



RECENT/ONGOING BSE MANDATES

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POSSIBLE ALIGNMENT OF THE EU BSE SURVEILLANCE WITH THE NEW WOAHP PROVISIONS



THE MANDATE : BACKGROUND

- Regulation (EC) No 999/2001 establishes EU TSE controls, including mandatory BSE surveillance.
- Adopted in 2001 post-epidemic, it introduced intensive active and passive surveillance.
- Testing targeted defined bovine risk groups based on age and slaughter category.
- Surveillance supported early detection and assessment of feed ban and SRM removal.



THE MANDATE BACKGROUND

- Current epidemiology: classical BSE rare; most EU MS have negligible risk status.
- WOAHA (2023) revised standards to prioritise clinical, targeted surveillance.
- Existing EU requirements may now be risk-disproportionate and resource-intensive.
- EFSA is requested to assess alignment with WOAHA for risk-based surveillance redesign.



TERMS OF REFERENCE

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 WOAHP surveillance provisions 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 by WOAHP, with critical justification considering BSE case detection (C-, H-, and L-type) and BSE risk mitigation measures in the current EU epidemiological situation.



AQ1 ASSESS THE CAPACITY OF WOAAH ARTICLE 11.4.20 SURVEILLANCE TO DETECT C-, H- AND L-TYPE BSE UNDER EU

- Estimate BSE cases since 2015 that could have been missed under WOAAH-only surveillance.
- Assess the current (2025) prevalence of BSE (C, H, L) in the EU and model future cases in the EU (2025-2029).
- Project BSE detections over the next five years under WOAAH surveillance, by surveillance stream.



CASES THAT COULD HAVE BEEN MISSED SINCE 2015

Table 3 Epidemiological data and individual judgments of the retrospective assessment of the BSE cases in the EU and UK

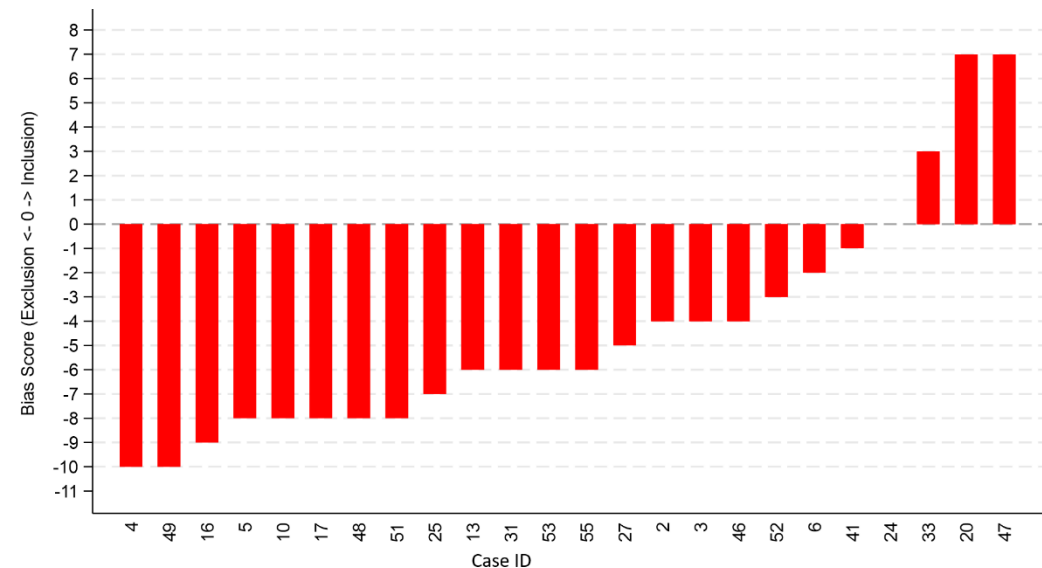
Case number	BSE Type	Age (in months)	Reporting country	Year of reporting	Surveillance Stream	Clinical signs*	Judgement 1	Judgement 2	Judgement 3	Judgement 4	Judgement 5	Judgement 6	Selected for testing by VQAP	Final status
1	C	90	UK	2024	FS	The farmer did not suspect notifiable disease and the carcase 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	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	Disagreement



CASES THAT COULD HAVE BEEN MISSED: RESULTS

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).

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.



BSE CASES PREDICTED (2025-2029) BY CURRENT EU SURVEILLANCE

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**
H-BSE	10.73 (6.6-17.19)	0*	0.21 (0.11-0.32)	0*
L-BSE	7.68 (3.77-13.06)	0.64 (0.32-1.07)	0.81 (0.11-3.12)	0*

*Lack of cases prevented the estimation of future occurrence and CI

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



PREDICTED NUMBER OF CASES USING EU AND WOAH SURVEILLANCE

	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



AQ2: EVALUATE WHETHER ADDITIONAL EU SURVEILLANCE MEASURES BEYOND WOAHA STANDARDS REMAIN NECESSARY

- Compare current EU surveillance with WOAHA provisions.
- Identify EU-specific additions to WOAHA surveillance suited to the current epidemiological context.
- Estimate future BSE detections under combined WOAHA and EU-specific surveillance components.



COMPARE CURRENT EU SURVEILLANCE (REG. 999/2001) WITH WOAHA ARTICLE 11.4.20 REQUIREMENTS.

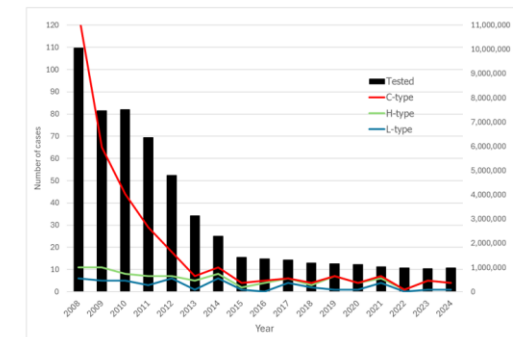
Target groups	EU	WOAH
Clinical suspects (alive)	All, with no age threshold	All, with no age threshold
Unable to rise and walk	Not explicitly targeted (possibly tested as ES or FS if >48 months)	Only those with clinical history, with no age threshold
Fallen Stock	Systematic testing of all bovines >48m	Only bovines with clinical history, with no age threshold
Emergency Slaughter	Systematic testing of all bovines >48m	Not targeted
Ante-Mortem inspection	Bovines >48m 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 behavioral or neurological signs, with no age threshold
Healthy Slaughtered	Mostly discontinued	Not targeted



IDENTIFY EU-SPECIFIC ADDITIONS TO WOAHS SURVEILLANCE SUITED TO THE CURRENT EPIDEMIOLOGICAL CONTEXT.

- Before EU compulsory surveillance (Reg. 999/2001), most BSE cases were detected as clinical suspects (SU) in the UK
- After 2001, reporting of Clinical Suspects in the EU has been very low:
- FS is the main source of BSE detection, contributing 92.2% of all cases since 2015; .
- Some FS cases show clinical signs and should be reported as Clinical Suspects but are not.

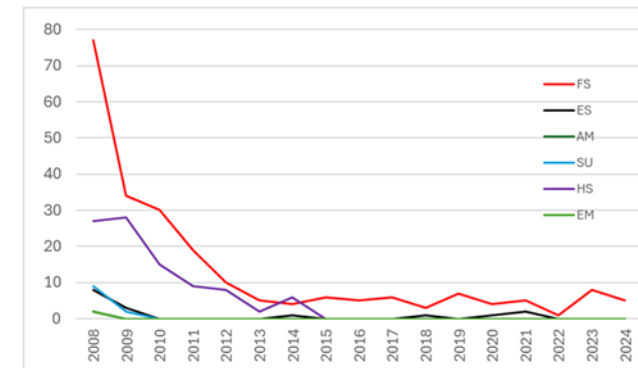
FIGURE 3 NUMBER OF CASES OF BSE BY TYPE AND YEAR REPORTED BY EU MEMBER STATES (UK UNTIL 2021 AND UNITED KINGDOM (IN



IDENTIFY EU-SPECIFIC ADDITIONS TO WOAAH SURVEILLANCE SUITED TO THE CURRENT EPIDEMIOLOGICAL CONTEXT.

- Healthy slaughter (HS) testing contributed substantially until its discontinuation in 2013–2014 (up to 54% of cases).
- Emergency slaughter (ES) detected 16 cases since 2008 (last in 2021).
- AM and EM streams have been the least productive: only two cases each (since 2008).
- C-BSE is typically detected in adult cattle (mean 5–6 years), whereas atypical BSE occurs mainly in older animals (mean ~12 years).

FIGURE 4 NUMBER OF CASES OF BSE (ALL TYPES) BY SURVEILLANCE STREAM REPORTED BY EU MEMBER STATES IN THE



13



14



PREDICTED NUMBER OF ANIMALS TESTED YEARLY AND OF BSE CASES DETECTED IN THE NEXT FIVE YEARS BY BSE TYPE UNDER DIFFERENT POSSIBLE ADDITIONAL COMPONENTS.

Additional component	Number of animals tested	% Reduction of tests (compared to 2024)	H-BSE (number)	L-BSE (number)
FS+ES >48m	839,160	14.4%	10.73	8.32
FS >48m	778,641	20.6%	10.73	7.68
ES >48m	60,519	93.8%	0.00	0.64
FS+ES >60m	644,706	34.3%	10.69	8.30
FS >60m	598,211	39.0%	10.69	7.66
ES >60m	46,495	95.3%	0.00	0.64
FS+ES >72m	480,609	51.0%	10.59	8.21
FS >72m	445,948	54.5%	10.59	7.58
ES >72m	34,661	96.5%	0.00	0.63



ESTIMATE FUTURE BSE DETECTIONS UNDER COMBINED WOAHA AND EU-SPECIFIC SURVEILLANCE COMPONENTS.

Table 1 Numbers of BSE cases (C-, H- and L-) predicted in the next five years in the EU under the proposed combinations of WOAHA provisions and the additional components compared with those under current EU provisions or WOAHA baseline

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

BCS: best-case scenario. WCS: worst-case scenario. Current EU provisions or WOAHA baseline compared with those under current EU provisions or WOAHA baseline.



ANSWER TO THE TOR (FIRST PART): DETECTING BSE CASES

- WOAHA surveillance provisions require clinical protocols for selecting animals for testing.
- WOAHA provisions are estimated to be 2 to 20 times less capable of detecting BSE cases than the current EU system.
- This is due to the inability to detect preclinical cases and an intrinsically low reporting rate of clinical suspects.
- WOAHA surveillance recommendations would primarily affect detection of atypical BSE cases
- But also reduce the likelihood of identifying new cases linked to any future re-emergence of classical BSE.



ANSWER TO THE TOR (2ND PART): WHAT TO KEEP

- Consider : 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.
- 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,



ANSWER TO THE TOR (2ND PART): WHAT TO KEEP

This will

- Document the effectiveness of BSE control measures
- Any reemergence of Classical BSE
- Monitor atypical BSE trends
- Maintain essential testing capabilities
- Further risk mitigation : cohort removal



RECOMMENDATIONS

- 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.
- any modifications to surveillance protocols should consider any potential adjustments to the other BSE control measures.





THE WORKING GROUP

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THE POTENTIAL BSE RISK OF ALIGNING THE EU REQUIREMENTS FOR SPECIFIED RISK MATERIAL (SRM)

WOAH Terrestrial Animal Health Code 2023

the following commodities should not be traded:

The distal ileum of bovines of any age and the skull, brain, eyes, vertebral column, and spinal cord from bovines over 30 months of age, or any commodity contaminated by these materials.....

if originated from countries.... posing:

an undetermined BSE risk, **or**

a controlled BSE risk if ... from bovines born before the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible.



THE POTENTIAL BSE RISK OF ALIGNING THE EU REQUIREMENTS FOR SPECIFIED RISK MATERIAL (SRM)

EU Rules

In countries with a **controlled or undetermined** BSE risk:

- The skull, excluding the mandible and including the brain and eyes, and the spinal cord of bovines over 12 months of age.
- The vertebral column (with limited exceptions) of bovines over 30 months of age,
- The tonsils, last four metres of the small intestine, caecum, and mesentery of bovines of all ages.



THE POTENTIAL BSE RISK OF ALIGNING THE EU REQUIREMENTS FOR SPECIFIED RISK MATERIAL (SRM)

EU Member State with negligible risk

the skull, excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months



TERMS OF REFERENCE

- to assess the risk of BSE (C-, L- and H-BSE) in the bovine population and of vCJD in humans in the EU, associated with aligning the EU list of Specified Risk Materials with WOAHA.
- justify not aligning the EU list of Specified Risk Materials (SRM) with WOAHA in the current epidemiological situation suggesting alternative measures



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