EFSA TSE ACTIVITIES 2022-2023

20th TSE EURL Annual meeting

2-3 October 2023

ISS. Rome

EUROPEAN FOOD SAFETY AUTHORITY

CONTENTS

Completed

- Chronic wasting disease IV (2023)
- Negligible risk classical scrapie CZ (CZ) (2023)

Ongoing

- 2022 TSE EU summary report (2023)
- BSE risk ruminant collagen and gelatine (2024)

CHRONIC WASTING DISEASE IV

EFSA is requested to provide a scientific opinion on the monitoring of CWD, based on the results of the above-mentioned monitoring programme including the statutory data available in the EFSA database, and any other monitoring data collected with the same epidemiological objective and having become available since the publication of previous EFSA opinions on CWD

- **ToR1**

  To analyse the results of the monitoring programme carried out in Norway, Sweden, Finland, Iceland, Estonia, Latvia, Lithuania and Poland between 1 September 2017 and 28 February 2022, and in particular, to assess if the two objectives as set in the 2016 EFSA opinion on CWD in cervids have been met.

CHRONIC WASTING DISEASE IV

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  To analyse the results of t… d out in Norway, Sweden, Finland, Iceland, Estonia, Lat… en 1 September 2017 and 28 February 2022, and in particular, to … objectives as set in the 2016 EFSA opinion on CWD in cervids have been met.

Detect disease
Estimate prevalence

CHRONIC WASTING DISEASE IV

- **ToR1**

  Descriptive analysis **statutory surveillance data**

  Description intensified surveillance NO, FI, SE

  Estimation prevalence, relative risk

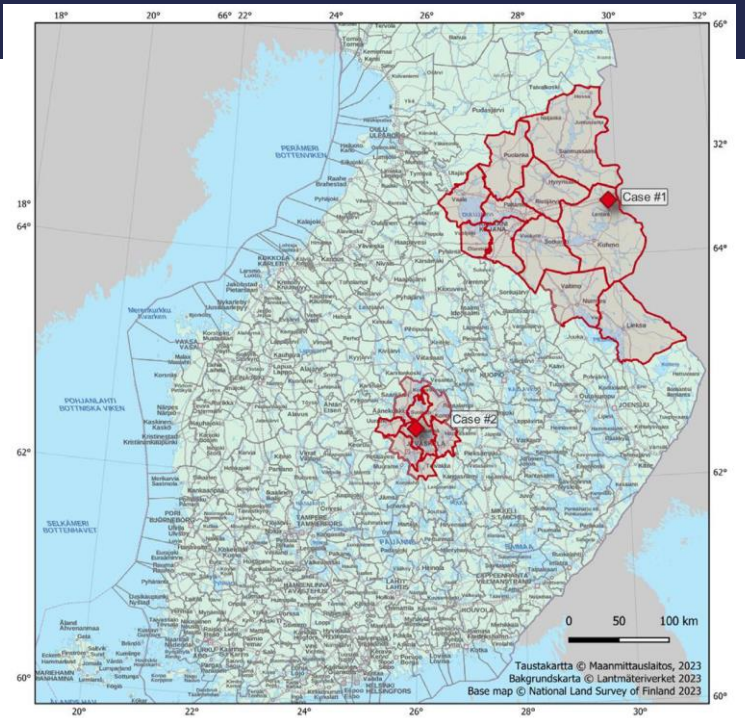
  Calculate minimum detectable prevalence: country, species, PSU

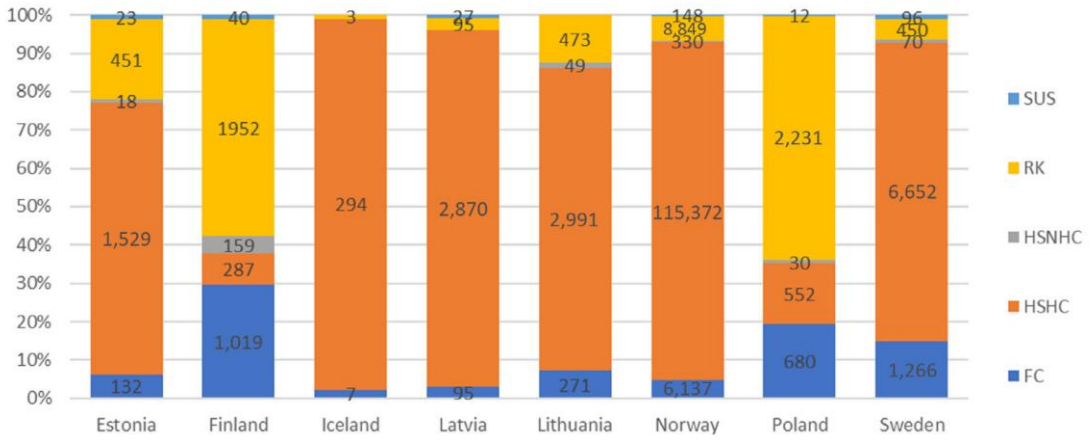
  Scenario tree modelling: estimate Sensitivity surveillance system

CHRONIC WASTING DISEASE IV

ToR 1

- 156,577 cervids > 12 m.o.a. tested during the period.
- >130,000 from Norway
- Heterogeneous implementation: species, numbers, target groups
- 46.8% reindeer, 20.8% moose, 19.6% red deer
- 83.6% healthy slaughtered for human (HSHC)
- CWD detected first time in SE and FI. cases in other areas of Norway
- During mandate period: 13 reindeer, 15 moose, 3 red deer

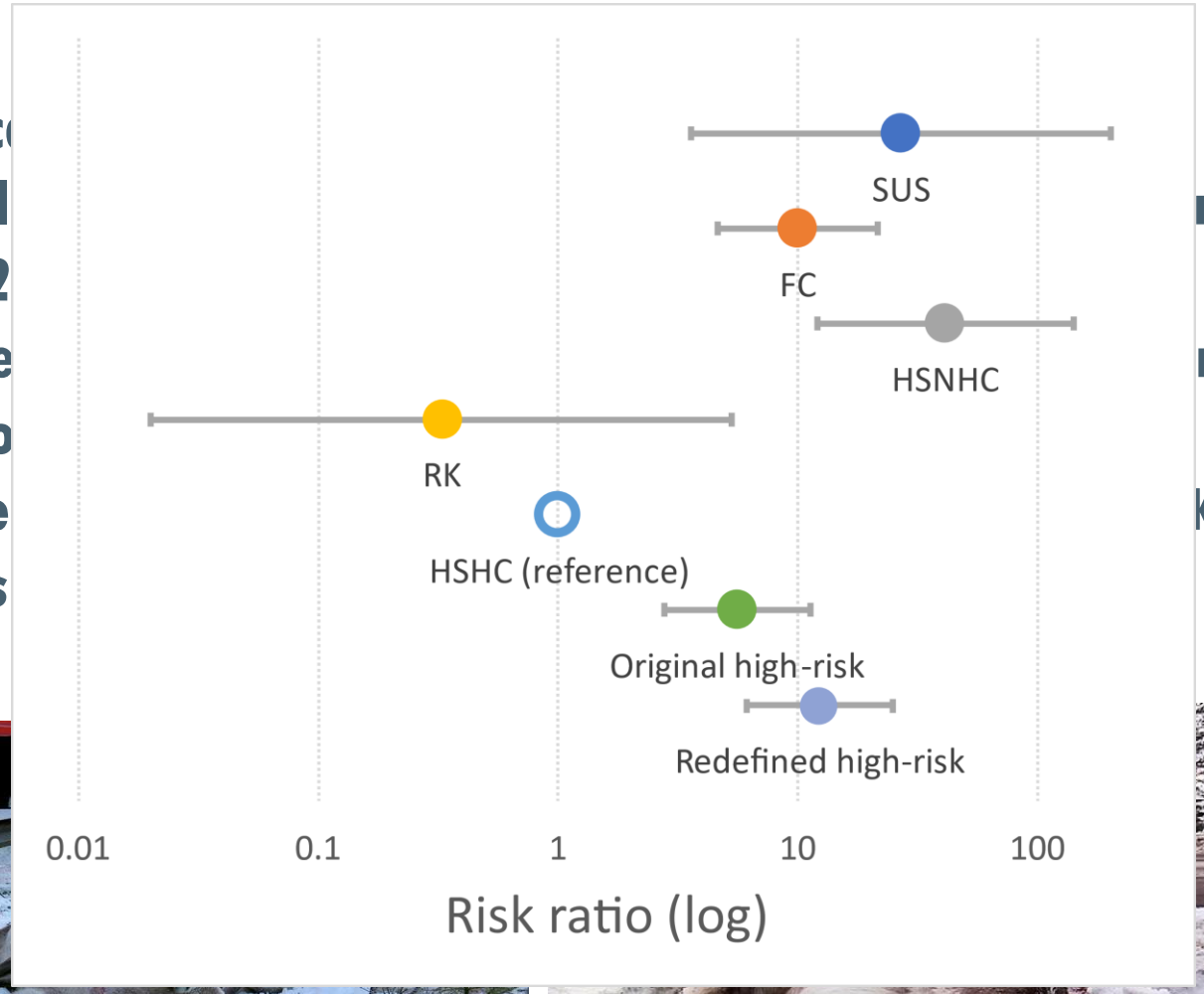




CHRONIC WASTING DISEASE IV

ToR 1

- **Two pathologic**
  Ly+: detectabl **r without deposits in brain**
  tissue) 0.2
  Ly-: detectable **mphoid tissues. ~0.05%**
  HSHC mo
- **Low prevalence** **K, SUS, FC, HSNHC)**
- **RK not high-ris**



CHRONIC WASTING DISEASE IV

ToR 1

- Minimum detectable prevalence: country, species ~ 0.1%
- 15.3% PSU: minimum detectable prevalence 10% or lower
- Se model (95%): 1 - 5% prevalence and RR 2 - 5

  All species: **Norway**, Sweden and **Poland**

  SD reindeer: **Norway**, Finland

  Moose: Norway

  Roe deer: Norway and **Poland**

  Red deer:

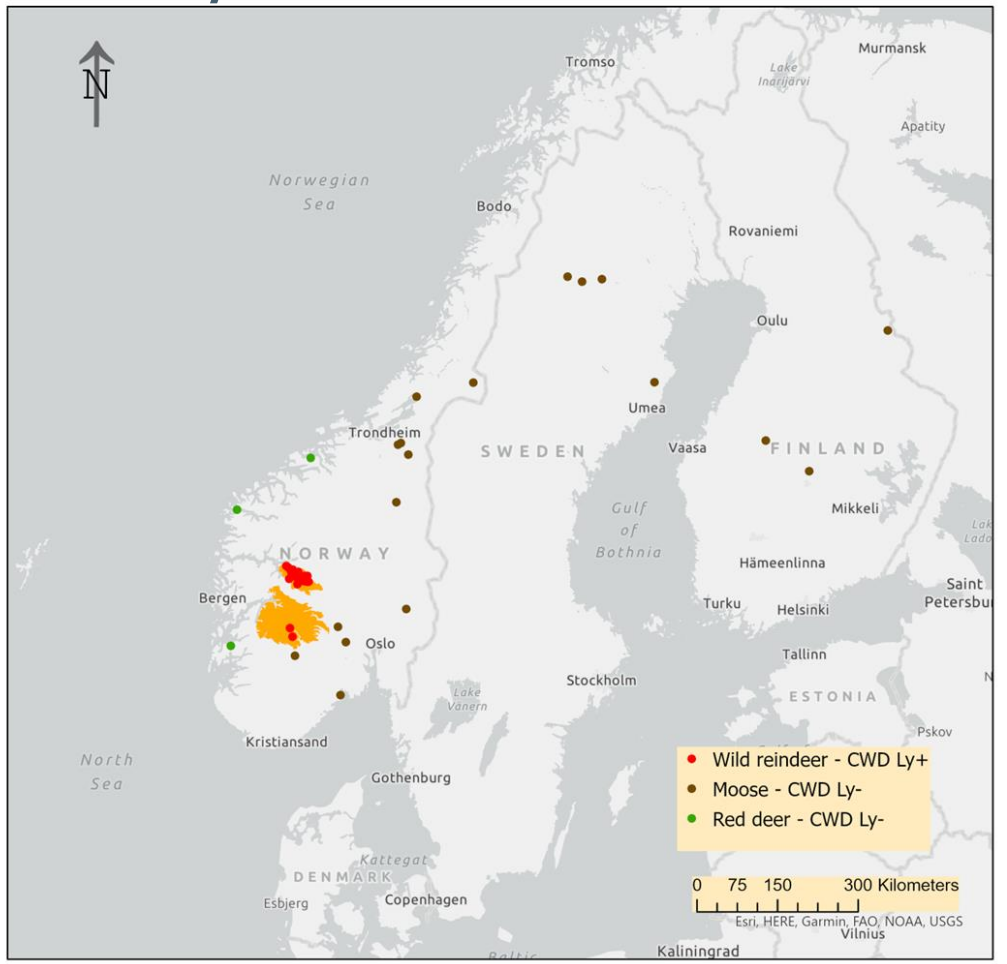
- Surveillance revealed presence of CWD in the EU
- In countries without cases, CWD cannot be ruled out

CHRONIC WASTING DISEASE IV

ToR2

To describe any new knowledge on the epidemiology of CWD in EU/EEA countries

- Sweden, Finland, areas of Norway. Red deer
- Hardangervidda: two cases.
  to Nordfjella
- Age, sex: associated with disease
- Genetic variation in Norwegian reindeer: wild
- Two *PRNP* alleles more frequent in Ly+

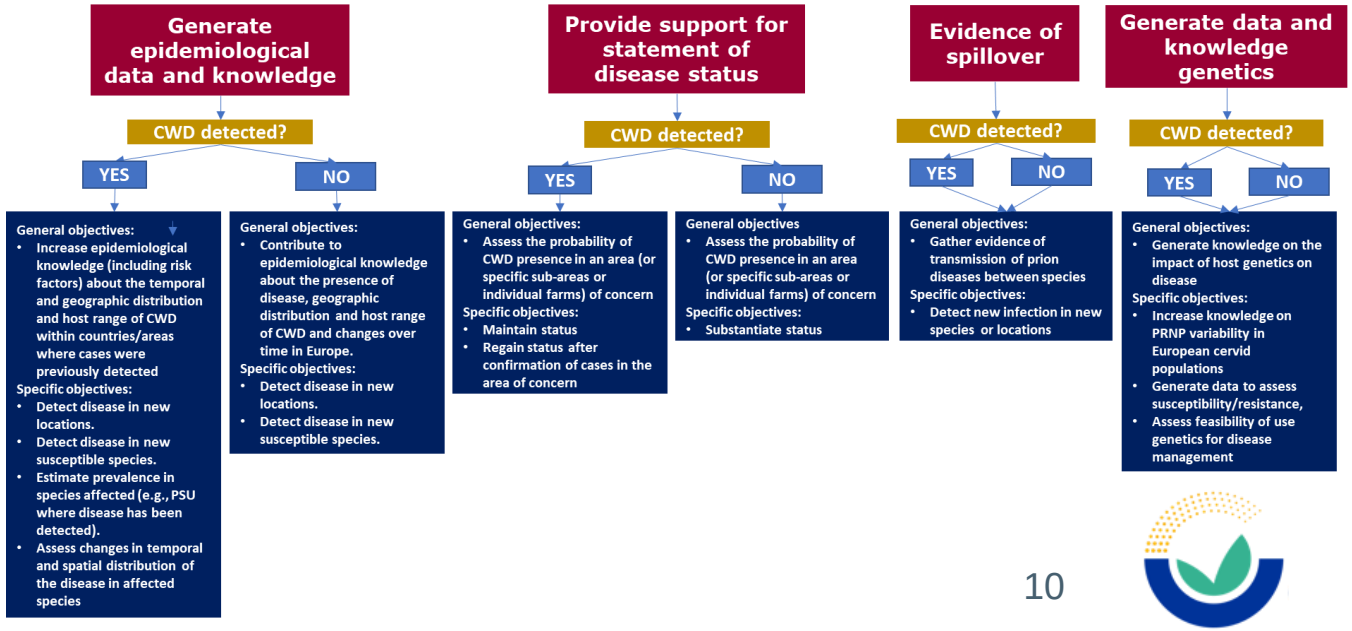


CHRONIC WASTING DISEASE IV

ToR3

To recommend, if considered appropriate, future CWD monitoring activities for the EU based on an assessment of the epidemiological situation ToR2

- **Minimum sustained surveillance: infrastructure system for sampling/testing relevant cervid species in high-risk target groups (SUS, FC, HSNHC), systematically and/or opportunistically acquired**
- **Beyond the minimum, objectives:**



CHRONIC WASTING DISEASE IV

ToR 3

Specific surveillance:

- different for countries with/without
- both retropharyngeal lymph node and brainstem
- testing animals over 2 years of age if possible;
- prioritize high-risk target groups within each selected area and management system;
  - sustained rolling time frame for accumulating surveillance data
  - in areas where disease is still undetected, design prevalence based on findings

CHRONIC WASTING DISEASE IV

ToR4

Based on what is known about the epidemiology of CWD in EU/EEA countries, to describe the criteria relevant for considering an area not to be infected with CWD.

- **Area not infected with CWD:** not possible.
- **Area of negligible risk of CWD:** not accepted.
- **Criteria for assessing the probability of CWD presence:**
  - ✓ definition geographical area: spatial boundaries;
  - ✓ annual assessment of the risk of introduction of CWD;
  - ✓ minimum sustained surveillance (ToR3);
  - ✓ training and engagement of stakeholders,
  - ✓ an "output based" surveillance based on data-driven input parameters.

CHRONIC WASTING DISEASE IV

ToR5

To provide the design of a genotyping protocol for positive samples, and for the negative samples of the 3-year monitoring programme stored as per point 3.3, section III.A of Annex III of Regulation (EC) No 999/2001, specifying which negative samples should be genotyped, the codons of the *PRNP* gene to be genotyped and recommending genotyping assay/s for the implementation of the requirement by the NRLs.

- All positive cases genotyped
- Negative samples: detect and estimate frequency polymorphisms (1%), susceptibility/resistance association
- Sample sizes by country (6) for moose, red deer, reindeer, roe deer and white-tailed deer
- Double strand sequencing of the entire *PRNP* open reading frame
- Centralised data collection system at EU level: genotype and metadata

CHRONIC WASTING DISEASE IV

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.7936

EFSA WG on CWD (IV):
Giuseppe. Ru (Italy) (chair)
Michael W. Miller (USA)
Atle Mysterud (Norway)
Maria Nöremark (Sweden)
Marion Simmons (UK)
Michael A. Tranulis (Norway)
Gabriele Vaccari (Italy)
Hildegunn Viljugrein (Norway)

Angel Ortiz (BIOHAW)

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

Request for scientific and technical assistance to evaluate the application of the Czech Republic to be recognised as having a negligible risk of classical scrapie

- **Art 31. Scientific and technical assistance**

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

- **In 2013, Regulation (EC) 630/2013, amending the Regulation (EC) 999/2001 (TSE regulation) (Section A, Chapter A, Annex VI)**
- **'classical scrapie free Member State' should be replaced by that of 'MS or zone of a MS with a negligible risk of classical scrapie'**
- **A Member State, or zone of a Member State can submit a request to be recognised as 'with a negligible risk of classical scrapie'.**
- **Aligned with Article 14.8.3 Terrestrial Animal Health Code of the WOAH**

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

Annex VIII, Chapter A, Section A, Regulation (EC) No 999/2001

Point 2.1:

c) for a period of at least 7 years, a sufficient number of ovine and caprine animals over 18 m.o.a, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95% level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1% and no case of classical scrapie has been reported during that period;

Point 2.2: The MS is to notify the EC of any change in the information submitted according to point 2.1. relating to the disease. The negligible risk status may be withdrawn in accordance with the procedure referred to in Article 24(2).

Point 3.2: The national scrapie control programmes of following Member States are hereby approved

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

- **2015: The EC requested the technical assistance of EFSA, to assess if Denmark, Finland and Sweden, in their respective applications…**


SCIENTIFIC REPORT

EFSA Journal

APPROVED: 28 October 2015

PUBLISHED: 19 November 2015

doi:10.2903/j.efsa.2015.4292

Evaluation of the application of Sweden to be recognised as having a negligible risk of classical scrapie

European Food Safety Authority


SCIENTIFIC REPORT

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APPROVED: 28 October 2015

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Evaluation of the application of Finland to be recognised as having a negligible risk of classical scrapie

European Food Safety Authority

- **And now… The Czech Republic**

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

To assess if the Czech Republic:

- **has demonstrated that, for a period of seven years (2015 to 2021), a sufficient number of ovine and caprine animals over 18 months of age, in the testing streams "slaughtered for human consumption" and "not slaughtered for human consumption", has been tested annually to provide a 95% level of confidence of detecting classical scrapie if it was present in that population at a prevalence rate exceeding 0.1%; and**

- **and will continue to carry out annually a sufficient number of tests of ovine and caprine animals over 18 months of age, in the testing streams "slaughtered for human consumption" and "not slaughtered for human consumption", to provide a 95% level of confidence of detecting classical scrapie, should it be present in that population at a prevalence rate exceeding 0.1%.**

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

- **Methodology: consistency with previous assessments.**
- **Scenario tree modelling. Parameters:**

  Design prevalence: 0.1%

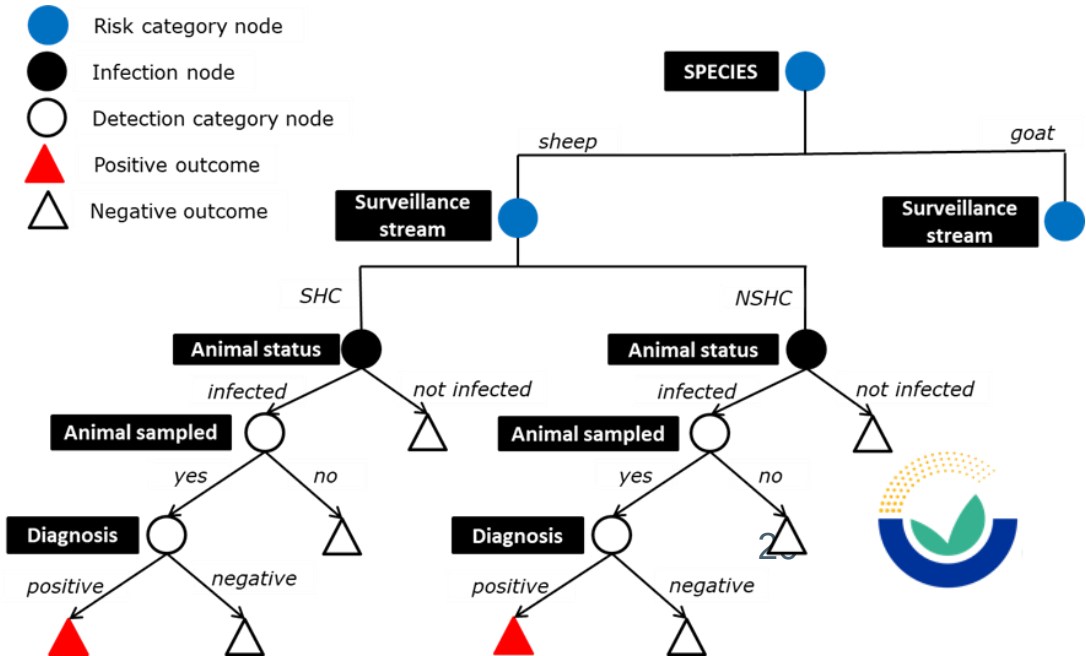
  Relative risk SHC/NSHC: EU surveillance data 2009-2021 (vs. 2002-2014)

  Relative risk sheep/goats: EU surveillance data 2009-2021(vs. 2002-2014)

  Se diagnostic test: 245/246, 90%, 80%, 70%, 60% and 50%

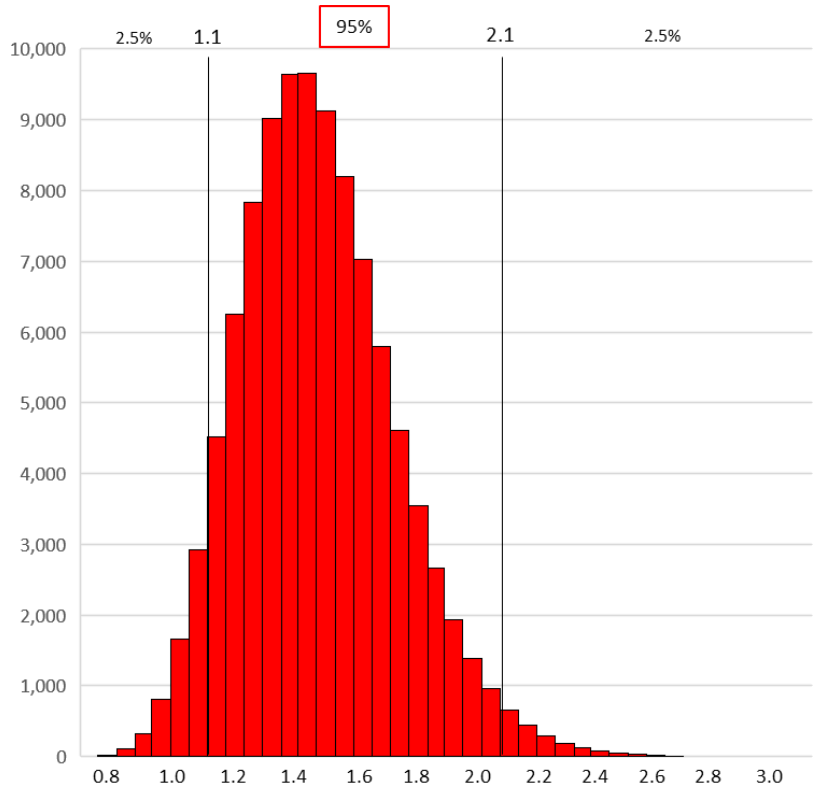
- **R code and RIBESS tool (EFSA) with *@t RISK***

add-in to Excel



CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

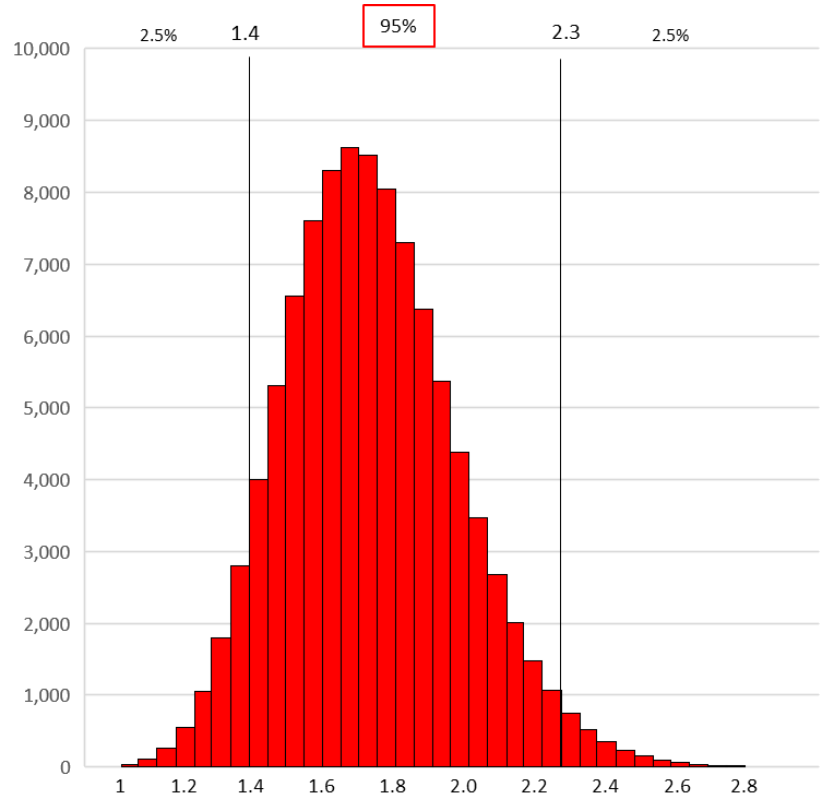
	Goats		Sheep		Total	
Country	Total tested	Number CS cases	Total tested	Number CS cases	Total tested	Number CS cases
BG	10,786	21	108,714	20	119,500	41
CY	73,187	2745	48,105	86	121,292	2831
DE			89,755	17	89,755	17
DK			6,067	0	6,067	0
EE			621	0	621	0
EL	50,188	135	139,811	1485	189,999	1620
ES	206,686	59	283,439	285	490,125	344
FI	349	1	949	3	1,298	4
FR	311,870	12	239,908	20	551,778	32
HU			38,572	3	38,572	3
IE			146,917	71	146,917	71
IS			16,874	7	16,874	7
IT	265,071	86	311,891	659	576,962	745
NL			61,992	7	61,992	7
PL			14,565	5	14,565	5
PT	14,482	2	192,368	25	206,850	27
RO	54,632	13	384,161	803	438,793	816
SE			11,304	3	11,304	3
SI			7,175	4	7,175	4
SK			53,211	45	53,211	45
UK	10,468	78	121,250	106	131,718	184
Grand Total	997,719	3,152	2,277,649	3654	3,275,368	6,806



RR sheep/goats:
1.5 (95% CI 1.1-2.1).

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

	NHSC		SHC		Total	
Country	Total tested	Number CS cases	Total tested	Number CS cases	Total tested	Number CS cases
BG	5,688	6	113,812	35	119,500	41
CY	70,710	1,687	50,582	1,144	121,292	2,831
DE	60,354	13	29,401	4	89,755	17
DK	6,067	0			6,067	0
EE	621	0			621	0
EL	93,035	1,313	96,964	307	189,999	1,620
ES	300,783	268	189,342	76	490,125	344
FI	1,298	4			1,298	4
FR	467,638	26	84,140	6	551,778	32
HU	14,023	0	24,549	3	38,572	3
IE	104,129	65	42,788	6	146,917	71
IS	201	3	16,673	4	16,874	7
IT	232,831	437	344,131	308	576,962	745
NL	19,716	3	42,276	4	61,992	7
PL	6,355	3	8,210	2	14,565	5
PT	102,246	16	104,604	11	206,850	27
RO	139,225	276	299,568	540	438,793	816
SE	11,304	3			11,304	3
SI	7,175	4			7,175	4
SK	49,380	23	3,831	22	53,211	45
UK	95,600	159	36,118	25	131,718	184
Grand Total	1,788,379	4,309	1,486,989	2,497	3,275,368	6,806



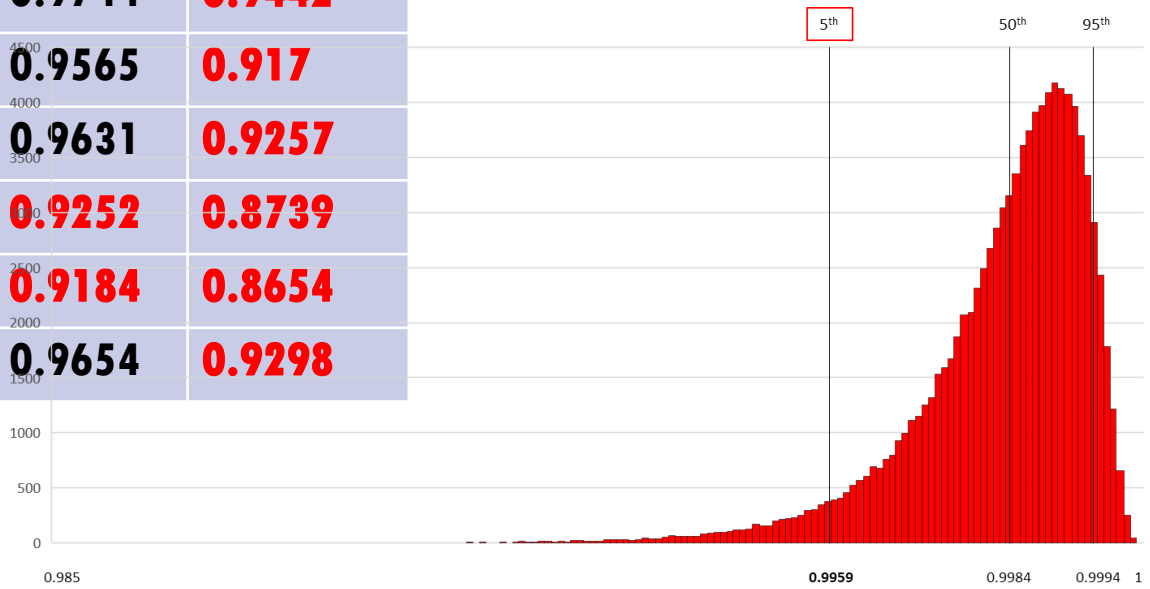
RR NSHC/SHC:
1.8 (95% CI 1.4-2.3)

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

	Total NSHC sheep N1	Total NSHC sheep tested n1	Total SHC sheep N2	Total SHC sheep tested n2	Total NSHC goats N3	Total NSHC goats tested n3	Total SHC goats N4	Total SHC goats tested n4	Total
2015	3,685	2,444	21,015	373	491	312	3,291	9	3,138
2016	3,881	2,846	23,759	28	617	416	3,869	0	3,290
2017	4,319	3,320	23,499	55	677	546	3,800	0	3,921
2018	3,897	2,918	24,818	3	717	449	4,531	0	3,370
2019	3,852	2,374	24,215	0	821	705	4,787	1	3,080
2020	3,317	2,382	22,134	14	906	735	4,512	0	3,131
2021	3,497	1,969	19,974	0	878	671	4,279	0	2,640
2022	3,514	1,874	17,413	1	991	713	4,783	0	2,588
2023	3,514	2,500	17,413	0	991	700	4,783	0	3,200

CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

Year	EU evaluation	90%	80%	70%	60%	50%
2015	0.9984	0.9959	0.9898	0.9776	0.9551	0.9156
2016	0.9996	0.9986	0.9954	0.9875	0.9708	0.9383
2017	0.9999	0.9997	0.9986	0.995	0.9857	0.9641
2018	0.9997	0.9989	0.9963	0.9895	0.9744	0.9442
2019	0.9988	0.9965	0.9908	0.9789	0.9565	0.917
2020	0.9994	0.9979	0.9935	0.9834	0.9631	0.9257
2021	0.995	0.9893	0.9779	0.9579	0.9252	0.8739
2022	0.9934	0.9868	0.9741	0.9527	0.9184	0.8654
Future	0.9994	0.9979	0.9938	0.9845	0.9654	0.9298



CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

To be published in October 2023

EFSA WG on CZ scrapie
Angel Ortiz (EFSA) (chair)
Giulio di Piazza (EFSA)
Tapani Lyytikäinen (FI)
Giuseppe Ru (IT)
Marion Simmons (UK)

2022 TSE EU SUMMARY REPORT

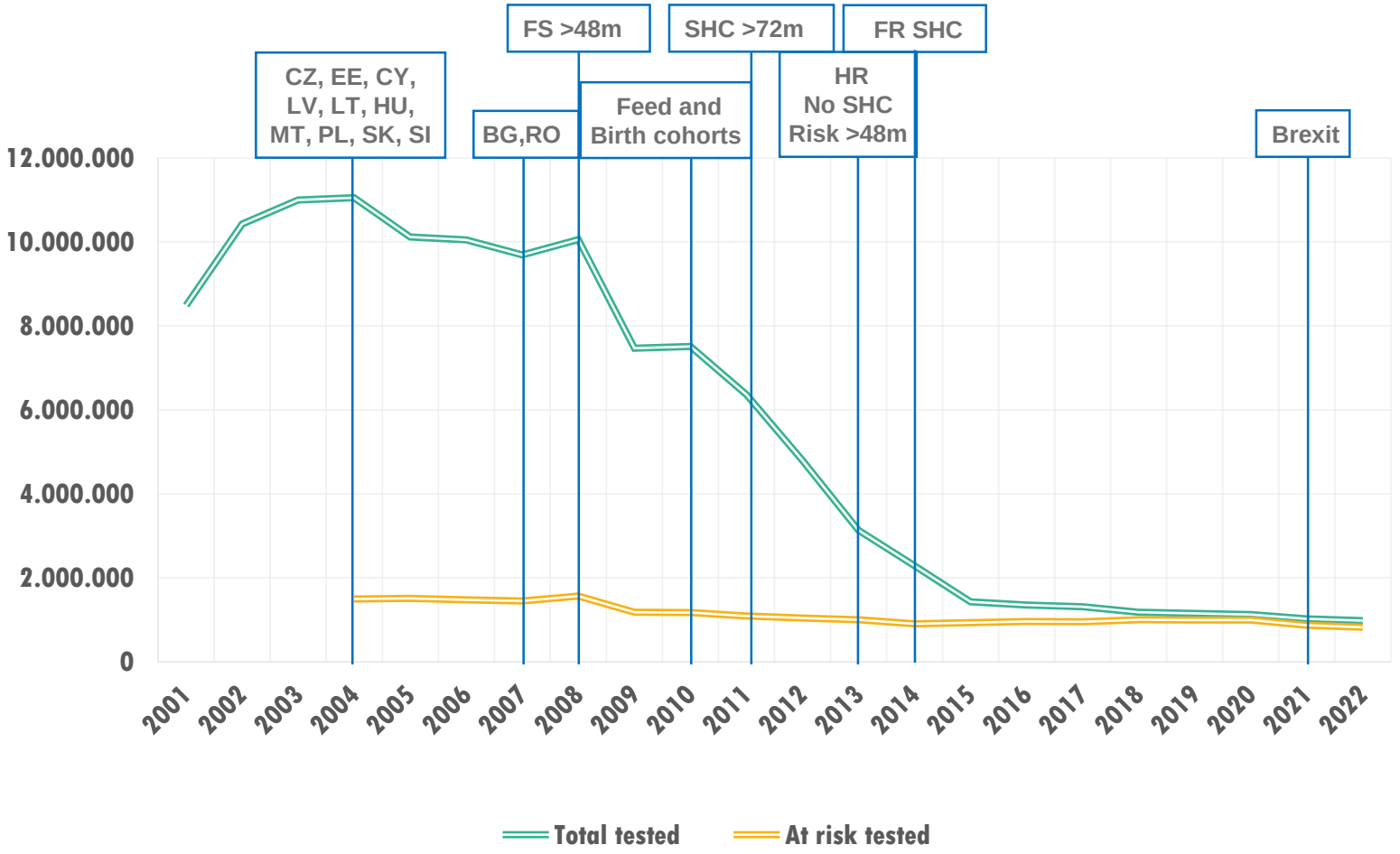
- **36 reporting countries:**
  27 Member States (MS, EU27) + the United Kingdom (in respect of Northern Ireland, (XI)),

  8 non-EU reporting countries: Bosnia and Herzegovina, Iceland, Montenegro, North Macedonia, Norway, Serbia, Switzerland and Turkey

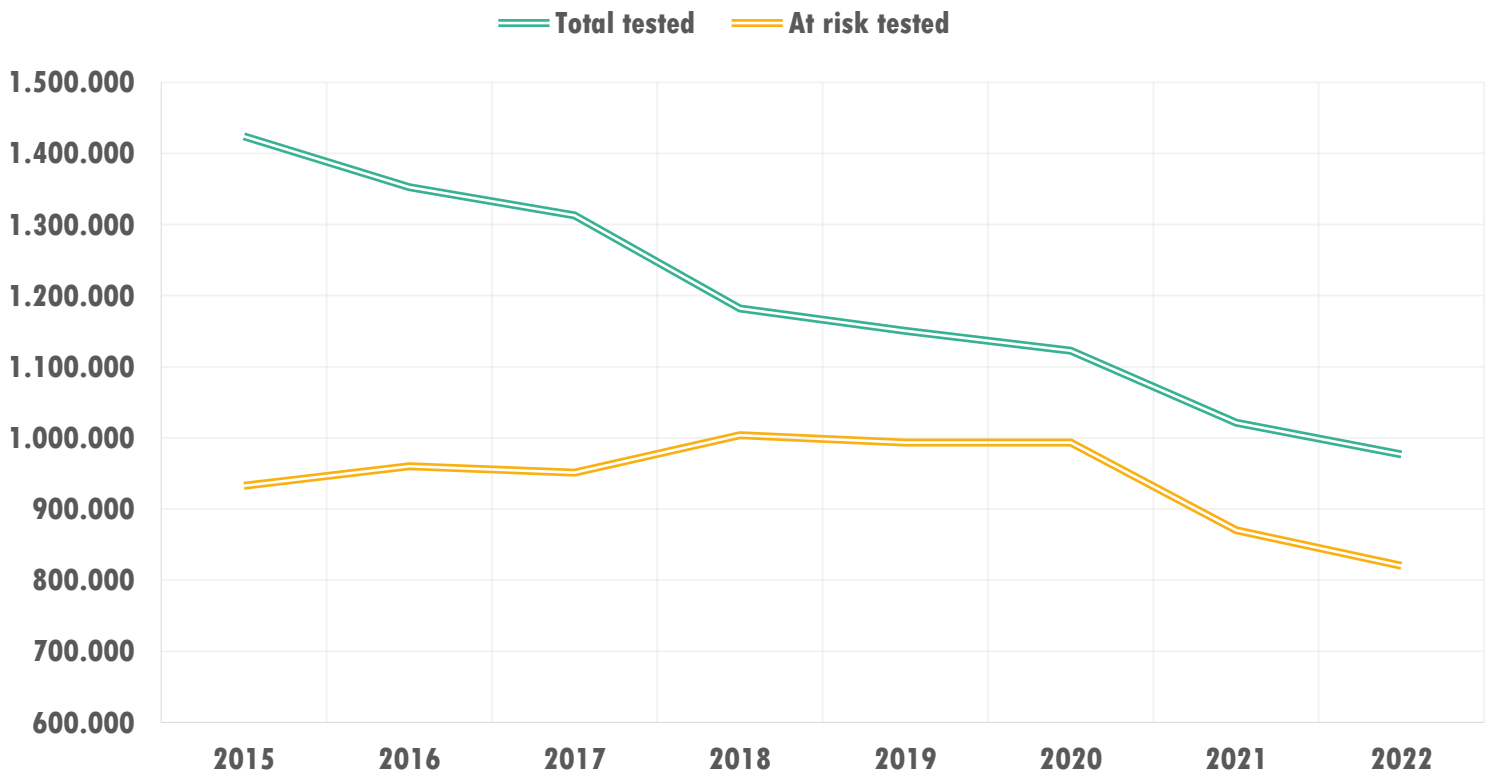
  Albania, Kosovo: no TSE surveillance

- **Genotypes of goat cases: 146 and 222**

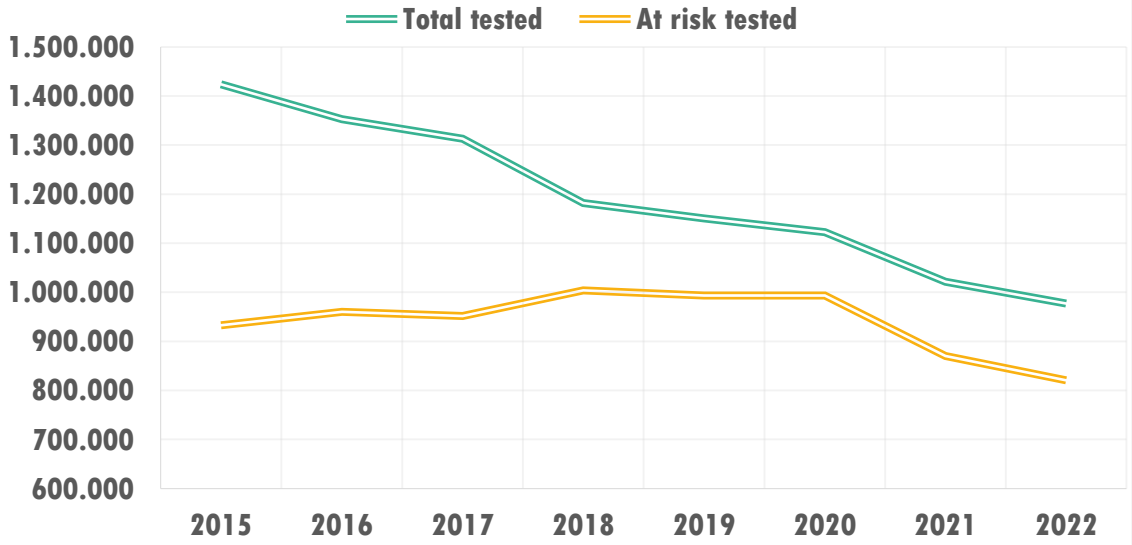
2022 TSE EU SUMMARY REPORT - CATTLE

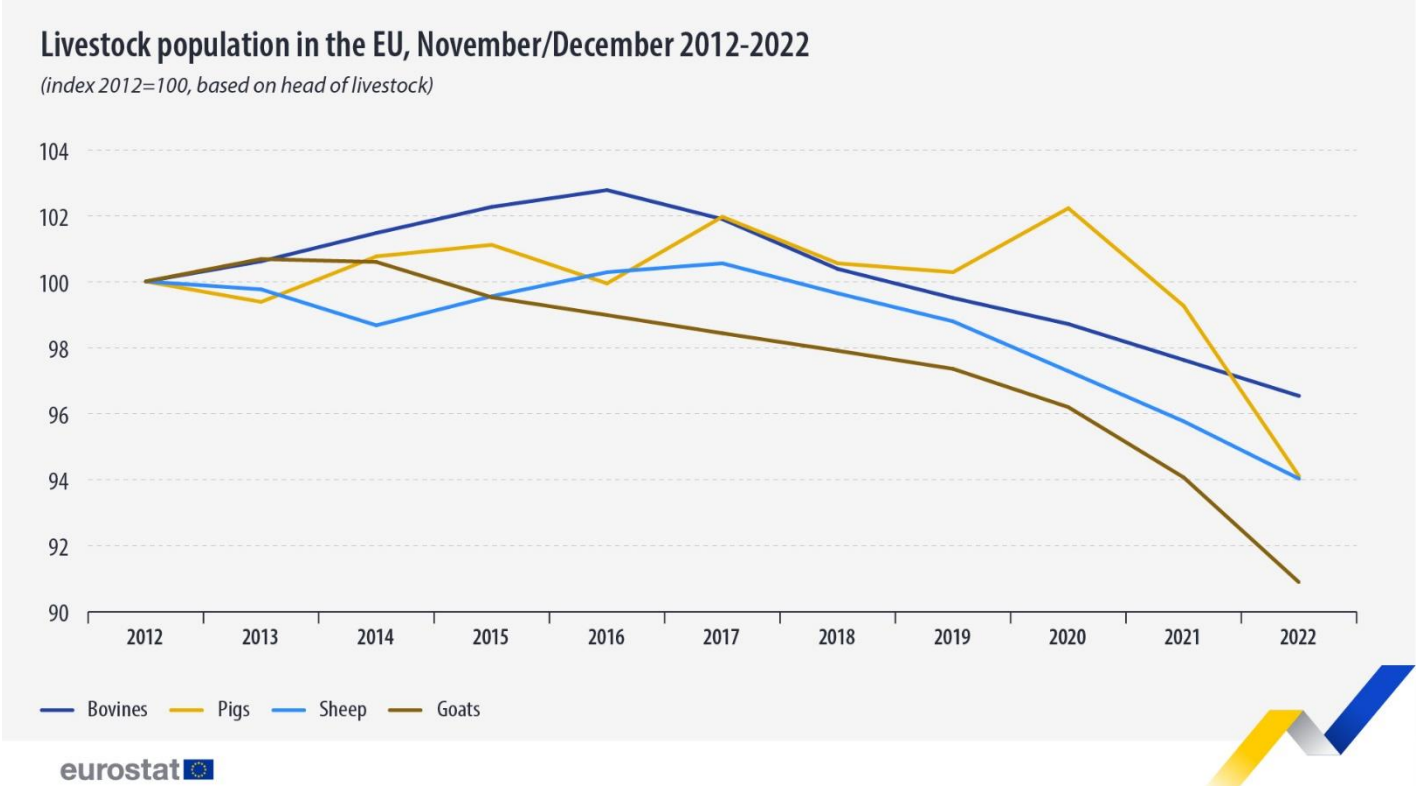


2022 TSE EU SUMMARY REPORT – CATTLE



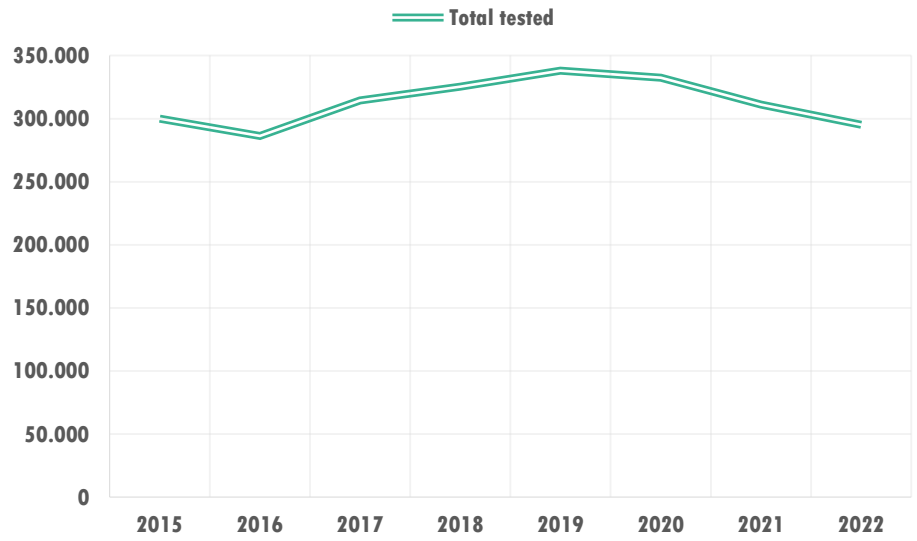
2022 TSE EU SUMMARY REPORT

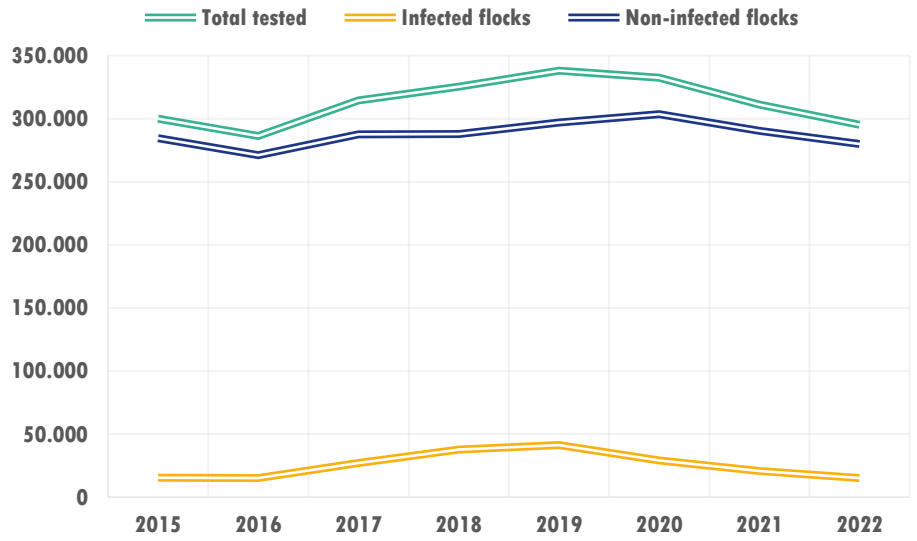




- **EU+XI:**
  977,008 (-4.3%). 820,561 risk groups (-5.7%).
  1 H-type BSE (FR): >12 years old. Beef. FS but showed clinical signs 1 month before
  No other cases in the world

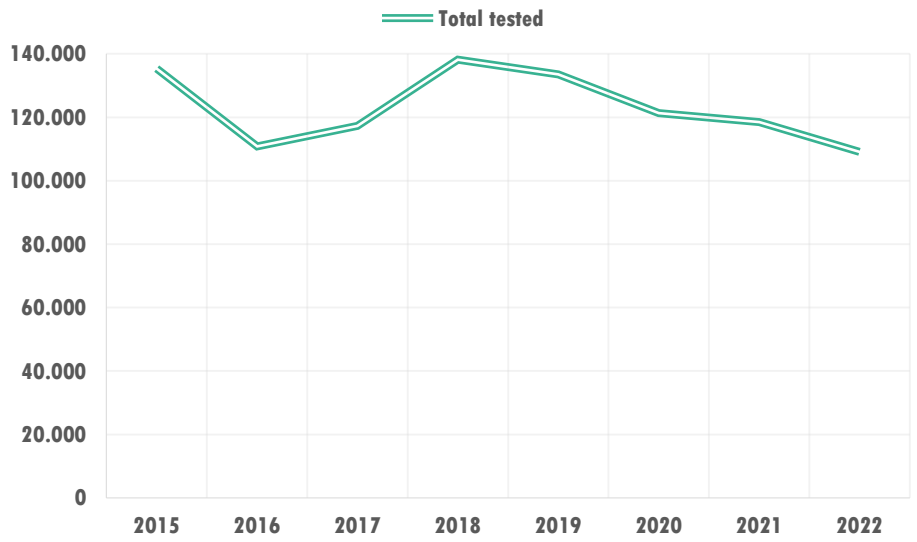
2022 TSE EU SUMMARY REPORT - SHEEP

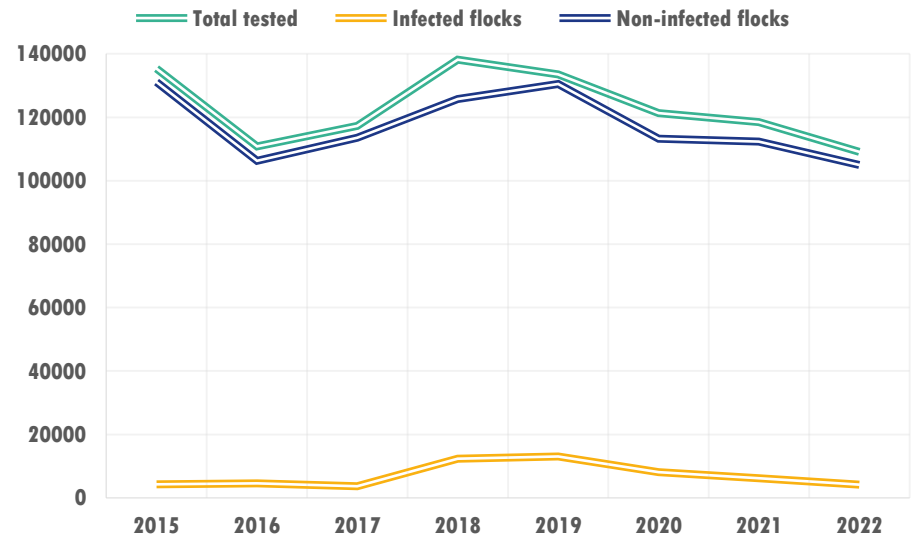




- **EU+XI: 295,115 (-5.2%). TSE-infected flocks (-27.4%) Non-infected flocks (-3.6%)**
  557 cases scrapie: 480 CS (5) 30.3% index cases– 77 AS (14+XI) (98.7%).
- **Non-EU: 16 AS (NO)**

2022 TSE EU SUMMARY REPORT - GOATS





- **EU+XI: 109,074 (-7.9%). TSE-infected flocks (-32.6%) Non-infected flocks (-6.6%)**
  224 cases scrapie: 216 CS (6) 15.6% index cases– 8 AS (4) (100%).
  2 heterozygous N146D scrapie cases in Cyprus
- **Non-EU: no cases**

2022 TSE EU SUMMARY REPORT - CERVIDS

- **EU+XI: 3,202 cervids (10) (-65%). RO and SE**
  wild cervids: 79.7% : roe deer and red deer
  HSHC: 63.2%
  1 positive female moose (FC) in Finland

- **Norway: 17,583 (-21.9%)**
  Semi-domesticated reindeer (37.9%), wild moose (17.9%), wild reindeer (17.5%)
  HSHC: 82%
  4 cases: moose (2), one wild reindeer (1) and one reindeer (1)

2022 TSE EU SUMMARY REPORT - CONCLUSIONS

- **Continuous decline in testing in all species.**

- **Cases BSE: variability rare events**

- **Sheep Classical scrapie: EL, ES, IT, RO.**
- **Sheep Atypical scrapie: cases/10,000 stable. Wider distributed.**

- **Goats Classical scrapie: no change. CY stable.**
- **Goats Atypical scrapie: variability rare events**

- **Cervids: sharp reduction in testing. Voluntary. Uncertainty**

2022 TSE EU SUMMARY REPORT

To be published in November 2023

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta
BIOHAW - EFSA
iDATA - EFSA

RUMINANT COLLAGEN AND GELATINE

- **BSE situation: since 2015, 5 cases of C-BSE in Europe**
- **Collagen and gelatine: hides, skins, bones, tendons and sinews**
- **WOAH: review BSE chapter Terrestrial Manual. Approved in May 2023**
- **Gelatine and collagen from bovine animals: safe commodity**

When authorising the importation or transit of the following commodities derived from bovines, Veterinary Authorities should not require any conditions related to BSE, regardless of the BSE risk posed by the bovine population of the exporting country, zone or compartment:

4) gelatine and collagen;

RUMINANT COLLAGEN AND GELATINE

- **Regulation (EC) No 999/2001: TSE Regulation**

  C&G from hides and skins of healthy ruminants: no restrictions. Safe commodity

  C&G from other than hides and skins of healthy ruminants: restrictions

- **Regulation (EC) No 853/2004: Food Regulation**

  For food: specific requirements for ruminant bones if from controlled/undetermined BSE risk

- **Regulation (EC) No 1069/2009 and (EU) No 142/2011: ABP Regulations**

  For feed: conditions for the production of gelatine and collagen

RUMINANT COLLAGEN AND GELATINE

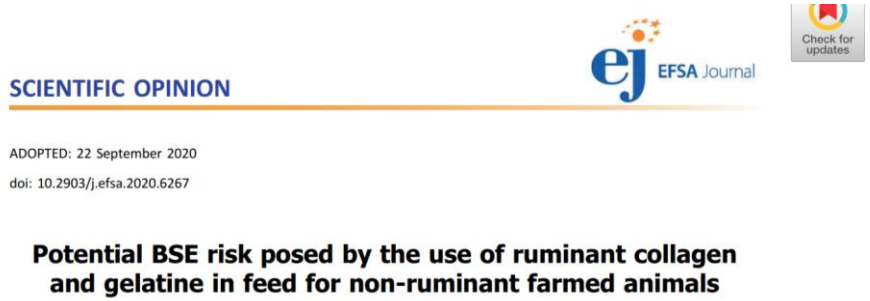
- **Regulation (EC) No 999/2001**
  - **Annex V: Restrictions Specified risk material (SRM)**
    - **From controlled/undetermined BSE risk / negligible BSE risk**
  - **Article 16.2**
    - **Placing on the market of products of animal origin**
  - **Annex IX Chapter C**
    - **Import of products of animal origin**
    - **Health certificate attesting …**

RUMINANT COLLAGEN AND GELATINE

Potential BSE risk posed by the use of ruminant collagen and gelatine produced in accordance with

- **Human consumption:** Section XIV and XV of Annex III to Regulation (EC) No 853/2004,
- **Animal by-products:** classified as Category 3 as referred to in Article 10 of Regulation (EC) No 1069/2009 and produced in accordance with Regulation (EU) No 142/2011,

in feed for non-ruminant farmed animals (2020).


SCIENTIFIC OPINION

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Potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminant farmed animals

RUMINANT COLLAGEN AND GELATINE

C&G from ruminant bones: human consumption and for feed for non-ruminants

Situation as of 7 Sept. 2021	Feed for farmed animals other than fur animals					Feed for pets and fur animals
	Ruminants	Non-ruminants (except fish)			Fish	
		Pigs	Poultry	Others		
• **Ruminant PAP**, including ruminant blood meal • **Blood products from ruminants**						
• **Gelatine and collagen from ruminants**		**2021**	**2021**	**2021**	**2021**	
• **Hydrolysed proteins other than those derived from non-ruminants or from ruminant hides and skins**						
• **Pig PAP** • **Poultry PAP** • **Other non-ruminant PAP,** including non-ruminant blood meal but excluding fishmeal		**2021**	**2021**		**2013**	
• **Insect PAP**		**2021**	**2021**		**2017**	
• **Fishmeal** • **Blood products from non-ruminants** • **Di and tricalcium phosphate of animal origin** • **Animal proteins other than those mentioned elsewhere in the table**						
• **Hydrolysed proteins from non-ruminants or from ruminant hides and skins**						
• **Gelatine and collagen from non-ruminants**						
• **Egg, egg products, milk, milk products, colostrum**						

RUMINANT COLLAGEN AND GELATINE

ToR1

To estimate the BSE risk (C-, L- and H-BSE) of gelatine and collagen derived from ovine or caprine material other than hides and skins, i.e., from bones, and produced only in accordance with:

- **all of the requirements laid down in Sections XIV and XV of Annex III to Regulation (EC) No 853/2004, excluding the provisions by which bones defined as specified risk material in Article 3(1)(g) of the TSE Regulation are prohibited, as well as point 1.(b) in Chapter III of both Sections.**
- **or the relevant provisions of Regulation (EC) No 1069/2009 and its implementing Regulation (EU) No 142/2011.**

RUMINANT COLLAGEN AND GELATINE

ToR2

To estimate the BSE risk (C-, L- and H-BSE) of gelatine and collagen derived from bovine material other than hides and skins, i.e., from bones, and produced only in accordance with:

- **all of the requirements laid down in Sections XIV and XV of Annex III to Regulation (EC) No 853/2004, excluding the provisions by which bones defined as specified risk material in Article 3(1)(g) of the TSE Regulation are prohibited, as well as point 1.(b) in Chapter III of both Sections.**
- **or the relevant provisions of Regulation (EC) No 1069/2009 and its implementing Regulation (EU) No 142/2011.**

RUMINANT COLLAGEN AND GELATINE

Work started in July 2023

Deadline for submission of scientific opinion: 30 September 2024

EFSA WG on ruminant collagen and gelatine

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Thanks for your attention!

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