



EFSA's TSE activities 2020-2021

**EURL web meeting
11 & 13 October 2021**

CONTENTS

Finished:

- Collage & Gelatine BSE risk (2020)
- Evaluation ABP applications (2) (2020 & 2021)
- Atypical scrapie (2021)
- 2019 TSE EUSR: published (2020)

Ongoing:

- 2020 TSE EUSR: preliminary (2021)

Other:

- Evaluation ABP tunnel composting (2020)
- ABP used as organic fertilisers / soil improvers (2021)

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BACKGROUND

Collagen:

"means protein-based products derived from hides, skins, bones and tendons of animals"

main fibrous structural protein of tendons, bones, cartilages and skins

Gelatine:

"natural, soluble protein, gelling or non-gelling, and obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals"

Commission Regulation (EU) No 142/2011)

BACKGROUND

FEED

PAP and constituents of animal origin	Ruminants	Unweaned ruminants	Non ruminants	Aquaculture	Pets and fur animals
Ruminant PAP (ruminant blood included)	UA	UA	UA	UA	A
Non-ruminant PAP	UA	UA	UA	A	A
Non-ruminant blood meal	UA	UA	UA	A	A
Insect PAP	UA	UA	UA	A	
Fishmeal	UA	A	A	A	A
Ruminant collagen and gelatine	UA	UA	UA	UA	A
Non-ruminant collagen and gelatine	A	A	A	A	A
Ruminant blood products	UA	UA	UA	UA	A
Non-ruminant blood products	UA	UA	A	A	A
Hydrolysed proteins from ruminants other than those derived from hides and skins	UA	UA	UA	UA	A
Hydrolysed proteins from non-ruminants	A	A	A	A	A
Hydrolysed proteins from ruminants derived from hides and skins	A	A	A	A	A
Di and tricalcium phosphate of animal origin	UA	UA	A	A	A
Milk and milk products	A	A	A	A	A
Colostrum and derivates	A	A	A	A	A
Eggs and egg products	A	A	A	A	A

UA: unauthorised; A: authorised.



TORS

ToR1

To estimate the **cattle BSE risk** (C-, L- and H-BSE) posed by the use of ruminant collagen/gelatine produced in accordance with Section XIV and XV of Annex III to Regulation (EC) No 853/2004 (**FOOD**) in **feed intended for non-ruminant animals** including aquaculture animals

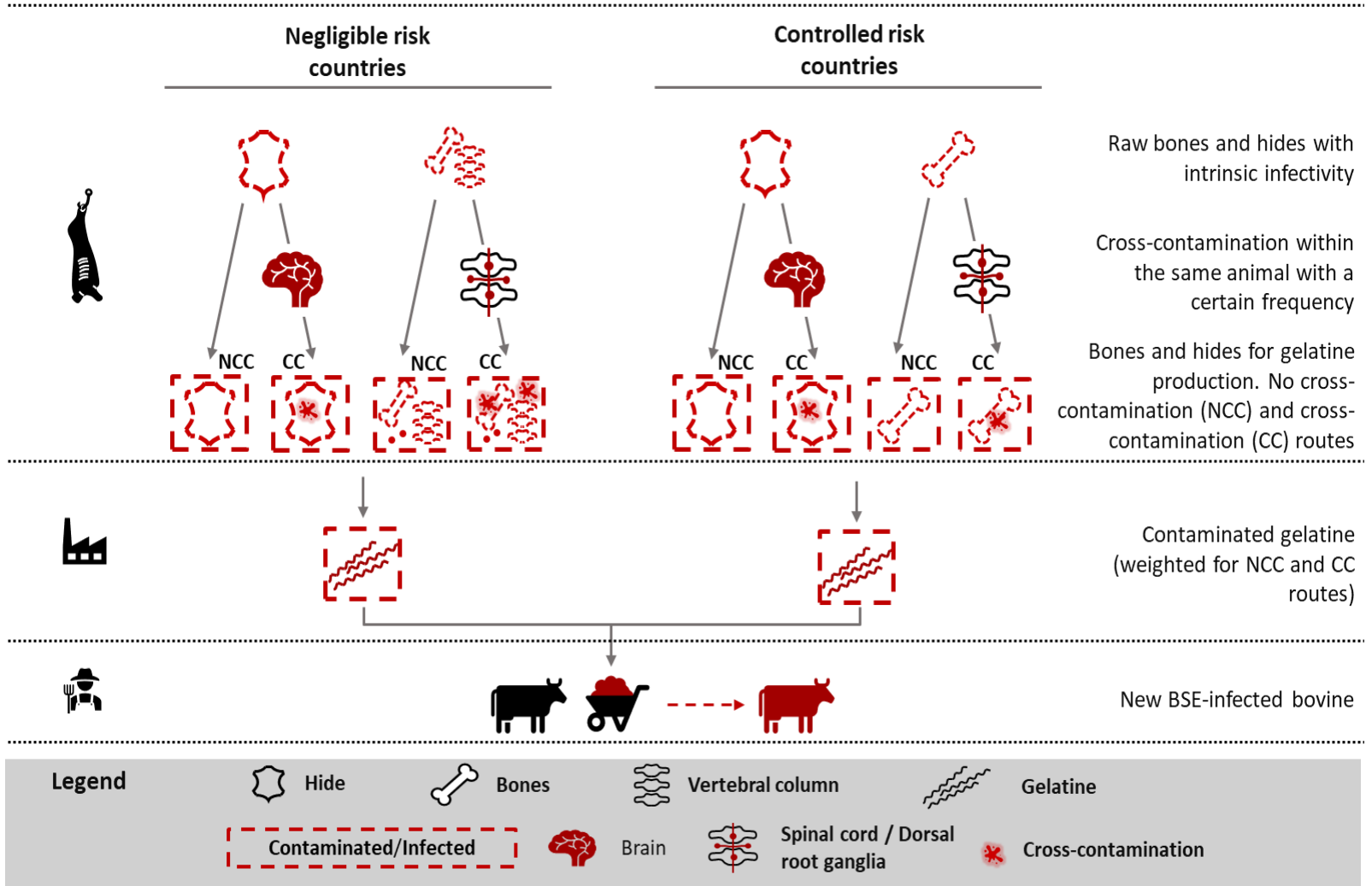
ToR2

To estimate the **cattle BSE risk** (C-, L- and H-BSE) posed by the use of ruminant collagen/gelatine classified as Category 3 (**ABP**) as referred to in Article 10 of Regulation (EC) No 1069/2009 and produced in accordance with Regulation (EU) No 142/2011 for **feed intended for non-ruminant animals** including aquaculture animals.

METHODOLOGY: MODEL



Slaughtered BSE-infected bovine

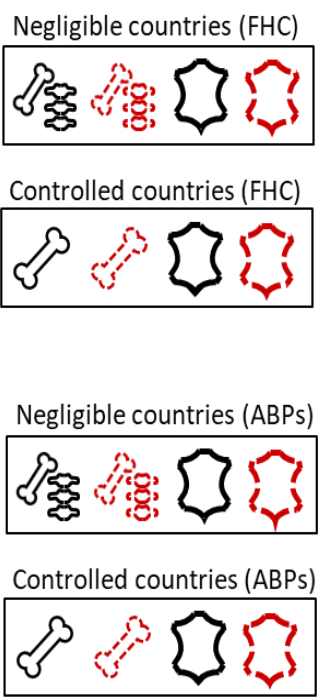


METHODOLOGY: MODEL RESULTS

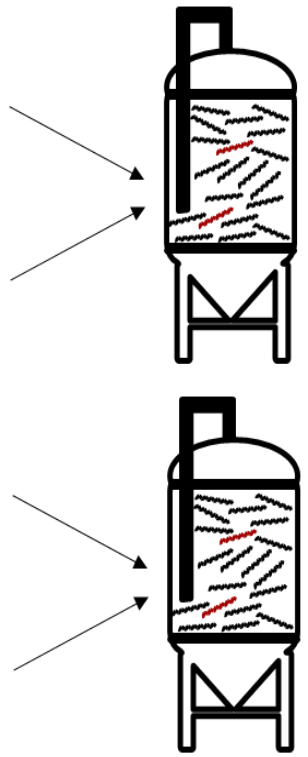
Risk status of country of origin/ outputs	Percentiles of the output distribution		
	5th	50th	95th
Negligible			
Infectivity contained in the gelatine produced from 1 BSE-infected animal (CoID50/kg)	8.0×10^{-3}	7.6×10^{-2}	0.8
No. of BSE-infected animals required to produce gelatine containing 1 CoID50 of BSE infectivity (number)	0.1	1.7	16
Amount of gelatine from infected animals required to contain 1 CoID50 of BSE infectivity (kg)	1.2	13.1	125.3
Controlled			
Infectivity contained in the gelatine produced from 1 BSE-infected animal (CoID50/kg)	2.9×10^{-5}	3.1×10^{-4}	4.1×10^{-3}
No. of BSE-infected animals required to produce gelatine containing 1 CoID50 of BSE infectivity (number)	33.8	449.8	4,745
Amount of gelatine from infected animals required to contain 1 CoID50 of BSE infectivity (kg)	244.9	3,257	34,360

METHODOLOGY: RISK PATHWAYS

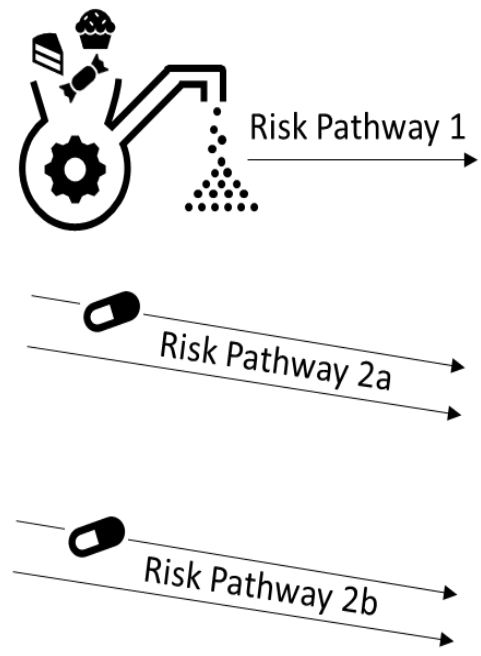
Raw material



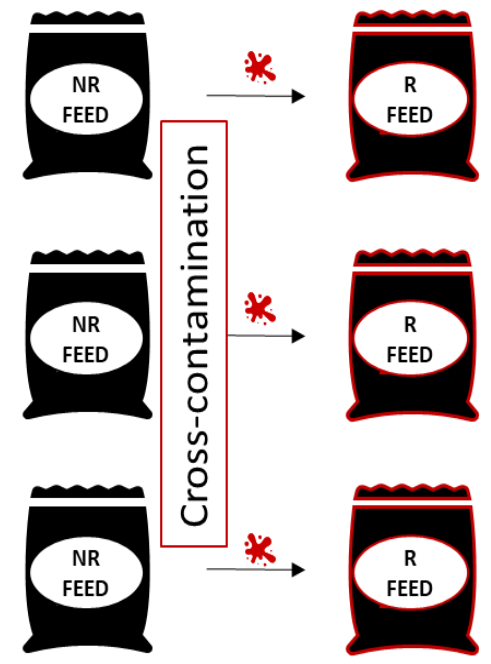
Production



Usage



End product



Legend

- Hide
- Bones
- Vertebral column
- Gelatine production
- Gelatine
- Non-ruminant feed produced with gelatine
- Contaminated/Infected
- Foodstuff produced with gelatine
- Bread meal production
- Additives
- Ruminant feed cross-contaminated with non-ruminant feed containing gelatine



CONCLUSIONS

- There is no evidence of difference in BSE risk between food-grade C&G and ABP C&G
- Qualitative RA of the three RP: multiple events. Lack of data
- One infected animal in a batch of gelatine: residual infectivity per kg of gelatine extremely low.
- If collagen made with hides only: lower infectivity
- Additional dilution effect of any residual infectivity from C&G included into non-ruminant feed through potential cross-contamination of ruminant feed.
- Temporal and geographical distribution of the exposure to the entire amount of infected material, and the individual host response to exposure.



CONCLUSIONS

- The probability that **no new case of BSE** in the cattle population **would be generated** through any of the three RP is larger than 99% (almost certain), given the estimated amount of BSE infectivity to which cattle would be exposed.
- This conclusion remains valid, even if all the estimated undetected BSE cases in the EU in a single year (50th percentile: 11.4) were used for the production of collagen or gelatine, either using raw materials fit for human consumption or Category 3 ABP raw materials.

Link to the scientific opinion:

<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.6267>

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ABP APPLICATIONS

Alternative method for production of biodiesel from processed fats derived from Cat. 1, 2 and 3 ABP

College Proteins. Ireland

Alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process)

BDI Bioenergy International. Austria

Standard processing method: Processing method 1 (pressure sterilization) **133 °C, 3 bar, 20 minutes**

- Pre-Cleaning
- Acidic esterification and transesterification with methanol: 140°C, 5.5 bar >4 h
- Distillation: 220°C 35 mbar

- Esterification and transesterification with methanol: >200°C, >70bar, >15min
- Distillation: 150° 10mbar



ABP APPLICATIONS (1)

- Most resistant hazard: TSE agent

Approach:

- The Panel decided that a **reduction of 6 log₁₀ in prion infectivity** by the alternative method is required to consider it at least equivalent, for Category 1 ABP, to the processing methods laid down in the legislation.
- This is in addition to the inactivation achieved by the pressure sterilisation method (Method 1) before the application of the alternative method. Estimated reduction of **3 log₁₀**

ABP APPLICATIONS

Evidence: 2 studies commissioned

- The prion reduction combined: at least 4.3 \log_{10} .
- 263K hamster strain spike,
- WB detection of the residual PrP^{Sc} signal.

Evidence: study commissioned and published (Mohammadi et al., 2020)

- The prion reduction in conversion: at least 6 \log_{10}
- sCJD and RML strains spike
- WB detection of the residual PrP^{Sc} signal.

Distillation: at least an additional 3 \log_{10} reduction

Link to the scientific opinion:
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.6089>

Link to the scientific opinion:
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6511>

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BACKGROUND

Regulation (EC) No 630/2013:

- Intensified monitoring in holdings where atypical scrapie has been confirmed for 2 years
 - ✓ All ovine and caprine animals >18 months and slaughtered for human consumption
 - ✓ All ovine and caprine animals >18 months which have died or been killed on the holding

...must be tested for the presence of TSE

- Purpose: *"to gather more scientific data on atypical scrapie"*

QUESTIONNAIRE

Template to collect data (June-July 2020):


Data collated from **21 MS + UK + NO**

- ✓ Flock ID
- ✓ Mixed flock (YES/NO)*
- ✓ Date of confirmation of the index AS case
- ✓ Date of start of intensified surveillance
- ✓ Date of end of intensified surveillance

Year 1 / Year 2

- ✓ Number of ovines/caprines over 18 months present at the time of confirmation of the index case
- ✓ Number of ovine/caprines tested during intensified surveillance: NSHC, SHC, EM, SUS
- ✓ Number of cases during intensified surveillance NSHC, SHC, EM, SUS

TORS



In a scientific opinion from 2014, EFSA stated: *“Atypical scrapie does not present, epidemiologically, like an infectious disease. This has been interpreted as evidence that it may be a spontaneous disease of older animals, and not contagious”*.

ToR1

Do the scientific data on the 2-year intensified monitoring collected by the EC provide **any evidence on the contagiousness** of atypical scrapie?

ToR2

Do the scientific data on the 2-year intensified monitoring collected by the EC provide **any other new knowledge on the epidemiology** of atypical scrapie?



METHODS TOR1

ToR1

- Descriptive: surveillance data 2013-2019
- Comparison prevalence index CS/AS in active surveillance (P1) with prevalence CS/AS in intensified monitoring in infected (P2). Assumption: if contagious, $P2 > P1$
- Design prevalence of the level of testing in intensified monitoring
- Simulation model: within-flock transmission of AS.
 - ✓ Contagious/transmission rate: prob. each infected sheep/goat infect another sheep in a year
 - ✓ Non-contagious/occurrence rate: each sheep fixed probability of becoming infected regardless number of infected sheep in flock

ToR2

- Literature review: Remaining knowledge gaps



RESULTS SHEEP

Country	N flocks with sheep AS index case	N tested animals in Year 1	N tested animals in Year 2	Sum of tested animals in Year 1 and Year 2	N secondary AS cases	N flocks with secondary AS cases
AT	11	152	169	321		
BE	1	1		1		
BG	3		234	234		
CZ	7	92	167	259		
DE	47	296	262	558		
DK	2	1		1		
ES	69	2,284	1,798	4,082	2	2
FI	8	132	108	240		
FR	40	841	800	1,641	1	1
HR	1	9	16	25		
HU	88	7,433	9,027	16,460	16	9
IE	37	1,174	758	1,932		
IT	41	488	186	674		
NO	127	2,390	1,547	3,937	4	4
PL	38	662	355	1,017	2	2
PT	92	1,434	876	2,310	6	6
SE	20	205	159	364	1	1
SI	10	30	28	58		
SK	27	2,428	2,990	5,418		
UK	73	1,371	957	2,328	3	3
Total	742	21,423	20,437	41,860	35	28

Median sheep index cases by country: 32 (range: 1–127)

Median sheep tested by country: 616 (range: 1–16,460)

RESULTS GOATS

Country	N herds with goat AS index case	N tested animals in Year 1	N tested animals in Year 2	Sum of tested animals in Year 1 and Year 2
AT	1	0	1	1
CY	1	3	9	12
DE	2	0	0	0
EL	4	253	49	302
ES	27	2,192	1,490	3,682
FR	20	138	124	262
IT	16	499	46	545
NO	1	52	4	56
PL	2	0	0	0
PT	1	3	2	5
SI	1	0	0	0
Total	76	3,140	1,725	4,865

Median goat tested by country: 12 (range: 0–3,682)



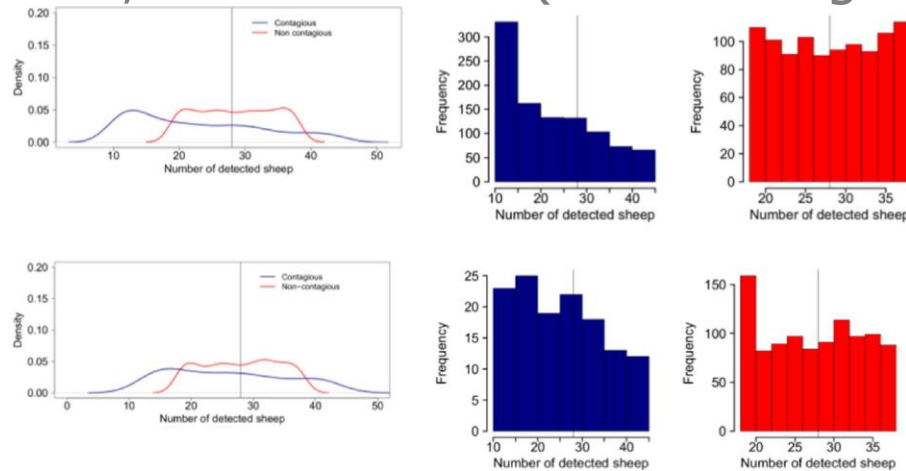
RESULTS

- **Non-statistically significant** stream-adjusted PR (**1.56; 95% CI: 0.96–2.51**) when comparing the prevalence of secondary cases in infected flocks with the prevalence of index cases in the non-infected flocks (a proxy for the prevalence in the general population).
- The intensified monitoring has **limited ability** to detect AS, based on the calculated **design prevalence** and on the model simulation on the detectable AS cases, with no difference between countries with or without secondary cases.



RESULTS

- Transmission rate (contagious): 5×10^{-4} (95% CI: $1.7 \times 10^{-4} - 1.1 \times 10^{-3}$)
 Occurrence (non-contagious) 2.8×10^{-3} (95% CI: $1.16 \times 10^{-3} - 54.9 \times 10^{-3}$)
- The model produced a **better fit for the non-contagious scenario** than for the contagious scenario.
- Goodness of fit:
 - 1.3% of 10,000 iterations (contagious)
 - 15.8% of 10,000 iterations (non-contagious)





CONCLUSIONS

- Based on the analyses of the data obtained from the intensified monitoring, and accounting for uncertainties and data limitations, it was concluded that:
 - ✓ There is **no new evidence** that AS can be transmitted between animals under natural conditions
 - ✓ It is considered **more likely** (subjective probability range **50–66%**) that **AS is a noncontagious**, rather than a contagious, disease.



CONCLUSIONS

- The results of the analysis confirmed that:
 - ✓ AS geographically widespread in countries with medium–large populations of either sheep or goats.
 - ✓ The confirmation of cases of AS rare event, with some exceptions
 - ✓ AS prevalence rates in goats are lower than in sheep.
- The results of the analysis revealed that:
 - ✓ Higher AS prevalence within infected flocks (although not statistically significant)
 - ✓ Apparent higher prevalence of AS in NSHC than in SHC

Link to the scientific report:

<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6686>

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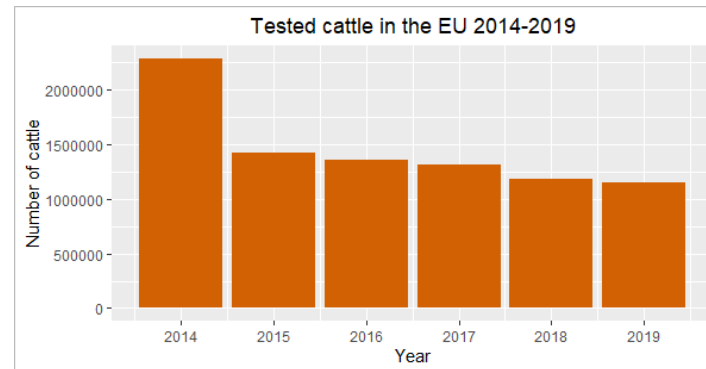
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TSE EUSR 2019-2020

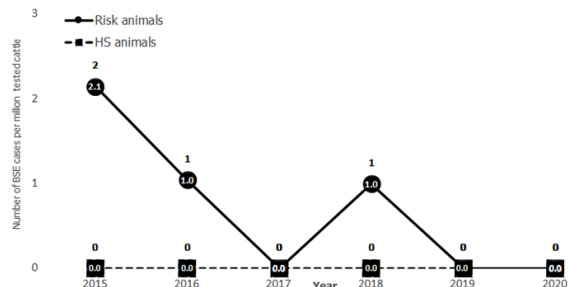
2019: 28 EU + 6 (CH, IS, **ME**, MK, NO, **RS**)
 2020: 27 EU + UK + 6 (CH, IS, **ME**, MK, NO, **RS**)

TESTED

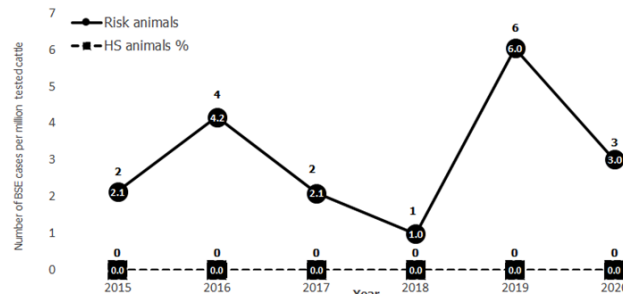
- **2020:** 1,122,671 (EU+UK) (-2.4%)
- **2021:** 1,150,388 (EU) (-2.7%)
- **2018:** 1,181,934 (EU) (-10%)
- **2017:** 1,312,714 (EU)



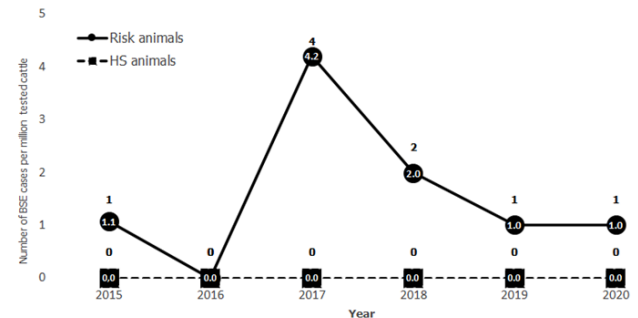
C-BSE



H-BSE



L-BSE





TSE EUSR 2019-2020

	2014	2015	2016	2017	2018	2019	2020
DE	2 (1H,1L)						
ES	1 (1C) 1 (1L)	1 (1L)	1 (1H)	3 (1H,2L)		2 (2H)	1(1H)
FR	3 (1H,2L)		1 (1C) 3 (3H)	2 (1H,1L)	3 (1H,2L)	4 (4H)	2 (1H, 1L)
RO	2 (2L)						
IE		1 (1C)		1 (1L)			1 (1H)
PL						1 (1L)	
PT	1 (1C)						
SI		1 (1H)					
UK	1 (1C)	1 (1C) 1 (1H)			1(1C)		
NO		1 (1H)					
CH							1 (1L)
Total	3 (3C) 8 (2H,6L)	2 (2C) 4 (3H,1L)	1 (1C) 4 (4H)	6 (2H,4L)	1 (1C) 3 (1H,2L)	7 (6H,1L)	5 (3H, 2L)



TSE EUSR 2019-2020 SHEEP

TESTED

2020: 332,513 (EU+UK) (-1.7%)

2019: 338,098 (EU) (+3.9%)

2018: 325,386 (EU) (+3.4%)

Increase in TSE-infected flocks: -29.5%

CASES

2020: 687 (EU+UK): 589 (C) 98 (A) 24.6% index (81,88)

2019: 997 (EU): 911 (C) 86 (A) 17.8 % index (97,80)

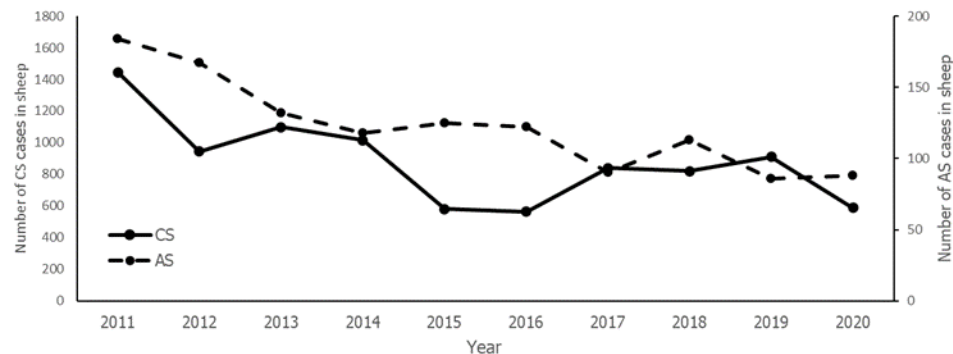
2018: 934 (EU): 821 (C) 113 (A) 21% index (99,105)

EL,ES,IT,RO:

97.4% all EU+UK CS

IS: 53 CS

NO: 12 AS





TSE EUSR 2019-2020 GOATS

TESTED

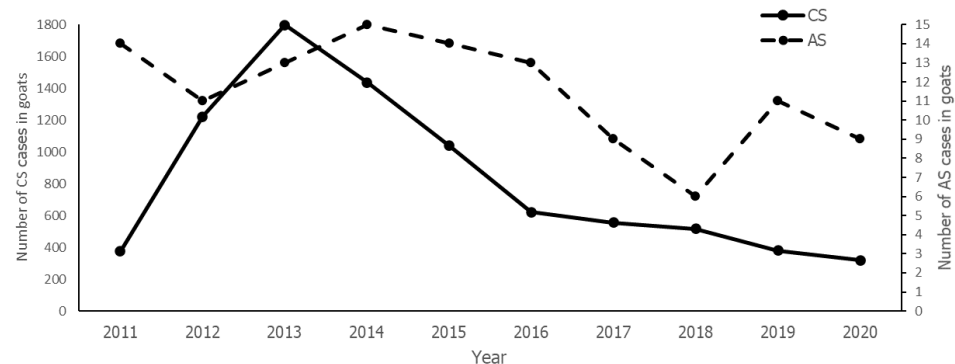
2020: 120,615 (EU+UK) (-16%)
2019: 143,529 (EU) (+ 3.9%)
2018: 138,128 (EU) (+ 18%)

Increase in infected herds (-38%) in non- infected (13.9%)

CASES

2020: 328 (EU+UK): 319 (C) 9 (A) 18.6% index (52, 9)
2019: 390 (EU): 379 (C) 11 (A) 8.7 % index (24,10)
2018: 523 (EU): 517 (C) 6 (A) 8.4% index (38,6)

CY: from 309 to 236
 ES: from 37 to 32





TSE EUSR 2019-2020 CERVIDS

TESTED

- **2020:** 9,171
- **2019:** 10,712 by 13 reporting countries

- **Estonia, Finland, Latvia, Lithuania, Poland and Sweden** (mandatory MS6): 6,974 (-12.6%)

- **Austria, Belgium, Hungary, Italy, Romania, Slovenia, Spain, United Kingdom:** 2,197 (-19.6%)

- **Norway:** 22,528
- **Iceland:** 33

CASES

- **Finland:** 1 wild moose
- **Sweden:** 1 wild moose.
- **Norway:** 1 wild moose and 1 wild reindeer.



Thank you

Questions?





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