



EFSA TSE ACTIVITIES 2023-2024

JOINT WORKSHOP TSE/AP EURL

13-15 MAY 2024

Rome

CONTENTS

Areas of work

Completed

- Negligible risk classical scrapie CZ (2023)
- 2022 TSE EU summary report (2023)

Ongoing

- BSE risk ruminant collagen and gelatine (2024)
- Negligible risk classical scrapie IS (2024)
- 2023 TSE EU summary report (2024)

Other

- Ash derived from Cat 1 material



AREAS OF WORK

Risk assessment related to feed, ABP and derived products

- Potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminant farmed animals (2020)
- Updated quantitative risk assessment (QRA) of the BSE risk posed by processed animal protein (PAP) (2018)
- BSE risk ruminant collagen and gelatine derived from bones (2024)

Risk assessment related to TSE diseases: surveillance, control, zoonotic

- Chronic wasting disease (2017, 2018, 2019, 2023)
- Analysis of the 2-year compulsory intensified monitoring of atypical scrapie (2021)
- Assessment of classical scrapie infectivity in sheep embryos (2017)
- Genetic resistance to TSE in goats (2017)
- BSE cases born after the total feed ban (BARB) (2017)



AREAS OF WORK

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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



ADOPTED: 22 September 2020

doi: 10.2903/j.efsa.2020.6267

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		
<ul style="list-style-type: none">• Ruminant PAP, including ruminant blood meal• Blood products from ruminants• Gelatine and collagen from ruminants• Hydrolysed proteins other than those derived from non-ruminants or from ruminant hides and skins		2021	2021	2021	2021	
<ul style="list-style-type: none">• Pig PAP• Poultry PAP• Other non-ruminant PAP, including non-ruminant blood meal but excluding fishmeal		2021	2021		2013	
<ul style="list-style-type: none">• Insect PAP		2021	2021		2017	
<ul style="list-style-type: none">• Fishmeal• Blood products from non-ruminants• Di and tricalcium phosphate of animal origin• Animal proteins other than those mentioned elsewhere in the table						
<ul style="list-style-type: none">• 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/ToR2

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

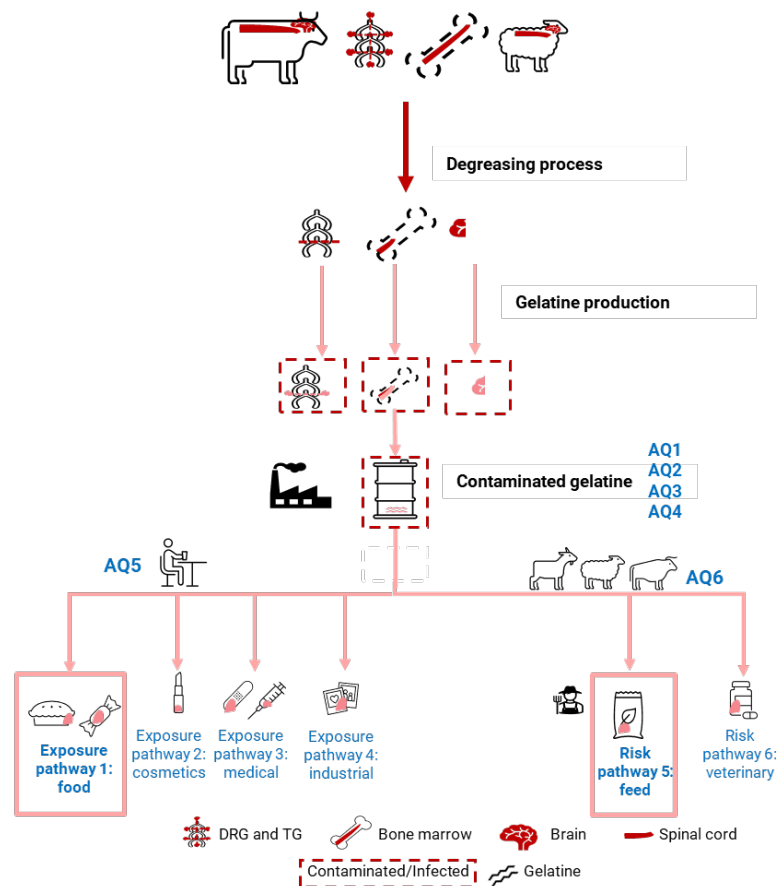
- all of the requirements laid down in Sections XIV and XV of Annex III to Regulation (EC) No 853/2004, excluding the provisions by which bones defined as specified risk material in Article 3(1)(g) of the TSE Regulation are prohibited, as well as point 1.(b) in Chapter III of both Sections.
- or the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

Work started in **July 2023**

Deadline for submission of scientific opinion: **30 September 2024**



RUMINANT COLLAGEN AND GELATINE



AQ1-AQ3: What is the BSE infectivity (cattle oral infectious dose 50, $CoID_{50}$) in the gelatine produced by all the bones from one adult BSE-infected ovine/bovine animal?

AQ2-AQ4: What is the total amount of BSE infectivity ($CoID_{50}$) per kg of gelatine in a hypothetical production batch that includes one BSE-infected ovine/bovine animal?

NO TSE restrictions: no SRM removal. Included brain, spinal cord, etc

AQ5: What is the maximum amount of BSE infectivity, expressed in $CoID_{50}$, that a human could be exposed to in a hypothetical worst-case scenario due to gelatine from a batch that includes one BSE-infected animal?

AQ6: What is the probability of a new case of BSE in cattle, sheep, or goats, due to exposure to gelatine from a batch that includes one BSE-infected animal?



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AQ2-AQ4: What is the total amount of BSE infectivity ($CoID_{50}$) per kg of gelatine in a hypothetical production batch that includes one BSE-infected ovine/bovine animal?

QRA of the residual BSE infectivity in gelatine
Probabilistic model

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AQ6: What is the probability of a new case of BSE in cattle, sheep, or goats, due to exposure to gelatine from a batch that includes one BSE-infected animal?

Maximum consumption gelatine in a single exposure event (daily) – maximum BSE infectivity exposed.

No estimation of risk.

Dose-response model: Probability of infection per meal (exposure event) per animal

Integration of evidence: epidemiology, susceptibility, species barrier, etc. Uncertainty





RUMINANT COLLAGEN AND GELATINE

To be submitted for adoption 12-13 June 2024

To be published July 2024

EFSA WG on ruminant C&G

Avelino Alvarez (ES)
Amie Adkin (UK)
Olivier Andreoletti (FR)
John Griffin (IE)
Romolo Nonno (IT)
Marion Simmons (UK)



CLASSICAL SCRAPIE NEGLIGIBLE RISK

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



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  <small>APPROVED: 28 October 2015 doi:10.2903/j.efsa.2015.4292</small> <small>PUBLISHED: 19 November 2015</small> Evaluation of the application of Sweden to be recognised as having a negligible risk of classical scrapie European Food Safety Authority	SCIENTIFIC REPORT  <small>APPROVED: 28 October 2015 doi:10.2903/j.efsa.2015.4294</small> <small>PUBLISHED: 19 November 2015</small> Evaluation of the application of Denmark to be recognised as having a negligible risk of classical scrapie European Food Safety Authority	SCIENTIFIC REPORT  <small>APPROVED: 28 October 2015 doi:10.2903/j.efsa.2015.4293</small> <small>PUBLISHED: 19 November 2015</small> Evaluation of the application of Finland to be recognised as having a negligible risk of classical scrapie European Food Safety Authority
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- **2023:**

SCIENTIFIC REPORT  <small>APPROVED: 28 September 2023 doi: 10.2903/j.efsa.2023.8335</small> Evaluation of the application of the Czech Republic to be recognised as having a negligible risk of classical scrapie <small>European Food Safety Authority (EFSA).</small>

- In **2024... Slovenia ...** by 31 October 2024



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

To assess if the Czech Republic/Slovenia:

- has demonstrated that, for a period of seven years (**2015/6 to 2021/2**), 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:

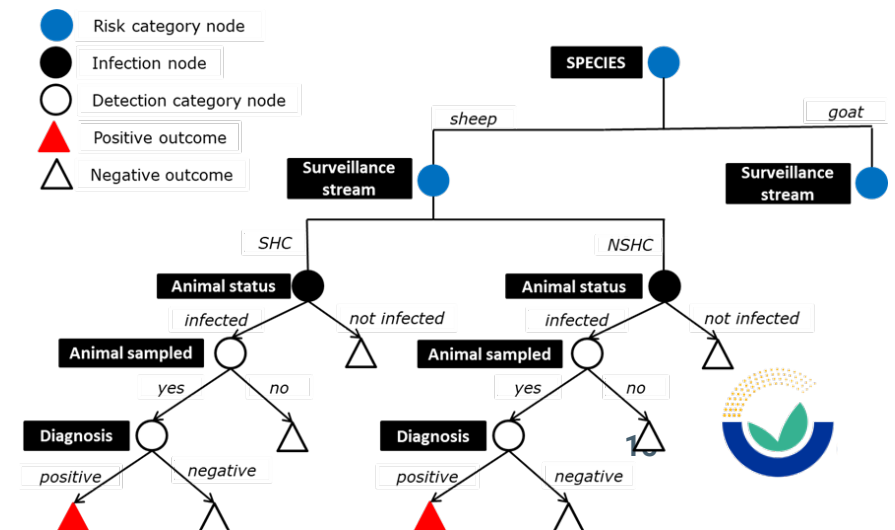
Design prevalence: 0.1%

Relative risk SHC/NSHC: EU surveillance data 2009/10-2021/22 (vs. 2002-2014)

Relative risk sheep/goats: EU surveillance data 2009/10-2023 (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

	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



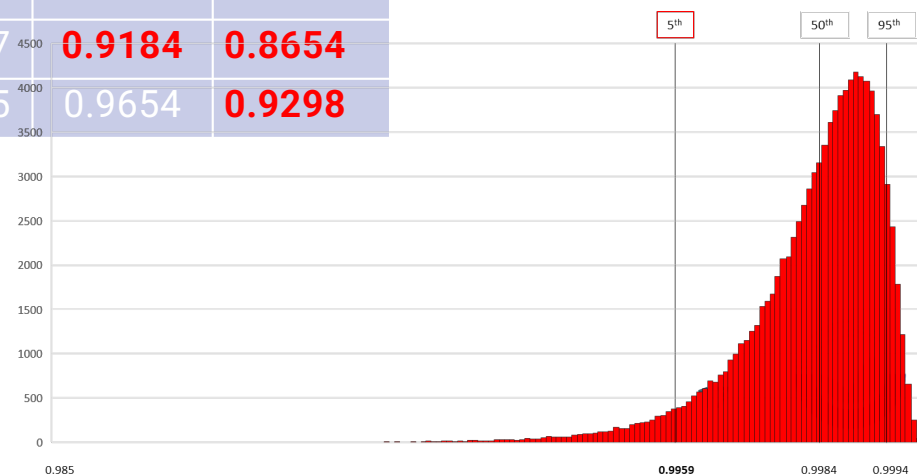
CZ CLASSICAL SCRAPIE NEGLIGIBLE RISK

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

Evaluation of the application of the Czech Republic to be recognised as having a negligible risk of classical scrapie - - 2023 - EFSA Journal - Wiley Online Library

EFSA WG on CZ scrapie

Giulio di Piazza (EFSA)
Tapani Lyytikäinen (FI)
Angel Ortiz (EFSA)
Giuseppe Ru (IT)
Marion Simmons (UK)



AREAS OF WORK

Assessment alternative processing of ABP and derived products (Article 20 Regulation 1069/2009)

Category 1 material: SRM... (prions)

- Application for a new alternative biodiesel process for rendered fat of Cat. 1 (BDI-RepCat Process, AT) (2021)
- An alternative method for production of biodiesel from processed fats derived from Cat. 1, 2 and 3 ABP (College Proteins) (2020)
- New alternative biodiesel production process for rendered fat of Cat 1 (BDI-RepCat process, AT) (2017)

Category 2-3

- Evaluation of Alternative Methods of Tunnel Composting (submitted by the European Composting Network) (2020-2024)
- Evaluation of a multi-step catalytic co-processing hydrotreatment for the production of renewable fuels using Category 3 animal fat and used cooking oils (2022)



AREAS OF WORK

Mandates submitted by the EC processing of ABP and derived products

- Efficacy of methods 2 to 5 and method 7 set out in Commission Regulation (EU) No 142/2011 to inactivate relevant pathogens when producing processed animal protein of porcine origin intended to feed poultry and aquaculture animals Application for a new alternative biodiesel process for rendered fat of Cat. 1 (BDI-RepCat Process, AT) (2021)
- Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers
- Request for a scientific opinion on the presence of biological and chemical hazards in ash from Category 1 material after incineration, co-incineration, and combustion



AREAS OF WORK

Mandates submitted by the EC processing of ABP and derived products

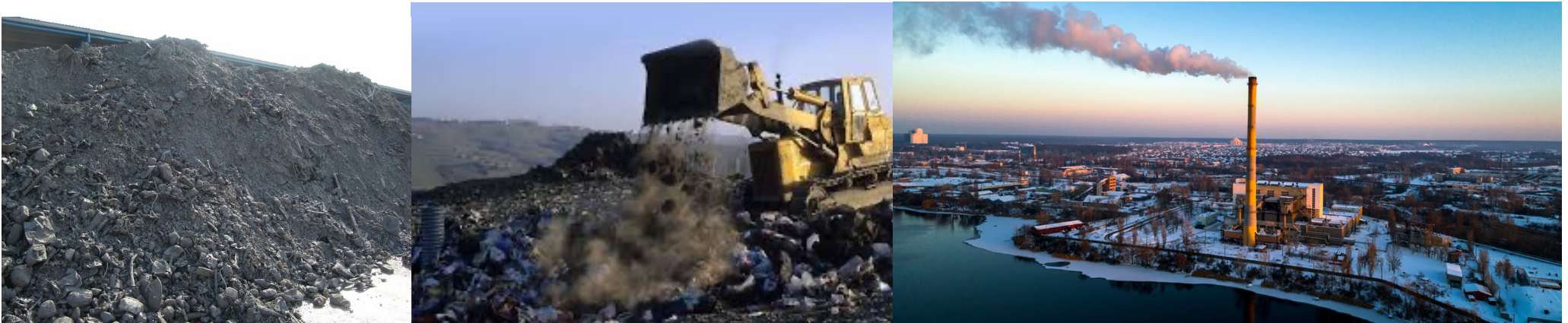
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CATEGORY 1 ASH

Request for a scientific opinion on the presence of **biological and chemical** hazards in ash from **Category 1** material after **incineration, co-incineration, and combustion**

- Ash from Category 3 and Category 2 materials may be used directly as fertiliser, mixed into compound fertilisers (EFSA BIOHAZ Panel, 2021)
- Ash from Category 1 material: banned due to TSE risk (SRM)
- Request from the fertiliser industry: revalorization as new resource for manufacturing fertilisers
- Large amounts of Cat 1 derived ash stored with no use



BACKGROUND

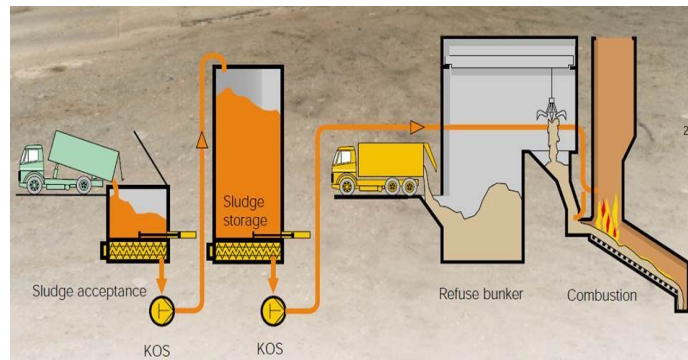
- **Article 12 Regulation (EC) 1069/2009**
Category 1 shall be:
 - a) **disposed of as waste by incineration**
 - b) **recovered or disposed of by co-incineration**
 - c) pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill
 - d) disposed of by burial in an authorised landfill (catering waste from means of transport operating internationally)
 - e) **used as a fuel for combustion with or without prior processing**
 - f) used for the manufacture of derived products (petfood, etc.)



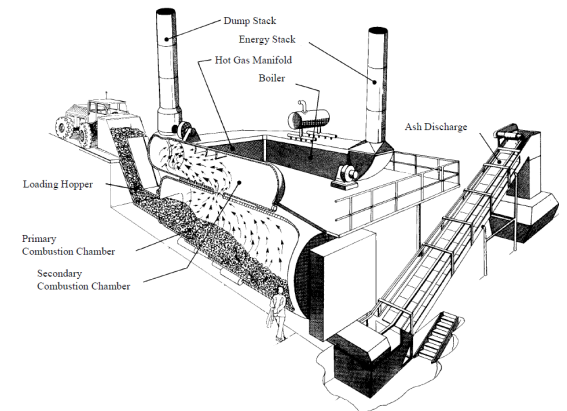
BACKGROUND

- Annex III, Chapter I, Regulation (EC) No 142/2011

“Incineration or co-incineration plants shall be ... and operated in such a way that the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of **850°C for at least 2 seconds** or to a temperature of **1100°C for 0.2 seconds**, as measured near the inner wall or at another representative point of the chamber where the incineration or the co-incineration is carried out”



Source: PUTZMEISTER (2000) and WASTEWATER SYSTEMS (n.y.)



TERM OF REFERENCE

ToR1

- to assess the effect of incineration, co-incineration, and combustion of Category 1 material referred to in Article 8 Regulation (EC) No 1069/2009 on the **BSE/TSE hazards** in the ash resulting from these treatments

If the outcome of ToR1 is that there is residual TSE/BSE infectivity, then there is NO need to proceed to ToR2

ToR 2

- to assess the effect of incineration, co-incineration, and combustion of Category 1 material referred to in Article 8 Regulation (EC) No 1069/2009 on the **biological hazards other than the BSE/TSE** and on the **chemical** hazards in the ash resulting from these treatments.



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



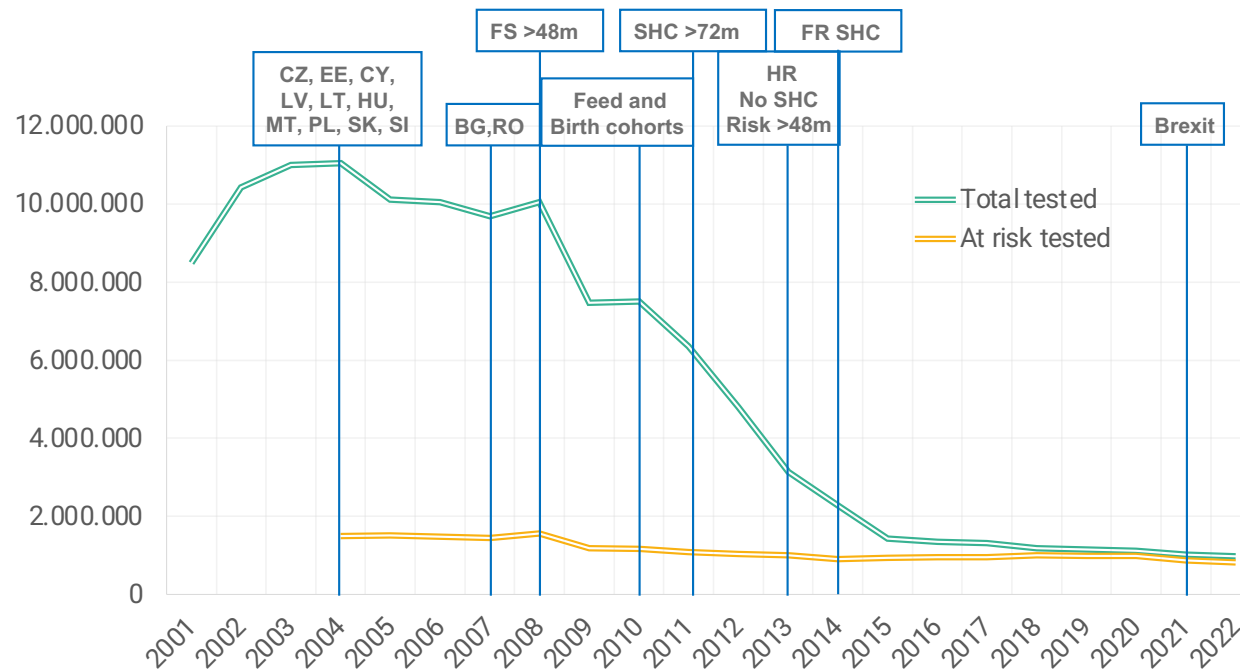
2022 TSE EU SUMMARY REPORT

- **EU+XI:**

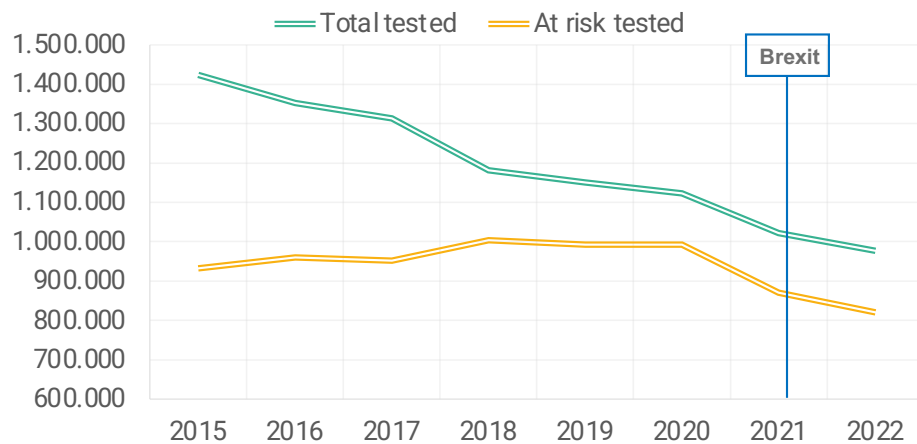
977,008 (-4.3%). 820,561 risk groups (-5.7%).

1 H-type BSE (FR): >12 years old. Beef. FS but showed clinical signs 1 month before

No other cases in the world

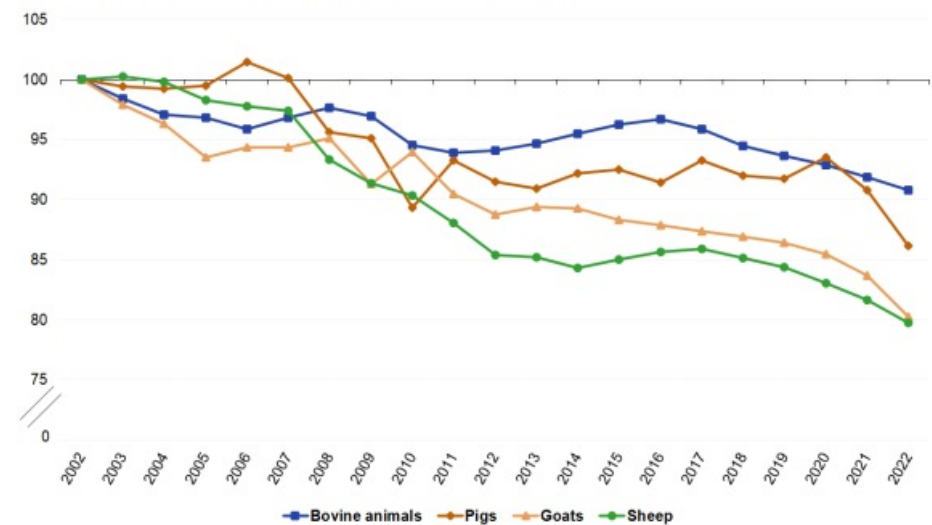


2022 TSE EU SUMMARY REPORT



-32% total tested 2015-2022
~12% due to Brexit

Developments of livestock populations
 (index 2002=100 based on heads of animals, EU, 2002-2022)



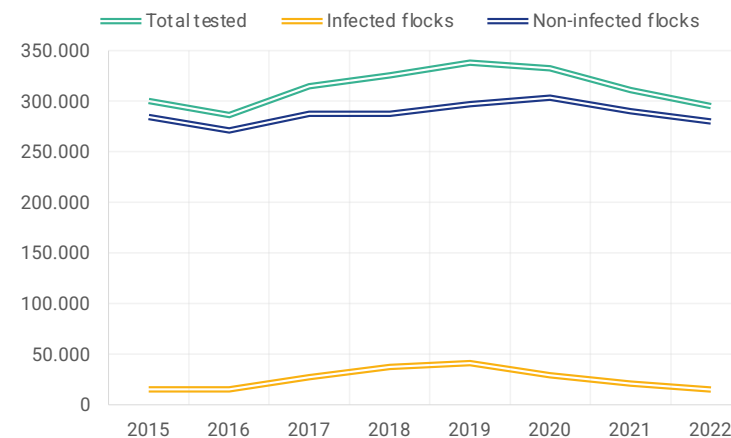
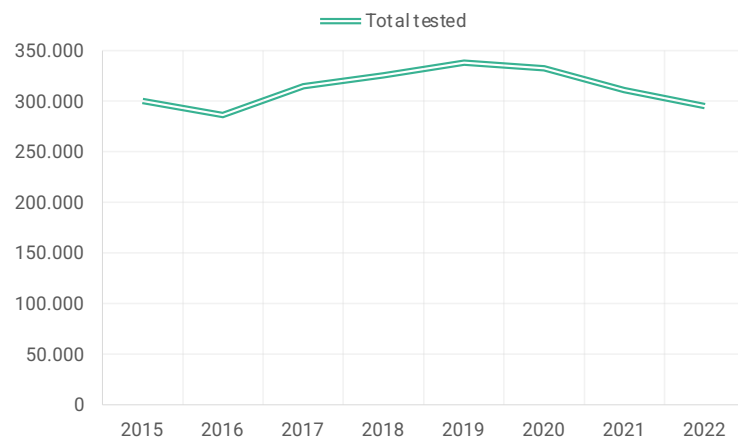
Source: Eurostat (online data code: apro_mt_lscatl, apro_mt_lspig, apro_mt_lssheep and apro_mt_lsgoat)

eurostat

- 5.6% bovine population 2015-2022



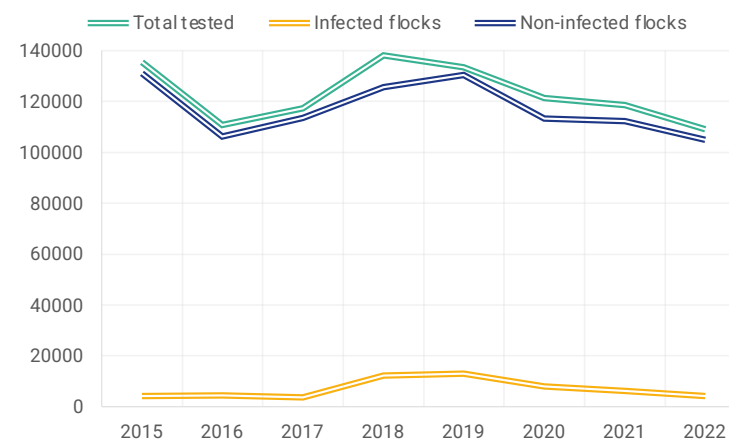
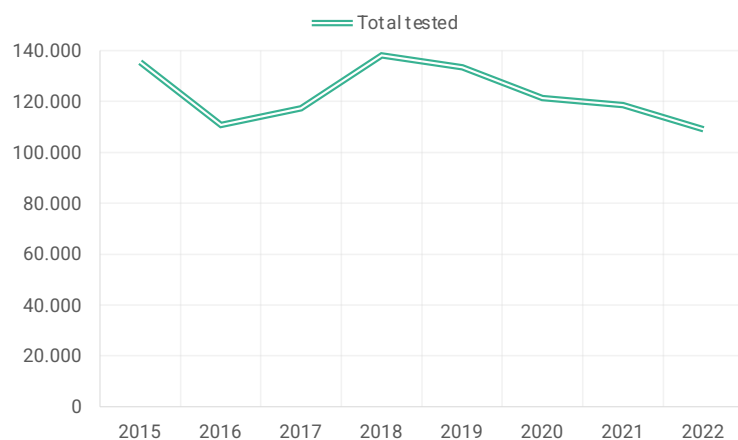
2022 TSE EU SUMMARY REPORT - SHEEP



- **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

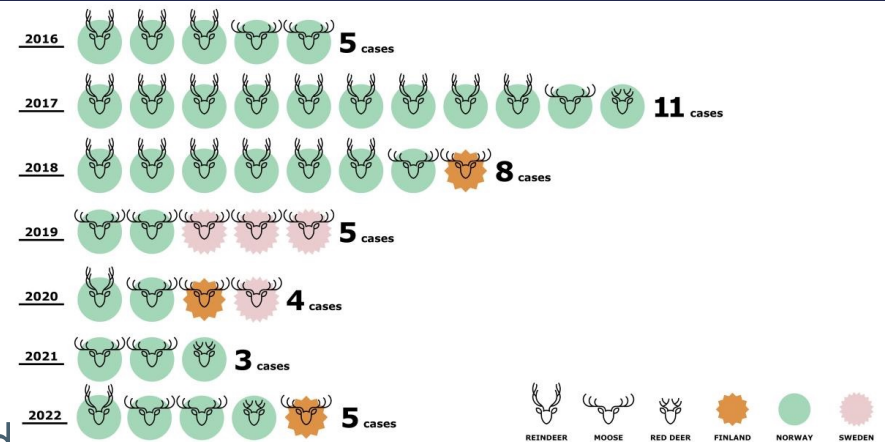


- **EU+XI: 109,074** (-7.9%). TSE-infected flocks (-32.6%) Non-infected flocks (-6.6%)
224 cases scrapie: 216 CS (6) 15.6% index cases– 8 AS (4) (100%).
2 heterozygous N146D scrapie cases in Cyprus (134)
- **Non-EU: no cases**



2022 TSE EU SUMMARY REPORT - CERVIDS

- **EU+XI:** 3,202 cervids (10) (-65%).
RO (38.9%) and SE (20.1%)
wild cervids: 79.7%
roe deer (48.6%) and red deer (21.6%)
HSHC: 63.2%
1 positive female moose (FC) in Finland

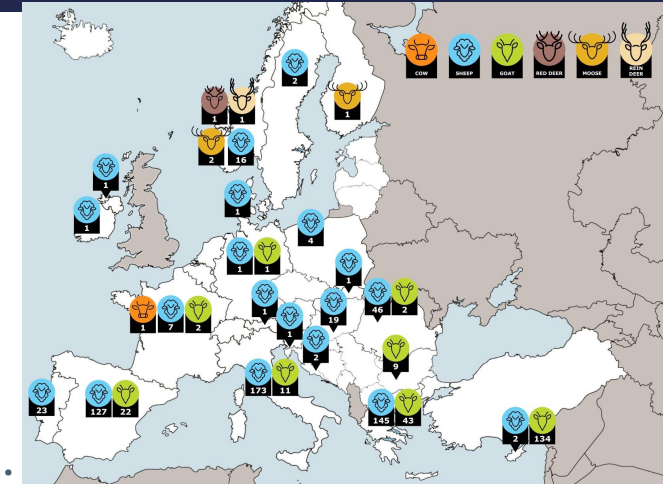


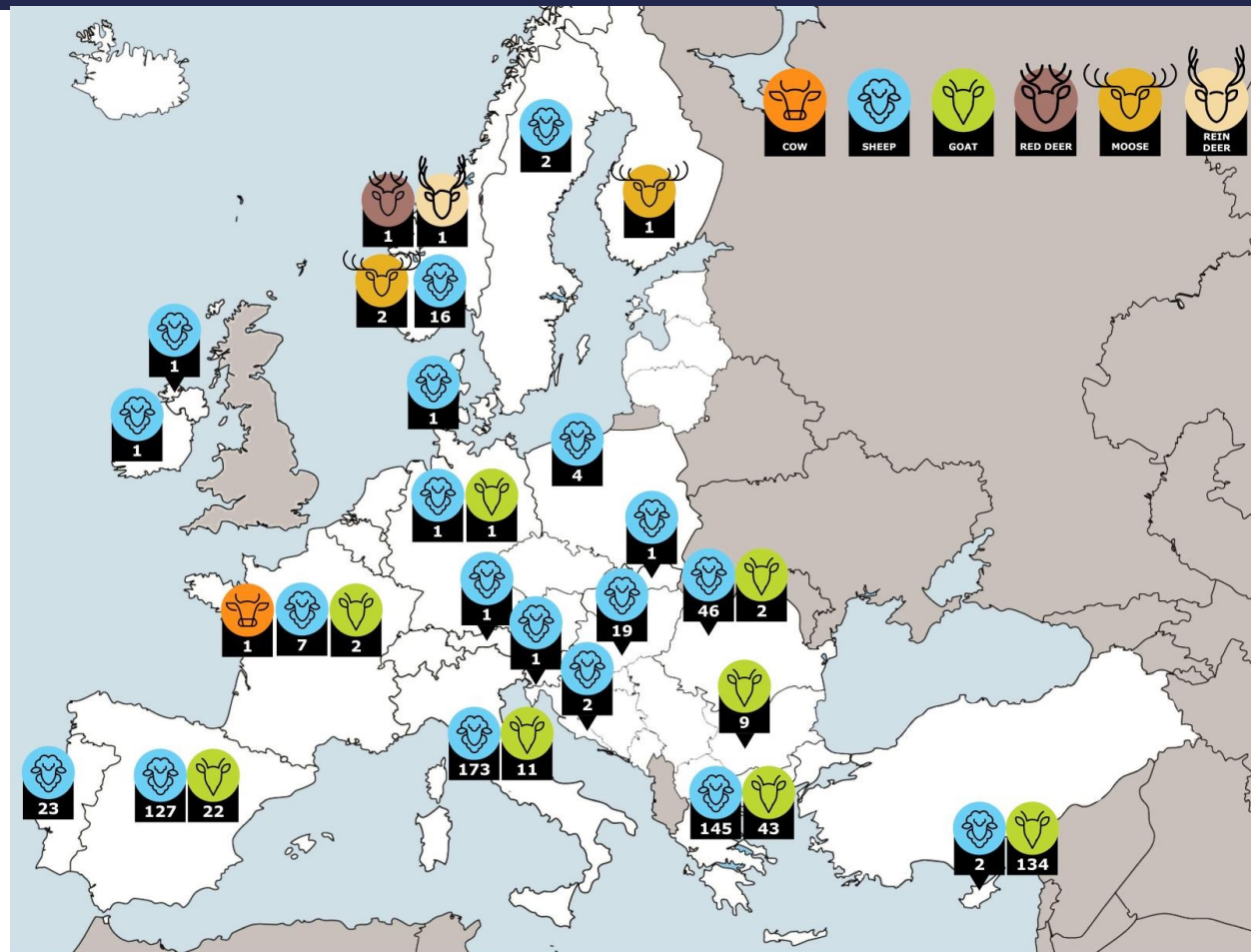
- **Norway:** 17,583 (-21.9%)
Semi-domesticated reindeer (37.9%), wild moose (17.9%), wild reindeer (17.5%)
HSHC: 82%
4 cases: moose (2), one wild reindeer (1) and one red deer (1)



2022 TSE EU SUMMARY REPORT - CONCLUSIONS

- Continuous decline in testing in all species.
- Cases BSE: variability rare events
- Sheep CS: EL, ES, IT, RO.
- Sheep AS: 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

Published on 28 November 2023

Report: <https://www.efsa.europa.eu/en/efsajournal/pub/8384>

Storymap: [Transmissible Spongiform Encephalopathies \(TSE\) \(arcgis.com\)](#)

Dashboard: [Cattle - BSE | EFSA \(europa.eu\)](#)

Acknowledgements:

Data providers

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta

BIOMO - EFSA

iDATA – EFSA

Trainees - BIOHAW





Thanks for your attention!



Angel Ortiz Pelaez

Senior Scientific Officer
Biological Hazards, Animal Health and Welfare Unit

angel.ortizpelaez@efsa.europa.eu

Tel. +39 0521 036 640

www.efsa.europa.eu



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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

