EFSA TSE/ABP ACTIVITIES 2023-2024

22nd Annual Meeting TSE EURL

12-13 Mayo 2025

EUROPEAN FOOD SAFETY AUTHORITY

CONTENTS

TSE

- BSE risk ruminant collagen and gelatine (2024)
- Negligible risk classical scrapie IS (2024)
- TSE EUSR 2023 (separate presentation)

ABP

- ABP application; alkaline hydrolysis (2025)
- Category 1 ash (2025)

RUMINANT COLLAGEN AND GELATINE

- BSE situation: since 2015, 6 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:*

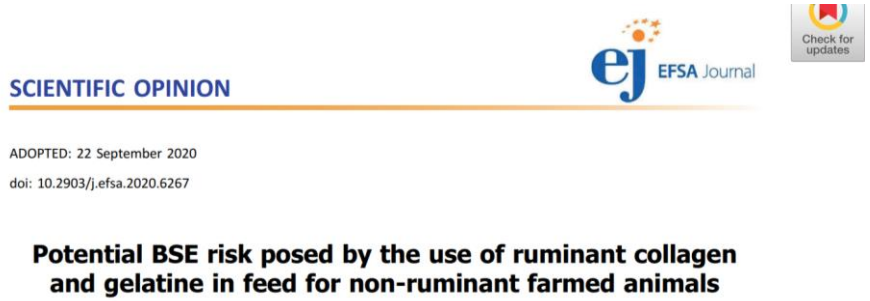
4) gelatine and collagen;

RUMINANT COLLAGEN AND GELATINE

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

EFSA Journal

Check for updates

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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

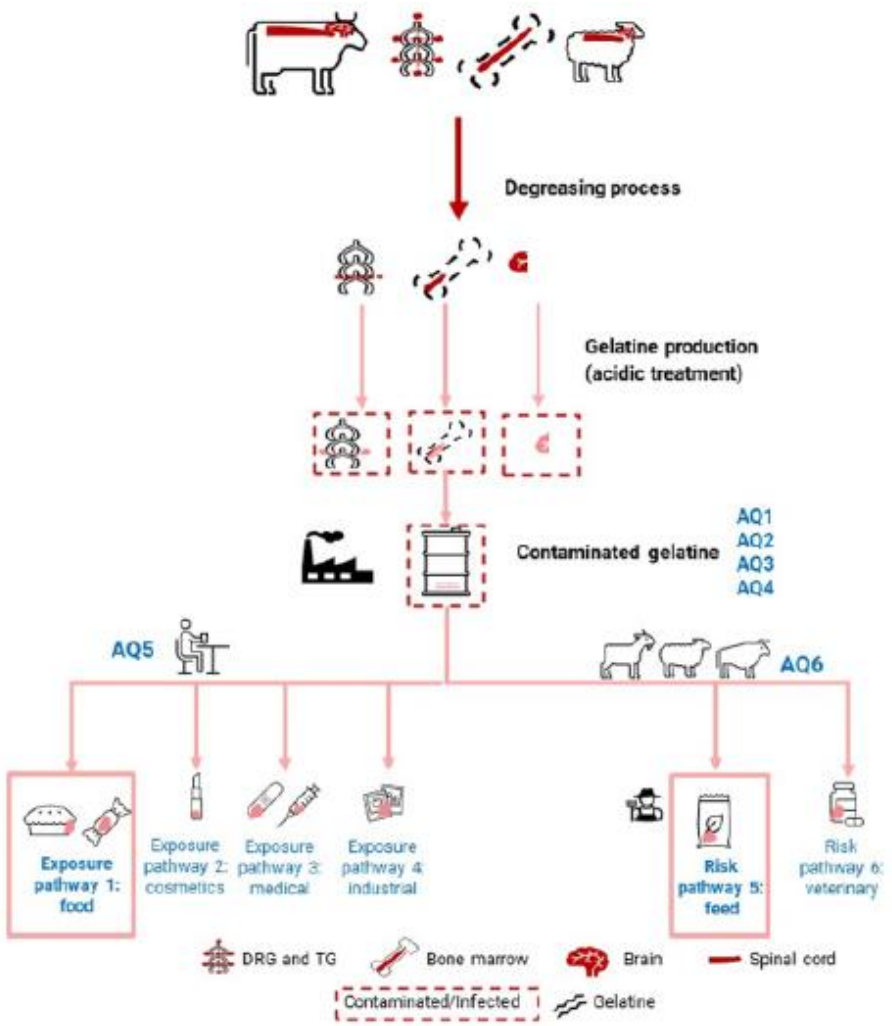
ToR1/ToR2

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.

RUMINANT COLLAGEN AND GELATINE

QRA of the residual BSE infectivity in gelatine



- All the bones (SRM) are used to produce one batch of gelatine.
- Intrinsic infectivity related to skeletal material in bone marrow.
- The infectivity contained in the skull is restricted to the brain. Other lymphoid tissues in the head assumed to be removed during the harvesting of the head, tongue, etc. at slaughter or during further processing
- The entire target tissues are assumed to remain attached to the bones (WCS), not being reduced by any cross-contamination to adjacent carcasses during dressing at slaughter
- Lower standard batch size
- Degreasing and acidic treatment
- Ovine BSE infectivity data: experimental. Calculation $CoID_{50}$

Parameter	5%	50%	Mean	95%
P23: Total number of $CoID_{50}$ in the gelatine produced with the bones of one BSE-infected bovine animal after acidic treatment	0.025	0.26	0.771	3.075
P24: Number of $CoID_{50}$/kg of gelatine in a small size batch that contains the bones of one BSE-infected bovine animal	3.3×10^{-5}	3.4×10^{-4}	1×10^{-3}	4×10^{-3}

RUMINANT COLLAGEN AND GELATINE

Exposure of humans to BSE infectivity through the use of C&G

- **Exposure pathway 1: Collagen and gelatine used for human consumption (oral);**
- Exposure pathway 2: Collagen and gelatine used in cosmetics (topical and parenteral);
- Exposure pathway 3: Collagen and gelatine used in medicinal products and medical devices (oral and parenteral);
- Exposure pathway 4: Collagen and gelatine used for an industrial purpose (different possible routes of exposure).

Country	Population group	50th percentile consumption per day (gr)	Number of consumption days (number of days available)*	Infectivity bovine BSE	Infectivity ovine BSE
France	Other children (from 36 months up to and including 9 years of age)	6.53	7	2.2×10^{-6}	3.4×10^{-5}
France	Adolescents (from 10 up to and including 17 years of age)	5.23	14	1.8×10^{-6}	2.7×10^{-5}
France	Adults (from 18 up to and including 64 years of age)	7.48	39	2.5×10^{-6}	3.9×10^{-5}
Hungary	Elderly (from 65 up to and including 74 years of age)	10	7	3.4×10^{-6}	5.3×10^{-5}
France	Very elderly (from 75 years of age and older)	21.07	4*	7.1×10^{-6}	1.1×10^{-4}

*These consumption values refer to 'consumption days only' and must be carefully interpreted because of the low number of consumers available.

RUMINANT COLLAGEN AND GELATINE

Exposure of animals to BSE infectivity through the use of C&G

- **Risk pathway 5: Collagen or gelatine in feed (oral)**
  The incorporation of collagen or gelatine directly in compound feed for livestock or in pet food;
  The incorporation of former foodstuffs containing collagen or gelatine in compound feed for livestock;
  The feeding of technological additives or nutritional supplements containing collagen or gelatine to livestock;
- Risk pathway 6: Collagen or gelatine used in veterinary medical products (oral and parenteral)

New case in bovine × bovine infectivity

Code and description	5%	50%	Mean	95%
P27: Probability of infection per meal per animal	1×10^{-5}	7.1×10^{-5}	2.1×10^{-4}	8.3×10^{-4}
P28: Number of animals infected from exposure to an infected batch	0.018	0.180	0.53	2.1

RUMINANT COLLAGEN AND GELATINE

Risk characterization

- The relationship between $CoID_{50}$ and risk
- Aggregation vs. dilution
- Dose-response relationship: cumulative vs. single dose
- Transmission barrier
- Efficiency of exposure routes: only oral

Further considerations

- Epidemiological situation
- The use of multiple worst- case scenarios
- Susceptibility
- Future usage
- Extrapolation to collagen

RUMINANT COLLAGEN AND GELATINE

- Worst-case scenarios: overestimation of the probabilities/risk

- For humans, exposure to infectivity cannot be directly translated to risk of disease because the transmission barrier has not yet been quantified.
- Potential parenteral exposure routes to BSE- infected gelatine and collagen in humans (through cosmetic, medical and surgical products) were identified but not quantified in this assessment.

- If all bones from one adult BSE- infected bovine animal are included in small batch, in up to 87% and 96% of the iterations, the number of new BSE cases potentially generated in bovine and small ruminants, respectively, is below 1.
- The probability that no new case of BSE in the cattle or small ruminant population would be generated through oral exposure to gelatine made of ruminant bones is 99%–100% (almost certain)

RUMINANT COLLAGEN AND GELATINE

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EFSA WG on ruminant collagen and gelatine
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Amie Adkin

Angel Ortiz (EFSA)

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

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

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

SI 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

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

- Annex VIII Chapter A Section A Point 4 Regulation (EC) 999/2001

ovine and caprine animals for breeding destined to Member States other than those with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:

ovine and caprine animals for all intended uses except immediate slaughter destined to Member States with a negligible risk of classical scrapie or with an approved national scrapie control programme shall (one of the options)

(ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie;

CLASSICAL SCRAPIE NEGLIGIBLE RISK

- **2013: Austria**
- **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

EFSA Journal

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

European Food Safety Authority


SCIENTIFIC REPORT

EFSA Journal

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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

- **2023**: **Czech Republic**


SCIENTIFIC REPORT

efsa JOURNAL

APPROVED: 28 September 2023

doi: 10.2903/j.efsa.2023.8335

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

European Food Safety Authority (EFSA)

- **2024… Slovenia**

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

To assess if Slovenia:

- 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%.

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

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

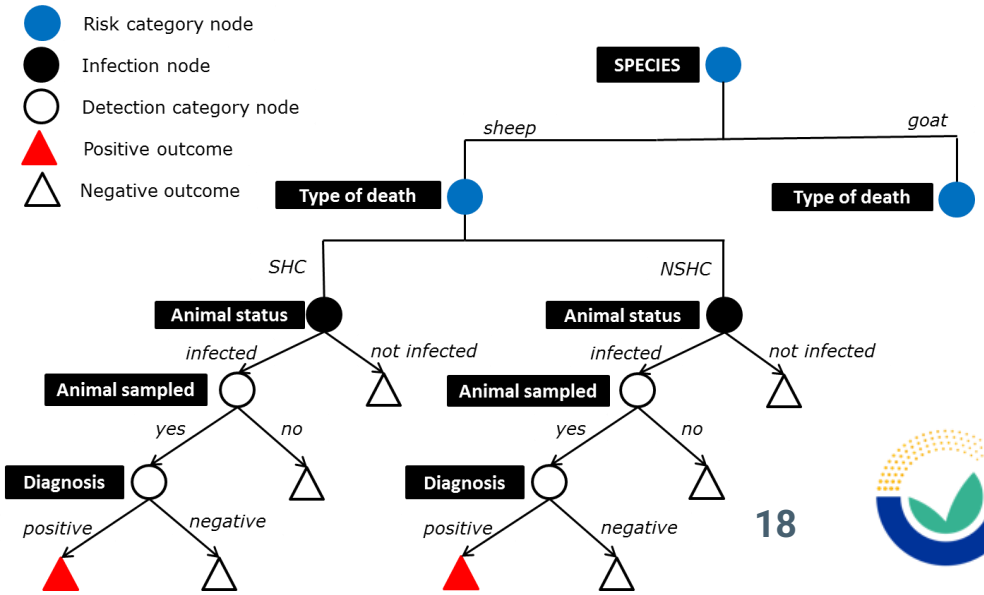
  Design prevalence: 0.1%

  Relative risk NSHC/SHC: EU surveillance data 2010-2022 (vs. 2009-2021)

  Relative risk sheep/goats: EU surveillance data 2010-2022(vs. 2009-2021)

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

- R code and RIBESS tool (EFSA) with *@t RISK* add-in to Excel



SI 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
2016	3011	2,192	202	202	2060	656	48	48
2017	6192	2,078	197	197	2358	434	74	74
2018	6300	2,308	214	214	2506	512	85	85
2019	6818	2,500	204	204	2769	476	45	45
2020	6613	2,344	171	171	2707	509	47	47
2021	6076	2,548	181	181	2445	528	55	55
2022	7003	2,244	198	198	2385	557	102	102
2023	7127	2336	196	196	3058	851	93	93
Future	7000	2500	180	180	2700	510	80	80

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

Year / Diagnostic sensitivity	EU evaluation	90%	80%	70%	60%	50%
2016	0.994	0.985	0.96	0.940	0.897	0.835
2017	0.973	0.950	0.922	0.885	0.836	0.770
2018	0.984	0.967	0.945	0.914	0.871	0.810
2019	0.984	0.970	0.949	0.920	0.878	0.820
2020	0.980	0.963	0.941	0.909	0.865	0.805
2021	0.988	0.975	0.957	0.930	0.890	0.833
2022	0.981	0.965	0.942	0.911	0.868	0.807
2023	0.988	0.977	0.960	0.935	0.898	0.844
Future	0.985	0.971	0.951	0.923	0.882	0.825

SI CLASSICAL SCRAPIE NEGLIGIBLE RISK

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EFSA WG on SI scrapie
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Marion Simmons (UK)

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

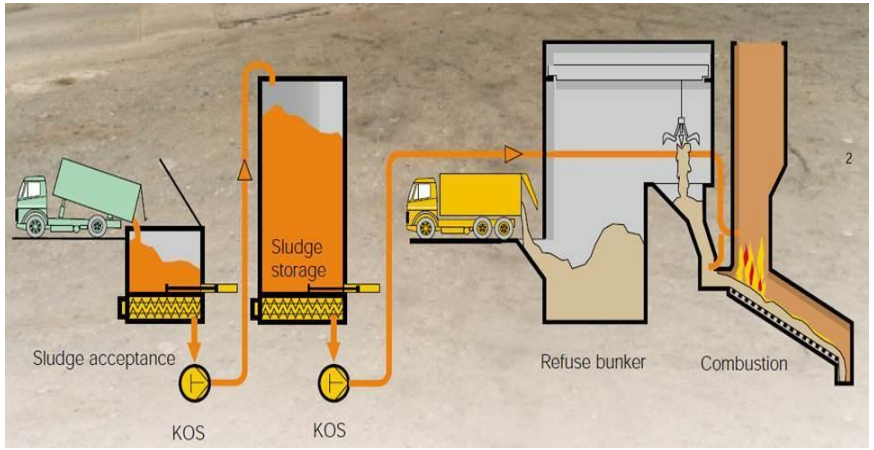
- **Article 12 Regulation (EC) 1069/2009**
  Category 1 shall be:

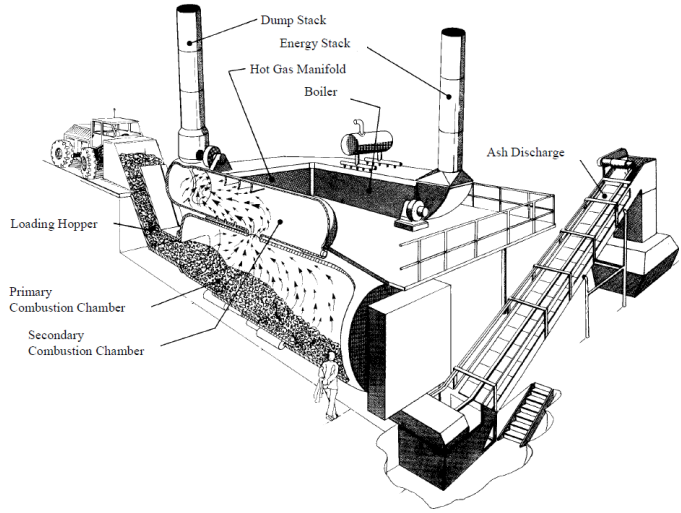
  a) **disposed of as waste by incineration**
  b) **recovered or disposed of by co-incineration**
  c) pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill
  d) disposed of by burial in an authorised landfill (catering waste from means of transport operating 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.)

TERMS 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.

METHODOLOGY: ASSESSMENT QUESTIONS

- AQ1: What is the most thermoresistant animal TSE field strain identified?
- AQ2: What are the relevant/actual scenarios used by the industry in the EU for the processing and/or disposal of Category 1 material?
- AQ3: What are the overall heat treatment (time/temperature) profiles of incineration, co-incineration or combustion processes before and after the gas resulting from the processes is raised to the minimum legal requirement of 850°C for at least 2s or 1100°C for 0.2s?
- AQ4: Can the presence of prions be excluded with more than 99% certainty in ash produced from Category 1 ABP after applying the time/temperature combinations of the relevant/actual scenarios identified in AQ2?

METHODOLOGY: DATA SOURCES

- Thermal inactivation of TSE agents: literature
- Previous RA by EFSA and SSC
- Data related to industry practices: hearing experts
- Other data sources: RA stakeholders

RESULTS

- Studies on the thermoresistance of EU TSE field strains are limited. At low temperatures (autoclaving) C-BSE strain is more thermostable than other evaluated strains.
- Only 4 studies have examined conditions approaching those used in incineration.
- C-BSE prions have been shown to survive at: 400°C for 20 minutes and at 180°C for 3 hours.
- Due to the limited sensitivity of the detection methods used in the few available studies, residual C-BSE prion infectivity cannot be ruled out even after treatment at 600°C or higher for 20m.
- C-BSE strain appears to be more thermoresistant than other strains evaluated.

RESULTS

- Category 1 ABP: is rendered into MBM (method 1 or method 4) + incineration or co-incineration or combustion.
- Rendering combined with co-incineration in cement plants and rendering with incineration in rotary kilns currently represent the most common disposal routes.
- Residency times may be considerably longer, and the actual temperatures reached by the material during the process may be higher than those required by the legislation.
- Not possible to generalize the time/temperature combinations for Category 1 ABP across all processes. It can only be assumed at least the **minimum legal requirements** as determined by the conditions of the **gas produced or injected into the process, namely, 850°C for 2s or 1100°C for 0.2s**.

CONCLUSIONS

- There is absence of sufficient relevant experimental data on the actual thermoresistance of TSE agents and on industrial operating conditions.
- Therefore, it is not possible to exclude -with high certainty (>99%)- the presence of residual BSE/TSE hazards in ash produced from the incineration, co-incineration, or combustion of Category 1 ABP material.

ASH FROM CATEGORY 1 ABP

Deadline opinion 1: 30 April 2025

EFSA WG on Cat 1 ash
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ALKALINE HYDROLYSIS UNDER ATMOSPHERIC PRESSURE

- Entire bodies and body parts of pet animals (**Category 1 ABP**)

  Regulation (EC) No 1069/2009)

  - Article 8(a)(iii): animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;
  - Article 3, Point 8: any animal belonging to species normally nourished and kept but not consumed (purposes other than farming).

- **Alkaline hydrolysis at atmospheric pressure**.

  - temperature (≥ 95,5 ºC);
  - Pressure (ambient);
  - exposure time (≥ 14 hours);
  - alkali concentration (13% or molar equivalency)
  - continuous circulation.

BACKGROUND

- Alternative to cremation
- The remaining bone and teeth remains for each individual pet animal are **milled or pulverized** into unrecognizable fragments or powdered ashes.

CONCLUSION

- Main biological hazard: prions

- Level of hazard reduction: 2 studies MALDI–TOF mass spectrometry (MS) for peptide- size detection.
  The method does not allow to directly demonstrate any quantitative reduction of prion infectivity. Not validated (sensitivity threshold?)

- In the absence of quantitative estimation of prion infectivity reduction, the alternative method cannot be considered equivalent to the alkaline hydrolysis process

CATEGORY 3 ABP ALKALINE HYDROLYSIS

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Thanks for your attention!

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