to the need of a well-defined target population for BSE surveillance and defined protocols describing which animals should be reported as BSE suspects to the relevant competent authority and which of those animals should be tested. WOAH then makes reference to the need for a well-described methodology for sample collection and laboratory testing. Finally, it points to the need for follow-up epidemiological investigations when BSE is confirmed.

The implementation of these required activities presents challenges. The extremely low prevalence of BSE in recent years implies the level of awareness and expertise regarding BSE clinical signs has declined among practitioners and stakeholders meaning that BSE might not feature in a list of differential diagnosis by a farmer or a veterinary practitioner when faced with an animal demonstrating clinical signs potentially consistent with BSE.

This and other challenges have been highlighted in the scientific literature where the effectiveness of clinical-based surveillance in the field of animal health can be significantly hindered by difficulties in clinical identification, behavioural reluctance to report and inadequate systemic support (Doherr et al., 1999; Doherr & Audige, 2001; Enticott et al., 2021; Gates et al., 2021; Hopp et al., 2007). The transition away from systematic testing could further limit the ability to detect cases, leading to reluctance to engage with the system unless full participation is encouraged and concealment is discouraged (Hernandez-Jover et al., 2025; McGowan et al., 2022; Salman, 2003; Uchtmann et al., 2015).

The change to the WOAH surveillance model will also require the mandatory systematic collection of data on bovine animals displaying neurological signs at farm level something that has not been mandatory in the EU up until now. EFSA does receive some clinical data collected retrospectively subsequent to the confirmation of a BSE case on a voluntary basis from EU Member States.

The consideration of the supporting activities and challenges to the implementation of the WOAH BSE surveillance provisions are outside the scope of this Scientific Opinion; however, it is important that they are recognised.

3.4 | Retrospective assessment of the capability of the new WOAH surveillance provisions to detect EU BSE cases 2015–2025 (SAQ 1.1)

3.4.1 | Description and results

To assess the potential impact of aligning EU BSE surveillance with the WOAH Terrestrial Code, the WG retrospectively elicited whether cases identified by current EU surveillance between 2015 and 2025 were likely to have been identified had the WOAH provisions been in place. This procedure provides an evidence-based judgement of the capability of the WOAH provisions to select actual BSE cases for testing and highlights the differences in case ascertainment.

Between 2015 and 2025, 55 cases were reported by EU surveillance, of which six were C-BSE, 31 H-BSE and 18 L-BSE. Most of the cases (51) were confirmed in the FS stream, with the remaining four cases detected in the ES stream. No cases were reported as clinical suspects or via the other surveillance streams (see Appendix B, Table B.1).

The following 55 data (Table 3) show the independent conclusion of individual experts when integrating (i) the documented clinical and epidemiological description of the last 55 EU case detections, (ii) extensive subject matter expertise about the clinical presentation of BSE-positive bovines and (iii) the prescribed details for selecting a bovine for testing under the new WOAH provisions. For example, the first EU veterinary report in Table 3 relates to fallen stock that was not noticed by the farmer beforehand. The experts read the data together with the limited specificity of fallen stock per se in indicating BSE (see Section 3.1), and the request for an appropriate supporting clinical history (see Section 3.2), in order to evaluate whether the animal would have been selected for testing or not.

TABLE 3 Epidemiological data and individual judgements of the retrospective assessment of the BSE cases in the EU and UK.

Case number	BSE type	Age (in months)	Reporting country	Year of reporting	Surveillance stream	Clinical signs[a]	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by WOAH? Final status
1	C	90	UK	2024	FS	UK report: The farmer did not suspect notifiable disease and the carcase was collected by the fallen stock company on the same day	Probably NO	NO	NO	NO	NO	Probably NO	**NO**
2	C	93	UK	2021	FS	Euthanised on farm (fallen stock). UK report: Clinical signs indicative of metabolic disease was first noted on the day prior to its death. Milk fever (hypocalcaemia) was suspected, and calcium was administered. There was no response to treatment, and she was euthanised on-farm the following day	Probably NO	Probably YES	Probably YES	Probably NO	NO	NO	**NO agreement**
3	C	65	UK	2018	FS	Falling, recumbent. UK report: 'The index case had not required any surgical veterinary treatment during her life, nor had she been subject to any artificial breeding procedures such as artificial insemination or embryo transfer'. The cow was initially noted to be unwell on 30 September 2018, showing clinical signs consistent with a diagnosis of hypomagnesemia. The cow was treated immediately by the private veterinary surgeon and made a partial recovery; however, 2 days later she fell into a watercourse, and as a result, a decision was taken to cull. She died prior to the knackery attending	Probably NO	Probably NO	I don't know	YES	NO	NO	**NO agreement**
4	C	59	FR	2016	FS	Euthanasia following a fall	NO	NO	I don't know	NO	NO	NO	**NO agreement**
5	C	72	UK	2015	FS	(EFSA TSE REPORT, 2016). Wales government: 'a single deceased bovine on a farm in Wales'	I don't know	NO	NO	NO	NO	I don't know	**NO agreement**

TABLE 3 (Continued)

Case number	BSE type	Age (in months)	Reporting country	Year of reporting	Surveillance stream	Clinical signs[a]	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by WOAH? Final status
6	C	54	IE	2015	FS	Animal had been recumbent after falling and had been euthanised. Reduced milk yield prior to falling; reduced body condition	Probably NO	Probably NO	Probably YES	YES	NO	Probably NO	**NO agreement**
7	H		UK	2025	FS	The animal showed some clinical signs of BSE and was humanely culled on farm and tested as part of Defra's routine surveillance programme	Probably YES	YES	YES	YES	YES	YES	**YES**
8	H	228	UK	2024	FS	The index case had been isolated in a field on her own for the past year due to her declining health, which was believed to be caused by old age. No clinical signs of BSE were observed. On 25 November 2024, this 19-year-old bovine was humanely euthanised on farm due to age-related deterioration	NO	NO	NO	NO	NO	Probably NO	**NO**
9	H	207	FR	2024	FS	NONE	NO	NO	NO	NO	NO	NO	**NO**
10	H	186	IE	2024	FS	Lateral recumbency	Probably NO	Probably NO	I don't know	NO	NO	NO	**NO agreement**
11	L	69	PL	2024	FS	One case of fallen stock was noted, with no other clinical signs observed	NO	NO	NO	NO	NO	NO	**NO**
12	H	204	UK	2023	FS	Isolated, single case of atypical H-type bovine spongiform encephalopathy (BSE) has been confirmed in a 17-year-old indigenous cow on a beef suckler farm. The cow was in calf and was found recumbent with no prior history of clinical signs or problems. The animal was humanely euthanised on 27 February 23, and the case was disclosed during routine national TSE statutory surveillance and testing of fallen stock cattle aged over 48 months	NO	NO	NO	NO	NO	NO	**NO**

(Continues)

TABLE 3 (Continued)

Case number	BSE type	Age (in months)	Reporting country	Year of reporting	Surveillance stream	Clinical signs[a]	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by WOAH? Final status
13	H	267	ES	2023	FS	Lateral decubitus position, semi-comatose, sunken eyes and hypothermia. The animal's condition significantly deteriorated within a 24-h period, as it had been standing upright the previous day. The animal was euthanised on the farm	Probably NO	Probably YES	I don't know	NO	NO	NO	**NO agreement**
14	H	193	ES	2023	FS	No clinical signs. Dead on farm	NO	NO	NO	NO	NO	NO	**NO**
15	H	180	FR	2023	FS	No	NO	NO	NO	NO	NO	NO	**NO**
16	H	128	IE	2023	FS	Acute pelvic injury, hindlimb splits	NO	Probably NO	I don't know	NO	NO	NO	**NO agreement**
17	L	99	NL	2023	FS	Dead on farm	I don't know	NO	NO	NO	NO	I don't know	**NO agreement**
18	L	160	CH	2023	FS	Yes	YES	YES	Probably YES	YES	Probably YES	Probably YES	**YES**
19	L	145	CH	2023	FS	Yes	YES	YES	Probably YES	YES	Probably YES	Probably YES	**YES**
20	H	154	FR	2022	FS	Difficulty to get up and stand up, always turning 'in circles' in the same direction, walking 'crab- wise'. Clinical signs started 1 month before death	Probably NO	YES	Probably YES	YES	YES	Probably YES	**NO agreement**
21	L	175	DE	2021	ES	NONE	NO	NO	NO	NO	NO	NO	**NO**
22	H	170	ES	2021	FS	NONE	NO	NO	NO	NO	NO	NO	**NO**
23	L	160	ES	2021	ES	NONE	NO	NO	NO	NO	NO	NO	**NO**
24	L	150	FR	2021	FS	Behavioural and locomotor disorders the day before the death of the animal	Probably NO	Probably YES	YES	NO	Probably NO	Probably YES	**NO agreement**
25	L	181	FR	2021	FS	Decubitus, left hemiparalysis	Probably NO	Probably NO	I don't know	NO	Probably NO	NO	**NO agreement**
26	H	161	FR	2021	FS	NONE	NO	NO	NO	NO	NO	NO	**NO**
27	L	158	CH	2020	ES	Recumbency at the transfer to the abattoir	Probably NO	Probably NO	Probably YES	NO	No answer	NO	**NO agreement**

TABLE 3 (Continued)

Case number	BSE type	Age (in months)	Reporting country	Year of reporting	Surveillance stream	Clinical signs[a]	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by WOAH? Final status
28	H	212	ES	2020	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
29	L	143	FR	2020	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
30	H	191	FR	2020	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
31	H	171	IE	2020	FS	N/A	I don't know	NO	NO	NO	I don't know	I don't know	**NO agreement**
32	H	66	ES	2019	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
33	H	222	ES	2019	FS	Not specific: Limp, ataxia and weight loss	Probably NO	Probably YES	YES	NO	Probably YES	YES	**NO agreement**
34	H	193	FR	2019	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
35	H	132	FR	2019	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
36	H	192	FR	2019	FS	Weight loss during previous months	NO	Probably NO	Probably NO	NO	NO	Probably NO	**NO**
37	H	200	FR	2019	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
38	L	138	PL	2019	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
39	L	92	FR	2018	ES	No clinical symptoms	NO	NO	NO	NO	NO	NO	**NO**
40	H	194	FR	2018	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
41	L	123	FR	2018	FS	Aggressive animal	Probably NO	Probably YES	I don't know	NO	Probably NO	YES	**NO agreement**
42	H	221	ES	2017	FS	No clinical symptoms	NO	NO	NO	NO	NO	NO	**NO**
43	L	182	ES	2017	FS	NO	NO	NO	NO	NO	NO	NO	**NO**
44	L	169	ES	2017	FS	No clinical symptoms	NO	NO	NO	NO	NO	NO	**NO**
45	L	173	FR	2017	FS	No clinical symptoms	NO	NO	NO	NO	NO	NO	**NO**
46	H	146	FR	2017	FS	Problems at hind limbs	Probably NO	Probably YES	Probably YES	NO	NO	Probably NO	**NO agreement**
47	L	226	IE	2017	FS	Stiff gait, ill thrift despite normal appetite, recumbency and euthanasia	I don't know	Probably YES	YES	YES	Probably YES	Probably YES	**NO agreement**
48	H	193	ES	2016	FS	Sialism	Probably NO	Probably NO	I don't know	NO	NO	NO	**NO agreement**

(Continues)

TABLE 3 (Continued)

Case number	BSE type	Age (in months)	Reporting country	Year of reporting	Surveillance stream	Clinical signs[a]	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by WOAH? Final status
49	H	186	FR	2016	FS	This cow was euthanised after an accident (slip on wet grass). It was found lying on its back and was unable to stand up	NO	NO	I don't know	NO	NO	NO	**NO agreement**
50	H	165	FR	2016	FS	NONE	NO	NO	NO	NO	NO	NO	**NO**
51	H	133	FR	2016	FS	The pregnant cow had paresis. It was euthanised after a caesarean section resulted in paraplegia	NO	Probably NO	I don't know	NO	Probably NO	NO	**NO agreement**
52	H	144	SI	2015	FS	Paresis	Probably NO	Probably YES	Probably YES	NO	Probably NO	Probably NO	**NO agreement**
53	H	143	UK	2015	FS	–	I don't know	NO	NO	NO	I don't know	I don't know	**NO agreement**
54	L	180	ES	2015	FS	NONE	NO	NO	NO	NO	NO	NO	**No**
55	H	192	NO	2015	FS	N/A	I don't know	NO	NO	NO	I don't know	I don't know	**No agreement**

Note: Expert judgements refer to whether a case would have been selected for testing by WOAH or not.

Abbreviation: N/A, not available.

[a]The terms 'NO' and 'NONE' have been considered equivalent and imply that there was no evidence of previous clinical symptoms.

Of the 55 cases, 28 (51%) had as the final decision 'NO' (it would not have been selected for testing by WOAH); three cases (5%) had 'YES' (it would have been selected for testing by WOAH); and 24 (44%) cases resulted in 'NO AGREEMENT'. The details of the individual judgements and the final result for each case are displayed in Table 3. The results of the exercise reflected the difficulty of reaching consensus among WG members on whether the EU cases would have been selected for testing, assuming the WOAH system had been implemented, without a specific implementation protocol for the WOAH provisions.

The 24 cases resulting in 'NO AGREEMENT' were sorted by their Consensus Bias Score. Results are presented in Figure 1.

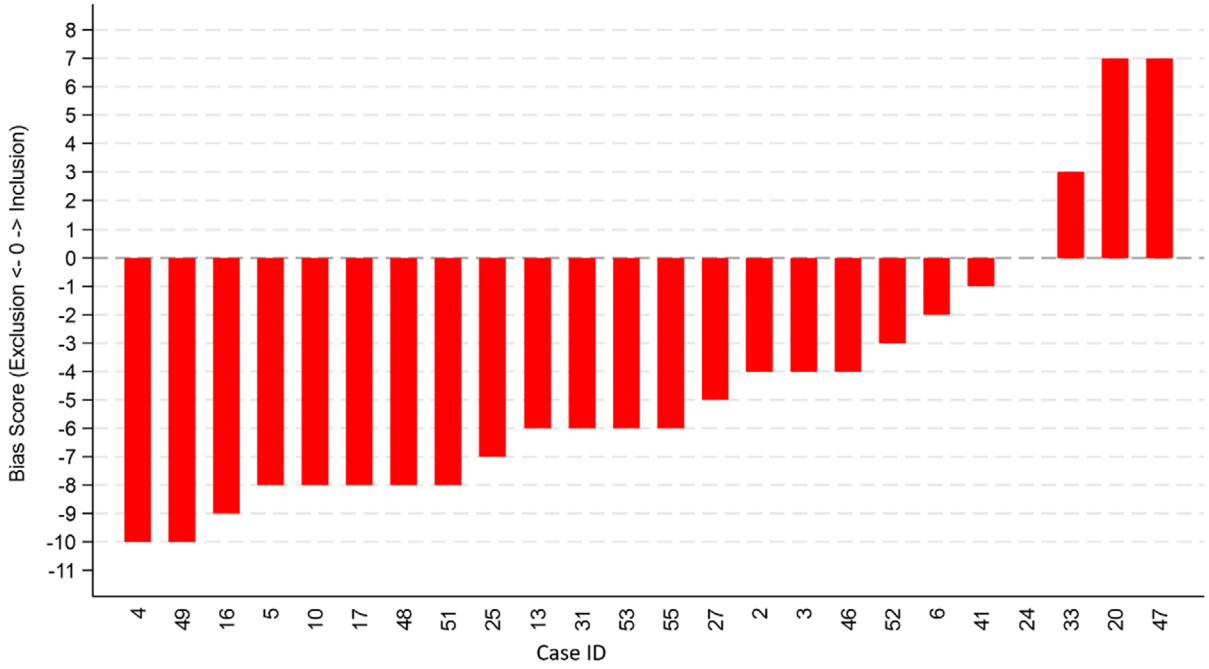

FIGURE 1 Consensus Bias Score for 24 cases resulting in 'NO AGREEMENT'. Qualitative answers were assigned numerical values (YES = 2, Probably YES = 1, Don't know = 0, Probably NO = −1 and NO = −2). The Bias Score was calculated by adding up the values for each case across experts.

Higher absolute Consensus Bias Scores, whether positive or negative numbers, indicate an increasing similarity in individual judgements.

The analysis of the Consensus Bias Score for the cases resulting in NO AGREEMENT indicates that only three cases had a positive Bias Score, i.e. the experts leaned towards inclusion on average, and two cases showed a high mixture of votes (scores of −1 and 0), suggesting true conflict or ambiguity regarding the case's classification. Hence, the vast majority (19 out of 24) were cases in which most experts leaned towards exclusion. Complete consensus was often (14 out of 24) prevented by 'I do not know' votes.

Interpretation of the results

There was variability in the judgements regarding the capability of clinical surveillance to detect the cases confirmed in the EU in the last 10 years, mostly due to the limited amount and the quality of the clinical data available. Under the worst-case scenario, only the three cases (5%), unanimously judged as ones that would have been selected for testing by the WOAH surveillance system, can be regarded as detectable with confidence. A high degree of uncertainty is reflected by the set of 24 cases with no agreement. Although the majority had a dominant negative Bias Score and hence are considered unlikely to be selected for testing, the quality of reported case data and the differences in individual interpretation of the potential diagnostic relevance of that case data led to contradicting individual judgements. The best-case scenario for the capability of the WOAH system would consider all the 24 cases non-unanimously judged as being selected for testing plus the three cases unanimously decided that would have been detected by WOAH (49%). Hence, an overall uncertainty in assessing the capacity of the WOAH system is reflected by the wide range from 5% to 49% of historic EU case records judged possible to be selected for testing. Ultimately, however, at least about half of the historic EU case records were identified as 'not selected for testing' when following the WOAH surveillance system definitions. This comes without uncertainty – other than potential incorrect case reports.

To conclude, the WOAH provisions would only have detected 5% of the cases identified through EU surveillance in a worst-case scenario (WCS) or up to 49% in a best-case scenario (BCS). The consequential potential decrease in the number of BSE cases (C, H and L) detected in the next 5 years in the EU, given the implementation of the WOAH provisions, will be analysed in Chapter 3.6.

Another interpretation of the results is that a future testing provision based on clinical history requires a clearly defined and harmonised case selection criteria to prevent ambiguities as found with the reports from the past 55 EU cases addressed in Table 3.

3.4.2 | Sources of uncertainty of the assessment

Reliance on clinical data collected for other purposes: The clinical signs used in this retrospective assessment may be inaccurate and/or incomplete. In most cases, it is likely that they were recorded after the case had already been confirmed. This retrospective documentation is vulnerable to recall bias and may not reflect the signs that were observable on the animal at the time of selection for testing. This limitation, due to incomplete case documentation, might have led to underestimation or overestimation of the capability of the WOAH provisions implementation to detect BSE cases (i.e. too few 'Yes').

Lack of national implementation of WOAH protocols including lack of exact definition of case selection criteria: Article 11.4.20 of the WOAH Terrestrial Code requires each Member Country to develop specific national robust, documented, evaluation procedures and protocols for BSE surveillance, including criteria for selecting animals for testing. This retrospective assessment does not necessarily reflect how WOAH principles might become operationalised in future EU national surveillance systems, should the WOAH provisions be enforced in the EU. This limitation could under- or over-estimate the capability of the WOAH provisions to detect BSE cases (i.e. clinical reports after implementation could be more or less precise than clinical information available from those of historic EU cases).

3.5 | Estimation of the current prevalence of BSE and prediction of cases detected in the EU (2025–2029) (SAQ 1.2)

An exponential decline was observed (2008–2024) in the estimated population prevalence of C-BSE, with an annual rate of decline of 38.3% (95% CI: 34.2%–43.4%). This finding is in agreement with the decline in fallen stock positives (Figure 2), where numbers tested have remained largely unchanged over time, apart from an increase in the age of testing from 24 to 48 months from 2009 onwards. The prevalence of C-BSE infection in the EU27 cattle population in 2024 was estimated to be 2.03×10^{-8} (95% CI: 2.48×10^{-9}–9.64×10^{-8}). Given the cattle population in the EU27 of 71.9 million,[12] this results in an estimate of 1.45 infected cattle in the EU27 in 2024 (95% CI: 0.18–6.89).

No temporal trend was observed in the population prevalence of either H-type or L-type BSE (Figure 2). The estimated prevalence of infection in the population in 2024 was 8.87×10^{-5} (95% CI: 6.63×10^{-5}–1.18×10^{-4}) for H-type and 8.97×10^{-5} (95% CI: 6.46×10^{-5}–1.18×10^{-4}) for L-type. Given the cattle population size in the EU27 of 71.9 million, this results in an estimate of 6378 infected cattle with H-type in the EU27 (95% CI: 4767–8484) and 6449 infected cattle with L-type in the EU27 (95% CI: 4645–8484).

The estimated proportion of animals with clinical disease that are reported for testing as SU was very low for all BSE types: 1.46×10^{-3} for C-BSE (i.e. 1 reported in 346 clinical animals) (95% CI: 6.76×10^{-4}–2.76×10^{-3}), 1.70×10^{-4} (95% CI: 9.11×10^{-6}–8.87×10^{-4}) for H-BSE and 2.93×10^{-4} (95% CI: 1.35×10^{-5}, 1.57×10^{-3}) for L-BSE.

[12]Point 1 of Article 11.4.20 of the WOAH Animal Terrestrial Code: BSE is a progressive, fatal disease of the nervous system of bovines that usually has an insidious onset and that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE: progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalisation, panic-stricken response and excessive alertness; postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head, head shyness, difficulty avoiding obstacles, inability to stand and recumbency; generalised non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

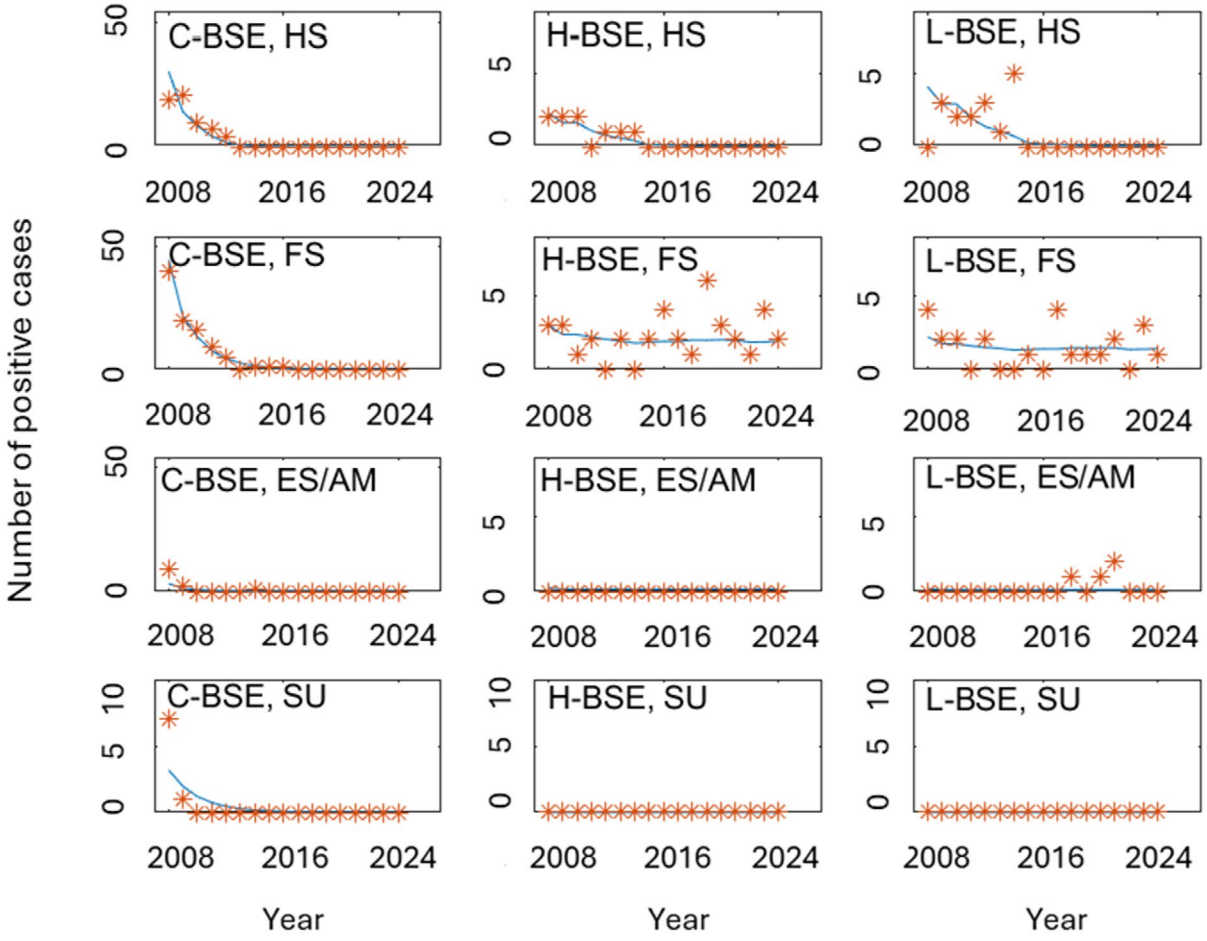

FIGURE 2 Fit of the back-calculation model for BSE (blue line) to the observed number of positives (orange symbols) by BSE type and surveillance stream: ES/AM, emergency slaughter/clinical signs at ante-mortem inspection; FS, fallen stock; HS, healthy slaughter; SU, clinical suspects.

The predicted number of cases by BSE type in EU27 detected in the FS stream for the 2025–2029 period were 0.018 (95% CI: 0.0035–0.076) for C-BSE; 10.73 (95% CI: 6.6–17.19) for H-BSE; and 7.68 (95% CI: 3.77–13.06) for L-BSE, assuming continuation of any detected annual trend and the same numbers tested annually as in 2024. The model predicted the total number of positives in the combined ES/AM streams in the next 5 years being 0.0016 (95% CI: 0.0003–0.0068) for C-BSE, 0.64 (95% CI: 0.32–1.07) for L-BSE and 0 for H-BSE. While the testing of HS is no longer mandatory except in Romania and Bulgaria, there are still many cattle tested in that stream overall (133,000 in 2024) and the model predicts the possibility of atypical BSE cases in HS: 0.21 H-type (95% CI: 0.11–0.32) and 0.81 L-type (95% CI: 0.11–3.12) in the next 5 years. No clinical cases (SU stream) were expected over the next 5 years in any of the BSE types. The summary of these results is shown in Table 4.

TABLE 4 Predicted number of cases by BSE type detected by the different surveillance streams in EU27 for the 2025–2029 period with 95% credible intervals.

	FS (inc. EM)	ES/AM	HS	SU
C-BSE	0.018 (0.0035–0.076)	0.0016 (0.0003–0.0068)	0.000032 (0.0000011–0.00029)	0[b]
H-BSE	10.73 (6.6–17.19)	0[a]	0.21 (0.11–0.32)	0[a]
L-BSE	7.68 (3.77–13.06)	0.64 (0.32–1.07)	0.81 (0.11–3.12)	0[a]

[a]Lack of cases prevented the estimation of future occurrence and CI.

[b]No cases since 2010: no reliable estimation of future occurrence and CI, as unable to infer temporal trend.

Summed over all the surveillance streams (see Table 4) this results in an expected total number of 0.0196 C-BSE cases detected (95% CI: 0.0055–0.077), 10.94 H-BSE cases (95% CI: 6.77–17.26) and 9.13 L-type cases (95% CI: 4.76–14.52), over a 5-year period (2025–2029). As the predicted number of C-BSE cases over the next 5 years is less than one (0.0196), the outcome of the model can also be interpreted as a 1.9% probability of detecting at least one case during this period.

3.6 | Assessment of the capability of the WOAH provisions to detect BSE cases in the EU (2025–2029) (SAQ 1.3)

The estimation of cases detected by the WOAH provisions should take into account that only the proportions of bovines derived from the retrospective assessment (i.e. between 5% and 49%) would be detected in FS and ES/AM, while no HS would be detected by WOAH. Bovines expected in the SU stream would be detected equally by the EU and WOAH provisions. However, given that no BSE cases are estimated to be detected in the SU stream and because of the extremely low number of expected cases in the HS surveillance stream, the prospective assessment of cases detected by WOAH was mainly based on applying the proportions derived from the retrospective assessment to the predicted cases in FS and ES/AM streams.

The predicted number of detected BSE cases under the current EU surveillance, between 2025 and 2029, is 0.0196 C-BSE cases, 10.94 H-BSE cases and 9.13 L-type cases. In detail, the WOAH baseline would detect 5% in the worst-case scenario, or up to 49% in the best-case scenario, of the predicted number of cases in FS and ES/AM surveillance streams, i.e. 0.0196, 10.73 and 8.32 cases for C-, H- and L-BSE, respectively (Table 4). This results in WOAH baseline detection of 0.0011, 0.58 and 0.45 cases (worst-case scenario) or up to 0.0096, 5.26 and 4.09 (best-case scenario) for C-, H- and L-BSE, respectively (Table 5).

TABLE 5 Predicted number of BSE cases (C-, H- and L-types) that could be detected between 2025 and 2029 under the current EU surveillance and the WOAH baseline best-case (BCS) and worst-case (WCS) scenarios.

	C-BSE	H-BSE	L-BSE
Current EU surveillance	0.0196	10.94	9.13
WOAH baseline best-case scenario (BCS)	0.0096	5.26	4.09
WOAH baseline worst-case scenario (WCS)	0.0011	0.58	0.45

In conclusion, based on the worst- and best-case scenarios of detected cases estimated by the retrospective assessment of EU clinical data (SAQ1.1), the capability of the WOAH's surveillance recommendations to detect BSE cases (C-, H- and L-type) is estimated to be between two and 20 times lower than that of the current EU surveillance system. As no C-BSE cases are estimated to be detected over the next 5 years (Table 5), the WOAH surveillance recommendations would primarily impact the capability to detect the atypical BSE cases (H- and L-type) predicted during this period, resulting in an estimated detection of between zero and five H-BSE cases and between zero and four L-BSE cases (Table 5). However, this reduced detection capability will also decrease the likelihood of detecting new cases associated with any future re-emergence of classical BSE.

3.7 | Concluding remarks to AQ1

- The absence of pathognomonic clinical signs of BSE poses a significant challenge to the sensitivity of surveillance systems that rely on clinical recognition. Early clinical signs may be very subtle or non-specific. More reliable signs can sometimes be elicited by experienced clinicians in certain settings, but such data would be unavailable retrospectively for dead or recumbent animals.
- The potential change from a combined framework of passive and active BSE surveillance to a strategy targeting only animals within the BSE clinical spectrum, as proposed in the revised WOAH provisions, represents a fundamental paradigm shift in the model of surveillance. Constraints compromising the effectiveness of clinical surveillance have been described.
- The WOAH surveillance provisions target bovines that lie on the clinical spectrum of BSE. Bovines in the preclinical phase of the disease would not be detected by WOAH surveillance. Thus, the implementation of the WOAH provisions would have a reduced capability to detect BSE cases compared to the current EU system.
- None of the BSE cases detected in the EU in the last 10 years have been reported as clinically suspect, emphasising the low sensitivity of current clinical surveillance in the EU.
- BSE cases detected by EU surveillance over the last 10 years were retrospectively assessed against the WOAH provisions. Results suggest a high degree of uncertainty, with fewer than 50% (ranging from 5% to 49%) of these cases estimated to have been selected for testing under the WOAH system.
- The estimated prevalence of C-BSE in the EU is declining and is currently very low. The estimated prevalence of H- and L-BSE is stable and similar for each strain, being three orders of magnitude higher than that of C-BSE.
- Overall, the capability to detect BSE cases (C-, H- and L-type) of the WOAH's surveillance recommendations is estimated to be between two and 20 times lower than that of the current EU surveillance system. As no C-BSE cases are estimated to be detected over the next 5 years, the WOAH surveillance recommendations would primarily impact the capability to detect the atypical BSE cases (H- and L-type) predicted during this period (11 H-BSE cases and 9 L-BSE cases), resulting in an estimated detection of between zero and five H-BSE cases and between zero and four L-BSE cases. However, this reduced detection capability will also decrease the likelihood of detecting new cases associated with any future re-emergence of classical BSE.

3.8 | Commonalities and differences between the WOAH and EU surveillance systems (SAQ 2.1)

3.8.1 | Commonalities

- **Disease status:** BSE is a notifiable disease in both WOAH and the EU. Article 11.4.20 of the WOAH Terrestrial Animal Health Code clarifies that the credibility of the surveillance programmes is also supported by the fact that BSE is a notifiable disease throughout the whole territory. Commission Decision 90/134/EEC[13] added BSE to the list of notifiable diseases. The legislation went through a series of updates under Regulation (EC) 999/2001 on the generalised rules for the prevention, control and eradication of TSE. Article 11 states that '*the Member States shall ensure that any animal suspected of being infected by a TSE is notified immediately to the competent authorities*'. Articles 12 and 13 of this regulation set out measures to be carried out in response to the identification of BSE suspect animals.
- **Risk-based surveillance:** Currently, both systems aim at identifying animals with a higher probability of having BSE compared to the general population, i.e. the clinical suspects and at-risk animals (AM, ES and FS).
- **Definition of clinical suspects**: There is little practical difference in the definitions of a clinical suspect in WOAH Article 11.4.20.2a and Article 3 of Regulation (EU) 999/2001.
- **Healthy slaughter testing**: Healthy slaughter surveillance, i.e. testing of cattle slaughtered for human consumption, is not required by the WOAH Terrestrial code. Using the authorisation provided in Commission Decision 2009/719/EC, most Member States do not test cattle slaughtered for human consumption or they test only very small numbers.

3.8.2 | Differences

- **Objectives of surveillance**: while WOAH's objective is '*to detect occurrence of BSE in the bovine population*', a monitoring programme is required in the EU. The recital of the original EU TSE Regulation states that '*Member States should carry out an annual programme for monitoring BSE and scrapie and should inform the Commission and the other Member States of the results and of the emergence of any other TSE*'. For EU MSs where BSE cases have already been detected, the objective of surveillance is to monitor the effectiveness of control measures by the trend of BSE prevalence and incidence. In countries where there have been no autochthonous cases of BSE, the objective of surveillance is to demonstrate that the prevalence of infection is below an agreed threshold. Specifically, Article 3 point 1(p) of Regulation (EC) 999/2001 defines active surveillance in the context of the EU surveillance obligations as '*the testing of animals not reported as suspected of being infected by a TSE…in order to determine the evolution and prevalence of TSE in a country or region thereof*'. In Annex III, Chapter B Section II of Regulation (EC) 999/2001 requests EFSA from 1 January 2016, '*to analyse the information referred to in Part I and publish by the end of November a summary report on the trends and sources of Transmissible Spongiform Encephalopathies in the Union*'.
- **Surveillance effort**: The WOAH provisions aim at maximising clinical case detection while minimising the surveillance effort by excluding the testing of non-clinical animals. The EU provisions aim at maximising case detection with high sensitivity and specificity of the surveillance.
- **Case selection principles:** WOAH prioritises clinical indicators, whereas the EU additionally tests animals with no documented clinical history (e.g. fallen stock) based on given age thresholds and target categories associated with different probabilities of detecting BSE.
- **Harmonised surveillance:** The WOAH provisions for surveillance allow for different protocols for implementation, as opposed to the EU rules that stipulate a standardised approach common for all MSs. The WOAH manual and guidelines provide the necessary information for countries to develop their own protocols, which could be very different, yet compliant with the WOAH provisions. These provisions offer flexibility and it is up to each member country to define key elements, such as what constitutes a 'clinical history' and who is responsible for selecting animals for testing (e.g. farmers, veterinarians, competent authorities), through their own national procedures for case reporting and investigation. By comparison, the classification of animals selected for testing cannot be altered by individual EU MSs unless it is enacted by an amendment of the TSE Regulation or associated legislation. Special derogations are allowed in exceptional circumstances (see 'fallen stock' below).
- **Multinational versus national implementation**: WOAH requires individual country-specific protocols, whereas the EU protocols apply across EU Member States. The EU is treated as a single epidemiological unit, avoiding a disproportionate burden on smaller EU countries.
- **Age Restrictions**: In the WOAH's previous terrestrial code, the scoring points were assigned depending on age categories (see Section 3.2). In contrast, there is no age limit set out in Article 11.4.20 of the new WOAH provisions. The WOAH recommendations on procedures and protocols in place for the investigation of reported animals, Article 1.8.5 point 4c, state that the '*procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the herd are taken into account*'. The EU's current age thresholds (older than 24 or 48 months) are scientifically justified by BSE's long incubation period and limitations of diagnostic tests. Using

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992D0450.

the authorisation provided in Commission Decision 2009/719/EC, most Member States increased the age for testing FS, ES and AM subpopulations to 48 months, which is more in line with the most likely incubation period of the disease and the time-dependent ability of the rapid test to detect the disease.

- **Classification of animals selected for testing:** The description of the animals to be included in each surveillance stream of the EU and WOAH surveillance systems presents some differences with limited overlapping. The comparison of the surveillance streams is summarised in Table 6 and elaborated in detail for each surveillance stream below.

Fallen stock (FS): The monitoring programme in Regulation (EU) 999/2001 specifies that all bovine animals above 24 months of age (increased to 48 months in most MS under derogation in Commission Decision 2009/719/EC), not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir must be tested.

Animals killed in the framework of an epidemic, such as foot-and-mouth disease, are explicitly excluded in Regulation (EU) 999/2001 but not in WOAH Article 11.4.20.2d. In Regulation (EU) 999/2001, there is a derogation for remote areas with a low animal density where no collection of dead animals is organised. This derogation does not exist in WOAH Article 11.4.20.2d.

Under WOAH Article 11.4.20.2d, animals falling into this category must only be tested if there is an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of death), with no age limit. Most animals classified as 'fallen stock' in the EU surveillance system would not qualify for testing under the WOAH surveillance system due to the absence of a supporting clinical history.

Ante-mortem inspection (AM): The EU regulation requires that bovine animals to be targeted for BSE testing at ante-mortem inspection are those 'with observations concerning accidents, or serious physiological and functional problems or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004 (2)',[14] whereas the WOAH definition is confined to animals 'showing behavioural or neurological signs'. Regulation (EU) 999/2001 specifies a lower age limit of 24 months (increased to 48 months in most MS under derogation in Commission Decision 2009/719/EC), and the WOAH Article 11.4.20.2d does not specify any age limit. Most animals in the ante-mortem subpopulation in the EU surveillance system would not qualify for testing under the WOAH surveillance system. Among those that would be tested, all would fall under the ante-mortem subpopulation category as defined in WOAH Article 11.4.20.2b.

Emergency slaughter (ES): The monitoring programme in Regulation (EU) 999/2001 specifies that all bovine animals above 24 months of age (increased to 48 months in most MS under derogation in Commission Decision 2009/719/EC), slaughtered for human consumption, where they have undergone emergency slaughter in accordance with point 1 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004, must be tested.

This subpopulation is not explicitly included as a separate category in WOAH Article 11.4.20.2. Consequently, animals in the emergency slaughter subpopulation in the EU surveillance system would not qualify for testing under the WOAH surveillance system.

Healthy cattle at slaughter (HS): Regulation (EC) 999/2001, as originally adopted, required the testing of all healthy bovine animals over 30 months of age slaughtered normally for human consumption. The age was increased in 2009 to all bovine animals above 48 months of age and to animals over 72 months of age in 2011. Commission Implementing Decision 2013/76/EU (amending Decision 2009/719/EC) authorised 25 Member States (excluding Bulgaria, Croatia and Romania) to revise their annual BSE monitoring programmes and to decide not to test animals slaughtered normally for human consumption. This resulted in the reduction or discontinuation of the testing of this surveillance stream in many Member States. As a result, the number of cattle tested in this category decreased from 2,138,114 in 2013 by EU28, to 902,271 in 2014 and 491,052 in 2015. Under Commission Implementing Decision 2016/851, Croatia was also allowed to revise its BSE annual monitoring programme. In 2024, 132,443 cattle were tested in the EU27; 106,812 (81%) and 23,421 (18%) of these were tested in Romania and Bulgaria, respectively, with the remainder being tested in various other Member States.

Currently, cattle slaughtered for human consumption are not required to be tested under WOAH Article 11.4.20.2. Prior to 2023, a small number of points were awarded for '*the testing of cattle over 36 months of age at routine slaughter*' in the Terrestrial Animal Health Code. This was removed following the revision of the Code in 2023, recognising that the testing of these animals had 'relatively very little value', assigning for each animal tested between 0 and 0.2 points, depending on the age.

Animals unable to rise or walk without assistance: Point 2 c) of Article 11.4.20 of the WOAH Terrestrial Animal Health Code requires the testing of all bovine animals '*unable to rise or walk without assistance, with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of recumbency)*'. This subpopulation is not explicitly included as a separate category in Article 6 of Regulation (EU) 999/2001. It is likely that some animals unable to rise or walk without assistance under the WOAH categorisation system would end up being tested in the emergency slaughter subpopulation or in the fallen stock subpopulation, according to the EU categorisation system.

[14]Point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004 (2) reads: Ante-mortem inspection must in particular determine whether, as regards the particular animal inspected, there is any sign: (a) that welfare has been compromised; or (b) of any condition which might adversely affect human or animal health, paying particular attention to the detection of zoonotic diseases and diseases on List A or, where appropriate, List B of the Office International des Epizooties (World organisation for animal health, OIE).

TABLE 6 Description of the surveillance streams according to Regulation (EC) 999/2001 and Article 11.4.20 WOAH Terrestrial Animal Health Code.

Target groups (described in WOAH, EU or both)	EU	WOAH
Clinical suspects (alive)	All, with no age threshold	All, with no age threshold
Unable to rise and walk	Not explicitly targeted (possibly tested as ES or FS if > 48 months)	Only those with clinical history, with no age threshold
Fallen stock	Systematic testing of all bovines > 48 months	Only bovines with clinical history, with no age threshold
Emergency slaughter	Systematic testing of all bovines > 48 months	Not targeted
Ante-Mortem inspection	Bovines > 48 months with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004 (2)	Bovines showing behavioural or neurological signs, with no age threshold
Healthy slaughtered	Mostly discontinued	Not targeted

3.8.3 | The potential objectives of future BSE surveillance in the EU

As explained in the previous sections, the four WOAH surveillance streams target only animals with clinical signs or a clinical history. Assuming a full implementation of the system with high compliance, the system would enable the detection of cases at the clinical stage only.

Aligning EU surveillance requirements with the revised Chapter 11.4 of the WOAH Terrestrial Code would represent a new approach to BSE surveillance. The new WOAH provisions, which are based on the notification of suspected cases with no predetermined prevalence design, have not been designed to meet the historical EU surveillance objectives described in Regulation (EC) 999/2001, such as to monitor BSE trends over time. The epidemiological situation of BSE has evolved over time, and this section aims to highlight the scientific rationale behind the potential objectives of future surveillance in the current EU context.

The context in which the future surveillance of the EU will be implemented differs from that of third countries, as the BSE epidemic originated in the EU and had the highest impact in a subgroup of EU MSs. The decline of C-BSE is a consequence of the implementation of the BSE control measures, such as the feed ban. However, several C-BSE cases born after the reinforced feed ban, termed 'BARB' cases (Born After the Reinforced Ban), have been detected since 2000, with a declining trend (Alarcon et al., 2023; Arnold et al., 2017; EFSA BIOHAZ Panel, 2017). Epidemiological studies did not support a spontaneous origin for these cases (Arnold et al., 2017; EFSA BIOHAZ Panel, 2017; Ortiz-Pelaez et al., 2012; Ryan et al., 2012). In 2017, EFSA assessed the origin of these cases and concluded that uncertainty remains high about the origin of disease at the individual level, with feed-borne exposure being the most likely explanation (EFSA BIOHAZ Panel, 2017). A modelling study indicated a common rate of decline of BARB cases in EU MS, with a projection of continuous decline to prevalence 0 and the possibility of occasional cases up until 2026 (Arnold et al., 2017). The C-BSE cases identified later in the UK (in 2018, 2021 and 2024) provide further evidence that bovine animals have been exposed to the C-BSE agent many years after the reinforcement of the feed ban (EFSA, 2025). A recent review on C-BSE in Great Britain concluded that there is still much uncertainty remaining on the causes of BARB cases (Alarcon et al., 2023).

In light of the fact that the period between events such as an increase in infectious agent circulation and the manifestation of their effects through surveillance can easily exceed 10 years for diseases such as BSE (Adkin et al., 2016), quantifiable outputs able to detect a potential re-emergence of the disease are needed. Additionally, given the uncertainties surrounding the origin of BARB cases and the last C-BSE case detected in the UK in 2024, the monitoring of near-term evolution of the disease in the EU would provide reassurance that the probability of BSE amplification would die out or remain limited to isolated cases.

With regard to atypical BSE, there is uncertainty about the origin of these two strains and their zoonotic potential. The advanced age of those affected, the rarity of the cases and the sporadic nature of their detection might suggest a spontaneous origin. However, it has also been argued that an infectious aetiology cannot be definitively ruled out. Several experimental studies demonstrated the capability of H- and L-BSE to acquire C-BSE strain properties during propagation in different experimental models (Baron et al., 2011; Beringue et al., 2007; Capobianco et al., 2007; Torres et al., 2011), suggesting that atypical BSE strains might be linked to the origin of C-BSE. These studies led to the hypothesis that atypical BSE may have existed at very low levels for a long time and, under certain conditions, could have given rise to C-BSE, which was then massively amplified by MBM recycling. Due to the lack of field evidence for this hypothesis, no definitive conclusion could be reached. The epidemiological features of the H- and L-BSE strain (old age at detection, no cases detected as clinical suspects) demonstrate that relying solely on clinical history is not a sensitive approach for monitoring atypical BSE strains. It has only been possible to extrapolate the clinical presentation of field cases of atypical BSE from experimental studies. Consequently, it has not been possible to define a clinical presentation on which to base standardised detection protocols. Continuing to actively monitor H- and L-BSE with comparable sensitivity to the current surveillance would offset these limitations and provide quantifiable outputs with the potential to detect any change in their trends.

The successful control of the BSE epidemic in the EU has been supported by three main pillars: the reinforcement of the feed ban, comprehensive surveillance and SRM removal. In this scientific opinion, only BSE surveillance is being considered. Even though the removal of SRM is predominantly aimed at preventing human exposure to infected material, and the feed ban at preventing the exposure of cattle to infected material, a reduction of the sensitivity of the surveillance system would create the potential for more cases to enter the food and animal by-products chain undetected. The destruction of the cases of BSE triggered by surveillance is a risk mitigation measure that would reduce human and animal exposure also in the case of re-emergence of C-BSE.

In conclusion, the potential objectives for future BSE surveillance in the EU that could be achieved by keeping some of the current EU provisions, in addition to those provided by the WOAH, are as follows:

- the ability to document in a consistent manner the continuing effectiveness of BSE control measures.
- the monitoring of residual BARB C-BSE cases or any re-emergence of C-BSE.
- the ability to detect changes in patterns of atypical BSE (H & L strains) given that little is known of origins and infectivity or zoonotic potential.
- the contribution to risk mitigation by triggering the removal of BSE cases and their disposal as high-risk animal by-products.

3.9 | Additional components for future BSE surveillance in the EU (SAQ2.2)

3.9.1 | The EU surveillance data

The number of cases of BSE (C, L and H) and the total number of animals tested for the period 2008–2024 by all surveillance streams are displayed in Figure 3.

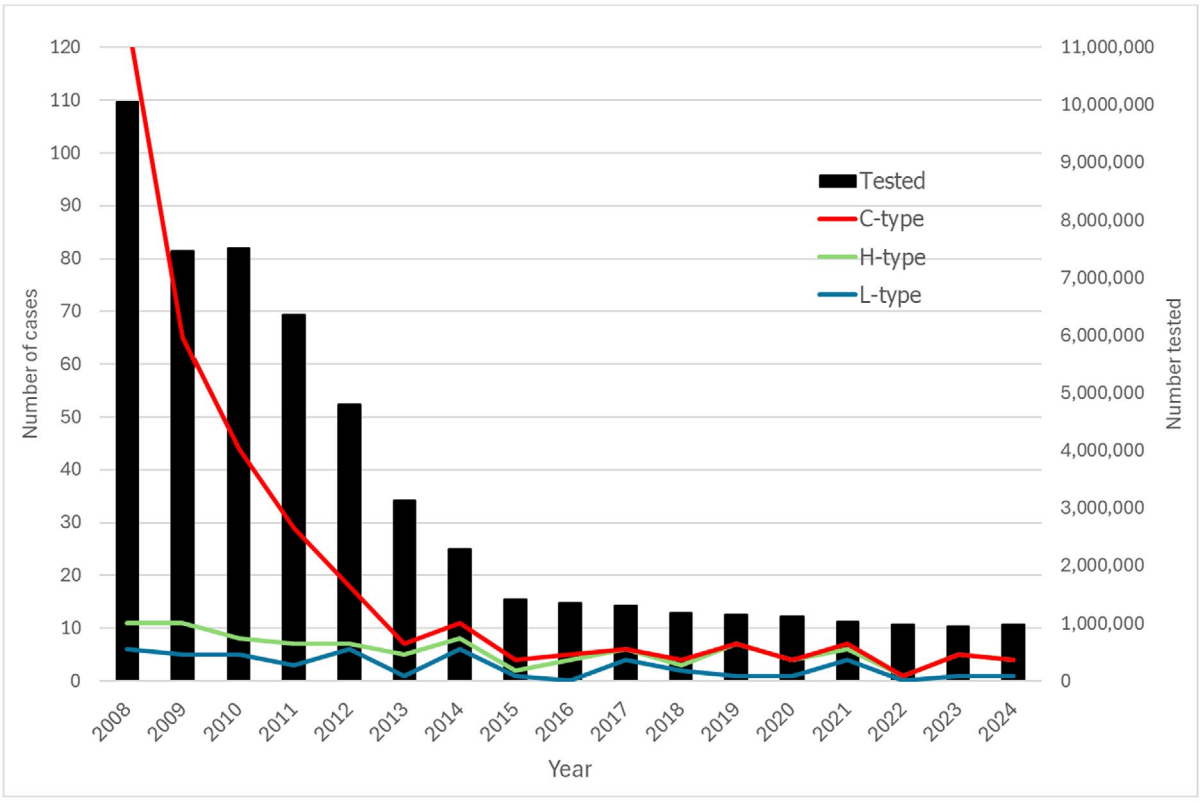

FIGURE 3 Number of cases of BSE by type and year reported by EU MSs (UK until 2021 and United Kingdom (in respect of Northern Ireland), from 2021) for the period 2008–2024 (left axis) and number of animals tested by year (right axis).

Figure 4 shows the case data of Figure 3 broken down by surveillance streams during the period 2008–2024. Details of the number of animals tested by year and surveillance stream are shown in Appendix B.

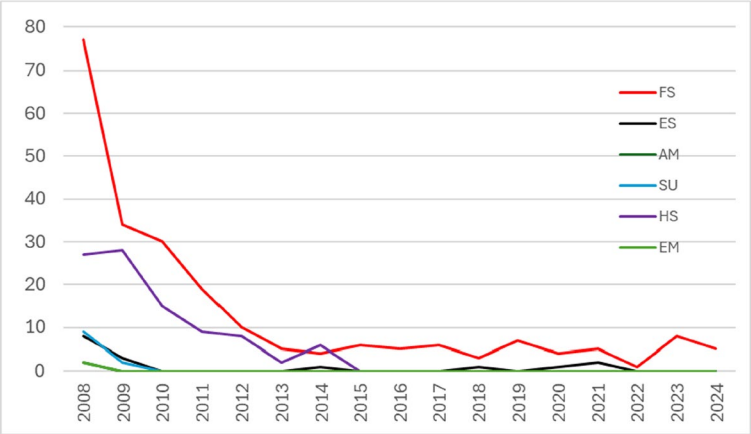

FIGURE 4 Number of cases of BSE (all types) by surveillance stream reported by EU MSs in the period 2008–2024 (UK until 2021 and United Kingdom (in respect of Northern Ireland) from 2021). AM, animals with clinical signs ante-mortem; EM, eradication measures; ES, emergency slaughtered; FS, fallen stock; HS, healthy slaughtered; SU, clinical suspects.

In the early stages of the epidemic, before the implementation of a compulsory surveillance programme in the EU (EC Regulation 999/2001), clinical suspects (SU) were the main source of detected cases in the UK, where more than 179,000 clinical suspects were confirmed as BSE positive since the late 80s.[15] In the rest of the EU MSs, after the implementation of EU surveillance in 2001, the rate of reporting clinical suspects has been very low, with a total of 13,461 clinical suspects reported and 11 confirmed as BSE positive (9 in 2008 and 2 in 2009) during the period 2008–2024, with some countries having reported none. Germany reported 67.6% of all clinical suspects in the EU (9103 animals). However, it has been clarified that most of these animals, although submitted as clinical suspects by Germany, were in fact fallen stock animals without previous history of clinical disease indicative for BSE and were therefore misclassified as SU (C. Fast, personal communication, 26 November 2025). The number of clinically suspect animals tested in 2024 was very low and variable, with 133 total tests, ranging from no tests in several countries to 40 animals in one country. The number of clinical suspects reported by country and year is displayed in Appendix A (Table A.1).

Fallen stock (FS) remains the surveillance stream that provides the largest number of BSE cases of all types, consistently contributing over 80% of the reported cases every year in the EU. Since 2015, 92.2% of all BSE cases of any type reported by MSs were from the FS stream. The number of animals tested in this subpopulation in 2024 under Regulation (EU) 999/2001 was very variable, ranging from 105 animals in one country to 176,097 in the country that tested the most.

It is important to highlight that some of the cases reported as FS showed clinical signs of disease on farm and were either euthanised and taken to a collection centre/rendering plant/knacker's yard or found dead after hours or days. If the animal was showing clinical signs compatible with BSE, it should have been reported as a potential SU (see Section 3.4).

The testing of healthy slaughtered (HS) animals substantially contributed to the caseload until its discontinuation in July 2013 in most Member States, with 33%, 32%, 44%, 28% and 54% of all cases in 2010, 2011, 2012, 2013 and 2014, respectively. Although more than 100,000 animals are still tested every year as HS, 80% of them are tested by only two MSs.

ES was the third surveillance stream in terms of number of cases detected since 2008, with 16 cases detected and over one million bovine animals tested. The last case was detected in 2021, with 2008 the most prolific year with eight cases confirmed. The numbers tested under this stream in 2024 were very variable, ranging from 0 (EL, FI, IE and SK) to 11,533 (DE). AM has been the least efficient of the compulsory surveillance streams with over 213,000 bovine animals tested in the last 17 years and only two cases confirmed, both in 2008. In 2024, five MS (AT, BG, CZ, HU and RO) tested animals over 24 months in this sub-population, and the other Member States tested animals over 48 months. However, it should be noted that the number of animals tested in this subpopulation under Regulation (EU) 999/2001 was very low in many Member States in 2023. In 12 Member States, no animals were tested in this sub-population. In contrast, 5777 animals were tested in a single MS (RO).

EM was a surveillance stream rarely used by MS with less than 6000 bovine animals tested since 2008, and only two cases, also both confirmed in 2008. In the last 5 years, only 21 animals were tested, although this stream is dependent on the BSE cases in previous years. The decay in the BSE caseload over the years affects directly the throughput of the EM.

It is important to note that, due to the extended incubation period of several years, C-BSE is typically identified in adult cattle with an average age of 5–6 years. Atypical BSE types are predominantly identified in older cattle with a mean age at detection of approximately 12 years (EFSA, 2025). Figure 5 provides a synopsis of the age at detection of BSE cases in Europe since 2015.

[15] https://www.gov.uk/government/publications/cattle-tse-surveillance-statistics.

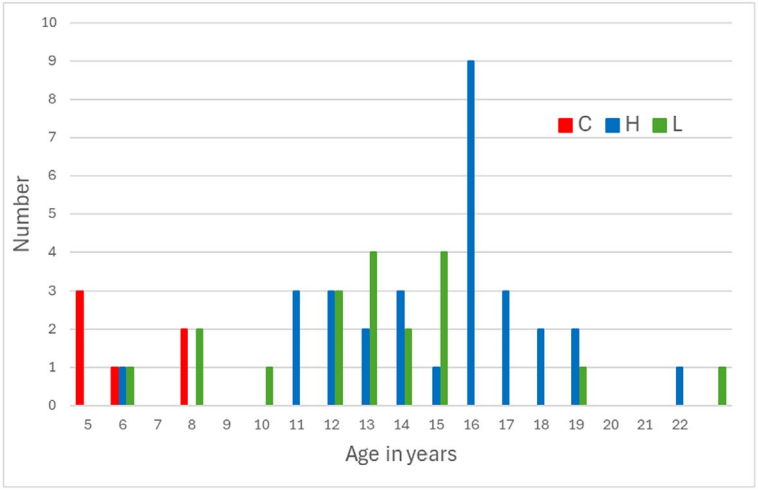

FIGURE 5 Age of BSE cases in years by BSE type for the period 2015–2024 ($n = 55$ cases). *X*-axis: Age at detection in years. *Y*-axis: Total number.

Table 7 presents the BSE detection proportions – the number of confirmed cases relative to the total tested population – for each surveillance stream during the aggregated 2008–2024 period. Furthermore, Table 7 details the relative risk (RR) of detection for each stream, utilising the HS sub-population as the reference baseline category. Raw data used in the calculations are shown in Appendix B. The results show that the probability of detection is the highest in SU, which will not be considered as an additional component because clinical suspects would be targeted by the WOAH baseline. FS, ES and AM are not statistically significantly different from each other. However, the relative risks of the FS and ES are all significantly higher than those for HS, while the relative risk of AM is not. The relative risks of ES and FS compared to HS are very similar, making these two surveillance streams the most effective of the compulsory streams after SU. These figures do not substantially change if the RR is calculated only for the 2008–2013 time period to account for discontinuation of testing in HS.

TABLE 7 Risk of BSE (all types) by surveillance stream for the period 2008–2024 and the relative risk (RR) using HS as baseline with 95% confidence intervals. Statistically significant RR are highlighted in bold.

Surveillance stream	Total tested	Total cases	Risk (cases/tested 2008–2024)		Relative risk (RR)	95% confidence interval
FS	15,921,080	229	14.4 per 10^6	**RR (FS/HS)**	**5.25**	**4.13–6.67**
ES	1,011,917	16	15.8 per 10^6	**RR (ES/HS)**	**5.77**	**3.4–9.80**
AM	213,256	2	9.3 per 10^6	RR (AM/HS)	3.42	0.84–13.89
SU	13,471	11	816.5 per 10^6	**RR (SU/HS)**	**298.03**	**159.68–556.25**
EM	5698	2	351 per 10^6	**RR (EM/HS)**	**128.11**	**31.58–519.61**
HS	35,919,261	95	2.6 per 10^6		**1**	
				RR (ES + AM + SU + FS/HS)	**5.49**	**4.34–6.94**

Abbreviations: AM, ante-mortem inspection; EM, eradication measures; ES, emergency slaughter; FS, fallen stock; HS, healthy slaughter; SU, clinical suspects.

3.9.2 | Prediction of cases detected in the next 5 years by the back-calculation model, with increased age thresholds

The extremely low prevalence of C-BSE, along with the declining trend, results in a very low expected number of positives, even if all FS over 48 months are tested (Table 8). Increasing the age of testing of FS from 48 to 72 months reduced the expected number of positives by only 0.002 (11%) over the 5-year period. However, the reduction was proportionately larger as the age increased above that. A similar trend was estimated by increasing the age of testing for ES and AM combined (Table 9).

For H- and L-types, increasing the age of testing of FS or ES from 48 to 72 months has a proportionately smaller impact on the expected positives than for C-BSE, due to the greater age at detection for the H- and L-types, and even increasing the age of testing up to 120 months results in a reduction of less than 50% in the expected number of FS positives (Tables 8 and 9).

TABLE 8 Predicted number of cases detected in the FS over the next 5 years by BSE type in EU27, assuming continuation of any detected annual trend and assuming the same numbers tested as in 2024, for six different age limits.

BSE-type	Age threshold (months)	Predicted detected cases (2025–2029)	95% CI
C	48	0.018	(0.0035, 0.076)
	60	0.017	(0.0035, 0.074)
	72	0.016	(0.0032, 0.064)
	84	0.013	(0.0028, 0.051)
	96	0.010	(0.0023, 0.036)
	108	0.007	(0.0020, 0.025)
	120	0.005	(0.0013, 0.016)
H	48	10.73	(6.6, 17.19)
	60	10.69	(6.58, 17.14)
	72	10.59	(6.52, 16.97)
	84	10.28	(6.32, 16.47)
	96	9.54	(5.87, 15.28)
	108	8.26	(5.08, 13.24)
	120	6.65	(4.09, 10.66)
L	48	7.68	(3.77, 13.06)
	60	7.66	(3.76, 13.01)
	72	7.58	(3.72, 12.89)
	84	7.36	(3.61, 12.56)
	96	6.83	(3.35, 11.61)
	108	5.91	(2.91, 10.01)
	120	4.76	(2.34, 8.10)

TABLE 9 Predicted number of cases detected in the ES and AM streams (ES/AM) over the next 5 years by BSE type in EU27, assuming continuation of any detected annual trend and assuming the same numbers tested as in 2024, for six different age limits. H-type BSE is not included in the table, as the expected positives were estimated to be close to 0 by the model.

BSE type	Age threshold (months)	Predicted detected cases (2025–2029)	95% CI
C	48	0.0016	(0.0003, 0.0068)
	60	0.0016	(0.0003, 0.0067)
	72	0.0015	(0.0003, 0.0064)
	84	0.0014	(0.0003, 0.0056)
	96	0.0011	(0.0002, 0.0045)
	108	0.0008	(0.0002, 0.0031)
	120	0.0006	(0.0002, 0.0022)
L	48	0.64	(0.32, 1.07)
	60	0.64	(0.32, 1.06)
	72	0.63	(0.31, 1.05)
	84	0.61	(0.31, 1.02)
	96	0.57	(0.29, 0.95)
	108	0.49	(0.25, 0.82)
	120	0.40	(0.20, 0.66)

3.9.3 | Selection criteria for the additional components

The second part of the ToR asks whether any current EU surveillance provisions should be kept, beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code.

It is assumed that, based on the WOAH provisions, the following four surveillance streams would constitute the baseline surveillance approach:

2.a. those displaying progressive clinical signs suggestive of BSE mentioned in point 1 that are refractory to treatment, and where the clinical presentation cannot be attributed to other common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes);
2.b. those showing behavioural or neurological signs at ante-mortem inspection at slaughterhouses/abattoirs;
2.c. those unable to rise or walk without assistance, with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of recumbency);
2.d. those found dead (fallen stock), with an appropriate supporting clinical history (i.e. the clinical presentation cannot be attributed to other common causes of death)'.

The output of AQ1 suggests that the detection capability of the four surveillance streams in the WOAH provisions would be between 2 and 20 times lower than the current capability in the EU. Therefore, if the potential objectives listed in Section 3.8.3 are to be fulfilled, it would be necessary to exceed the WOAH provisions by implementing additional components from the current EU surveillance system. The additional components proposed have been designed to complement the four surveillance streams set out in the WOAH Terrestrial Code, with the aim of achieving the potential objectives listed in the previous section.

Of the surveillance streams established by the TSE regulation, the SU stream is already fully implemented under those recommended by WOAH provisions, while the HS stream has become voluntary in most of the EU Member States, leaving only the other three as potential additional components: FS, ES and AM.

In the EU surveillance system, the selection of a bovine animal for systematic testing is based on the combination of two conditions: that it falls within one of the surveillance streams and that it has reached the minimum age for testing. With a few exceptions (e.g. animals covered by the remote area derogation), all the animals within these two conditions must be tested for BSE. Any proposed current EU provision to be kept – beyond those recommended by WOAH – should then consider the two conditions (age and surveillance stream) described above.

With regard to the age threshold, it is noteworthy that the age at detection of BSE cases of all strains in the last 10 years has ranged from 5 to 22 years. Therefore, continuing to increase the minimum age for testing would be the natural flow, as it has been done repeatedly during the last 16 years within the TSE regulation (e.g. the increase in the minimum age of the FS from 24 months to the current 48 months of age).

In terms of the ability to detect cases in the various surveillance streams, after the discontinuation of testing HS, most of the cases were detected in FS, with ES being the only other surveillance stream providing cases in the last 10 years. The calculation of the relative risk for the period 2008–2025 showed that FS and ES have very similar probabilities of detection, approximately five times higher than the HS used as baseline, and cases have been regularly detected over the entire period. AM seems less efficient, not being statistically different from the baseline HS. Therefore, it seems appropriate to consider testing in FS and ES, with the age threshold remaining as it is or being modified, in addition to the four surveillance streams as defined in the WOAH provisions.

The relative risk of the different surveillance streams, the outputs of the model and the surveillance data (age category of animals tested by year) have been considered to compare a set of components to supplement the WOAH baseline. The additional components considered are modified versions of the EU surveillance streams already in place. They are presented in Table 10, where the data are as follows:

- Number of animals tested. It is assumed that the number of tests per surveillance stream will remain constant in the next 5 years, as in 2024. Therefore, the baseline number of tests per year and surveillance stream is derived from the last available EU yearly data. In 2024, there were 980,624 bovine animals tested, 839,160 of which were tested under the FS (778,641) or ES (60,519) streams.
- The percentage reduction in tests under the proposed additional components is calculated by considering the number of animals to be tested under the additional components versus those tested in all surveillance streams in 2024 (980,624).
- Cases detected within the next 5 years. The back calculation model estimated the number of cases detected under the current EU surveillance system (0.0196 for C-BSE, 10.94 for H-BSE, 9.13 for L-BSE; Section 3.5), as well as under scenarios involving increased age thresholds for FS (Table 8) and ES (Table 9) streams, which have been used to compare the sensitivity of the additional components proposed in Table 10. These estimates do not consider the concurrently operating WOAH surveillance streams (see next Section 3.10).
- The percentage reduction in the number of cases detected by each additional component has been calculated in relation to the number of cases expected to be detected by all current EU surveillance streams (see the final output of SAQ1.2).

TABLE 10 Predicted number of animals tested yearly and of BSE cases detected in the next 5 years by BSE type under different possible additional components. See text above for explanation of the data.

Prediction of BSE cases in the next 5 years								
Additional component	Number of animals tested	% Reduction of tests (compared to tested in 2024)	C-BSE (number)	H-BSE (number)	L-BSE (number)	C-BSE (%)	H-BSE (%)	L-BSE (%)
FS + ES > 48 months	839,160	14.4%	0.0196	10.73	8.32	100.0%	98.2%	91.1%
FS > 48 months	778,641	20.6%	0.0180	10.73	7.68	91.8%	98.2%	84.1%
ES > 48 months	60,519	93.8%	0.0016	0.00	0.64	8.2%	0.0%	7.0%
FS + ES > 60 months	644,706	34.3%	0.0186	10.69	8.30	94.9%	97.8%	90.9%
FS > 60 months	598,211	39.0%	0.0170	10.69	7.66	86.7%	97.8%	83.9%
ES > 60 months	46,495	95.3%	0.0016	0.00	0.64	8.2%	0.0%	7.0%
FS + ES > 72 months	480,609	51.0%	0.0175	10.59	8.21	89.3%	96.9%	89.9%
FS > 72 months	445,948	54.5%	0.0160	10.59	7.58	81.6%	96.9%	83.0%
ES > 72 months	34,661	96.5%	0.0015	0.00	0.63	7.7%	0.0%	6.9%
FS > 84 months	321,320	67.2%	0.0130	10.28	7.36	66.3%	94.1%	80.6%
FS > 96 months	229,473	76.6%	0.0100	9.54	6.83	51.0%	87.3%	74.8%
FS > 120 months	118,695	87.9%	0.0050	6.65	4.76	25.5%	60.8%	52.1%

Although the data in Table 10 do not account for the WOAH surveillance system operating alongside the additional EU component in the present scenario, it enables different scenarios involving these components to be compared:

- If only one or more surveillance streams are discontinued and the age threshold remains the same (> 48 months, first three rows in Table 10), applying FS + ES streams or just the FS stream would keep detection high but would still require high testing volumes, with a reduction of 14.4% or 20.6%, respectively. Conversely, retaining only the ES stream (> 48 months) would add little value in terms of cases detected (between 0% and 8.2% of baseline cases).
- Maintaining both the FS and ES surveillance streams with an increased age threshold of 60 or 72 months would enable the detection of a high proportion of the expected BSE cases (between 94.9% and 97.8% with age limit at 60 months and between 89.3% and 96.9% with age limit at 72 months, depending on the BSE type), while reducing the testing by 34.3% or 51%, respectively. Under both age limits (60 or 72 months), retaining only the ES stream would lead to a great loss of sensitivity, being able to detect between 0% and 8.2% of the expected cases. In contrast, maintaining only the FS stream would have little impact on the number of cases detected compared to maintaining the FS + ES streams, while leading to a further reduction in tests (39% and 54.5% for age limits at 60 or 72 months, respectively). Overall, these figures suggest that keeping the ES stream alone would provide little additional value.
- The increase of the age limit to 72 months for FS would still ensure a high capability of detection. Further increases in the minimum testing age of FS to 84, 96 or 120 months would reduce the ability to detect C-BSE cases (to 66.3%, 51% or 25.5% of current detection, respectively), with a comparatively smaller reduction in atypical BSE cases.

Therefore, it appears that, in order to achieve the proposed surveillance objectives, maintenance of testing within at least the fallen stock (FS) stream would be the minimum additional surveillance component capable of detecting BSE cases with sufficient sensitivity. Increasing the age limit to either 60 or 72 months achieves a balance between case detection capability and the number of tests required.

3.10 | Prospective assessment of the detection of BSE cases in the EU under the additional components in the next 5 years (SAQ 2.3)

In terms of implementing the proposed surveillance schemes, which combine WOAH surveillance with the additional components, it is necessary to sum the estimated detection capability of the WOAH baseline (SAQ1.3 output) with that of the additional components. However, some of the cases expected to be detected by the additional components – those with an appropriate clinical history – would already be detected under WOAH surveillance streams. This could result in an overestimation of cases detected by the additional EU components when they overlap with WOAH provisions. To avoid this overestimation, the detection capability of WOAH, i.e. 49% for BCS and 5% for WCS, has been subtracted from the estimated capability of the additional component. The resulting overall capability of the proposed combinations is reported in Table 11 and compared to the current EU and WOAH baseline estimated detection capacities. This table displays the estimated number of cases that could be detected in the EU over the next 5 years under the proposed combinations of WOAH provisions and additional components, compared to the number that would be detected under current EU provisions or

the WOAH baseline. As discussed in the previous section, the additional components proposed include the current FS surveillance stream alone or in combination with the ES, with age limits of > 60 or > 72 months, which are the ages that retain high detection capability.

The estimation of the capability of the proposed additional components is calculated assuming that all other current EU surveillance streams are not implemented.

TABLE 11 Numbers of BSE cases (C-, H- and L-) predicted in the next 5 years in the EU under the proposed combinations of WOAH provisions and the additional components compared with those under current EU provisions or WOAH baseline.

	C-BSE		H-BSE		L-BSE	
	0.0196		10.94		9.13	
Current EU surveillance	BCS	WCS	BCS	WCS	BCS	WCS
WOAH baseline	0.0096	0.0011	5.26	0.58	4.09	0.45
WOAH + FS > 72 months	0.0177	0.0162	10.65	10.60	7.95	7.62
WOAH + FS > 60 months	0.0183	0.0172	10.70	10.69	7.99	7.69
WOAH + FS + ES > 72 months	0.0185	0.0176	10.65	10.60	8.27	8.21
WOAH + FS + ES > 60 months	0.0191	0.0187	10.70	10.69	8.31	8.30

Note: Current EU provisions or WOAH baseline compared with those under current EU provisions or WOAH baseline.
Abbreviations: BCS, best-case scenario; WCS, worst-case scenario.

Assuming that compliance with the new WOAH provision constitutes the baseline, the overall capability of the proposed surveillance schemes that combine the WOAH baseline with the additional proposed component as in Table 11 would significantly exceed the WOAH baseline and would achieve a detection capability close to current EU levels.

Table 11 also shows that maintaining the active surveillance streams of FS or FS + ES from the current EU provisions would offset the uncertainty surrounding the expected capability of the WOAH baseline, as this would dramatically reduce the difference between the best- and worst-case scenarios.

3.10.1 | Added value of the additional components

The overarching added value of the additional components proposed in the previous section (Table 11) is the higher capability to detect cases, including preclinical classical and atypical BSE cases, compared to the WOAH baseline alone. This would fulfil the potential objectives set out in Section 3.8.3. In particular:

1. Continuity of analyses of epidemiological trends: The extra throughput achieved by testing all animals in high-risk groups over a certain age provides a more robust data set for statistical analysis. This supports continuing to treat the EU as a single epidemiological unit and ensures that smaller nations do not face a disproportionate burden in meeting surveillance targets or designing complex national protocols on their own. By maintaining this high baseline across the Union, the WOAH baseline together with the additional components would enable continued consistent monitoring of prevalence and incidence trends. Furthermore, this continuity would also increase scientific assurance that the decline of classical BSE (C-BSE) is sustained, while maintaining the sensitivity required to detect any potential re-emergence.
2. The ability to detect BSE-infected bovines in the preclinical phase: The proposed additional components enable preclinical cases to be detected alongside those targeted by the WOAH baseline, which focuses on bovines displaying clinical signs or with a clinical history. BSE is characterised by a long asymptomatic incubation period of between 2 and over 10 years. Diagnostic tests can detect positive animals up to 12 months before the end of the incubation period, i.e. before any clinical signs become apparent. This provides a much larger time window for case detection than relying on the clinical phase alone.
3. Early identification of trends: Identifying these additional preclinical cases could facilitate the earlier identification of disease trends, which is vital for detecting any re-emergence of classical BSE (e.g. in the event of other disease control measures such as the feed ban or SRM controls being breached or relaxed).
4. Contributing to the risk mitigation measures: The cases detected by surveillance are those accumulating the highest level of infectivity because they are in an advanced stage of incubation, while the not detectable infected cases that are in the earlier stages would provide a much lower risk of infectivity entering the food and animal by-products chains. The destruction of all tissues from BSE cases prevents the re-circulation and amplification of BSE infectivity from these cases. However, most of the cases are predicted to be found in the FS stream by the proposed additional components. Although FS cases must be disposed of as Cat 1 ABP and cannot be used for food or feed, the detection of a case only contributes indirectly to risk mitigation by the killing and destruction of bovine animals in the birth and feed cohorts, if implemented – animals that would otherwise remain in the system. It is important to note that the current EU surveillance also indirectly contributes to risk mitigation since most of the cases are detected in fallen stock animals.

5. Reliable detection of atypical BSE trends: Atypical BSE strains (H- and L-type) are sporadically detected in older cattle, but their epidemiological features – such as old age at detection and the fact that they are rarely detected as clinical suspects – make clinical history an insensitive detection method. High-risk groups, particularly FS, are essential for detecting these cases. While C-BSE has declined by 38.3% annually, atypical BSE prevalence has remained stable, making continued systematic testing necessary to detect any potential changes in their trends or patterns.
6. Contributing to mitigate the impact of possible low reporting rate of bovines that lie on the clinical spectrum of BSE: Reporting of clinical suspects is often hindered by the difficulty of recognising the clinical signs (see Section 3.1) and the availability of clinical history (see Section 3.4). A low rate of reporting of clinical suspects is also estimated by the model, with an estimated reporting rate of 1 out of 346 expected clinical cases (see Section 3.5). Systematic testing bypasses these barriers by using objective sampling methods (such as age-based thresholds in fallen stock) that do not rely on recognition of clinical signs. This ensures that the system remains sensitive even when under-reporting could occur under certain circumstances.
7. Maintenance of laboratory proficiency: Similar to the WOAH surveillance system, the EU surveillance system requires targeting animals clinically suspected of being infected by BSE. However, the number of tests conducted through EU clinical surveillance has remained consistently very low over the past 10 years, with only 133 tests recorded in 2024 (EFSA, 2025). The regular throughput of samples from systematic testing would provide the additional benefit of facilitating National Reference Laboratories (NRLs) to maintain their proficiency. This constant activity is vital for preserving diagnostic standards and technical expertise within the EU laboratory network.
8. Monitoring the biological variability of BSE strains: The detection of additional cases would provide significant scientific insight into BSE risk characterisation. This would enable the collection of material needed to investigate the biological variability of BSE strains, providing a deeper understanding of their origin and zoonotic potential. It would also facilitate the identification of new BSE strains, should they emerge. These could be considered complementary benefits of the proposed surveillance framework.

3.11 | Concluding remarks for AQ2

- The commonalities of the EU and WOAH systems are that they are both risk-based surveillance systems and they share definitions for disease status and clinical suspects. There are several key differences between the two approaches. These include the objective and type of surveillance, the case selection principles, the definition of the surveillance streams and the age and clinical status of animals to be tested.
- The objective of the WOAH surveillance is the detection of cases, whereas the current EU surveillance objectives are broader, including prevalence monitoring and trend analysis.
- The new WOAH system is designed to meet different objectives than those historically defined by the EU. In light of the historical context within the EU, the current epidemiological situation and the associated uncertainties regarding BSE strain variants, the following potential objectives could be considered for future EU surveillance: the ability to document in a consistent manner the continuing effectiveness of BSE control measures; the monitoring of residual BARB C-BSE cases or any re-emergence of C-BSE; the ability to detect changes in patterns of atypical BSE (H & L strains); and the contribution to risk mitigation by triggering the removal of BSE cases and their disposal as high-risk animal by-products.
- The potential impact on surveillance detection capability and burden of maintaining any of the current surveillance streams as an additional component was examined. Assuming that compliance with the new WOAH provision is the baseline, the overall capability of a surveillance system incorporating the WOAH system and the proposed additional components (ES + FS > 60 months; ES + FS > 72 months; FS > 60 months; FS > 72 months), as in Table 11, would significantly exceed the WOAH baseline, achieving a detection capability near to current EU levels. These proposed schemes would also offset the uncertainty surrounding the expected capability of detection based only on clinical surveillance. The proposed surveillance schemes, which combine WOAH surveillance with the additional components, would imply discontinuing testing in all other EU active surveillance streams currently in place, as well as in the ES and/or FS streams for animals aged between 48 and 60 or 72 months.
- The detection capability of the proposed surveillance framework would ensure continuity in epidemiological trend analysis, providing scientific assurance that the decline in classical BSE (C-BSE) is sustained, while maintaining the sensitivity required to detect potential re-emergence of the disease. This approach would enable the detection of BSE-infected bovines in the preclinical phase and the early identification of disease trends, thus allowing the fulfillment of the proposed objectives, such as documenting in a consistent manner the continuing effectiveness of control measures, reliably monitoring atypical BSE trends and contribute to mitigating the risk of exposure to BSE infectivity.
- Additional benefits of the proposed surveillance framework include mitigating the impact of a potential low reporting rate for bovines that lie on the BSE clinical spectrum, while also contributing to the maintenance of laboratory proficiency and to monitoring the biological variability of BSE strains.

4 | UNCERTAINTY ANALYSIS

The sources of uncertainty, the nature of uncertainty and the impact of uncertainty on the results and conclusions are described in Table 12 below.

TABLE 12 Sources of uncertainty and their possible impact on the estimates obtained.

Sources of uncertainty	Nature of uncertainty	Impact of uncertainty on the results and conclusions
Surveillance	The capability of the WOAH system to detect cases depends on robust, documented, evaluation procedures and protocols. Under the WOAH system, the onus is on the member country to design a surveillance system that allows it to detect, select and test the animals that meet the requirements. The quality and consistency of the systems that would be put in place in individual MS in the EU are not clear	Lack of implementation of high-quality surveillance systems in EU MS would decrease the capability of the WOAH system to detect cases of BSE and could lead to an overestimation of the capability of the WOAH surveillance system to detect BSE cases. In particular, the lack of a standardised EU-wide protocols may result in uneven detection thresholds across the Union
	The extent to which the clinical signs are exhibited by classical and atypical cases of BSE, and the extent to which these clinical signs would be detected and reported within the WOAH surveillance system is unclear	The lack of display of clinical signs by classical and atypical BSE cases is likely to decrease the capability of the WOAH system to detect cases of BSE and could have led to an overestimation of the capability of the WOAH surveillance system to detect BSE cases. Since BSE lacks pathognomonic signs, and cases are rarely reported as clinical suspects, the reliance on clinical signs will inevitably lead to a significant under-detection of the true infected population
	The capability of the WOAH system to detect cases depends on a high level of training of livestock raisers and veterinarians being put in place, and on a high level of information-raising campaigns also being put in place. The extent to which this will happen and its impact is not clear. The effectiveness of such an approach is impossible to quantify	The lack of implementation of high-quality training and awareness programmes for livestock raisers and vets is likely to decrease the capability of the WOAH system to detect cases of BSE and could have led to an overestimation of the capability of the WOAH surveillance system to detect BSE cases
	The initial notification of a potential BSE case under the WOAH system would come from livestock raisers or private veterinary practitioners. Even if they are familiar with surveillance criteria, economic, social or personal concerns may discourage reporting. The notification also depends on the capacity of the official veterinarian to confirm suspicion in referred cases. In general, notification of cases is likely to be very uncertain and inconsistent	Stigma and economic fears create a 'reporting gap' that active surveillance currently bypasses. The reluctance of livestock raisers or private veterinary practitioners to report cases is likely to decrease the capability of the WOAH system to detect cases of BSE and could have led to an overestimation of the capability of the WOAH surveillance system to detect BSE cases
	The surveillance system depends on the proficiency of the BSE testing laboratories. Given the small number of samples that would potentially be processed under the WOAH system in EU MS, it is not clear if this proficiency would be maintained	Lack of proficiency of laboratories would decrease the capability of the WOAH system to detect cases of BSE and could have led to an overestimation of the capability of the WOAH surveillance system to detect BSE cases. Furthermore, this uncertainty implies a long-term risk to the EU's diagnostic expertise, potentially leading to delayed or incorrect results during a future re-emergence
Retrospective assessment	The clinical data used in the retrospective assessment were likely to be unreliable and incomplete. Because clinical histories were often recorded post-confirmation, they may suffer from recall bias	The unreliability and incompleteness of the clinical data used in the retrospective assessment could have led to an overestimation or underestimation of the number of cases that could have been detected by WOAH surveillance system
	Expert elicitation exercises of this nature are inherently subject to bias by the experts involved. The high proportion of 'NO AGREEMENT' shows that interpretation differed substantially between the experts, reducing confidence in the final classification	Bias among the experts involved in the retrospective analysis could have led to an overestimation or underestimation of the number of cases that would have been detected by WOAH surveillance system. This was dealt with by providing best- and worst-case scenarios
	The exercise only covers 2015–2025; results may not extrapolate to earlier or future periods with different surveillance intensity or case distribution. Furthermore, the number of cases included in the retrospective analysis was relatively small. This limited the reliability of the exercise to determine the proportion of cases that could have been detected by the WOAH system	The small number of cases included in the retrospective analysis could have led to an overestimation or underestimation of the number of cases that could have been detected by WOAH surveillance system
	Lack of national implementation of WOAH protocols including lack of exact definition of case selection criteria: Article 11.4.20 of the WOAH Terrestrial Code requires each Member Country to develop specific national robust, documented, evaluation procedures and protocols for BSE surveillance, including criteria for selecting animals for testing	This retrospective assessment does not necessarily reflect how WOAH principles might become operationalised in future EU national surveillance systems, should the WOAH provisions be enforced in the EU. This limitation could under- or over-estimate the capability of the WOAH provisions to detect BSE cases (i.e. clinical reports after implementation could be more or less precise than clinical information available from those of historic EU cases)

TABLE 12 (Continued)

Sources of uncertainty	Nature of uncertainty	Impact of uncertainty on the results and conclusions
Model	The incubation period of H- and L-type BSE was derived using age of onset data and assuming infection close to birth. If cattle do not become infected with atypical BSE until they are older, then the incubation period would be shorter than estimated	This would result in lower numbers of animals infected. However, it would not affect model predictions of the number detected in each surveillance system and key conclusions
	Estimated sensitivity of diagnostic test, especially regarding atypical BSE. The sensitivity of the diagnostic test for detected H- and L-type BSE is based on estimates obtained for C-BSE	If the sensitivity of the test differed for H- and L-type BSE, this would affect the estimate of the numbers of animals infected for H- and L-type BSE. However, the comparison between the EU and WOAH systems remains valid, as both are evaluated using the same sensitivity assumptions

5 | ANSWERS TO THE TOR

To assess the capacity of the surveillance provisions recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code in terms of detection of potential BSE cases (C-, H- and L-type) in the case of the EU situation;

The WOAH surveillance provisions are based on clinical surveillance and require the implementation of standardised, precise clinical protocols for selecting animals for testing. A retrospective assessment of the cases identified over the last 10 years in the EU, together with prediction of case detections, indicated that the capability of the surveillance provisions recommended in Article 11.4.20 of the WOAH Terrestrial Animal Health Code to detect potential BSE cases (C-, H- and L-type) is estimated to be between two and 20 times lower than that of the current EU surveillance system. This is due to the inability to detect preclinical cases, as well as an intrinsic low reporting rate of clinical suspects. Since the probability of detection of C-BSE cases in the EU over the next 5 years is very low, the WOAH surveillance recommendations would primarily impact the capability to detect atypical BSE cases (H- and L-type). However, this reduced detection capability would also decrease the likelihood of detecting new cases associated with any future re-emergence of classical BSE.

To propose if any current EU surveillance provisions should be kept, beyond those recommended in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code, considered necessary and proportionate, with critical justification of their added value in ensuring the detection of potential BSE cases (C-, H- and L-type) and of BSE risk mitigation measures in the current EU epidemiological situation.

When designing future surveillance in the EU, the epidemiological features of the EU C-BSE epidemic, the potential presence of C-BSE infectivity across the EU and the uncertainties regarding the origin and the zoonotic potential of the different BSE strains should be considered.

Of the current EU surveillance streams, testing fallen stock bovines over 48 months of age provides the greatest capability to detect the BSE cases (C-, H- and L-type) in the subpopulation of interest, i.e. those infected animals that are detectable by the current streams and diagnostic tests. Supplementing the WOAH minimum requirements with the systematic testing of fallen stock (with or without emergency slaughtered bovines) older than 60 or 72 months would ensure a detection capability close to current EU levels. Systematic testing of high-risk streams has the capability to detect preclinical cases as well as cases that lie on the BSE clinical spectrum, which may not have been reported otherwise. Importantly, it would offset the uncertainty surrounding the expected capability of detection based only on clinical surveillance.

This approach would enable the effectiveness of BSE control measures to be documented in a consistent manner, providing assurance that the decline in C-BSE cases is sustained. It would also enhance the detection of any potential re-emergence of C-BSE cases, enable reliable monitoring of atypical BSE trends and would contribute to maintaining essential testing capabilities.

The enhanced capability of this proposed framework would further mitigate risk by ensuring that identified BSE cases trigger immediate statutory control measures. Since fallen stock are already excluded from the human food and animal by-product chains, the primary added value of detecting these cases lies in the subsequent identification and destruction of their birth and feed cohorts, when implemented, thereby preventing further transmission or exposure.

6 | RECOMMENDATIONS

- It is recommended that BSE surveillance in the EU includes targeted testing of high-risk cattle populations in addition to the minimum surveillance provisions described in Article 11.4.20 of Chapter 11.4 of the WOAH Terrestrial Code, in particular through the systematic testing of fallen stock bovines above an appropriate age threshold (e.g. 60 or 72 months), as this surveillance stream provides the greatest capability to detect potential BSE cases (C-, H- and L-type), including cases that may not be identified through clinical surveillance alone.
- It is recommended that any modifications to surveillance protocols should consider any potential adjustments to the other BSE control measures.

ABBREVIATIONS

ABP	Animal by-product
AM	Ante-mortem inspection
AQ	Assessment question
BARB	Born after the reinforced ban
BCS	Best-case scenario
BSE	Bovine spongiform encephalopathy
C-BSE	Classical bovine spongiform encephalopathy
Cat 1 ABP	Category 1 animal by-products
CI	Confidence interval
DEFRA	Department for Environment, Food & Rural Affairs
EC	European Commission
EM	Eradication measures

ES	Emergency slaughter
EU27	European Union (27 Member States after 2021 & Northern Ireland)
EU28	European Union (28 Member States before 2021, including UK)
FS	Fallen stock
H-BSE	H-type atypical bovine spongiform encephalopathy
HS	Healthy slaughter
L-BSE	L-type atypical bovine spongiform encephalopathy
MBM	Meat and bone meal
MS	Member State(s)
NRL	National Reference Laboratory
PrPSc	Abnormal prion protein
RR	Relative risk
SAQ	Sub-assessment question
SRM	Specified risk material
SU	Clinical suspects
ToR	Terms of reference
TSE	Transmissible spongiform encephalopathy
TSEMM	Transmissible spongiform encephalopathies monitoring model
TSE-survE	Transmissible spongiform encephalopathy surveillance evaluation model
vCJD	Variant Creutzfeldt–Jakob disease
WG	Working Group
WinBUGS	Windows Bayesian inference using Gibbs sampling
WOAH	World Organisation for Animal Health (former OIE)
WCS	Worst-case scenario

COUNTRY CODES

Code	Country
AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czechia Republic
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
EL	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
ME	Montenegro
NL	Netherlands
XI	Northern Ireland
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
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SUPPORTING INFORMATION

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APPENDIX A

Clinical suspects in the EU 2008–2024

TABLE A.1 Number of bovine animals submitted as clinical suspects in the period 2008–2024 by year and country.

Country	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
AT	4	2	4	6	10	25	23	25	15	17	17	19	8	10	8	8	4	**205**
BE	58	37	44	31	29	30	18	34	27	10	14	8	6	9	1	23	23	**402**
BG	771	4	1	0	0	0	0	3	0	0	0	6	0	0	1	0	9	**795**
CY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
CZ	1	0	0	0	2	2	0	3	2	2	0	2	5	1	0	2	2	**24**
DE	1287	517	496	500	453	528	457	500	461	453	515	584	697	599	648	407	1	**9103**[a]
DK	3	2	2	5	1	2	2	3	1	1	1	1	0	0	0	0	0	**24**
EE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
EL	0	0	0	0	0	15	0	0	6	6	0	5	0	12	20	10	9	**83**
ES	9	13	3	5	8	5	1	3	3	4	3	0	1	4	0	1	0	**63**
FI	1	3	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	**6**
FR	12	9	10	6	4	3	2	1	5	4	3	1	3	1	1	1	0	**66**
HR	–	–	–	–	6	0	0	2	1	4	0	0	2	0	3	5	0	**23**
HU	10	16	9	3	5	3	3	6	2	10	2	12	13	13	10	12	17	**146**
IE	94	170	30	21	14	11	2	0	0	16	20	8	9	6	5	5	6	**417**
IT	5	0	2	1	0	0	1	0	0	1	0	0	0	0	0	2	0	**12**
LT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
LU	7	1	2	5	2	1	2	2	2	2	3	3	2	2	3	3	0	**42**
LV	1	0	5	6	9	3	7	2	3	1	5	1	1	14	6	4	5	**73**
MT	0	0	0	0	0	5	0	0	1	0	0	0	0	0	0	0	0	**6**
NL	9	4	2	3	0	0	0	0	0	2	0	0	1	0	0	0	0	**21**
PL	9	7	3	8	13	38	25	12	20	13	10	14	4	7	6	1	0	**190**
PT	9	1	1	0	2	0	1	1	1	1	0	6	14	6	7	3	1	**54**
RO	2	7	7	81	171	343	76	48	70	100	40	70	39	45	53	53	40	**1245**
SE	5	3	2	3	3	4	3	1	2	2	30	19	10	14	8	2	13	**124**
SI	12	26	17	17	8	12	12	12	13	14	11	8	16	17	10	14	3	**222**
SK	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	**2**
UK/XI[b]	43	21	19	11	4	5	3	0	1	3	1	0	2	0	0	0	0	**113**
TOTAL	**2352**	**843**	**660**	**713**	**745**	**1036**	**638**	**658**	**636**	**666**	**675**	**767**	**833**	**760**	**790**	**556**	**133**	**13,461**

[a]It has been clarified that the vast majority of these cases have been erroneously reported as clinical suspects instead of FS.

[b]Data from XI, i.e. United Kingdom (in respect of Northern Ireland), are available from 2021 onwards.

APPENDIX B

EU surveillance data

TABLE B.1 Number of bovine animals tested and number of BSE cases in the period 2008–2024 by year and surveillance stream **by the EU member states**.[a]

Target group	Fallen stock (FS)		Emergency slaughter (ES)		Ante-mortem inspection (AM)		Clinical suspects (SU)		Healthy slaughter (HS)		Eradication measures (EM)	
Tests / Year	Tested	CASES FS	Tested ES	CASES ES	Tested AM	CASES AM	Tested SU	CASES SU	Tested HS	CASES HS	Tested EM	CASES EM
2008	1,447,974	77	68,258	8	41,639	2	2352	9	8,490,407	27	1105	2
2009	1,108,736	34	51,926	3	18,881		843	2	6,285,912	28	1052	
2010	1,101,744	30	50,885		29,440		660		6,330,680	15	378	
2011	1,022,852	19	50,620		16,720		713		5,270,593	9	93	
2012	962,085	10	59,484		15,828		745		3,757,089	8	101	
2013	923,489	5	59,190		14,100		1036		2,138,114	2	29	
2014	838,392	4	56,101	1	7778		638		138,862	6	14	
2015	866,208	6	59,936		5924		658		491,052		50	
2016	894,011	5	60,599		5569		636		390,586		1184	
2017	882,533	6	61,370		7413		666		359,137		1595	
2018	932,049	3	64,262	1	7396		675		177,536		16	
2019	918,182	7	68,696		6454		767		156,229		60	
2020	924,698	4	63,229	1	5263		833		128,648		0	
2021	805,512	5	58,302	2	6514		760		150,157		7	
2022	752,310	1	59,375		8876		790		155,657		0	
2023	761,696	8	59,752		6582		556		119,575		4	
2024	778,609	5	59,932		8879		143		133,027		10	
TOTAL	**15,921,080**	**229**	**1,011,917**	**16**	**213,256**	**2**	**13,471**	**11**	**34,673,261**	**95**	**5698**	**2**

[a]Data from XI, i.e. United Kingdom (in respect of Northern Ireland), are included from 2021 onwards.

APPENDIX C

Age of testing in the EU by target group

TABLE C.1 Testing regime (age of the animals selected for testing in months) for BSE surveillance in cattle by the EU member states in 2024.

	Surveillance target group					
Country	**ES**	**AM**	**FS**	**HS**	**SU**	**EM**
AT	> 24	> 24	> 48[a]	No testing[b]	No age limit	No age limit
BE	> 48	> 48	> 48	No testing	No age limit	> 24
BG	> 24	> 24	> 24	> 30	No age limit	No age limit
CY	> 48	> 48	> 48	No testing	No age limit	> 48
CZ	> 24	> 24	> 24	No testing	No age limit	No age limit
DE	> 48	> 24	> 48	No testing	No age limit	No age limit
DK	> 48	> 48	> 48	No testing	No age limit	> 48
EE	> 48	> 48	> 48	No testing	No age limit	No age limit
EL	> 48	> 48	> 48	No testing	No age limit	No age limit
ES	> 48	> 48	> 48	Born before 2001 and coming from herds with BSE positive cases	No age limit	No age limit
FI	> 48	> 48	> 48	No testing	No age limit	No age limit
FR	> 48	> 48	> 48	Born before 01/01/2002	No age limit	> 48
HR	> 48	> 48	> 48	No testing	No age limit	No age limit
HU	> 24	> 24	> 24	No testing	No age limit	No age limit
IE	> 48	> 48	> 48	No testing	No age limit	> 48
IT	> 48	> 48	> 48	No testing	No age limit	No age limit
LT	> 48	> 48	> 48	No testing	No age limit	No age limit
LU	> 48	> 48	> 48	No testing	No age limit	> 48
LV	> 48	> 48	> 48	No testing	No age limit	No age limit
MT	> 48	> 48	> 48	No testing	No age limit	No age limit
NL	> 48	> 48	> 48	No testing	No age limit	No age limit
PL	> 48	> 48	> 48	No testing	No age limit	No age limit
PT	> 48	> 48	> 48	No testing	No age limit	No age limit
RO	> 24	> 24	> 24	> 30	No age limit	No age limit
SE	> 48	> 48	> 48	No testing	No age limit	No age limit
SI	> 48	> 48	> 48	No testing	No age limit	No age limit
SK	> 48	> 48	> 48	No testing	No age limit	No age limit
XI[c]	> 48	> 48	> 48	No testing	No age limit	No age limit

Abbreviations: AM, animals with clinical signs ante-mortem; EM, animals culled under BSE eradication measures; ES, emergency slaughtered; FS, fallen stock; HS, healthy slaughtered; SU, animals clinically suspected of being infected with BSE.

[a]If surveillance target group is FS and animals are born in Romania, Bulgaria or Switzerland, or the United Kingdom (with the exception of Northern Ireland and if the movement to the European Union took place since 1 January 2021), then the age limit is > 24 months.

[b]If surveillance target group is HS and animals are born in Romania, Bulgaria, Switzerland or the United Kingdom (with the exception of Northern Ireland and if the movement to the European Union took place since 1 January 2021), then the age limit is > 30 months.

[c]Data from XI, i.e. United Kingdom (in respect of Northern Ireland), are available from 2021 onwards.