SAFOSO

Because Animal Health Matters.

Prepared for
European Sustainable Phosphorus Platform (ESPP)
Brussels, Belgium

Project report

Risk appraisal of use of Category 1 animal by-products ash as fertiliser

Final 5 September 2024

www.safoso.ch

We use our knowledge to improve animal health, because animal health matters…

SAFOSO
Because Animal Health Matters.

Content

List of acronyms

ABP	Animal By-Product
BSE	Bovine Spongiform Encephalopathy
Cat 1 (ABP)	Category 1 (ABP)
vCJD	Variant Creutzfeldt Jakob Disease
CWD	Chronic Wasting Disease
EFPRA	European Fat Processors and Renderers Association
EFSA	European Food Safety Authority
ESPP	European Sustainable Phosphorus Platform
EU	European Union
EU-27	27 EU countries (post-Brexit)
EU-28	27 EU countries + United Kingdom (pre-Brexit)
MBM	Meat and Bone Meal (Cat 1 and Cat 2 ABP origin)
MBMA	Meat and Bone Meal Ash
PAP	Processed Animal Proteins (Cat 3 ABP origin)
SRM	Specified Risk Material
TOC	Total Organic Carbon
TSE	Transmissible Spongiform Encephalopathy
WOAH	World Organisation for Animal Health (formerly OIE)

Summary of findings

- The evidence gathered suggests that rendering treatment of animal by-products in accordance with EU requirements contributes to prion risk reduction in the resulting product, meat and bone meal, but data is only available for the use of Method 1, not for the other methods most used by industry.

- The BSE incidence has reduced dramatically since its peak at the beginning of the century. Between 2014 and 2019 only 4 cases of classical BSE were detected in the EU-27, and none between 2019 and 2023. The scenario used in this report to estimate the reduction of infectivity by rendering and incineration using 5 infected cows in a single rendering batch as a starting point therefore reflects a worst-case scenario.

- The practice of fertilising fields with fertilisers with ash from processed Category 1 animal by-products has taken place for over a decade in the UK (approximately 70 000 t/year), without any noticeable increase in cases of classical BSE in the region. It is worth noting, this practice started at a time when the incidence of BSE cases was still higher than it is today.

- Similarly, use of 2500 t/y of Cat1 ABP ash as fertiliser in forestry in Portugal for over five years and reported practices of routinely handling Cat 1 ash without particular precautions (often to non-hazardous landfill), are also not associated with any increase in classical BSE occurrence.

- There is currently no applicable study to determine if any BSE prion hypothetically present in ash-based fertiliser could be absorbed by plants and ingested as infective prions by grazing cattle under natural conditions.

- This report found no evidence to suggest that ash produced from Category 1 animal by-products treated according to EU regulations, and used as fertiliser after approval poses a risk of BSE transmission.

1 Background

Transmissible spongiform encephalopathies (**TSE**) are a group of diseases defined by the accumulation of an abnormal infectious protein (prion) in the nervous tissues. Prion diseases include Bovine Spongiform Encephalopathy (**BSE**) in cattle, **scrapie** in sheep and goats, chronic wasting disease (**CWD**) in cervids, and variant Creutzfeldt-Jakob disease (**vCJD**) in humans, among other diseases. BSE presents two forms, one atypical resulting from the spontaneous mutation of the prion protein, and the classical BSE associated with the ingestion by cattle of prion-contaminated feed of bovine origin. An epidemic of classical BSE in the mid-1980s to mid-2000s resulted in a major public health and food safety crisis worldwide and was linked to cases of vCJD. Strict control measures and regulations were established to prevent any potential prion-contaminated animal material to enter the food chain. Today, the incidence of both forms of BSE is considered negligible (WOAH, 2023a).

The articulation of the regulations in effect in the European Union (EU), such as the legal definition of risk categories for animal by-products, or **ABPs** (Regulation (EC) 1069/2009), makes it challenging for the advance of pathways to treat and recycle elements of ABPs for non-feed purposes, such as the use of Category 1 ABP ash as fertiliser. As part of recycling chemical elements from used biological resources (such as manure, sewage/sewage sludge, meat and bone meal), Cat 1 ABP ash would provide a very clean source of phosphorus, to be either utilised directly as fertiliser or to be further processed to fertiliser. There is substantial interest from various sectors (in particular, the fertilising industry) in recycling phosphorus from processed ABPs as they contain high levels of the element, but a better understanding of the associated TSE risk is needed.

The current regulation on fertilising products (Regulation (EU) 2019/1009) does not mention Cat 1 ABP ash but authorises (subject to conditions) the use of Cat 2 and Cat 3 ABP ash as in EU fertilising products. The European Commission recently requested an opinion based on today's available information, from the European Food Safety Authority (EFSA) on the risk associated with Category 1 ABP ash, in the context of their possible use in the manufacturing of fertilisers. The European Sustainable Phosphorus Platform (ESPP) asked SAFOSO for a risk appraisal report which ESPP will submit to EFSA for their consideration when developing their opinion on this matter.

This report aims to document and evaluate the steps contributing to minimizing the potential risk associated with the presence of prion throughout the processing operations of Cat 1 ABP until the production of ash (ready for potential Phosphorus extraction as a further step). Current practices with regards to using Cat 1 ABP ash as fertiliser in the European region and North America will be discussed in the light of prion disease data trends.

2 Production of Animal By-Products ash and risk reduction

2.1 Definition of Category 1 Animal By-Products (ABP)

Animal by-products (ABPs) can be defined as the entire body or part of an animal or a product of animal origin, none of which is intended for human consumption (Appendix 1). Examples include slaughterhouse waste, fallen stock (animal found dead or killed on a farm, regardless of cause), animal-based products which are not or are no longer fit for human consumption and manure (Regulation (EC) 1069/2009).

2.1.1 European Union countries

ABPs have been legally assigned to 3 categories that are based on the risk they present to human and animal health and associated with specific requirements for handling and disposal of ABPs (Regulation (EC) 1069/2009). **Category 1** corresponds to the highest risk material and includes very high-risk material such as **Specified Risk Material** (SRM) (see legal definitions in Appendix 1). Any mixture of Category 1 (Cat 1) material with Categories 2 and/or 3 is classified as Category 1.

The disposal of Cat 1 ABP and products therefrom is regulated by EC regulation 1069/2009, which repealed the original regulation put in place in 2002 in response to the BSE epidemic. The parts of an animal classified as SRM are defined by EC regulation 999/2001 and may differ between EU Member States based on BSE status (Appendix 1).

For the purpose of this report, we will focus the risk reduction considerations on the potential presence of prion in Cat 1 ABPs and subsequent products from the treatment processes.

2.1.2 Equivalent denomination in other countries

United Kingdom (UK)

At the time of writing this report, the UK apply the same EU legislation that was in place prior to leaving the European Union, i.e. Regulation (EC) 1069/2009 on animal by-products and derived products not intended for human consumption (The Animal By-Products Regulations 2013, SI No 2013/2952). This includes the **same definitions of ABPs and Cat 1 material as used by EU Member States**, including SRM and entire bodies or part of dead animals containing SRM at the time of disposal.

Therefore, rendering and incineration regulatory requirements for handling Cat1 material in the UK are the same as in the EU.

United States (US)

The section of the Code of Federal Regulations on Animals and Animal products provides a definition of **Specified Risk Materials from cattle** as well as their handling and disposition (US Code of Federal Regulations, 2024a). Animal by-products are not classified in categories like in the EU and the UK.

The requirements related to BSE do not apply to cattle material from countries that can demonstrate that their BSE risk status provides "the same level of protection from human

exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States".

For countries for which SRM requirements apply, these focus on cattle from 30 months of age and older for elements of the nervous system and spine, and on cattle of all ages for elements of the small intestines.

Canada

The Canadian Government uses the same definition of **Specified Risk Materials** as the US, which also applies to cattle of 30 months of age and older (Health of Animals Regulations, 2022a). A difference is that Canada considers tonsils as SRM for cattle of all ages (instead of only cattle of 30 months of age and over in the United States).

As in the US, animal by-products in Canada are not classified in categories. Likewise Canadian authorities retain the right to determine the BSE status of a country based on a case-by-case basis: "For the purpose of preventing the introduction of a disease into Canada from an animal or thing imported into Canada, the Minister may designate a country or part of a country as being free of a disease or as posing a negligible risk for a disease" (Health of Animals Regulations, 2022b).

2.2 Treatment of Cat 1 ABP

Rendering and incineration are two separate processes to treat Cat 1 ABPs but in practice, facilities handling ABPs must be approved by the authorities to provide both types of treatment. The term *pre-rendering* was found in the grey literature but its meaning is not clear. For this report we have assumed that the "rendering" process includes the following steps: size reduction if necessary, pre-heating, treatment as per one of the methods specified in the ABP Regulations, and quality control. For the vast majority, size reduction is undertaken at a treatment facility. Each individual step presented in Figure 1a below is discussed in more detail in the sections thereafter.

For this report, we will consider **rendering and incineration as two distinct treatment processes**, each with their own contribution towards prion risk reduction.

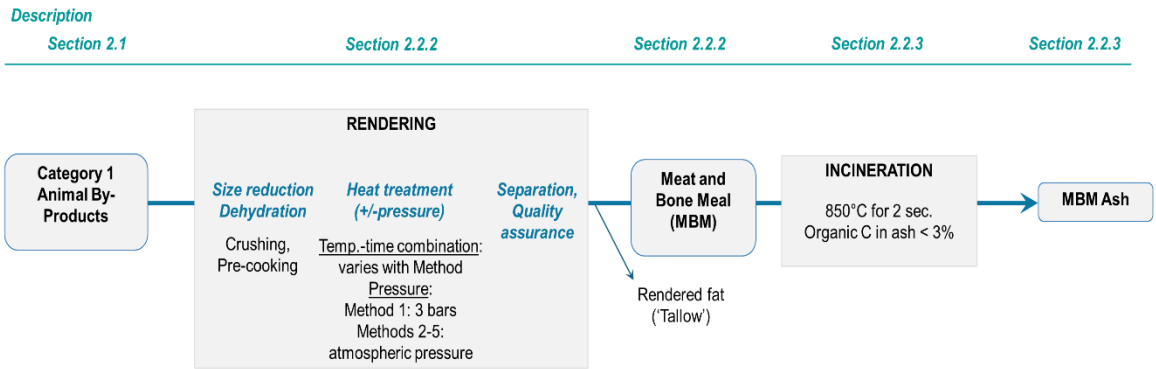

Figure 1a: *Processing steps of Category 1 Animal By-Products into ash with reference to the relevant sections of this report.*

2.2.1 Relative volumes of Cat1 ABP directed for treatment

The disposal and use of Cat 1 ABPs in the EU-27 and UK, and of SRMs in the US and Canada are regulated. Cat 1 ABPs including SRM must be removed, separated and where appropriate marked for traceability at authorised slaughterhouses, cutting plants or other place of slaughter if appropriate (Regulation (EC) 999/2001).

In the EU-27, over 20 million tons of ABPs emerge annually from slaughterhouses, plants producing food for human consumption, dairies and as fallen stock from farms (EC Food Safety, Animal by-products). Of these, between 3 and 4 million tons are rendered as Cat 1 ABPs, usually a mix of Cat 1 and Cat 2 ABPs for logistical and economic reasons (see **Table 1** below).

***Table 1**: Volumes of Category 1 Animal By-Products (ABPs) and products following treatment steps in the European Union (estimates per year).*

Step	Volume (tons)	Category (as per EC 1069/2009)	Products after treatment	Volume after treatment (tons)	Source of information
Identified as ABPs	20 million	ABPs (all Cat)	-	-	EC Food Safety, 2024
Going to rendering	3.14- 4.2 million	Cat 1 (mix Cat 1/ Cat 2)	Cat 1 meat and bone meal (MBM[1])	1 million	ESPP, 2023; EFPRA, pers. comm.
Going to incineration	1 million	Cat 1 (mix Cat 1/ Cat 2)	MBM ash	100 000 - 310 000	Coutand et al., 2008

[1]MBM means animal protein derived from the processing of Category 1 or Category 2 materials in accordance with one of the processing methods set out in Chapter III of Annex IV of Commission Regulation (EU) 142/2011.

2.2.2 Rendering

Definition

The rendering of ABPs, referred to as *pressure sterilization* in the EU legislation, requires dedicated facilities and is regulated under Commission Regulation (EU) 142/2011. The European Fat Processors and Renders Association, EFPRA, counts 82 rendering plants approved to process Cat 1 ABP amongst its members (EU-27, UK, Switzerland, Norway and Serbia); nearly all Cat 1 plants render a mixture of Cat 1, Cat 2 and partly Cat 3 ABPs (EFPRA, pers. comm.).

Rendering consists in applying heat over time to animal material leading to stable, sterilised products, e.g. animal fat and dried animal protein (EFPRA, 2022). Following size reduction (through crushing of ABPs), the application of steam at high pressure evaporates large amounts of water, which prevents decomposition of by-products (stabilisation): usually around 65% (up to 80%) of water by weight is extracted (Woodgate, 2023). The final end-products are water, meat and bone meal (MBM) and rendered fat (tallow). The application of heat over time guarantees a sterilisation of the products during this process.

Sterilisation effectively inactivates all pathogenic agents, except prions (WOAH, 2023b). The titre of infectivity for prions after sterilisation is reduced by log 3.3 (Taylor et al., 1998).

Methods available

There are five processing methods approved for rendering Cat 1 and 2 ABPs that are described in Chapter III of Annex IV of Commission Regulation (EU) 142/2011. Method 1 sets the following pressure sterilisation conditions: "133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars, particles size 50mm". The other four methods are variations from Method 1.

Method 1 is compulsory in some Member states (e.g., Germany, Hungary). It is also often preferred because the obtained fat can then be used to produce biofuel. Alternatively, one of the other four methods must be used: "Unless the competent authority requires the application of pressure sterilisation (Method 1), Category 1 and Category 2 material shall be processed in accordance with processing methods 2, 3, 4 or 5 as referred to in Chapter III" (Commission Regulation (EU) 142/2011).

In practice

Upon arrival at the rendering plant, the ABP material is assigned to different reception bunkers, based on their structure (not by species): hard bone material is separated from soft material (such as intestines and other viscera).

To guarantee a stable process both fractions are constantly mixed. This implies that there is no rendering batch reserved for ruminants or for SRM only. ABPs from multiple species and from both Cat 1 and 2, are routinely mixed (EFPRA, pers. comm.).

To optimize incineration capacity (which would be highly limited by processing whole animals), it is **routine practice to render all Cat 1 ABP** into sterilised, stable and storable MBM prior to incineration (EFPRA, pers. comm.).

In the EU-27, there are noticeable variations between countries and Methods 2-4 are used in majority compared to Method 1 (EFPRA and SARIA UK, pers. comm.). Likewise in the UK, Method 4, which process involves continuous addition of fat, heating and drying at atmospheric pressure and a maximum ABP particle size of 30mm, is the method of choice for Cat 1 ABP processing.

2.2.3 Incineration

Definitions

Incineration consists in the complete burning and reduction to ash of MBM and/or rendered fat and/or whole dead animals or parts of animals in a dedicated facility (WOAH, 2023b). Chapter I of Annex III of Commission Regulation (EU) 142/2011 sets the required parameters for incineration at 850 °C for at least 2 seconds or 1100 °C for 0.2 seconds. These conditions (minimum 850°C for at least 2 seconds, and a TOC (total organic carbon) in ash of less than 3%) are also stated in Article 50 of Chapter IV of the Industrial Emissions Directive (IED), the main EU instrument regulating pollutant emissions from industrial installations (Directive 2010/75/EU).

Incineration processes can be distinguished between two approaches:

Mono-incineration is defined as a technology utilizing the input of one basic incineration material (such as meat and bone meal) resulting in incineration ash and thermal energy as the end-products (Wagner et al., 2020).

Co-incineration means the recovery (to extract value) or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant (Annex I of Commission Regulation (EU) 142/2011). In practice, co-incineration uses waste as a fuel or raw material in industrial processes that are not primarily intended to treat waste (e.g. cement kilns, power plants, and steel mills).

Lastly the term **Combustion** is a broader term also used in the literature: it means a rapid, exothermic process involving the oxidisation of fuel in order to use the energy value of the animal by-products or derived products, if they are not waste (point 41, Annex I of Commission Regulation (EU) 142/2011). The main purpose of combustion is the production and recovery of energy from a chemical reaction, while incineration is referred to as a waste disposal method, with potential energy recovery as a secondary benefit.

Meat and Bone Meal Ash (MBMA) is produced by mono-incineration of MBM in a heat process conform to Directive 2010/75/EU (ESPP, pers. Comm.).

Method(s) available

In the EU, incineration and co-incineration of ABPs must take place in facilities that have been approved by the competent authority in compliance with Directive 2010/75/EU (referred to as the Industrial Emissions Directive (IED).

There are many different types of incinerators, each associated with a particular method (EFPRA, pers. comm.). However, all must meet the requirements set by Directive 2010/75/EU.

In practice

All Cat 1 ABP are required to be incinerated, as both Cat 1 and Cat 2 proteins and fats must not enter the food chain (Woodgate, 2023). Although rendering is not a legal requirement prior to incineration (under Regulation (EC) 1069/2009), it is largely practiced by the industry sector for practical and economic reasons (EFPRA, pers. comm.).

The most common type of incinerators is a rotating kiln, in which the material is burnt in a rotating chamber (EFPRA, pers. comm.). The conditions used by industry for waste incineration are 850 ºC for at least 2 seconds. The approval conditions for some incineration plants might differ for the carbon content in the ash (but remain in line with the Directive 2010/75/EU requirements). In theory and officially as per the Commission Regulation (EU) 142/2011, 1100ºC for 0.2 sec is an option but in practice it is only used to process fats, not MBM (EFPRA, pers. comm.).

Additional consideration on incineration: fly ash, bottom ash and slag

The main products of incineration are bottom ash, slag and fly ash. Fly ash consists of fine particles recovered from exhaust gases during the incineration of waste. Bottom ash is the residue consisting of larger particles that do not combust completely and is usually coarser compared to incinerator slag. Slag is the solid residue obtained after incineration; it consists of non-combustible materials and may contain high concentrations of heavy metals and other pollutants. Slag is often denser and more homogeneous compared to bottom ash.

Paisley & Hostrup-Pedersen (2005) explored the potential BSE infectivity of fly ash and slag when (rendered) MBM was used as a co-fuel in a gas-fired power plant. The model of incinerator used in this experimental study included the recuperation and re-incineration of slag. The authors assumed that most of the residual infectivity, if any, would mainly reside within the slag, which undergoes subsequent re-processing and re-incineration. They ran a simulation using the BSE incidence based on the observations in 2001. The authors concluded that the BSE risk from use of the fly ash (including re-incinerated slag) for the phosphate or fertiliser industry was negligible. Additionally, the declining trend in annual BSE cases post-study would have further reduced the risk since then.

The study by Paisley & Hostrup-Pedersen (2005) was run under experimental conditions but in practice, there is not necessarily any segregation between types of ash. For example, a fertilising product in the UK (section 3.3) is made of all of the ash produced from the combustion of MBM and is not separated into fly/bottom or slag (SARIA UK, pers. comm.).

2.3 Risk reduction data and assessment

2.3.1 Dilution of Cat 1 ABPs with other animal materials

Every year in Europe (EU-27 and UK), over 325 million of cattle, sheep, goats and pigs are slaughtered (EFPRA, 2022). Proportions of animal liveweight (across cattle, sheep, pigs and poultry) identified as ABPs are outlined by Woodgate (2023) for Europe: typically, of the 40% of meat and products from cattle that are not intended for human consumption, 3% will be Cat 1 and 17% Cat 2. For ABPs from sheep, the proportion is similar. Cat 1 ABP does not include any pig or poultry. It is therefore understandable why treatment of ABPs requires mixing of Cat 1 and Cat 2 and of species to remain logistically and economically viable. In practice, Cat 1 ABP combines Cat 1 and Cat 2 material from cattle and sheep.

Concerning the collection of ABPs in cattle and other ruminant slaughterhouses Cat 1 is collected separately from Cat 3 and in most cases Cat 1 is collected together with Cat 2. In mixed species plants the joint collection of Cat 1 and 2 ABPs is also very common (EFPRA, pers. comm.).

The collection of fallen stock is usually undertaken in one truck and implies the attribution of Cat 1 to the batch in the presence of any Cat 1 ABP. Only in areas with a very high number of poultry and pigs, and where a dedicated Cat 2 facility exists, fallen stock may be collected and processed by species.

The mixing of Cat 1 and 2 ABPs, and between species, suggests that volumes of ABPs treated as Cat 1 for rendering then incineration contain in practice much less Cat 1 material, and any modelling of potential prion contamination and material infectivity that would be based on Cat 1 ABP volumes should account for this dilution factor.

2.3.2 Information about risk reduction during transformation

The following **assumptions** are needed before appraising the information available on prion risk reduction throughout the ABPs treatment processes:

- Rendering and incineration plants and all associated operations (such as collection and transport of ABP) are compliant with regulations in place.

- It is accepted that incineration occurs after rendering of Cat 1 ABP.
- The ash produced in incineration is assumed to originate only from MBM without any mixing with other materials.

The process of rendering (under current regulatory specifications) is not accepted as means to inactivate prion, but it is recognised to reduce its infectivity (Woodgate & Wilkinson 2021). Combinations of rendering parameters (ABP particle size, fat treatment, process temperature and transit time) have been assessed for their ability to inactivate TSE agents (Taylor & Woodgate, 2003; Woodgate and Wilkinson, 2021). Method 1 (particles under 50mm, 133°C under a pressure of 3 bar for 20 min) is the most stringent combination of all and would result in the largest reduction of TSE infectivity (up to a 1000-fold: Taylor & Woodgate, 2003).

The role of rendering in reducing TSE infectivity remains undocumented for Methods 2-5 (EFPRA and SARIA UK, pers. comm.) but there is some evidence, albeit limited, suggesting that set conditions comparable to these methods have some effect on reducing infectivity (Taylor et al., 1995, 1997). This limited reduction is also implied but unquantified in an EFSA report assessing the risk of BSE-contaminated processed animal proteins (PAP, from Cat 3 ABP) entering cattle feed in the EU-28 and potential new BSE cases (EFSA Panel on Biological Hazards, 2018). The report states that "[methods 2 to 5] require different combinations of time and temperature, making them less effective in reducing TSE infectivity" than Method 1 (EFSA Panel on Biological Hazards, 2018).

One of the model scenarios in this EFSA report assumed the absence of controls at abattoirs to remove SRM and the absence of BSE infectivity reduction through rendering, followed by the use of PAP for cattle feed. This hypothetical scenario resulted in an estimate of up to four new cases of BSE each year for each single BSE infected cow arriving at the abattoir. Given the stringent regulations for removal and disposal of SRM in place to date across the EU-27 (and still in the UK), and the recognised BSE risk reduction through rendering processes (in line with regulations), a reversal of the declining trend of BSE cases in the EU and UK is highly unlikely and has not been observed to date.

TSE infectivity in **incineration** products was investigated by Brown et al. (2000, 2004). The authors subjected brain material infected with scrapie to temperatures varying between 600°C and 1 000°C. Their experiments provided actual data on inactivation under incineration conditions and a certain level of evidence that temperatures "well above 600°C" will lead to reducing BSE infectivity in commercial MBM incineration settings under requirements from the Commission Regulation (EU) 142/2011.

Paisley & Hostrup-Pedersen (2005) are amongst several other sources to use 10^6 BSE infectivity reduction with accepted incineration parameters (850°C, >2 seconds). This risk reduction was originally recommended by the SEAC (Spongiform Encephalopathy Advisory Committee) in 1997 (DNV, 1997a, Appendix VI).

2.3.3 Estimation of BSE infectivity In Cat 1 MBM ash using a worst-case scenario

To illustrate the reduction of BSE infectivity of Cat 1 ABP resulting from rendering and incineration processes, a worst-case scenario (with a variation based on the rendering method selected) was developed:

- 5 cows at their peak of BSE infectivity are processed in a single batch at a single processing plant;

- The batch undergoes rendering (a. Method 1 or b. any of Methods 2-5) followed by incineration in line with required parameters.

Assumptions and rationale

- This is a **deliberate worst-case scenario**:
  - the number of classical BSE cases in EU-27 was 4 between 2014 and 2023, as per Table A1 in Appendix 2 (a 5th case was recently reported). Therefore, selecting a starting number of 5 infected cows, processed in a single batch (with other cattle, making up to a volume of 10 tonnes), at a single plant, by far exceeds the current BSE risk situation.
  - the infectivity dose per cow is based on peak infectivity: 9864 Bovine oral (Bo) ID50/carcass of one BSE infected cattle (Adkin et al., 2013).
- A **Bovine oral ID50** (amount of infectivity that will cause infection in 50% of cattle exposed to it) is assumed to be lower in humans (factor of 10, as proposed in DNV, 1997a).
- To simplify, the **total infectivity per cow** only considers Central Nervous System (CNS) material as a source of infectivity, as intestines and mesentery present a marginal BoID50 (Adkin et al., 2014).
- The starting **volume** for rendering was rounded to 10 000kg or 10 tons for ease of calculations. This is a conservative volume (the smaller the volume, the greater the final concentration of risk per kilo of ash); there can be large variations of capacity between plants. This volume/weight would correspond to an average 16 to 18 entire adult cattle, including the 5 infected animals. Step-by-step risk estimates are presented in Figure 1b.
- The rendering method applied to this scenario is either a) Method 1 (for which the risk reduction estimate is known) or b) any of Methods 2-5 (see report section 2.2.2.), for which there is no TSE risk reduction estimate available in the literature. In absence of data on infectivity reduction for Methods 2-5, the scenario variation b) follows the strict and conservative assumption that using Methods 2-5 for rendering does not result in reduced TSE infectivity of the rendered products (MBM).

Batch infectivity

- Batch infectivity at start:

The infectivity dose per cow carcass was estimated based on infectious CNS tissue for an animal at maximal infectivity, that is at clinical onset (Adkin et al., 2013). The weight of the CNS and BoID50 in intestine and mesentery did not affect our approach to estimate risk reduction and were therefore not included. The starting infectivity dose per BSE infected cow was rounded to 9 870 BoID50, and the batch infectivity is presented in Table 2.

- Batch infectivity after rendering:

The TSE infectivity reduction during rendering materials containing naturally BSE infected brain tissue and carried out according to the '133°C/20'/3 bars' standard (Method 1) is recognised to be "not less than 10^3" (EC SSC, 1998a, 1998b, 1999). The TSE reduction during rendering using Methods 2-5 for variation b) of the scenario is considered nil. The volume of Cat 1 MBM is reduced down to 30% of the initial theoretical volume (or 3 000 kg) (DNV, 1997c).

***Table 2**: TSE infectivity of batch and infectivity density per kg for scenario variations 'a' (using rendering Method 1) and 'b' (using rendering Methods 2-5).*

Step	TSE infectivity [density per kg]	
	Scenario a (rendering Method 1)	Scenario b (rendering Methods 2-5)
At start (5 BSE infected cows)	49 350 BoID50 / 10 000 kg of ABP [4.935 BoID50/kg]	
Rendering	49 350 x 10^{-3} BoID50/ 3 000 kg of MBM [16.45 x 10^{-3} BoID50/kg]	49 350 BoID50 / 3 000kg of MBM [16.45 BoID50/kg]
Incineration	49 350 x 10^{-9} BoID50/ 300-900 kg of MBM [5.5-16.4 x 10^{-8} BoID50/kg]	49 350 x 10^{-6} BoID50/ 300-900 kg of MBM [5.5-16.4 x 10^{-5} BoID50/kg]

- Batch infectivity after incineration:

As per DNV (1997a, b), the risk reduction for BSE infectivity after incineration, under normal operating conditions, at 850°C or more is accepted as 10^6. The reduction in batch volume after incineration results in 300-900kg of Cat 1 MBM ashes (10-30% reduction of the initial MBM volume, see section 2.1).

- Overall infectivity reduction:

The overall infectivity reduction factor is in the order of 30 to 100 thousand for any of Methods 2-5, and 30 to 100 million for Method 1, based on this worst-case scenario.

Contextualisation of BSE risk exposure to cattle

The review of BSE infectivity risk via environmental pathways in the UK showed that the maximum individual exposure (mainly from drinking groundwater) was less than 1 millionth of an infective dose per year, based on an even worse case scenario (burial of whole untreated carcasses of infected cattle at the peak of the BSE crisis) (DNV, 1997a).

The level of infectivity (5.5-16.4 x 10^{-5} Bo ID50/kg of Cat 1 MBM ash) from the scenario used in this report suggests that a cattle would need to consume significantly large volumes of ash to become infected. Estimating the probability of animals becoming infected with BSE, when ash as fertiliser would be applied at a standard rate on pasture fields, was considered. Cummins and Adkin (2007) conducted a TSE exposure assessment from spreading of contaminated Cat 3 MBM (PAP) on non-pasture land. Their studies concluded to low infectivity density but the model assumptions are not comparable with the scenario proposed in this report.

There is scientific evidence that prions can bind to plants and be absorbed in root and leave tissues, and that ingestion of such contaminated plant material by rodents lead to experimental infection (Pritzkow et al., 2015, Carlson et al., 2023). However, these studies investigate the contamination of plants by infectious material (homogenised brain tissue, urine and faeces from experimentally-infected animals) that has not been processed, and under non-natural conditions.

Given the infectivity risk dilution and the uncertainty and multiplicity of environmental and management factors, it was decided not to pursue the estimation for this appraisal.

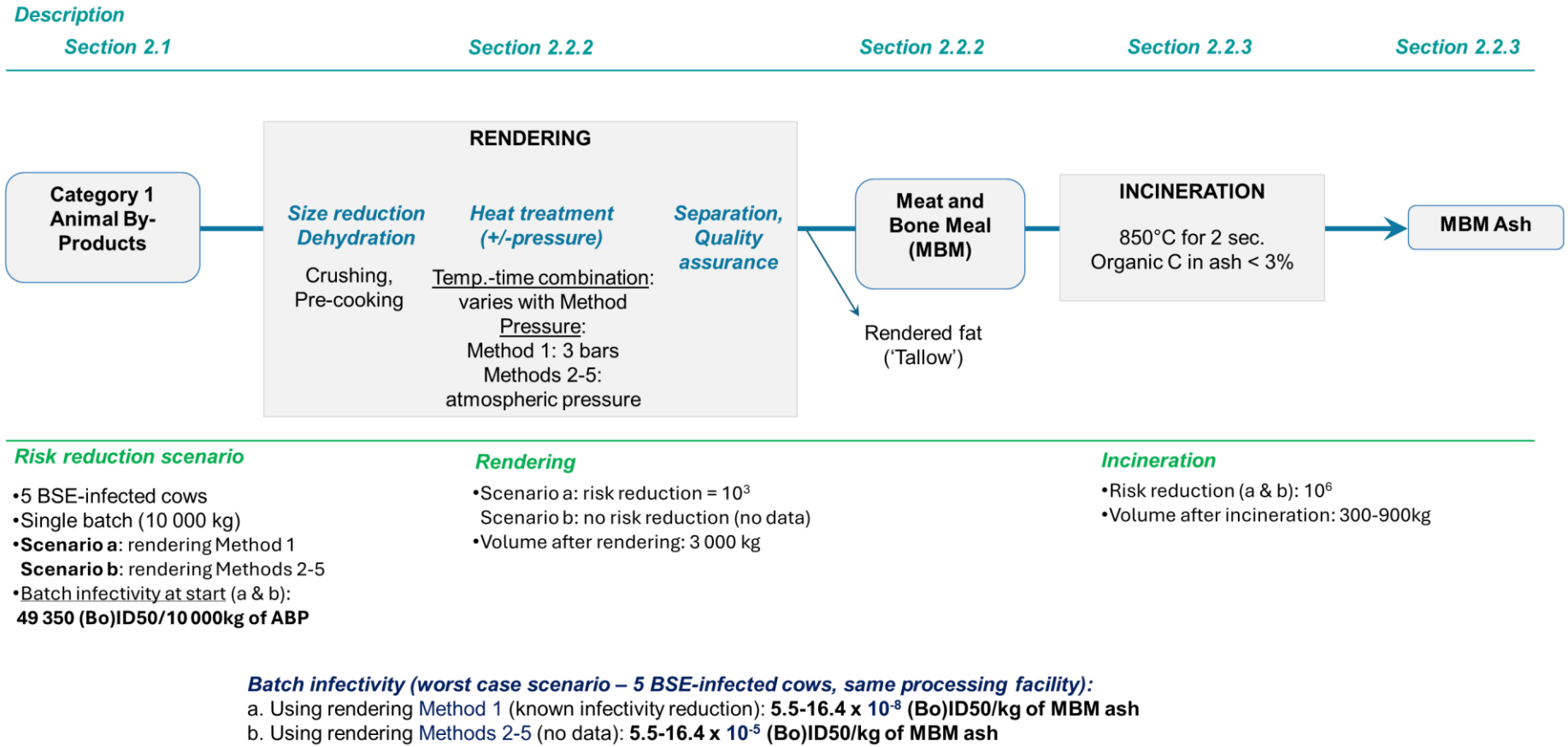

***Figure 1b**: Processing steps of Category 1 Animal By-Products into ash illustrated with a risk reduction scenario.*

3 Use or disposal of Cat1 ABP (MBM) ash

3.1 Current practices in the EU-27

3.1.1 Common practices

In the EU-27, Cat 1 ABP ash (and Cat 1 MBM ash) cannot be used for animal feed. In practice MBM is either incinerated in a cement kiln (in which case the resulting ash is sequestered in concrete), used in power stations using coal or partly other wastes, or processed in dedicated incinerators with possibly other wastes and with energy recovery.

The use of MBM in cement kiln incinerators means that all the MBM is disposed of, leaving no residue for disposal to landfill (Department of Agriculture (Ireland), 2023), but also no possibility to recycle phosphorus for other uses. The cement issued from cement kiln using MBM is directed to the construction sector and for products sold to the general public, without any precautionary requirements.

Cat 1 MBM may also be treated by mono or co-incineration for energy production, and the resulting ash must be managed. National regulations tend to direct Cat 1 MBM ash to landfills (the words "authorised landfills" are not consistently used), but the transfer of responsibility to manage this type of ash is not systematically defined at EU level: it is unclear if Cat 1 MBM ash is generally directed to "Hazardous" or to ordinary landfill in the EU today. There may be variations of interpretation and directions at local level.

Transport of MBM ash from incineration facilities to landfill sites is not subject to specific requirements, and generic health and safety measures apply (EFPRA, pers. comm.).

3.1.2 The case of Portugal: use of Cat 1 MBM ash as fertiliser in forestry

Since 2016, between 2 000 and 2 500 ton per year of bottom ash from Cat 1 MBM rotary kiln have been used as fertiliser in eucalyptus woods in Portugal (ETSA, pers. comm.). Prior to being used in the forestry sector, Cat 1 MBM ash was sent to an approved industrial (non-hazardous) landfill site. The underlying factor enabling this practice is that the MBM ash are considered as non-hazardous waste by the approving authorities.

3.2 Current practices in Switzerland

In Switzerland, the use of ash derived from Cat 1 ABP as fertiliser is in theory possible, for as long as requirements for limiting specific pollutants (such as heavy metals and organic contaminants such as Polycyclic Aromatic Hydrocarbons or PAH) are met (FHNW, pers. comm.). Regulatory requirements for recycling products (risk minimisation, restrictions, and bans) do not include risks related to prions but focus on chemical risks and the mineral composition of the (ash) fertiliser (Federal Council of Switzerland, 2016).

To date, no product containing Cat 1 MBM ash has been registered on the market (Federal Office for Agriculture, pers. comm.). Two companies are active in the processing of Category 1 animal by-products: Centravo (https://www.centravo.ch/en/) and ZAB (https://zab.ch/). They utilise the processed MBM as CO2-neutral fuels. The "by-

products" from energy production are highly polluted wastewater and exhaust air, which are then cleaned in additional production processes. There is no information publicly available on how any ash product is disposed of.

3.3 Current practices in the United Kingdom

Cat 1 ABP cannot be used in fertilisers but ash originating from Cat 1 ABP (MBM ash) has been used as fertiliser in the UK for at least a decade (FabraUK, pers. comm.). Kalfos® is an example (see textbox on next page). The approval to use this type of ash for fertilising follows a case-by-case regulatory assessment, the End-of-Waste test.

In the UK, MBM ash can be considered for use as fertilisers if it receives approval after passing the End of Waste test (Environment Agency, 2012). The risk assessment for this test is based on level of environmental contaminants; the risk in relation to TSE is deemed to be negligible as it is no longer considered to fall under the restrictions of the ABP Regulations. In addition to the waste classification tests for the ash (metals, total organic carbon, dioxins, furans, and Polychlorinated biphenyls (PCBs)), the UK Environment Agency may require a test for presence of protein depending on the testing objectives. The protein test is based on the M4 guidance for ash sampling and analysis and aims to demonstrate the absence of animal protein (Environment Agency, 2016). Analysis of bottom ash and fly ash for total organic carbon and protein may be undertaken at incineration plants processing MBM ash as part of the End of Waste approval process.

In addition, UK sustainable certification schemes (meeting environmental, food safety and animal welfare criteria) have been considering this type of fertilisers: Red Tractor (a farm assurance programme for food products, animal feed and fertiliser) has recently approved the MBM ash-origin fertiliser and Tesco (UK largest supermarket chain) could be next (FabraUK, pers. comm.).

Overall, the five plants incinerating Cat 1 MBM in the UK produce around 70 thousand tons of ash per year (FabraUK, pers. comm.). This volume is high compared to the whole of the EU-27 (up to 310 000 per year, Table 1). It is our understanding that in the UK volumes of Cat 1 ABP are inflated with significant volumes of Cat 2 ABP from the start, whereas in the EU (for example France, Spain) Cat 2 ABP are rendered separately for commercial reasons (SARIA UK, pers. comm.). The volume associated with production of cement is negligible but is significant in some European countries. The vast majority of Cat 1 MBM ash in the UK is today, and has been for a decade or more, used as arable fertiliser under an "End of Waste" status or in fertilising products (SARIA UK, pers. comm.). Before this authorisation of use of Cat 1 ash as fertiliser in the UK, the bottom ash was sent to non-hazardous landfill, but the fly ash was only accepted by hazardous landfill sites, because of its high sulphur content (FabraUK, per. Comm.), not because of any TSE risk-related concern.

Example of the commercial product range Kalfos® in the UK (https://kalfos.co.uk/)

Origin: Cat 1 ABP from the UK under an approval from the UK Department for Environment, Food & Rural Affairs (DEFRA) and a permit from the Environment Agency.

Transformation process: Cat 1 ABP are rendered using Method 4 at an approved facility dedicated to processing Cat 1 ABP. Rendering is only used as a preparation process as the risk reduction step has been agreed by the relevant authorities to be the combustion process. MBM are further processed using fluidised bed combustion technology (Fluid-Phos) that ensures the absence of protein and a TOC of less than 0.1% in the ash products. The phosphate-based ash product is a mixture of coarse ash (20%, 0.5-4mm particle size) and fly ash (80%, less than 0.5mm particle size); it is commercialised as Kalfos® products.

Regulatory status: awarded End of Waste status in 2014 after assessments and testing by Environment Agency's End of Waste panel and DEFRA.

Certifications: it can be utilised on land covered by various farm assurance schemes, including The Red Tractor Scheme.

Production: the SARIA Group produces around 12 000 t/year of phosphorus fertiliser/soil conditioner from MBM ash.

Use: since 2014, KalFos has been used to grow crops and grass (including animal pasture) in the UK. In line with strict rules and regulations that govern the production process, KalFos can be utilised as a fertiliser without requiring any permitting or restrictions as it is no longer under ABP Regulations.

3.4 Current practices in North America

3.4.1 United States (US)

In the US, FDA (Food and Drug Administration)'s animal feed regulations were amended in 2008 to increase protection from BSE; removal of Cattle Material Prohibited in Animal Feed/Food (CPMAF) is deemed central to this protection. CPMAF include SRM (see definition by Code of Federal Regulations, section 2.1.2) as well as products from rendering process (FDA, 2024).

SRM are only removed at slaughterhouses. If SRM cannot be rendered (i.e. if there is no specialised line for treating SRM at a rendering facility), it will be landfilled (EFPRA, pers. comm.). All fallen stock can be rendered for animal feed (all species), but SRM from cattle has to be removed first. Tallow (rendered fat) is often used as feed or biofuel.

On farm, there is no apparent obligation to collect fallen stock, nor to collect SRM from that stock. Fallen stock are buried onsite or sent to landfill but are prohibited from use in animal food or feed (US Code of Federal Regulations, 2024b).

There are no official standards for processing conditions for rendering or incineration (EFPRA, pers. comm.). US legislation does not prohibit the use of CPMAF as fertiliser after rendering (FDA, 2024), but in practice, this material is used more for energy production (EFPRA, pers. comm.).

To date no information could be obtained as to the fate of the ashes after combustion of CPMAF for energy production.

3.4.2 Canada

In Canada, amendments to soil regulations to allow ash from SRM as fertiliser were under consideration: however concerns from the fertilising industry about strong public risk perceptions and lack of competitiveness with non-organic fertiliser production stalled the initiative (EFPRA, pers. comm.). The lack of economic viability of packaging and transport, and of chemical efficiency of SRM transformation meant that the main disposal option was a specific landfill that provided a relatively low disposal cost plus a single bulk shipping route (EFPRA, pers. comm.). Therefore, despite the absence of specific regulatory ban to use processed SRM as fertiliser, the main means of disposal are therefore burial in landfill or incineration (combustion) as fuel (EFPRA, pers. comm.).

4 Disease data

Records of cases of TSEs and vCJD reported by country and year are presented in Appendix 2. Additional context and information are provided in this section.

4.1 Animal TSEs (BSE, Scrapie, Chronic Wasting Disease)

4.1.1 BSE

Data on BSE occurrence worldwide is available through annual reports from EFSA (EFSA, 2023) and WOAH's WAHIS database (https://wahis.woah.org/). A consolidation of cases between 2004 and 2023 (by periods of 5 years) is presented in Appendix 2, Table A.1. The two types of BSE are distinguished: classical BSE (which occurs in bovines after ingesting prion-contaminated feed), which is of interest for this appraisal report, and atypical BSE (suspected to occur spontaneously in all bovine populations and with no recognized link to human vCJD).

No case of classical BSE was found in EU-27 in 2019-2023 (and only 4 in the previous 5-year period). In the UK, 1 case of classical BSE was reported for 2019-2023 (3 in the previous 5-year period). No cases of classical BSE were reported for the US, Canada and Switzerland for 2019-2023.

Note: a single case of classical BSE was confirmed in May 2024 in a 7.5-year-old indigenous cattle in Scotland: "the case was disclosed during routine national statutory surveillance and testing of fallen stock cattle aged over 48 months" (WAHIS, 2024).

4.1.2 Scrapie

Two types of scrapie exist in sheep and goats: the classical form is a long-known pathology that is transmissible between individuals (TSE), while the atypical form, more recently discovered seems to be naturally occurring in older animals. There is no evidence of a causal link between classical or atypical scrapie and human TSEs (WOAH, 2022).

Tables on scrapie in goats and sheep (Tables A.2 and A.3 respectively) were consolidated from data from EFSA for the EU-27 and UK, and from WOAH for the US and Canada. In the EU and for the period 2019-2023, two countries account for the majority of cases for classical scrapie in goats - Cyprus and Estonia; likewise, Greece and Spain had the majority of cases in sheep over the same period.

4.1.3 Chronic Wasting Disease

Data for Chronic Wasting Disease (CWD) for the EU-27 was obtained from EFSA (EFSA Panel on Biological Hazards, 2023). The first detection of CWD in the European region was in Norway in 2016 (Norwegian Veterinary Institute, 2016). Table 2 below presents the cases reported across Finland (FI), Sweden (SE) and Norway (NO) since 2016 and up to 2022.

In the US, CWD occurs on average in 10% of free-ranging deer and elk (USGS National Wildlife Health Center, 2024). The disease is widespread across the US and has been reported in 34 states in the US since first being identified in wild deer in 1981. The infection

rates among captive deer can be much higher, with a prevalence of 79% (nearly 4 in 5) reported from at least one captive herd (CDC, 2024a). For Canada, domestic cervid herds (elk and deer) confirmed positive for CWD are listed on an official website (data is available since 2011; CFIA, 2024). During the period 2016-2024, a total of 62 positive animals were reported.

***Table 3**: Number of reported Chronic Wasting Disease (CWD) cases in Europe by country and year, 2016-2022.*

Country	2016	2017	2018	2019	2020	2021	2022	Total
Finland			1		1			**2**
Norway	5	8	7	2	2	3	3	**25**
Sweden				3	1			**4**
Total	**5**	**8**	**8**	**5**	**4**	**3**	**3**	**31**

4.2 Variant Creutzfeldt Jacob Disease in humans

Variant Creutzfeldt-Jakob disease (vCJD) is classified as a TSE; most reported cases seem to have been infected through the consumption of bovine meat products contaminated with the agent of BSE[1] (ECDC, 2017).

Data on vCJD from ECDC resources (Creutzfeldt-Jakob Disease International Surveillance Network, 2021; ECDC, 2024) were consolidated in Table 3. France and the UK lead the number of cases, with the highest annual incidence in the mid-2000s.

The last case of vCJD in the UK was in 2016.

The US has had a total of 4 vCJD cases, the latest in 2014 (CDC, 2024b); in Canada, the last case was reported in 2011 (Government of Canada, 2024).

***Table 4:** Number of reported variant Creutzfeldt-Jakob disease (vCJD) cases by country, 2004–2021.*

Country	2004-2008	2009-2013	2014-2018	2019-2021	Total
France	17	3	2	1	**23**
Spain	4	1	0	0	**5**
Ireland	3	0	0	0	**3**
Italy	0	1	1	0	**2**
Netherlands	3	0	0	0	**3**
Portugal	1	1	0	0	**2**
Total EU-27	**28**	**6**	**3**	**1**	**38**
UK	26	12	1	0	**39**
USA	3	0	1	0	**4**
Canada	0	1	0	0	**1**
Total non-EU	**29**	**13**	**2**	**0**	**44**

[1] ECDC: "in three cases, reported by the UK, the mode of transmission is thought to be through receipt of blood from an asymptomatic, infected donor".

5 Synthesis: appraisal of evidence

Risk appraisal in context

The present report is based on a combination of official publicly available information, scientific publications, grey literature and personal communications from diverse industry groups (across the rendering, waste management and fertiliser sectors). Analysis and appraisal of the data were undertaken within this context.

Risk minimisation: the role of rendering and incineration

The evidence gathered suggests that rendering treatment of animal by-products in accordance with EU requirements contributes to prion risk reduction in the resulting product, meat and bone meal, but data is only available for Method 1, not for the other methods routinely used by industry.

Incineration of meat and bone meal at the conditions set by the Industrial Emissions Directive results in ash which composition supports the negligible risk of fly ash and slag for prion protein.

Using risk reduction factors for rendering and for incineration from the 1998-1999 European Commission Scientific Steering Committee reports and a worst-case scenario of BSE-infected cattle entering the Category 1 processing chain, the overall BSE infectivity reduction factor under normal operative conditions should be somewhere between 30-100 thousand and 10-30 million.

From fertiliser to animal feed to food?

The risk appraisal undertaken for this report does not consider the use of ash from meat and bone meal for animal feed or in the human food chain. Only ash intended for use as fertiliser or in fertiliser production was considered.

There is currently no applicable study to determine if any BSE prion hypothetically present in ash-based fertiliser could be absorbed by plants and ingested as infective prions by grazing cattle under natural conditions. Yet the practice of fertilising fields with fertilisers with ash from processed Category 1 animal by-products has taken place for over a decade in the UK, without any noticeable increase in cases of classical BSE in the region. It is worth noting that this practice started at a time when the incidence of BSE cases was still higher than it is today.

What does the disease data tell us?

Overall BSE incidence has been consistently declining since 2004. Classical BSE cases are now rare (but not nil). In countries where ash produced from Category 1 animal by-products is used as fertiliser (UK, Portugal), there is no evidence that reduction of classical BSE cases stalled or even increased. In particular, the use of approximately 70 000 tons per year of Cat 1 MBM ash as fertiliser for over a decade in the UK has not resulted in any detectable transmission of BSE to cattle or to humans.

The situation with Chronic Wasting Disease in free-ranging cervids in North America since the 1980s suggests that despite the presence of infected animals across an increasingly large area, and the difficulty in removing infected cases from the population, no evidence of prion transmission from cervids to humans (through consumption of game meat or contact with infected animals or materials) has been documented.

Data from other Transmissible Spongiform Encephalopathies provide useful insights into the effectiveness of measures to reduce the number of infected animals entering the animal feed and food chain. Where they can be applied, measures such as separation of risk material for treatment and surveillance systems contribute to removing TSE risk material from the animal food chain and production environment.

Conclusion

This report found no evidence to suggest that ash produced from Category 1 animal by-products treated according to EU regulations, and used as fertiliser after approval poses a risk of BSE transmission.

6 References

Adkin A., Donaldson N., Kelly L., 2013. A quantitative assessment of the amount of Prion diverted to Category 1 materials and wastewater during processing. Risk Analysis, 33 (7), 1197-1211.

Adkin A., Simmons R. and Arnold M., 2014. TSE infectivity model (TSEi) in animal tissues: bovine intestines and mesenteries. EFSA supporting publication 2014:EN-559, 74 pp BSE_risk_may14.pdf (dtu.dk)

The Animal By-Products (Enforcement) (England) Regulations 2013, SI No 2013/2952. https://www.legislation.gov.uk/uksi/2013/2952

Brown P., Rau E.R., Johnson B., Bacote A., Gibbs C., Gajdusek, D., 2000. New studies on the heat resistance of hamster-adapted scrapie agent: Threshold survival after ashing at 600ºC suggests an inorganic template of replication. Proceedings of the National Academy of Sciences of the United States of America. 97. 3418-21. 10.1073/pnas.050566797.

Brown P., Rau E.R., Lemieux P., Johnson B.K., Bacote A.E., and Gajdusek D.C., 2004. Infectivity Studies of Both Ash and Air Emissions from Simulated Incineration of Scrapie- Contaminated Tissues. *Environmental Science & Technology 38* (22), 6155-6160. DOI: 10.1021/es040301z

Carlson C. M., Thomas S., Keating M. W., Soto P., Gibbs N. M., Chang H., Wiepz J. K., Austin A. G., Schneider J. R., Morales R., Johnson C. J., and Pedersen J. A., 2023. Plants as vectors for environmental prion transmission. *iScience*, *26*(12), 108428. https://doi.org/10.1016/j.isci.2023.108428

CDC, 2024a. Where CWD Occurs. https://www.cdc.gov/chronic-wasting/data-research/index.html (Accessed online 13 April 2024).

CDC, 2024b. About Variant Creutzfeldt-Jakob Disease (vCJD). https://www.cdc.gov/variant-creutzfeldt-jakob/about/?CDC_AAref_Val=https://www.cdc.gov/prions/vcjd/vcjd-reported.html (Accessed online 13 April 2024).

CFIA, 2024. Herds infected with chronic wasting disease in Canada. https://inspection.canada.ca/en/animal-health/terrestrial-animals/diseases/reportable/cwd/herds-infected (Accessed online 2 May 2024).

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that. https://eur-lex.europa.eu/eli/reg/2011/142/oj

Coutand M., Cyr M., Deydier E., Guilet R. and Clastres P., 2008. Characteristics of industrial and laboratory meat and bone meal ashes and their potential applications. Journal of Hazardous Materials, 150 (3), 522-532. doi: 10.1016/j.jhazmat.2007.04.133

Creutzfeldt-Jakob Disease International Surveillance Network, 2021. A University of Edinburgh project (data collected until 2021), https://www.eurocjd.ed.ac.uk/data

Cummins E. and Adkin, A., 2007. Exposure Assessment of TSEs from the land spreading of Meat and Bone Meal. *Risk Analysis, 27(5), 1179–1202*. doi:10.1111/j.1539-6924.2007.00953.x

Department of Agriculture, Food and the Marine (Ireland), 2023. Scheme to facilitate the use of meat and bonemeal as a renewable energy source in the cement industry. https://www.gov.ie/en/service/ae7da-scheme-to-facilitate-the-use-of-meat-and-bonemeal-as-a-renewable-energy-source-in-the-cement-industry/

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control). http://data.europa.eu/eli/dir/2010/75/oj

DNV, 1997a. Overview of Risk from BSE via Environmental Pathways. Report to the Environment Agency. Det Norske Veritas C7243.

DNV, 1997b. Risks from Disposing BSE Infected Cattle in Animal Carcass Incinerators. Report to the Environment Agency. Det Norske Veritas C7243.

DNV, 1997c. Risks from Burning Rendered Products from the Over Thirty Month Scheme in Power Stations. Report to the Environment Agency. Det Norske Veritas C7243.

ECDC, 2017. Facts about variant Creutzfeldt-Jakob disease. https://www.ecdc.europa.eu/en/vcjd/facts (Last updated: 26.06.2017).

ECDC, 2024. Surveillance and disease data for variant Creutzfeldt-Jakob disease https://www.ecdc.europa.eu/en/vcjd/surveillance (Accessed online 1 May 2024).

European Commission Food Safety, 2024. Animal by-products. https://food.ec.europa.eu/safety/animal-products_en (Accessed online 1 May 2024).

EC SSC, 1998a. Opinion of the Scientific Steering Committee on the safety of meat and bone meal from mammalian animals, naturally or experimentally susceptible to Transmissible Spongiform Encephalopathies. Adopted on 26-27 March 1998. 3e640b3b-f44a-44e0-953a-6ed0e16f396a_en (europa.eu)

EC SSC, 1998b. Opinion of the Scientific Steering Committee on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent. Adopted by the Scientific Steering Committee at its meeting of 24-25 September 1998. out24_en.pdf (europa.eu)

EC SSC, 1999. Scientific Report of the European Commission Scientific Steering Committee on the Risks of Non-Conventional Transmissible Agents, Conventional Infectious Agents or Other Hazards such as Toxic Substances Entering the Human Food or Animal Feed Chains via Raw Material from fallen Stock and Dead Animals (including also: Ruminants, Pigs, Poultry, Fish, Wild/Exotic/Zoo Animals, Fur Animals, Cats, Laboratory Animals and Fish) or via Condemned Materials. https://food.ec.europa.eu/document/download/2b06b2a8-ad5c-4c85-9cee-fa9787f33a5b_en

EFPRA, 2022. Rendering in numbers [Infographic]. Available at: https://efpra.eu/publications/

EFSA, 2023. Data collection: transmissible spongiform encephalopathies (TSEs). https://www.efsa.europa.eu/en/resources/data-collection-tse

EFSA Panel on Biological Hazards, 2018. Scientific opinion on an updated quantitative risk assessment (QRA) of the BSE risk posed by processed animal protein (PAP). EFSA Journal, 16(7):5314, 111 pp. doi: 10.2903/j.efsa.2018.5314

EFSA Panel on Biological Hazards, 2023. Monitoring of chronic wasting disease (CWD) (IV). EFSA Journal, 21(4):7936. doi: 10.2903/j.efsa.2023.7936

Environment Agency, 2016. Technical Guidance Note: M4 Guidelines for Ash Sampling and Analysis. https://www.gov.uk/government/publications/m4-guidelines-for-ash-sampling-and-analysis

ESPP, 2023. Category 1 animal by-product ash safety and prions [Webinar], held on 22 May 2023. https://www.phosphorusplatform.eu/images/Regulatory%20activities/Summary%20ESPP%20ABP%20webinar%2022_5_23.pdf

FDA, 2024. Feed Ban Enhancement: Implementation Questions and Answers. https://www.fda.gov/animal-veterinary/bovine-spongiform-encephalopathy/feed-ban-enhancement-implementation-questions-and-answers#Disposal (Content current as of 04.29.2024).

Federal Council of Switzerland, 2016. Notification Authority for Chemicals: Chemical Risk Reduction Ordinance (ORRChem). https://www.anmeldestelle.admin.ch/chem/en/home/themen/recht-wegleitungen/chemikalienrecht/chemikalien-risikoreduktionsverordnung.html

Government of Canada, 2024. Creutzfeldt-Jakob disease surveillance system (CJDSS) report. https://www.canada.ca/en/public-health/services/surveillance/blood-safety-contribution-program/creutzfeldt-jakob-disease/cjd-surveillance-system.html#cases. (Accessed online 1 May 2024).

Health of Animals Regulations, 2022a. C.R.C. c. 296, Part I.1 Specified Risk Material (2022). https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._296/page-2.html#h-547002

Health of Animals Regulations, 2022b. C.R.C. c. 296, Part II Importation (2022). https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._296/page-2.html#h-547068

Norwegian Veterinary Institute, 2016. The first detection of Chronic Wasting Disease (CWD) in Europe. https://www.vetinst.no/sykdom-og-agens/chronic-wasting-disease/the-first-detection-of-chronic-wasting-disease-cwd-in-europe

Paisley L.G., and Hostrup-Pedersen J., 2005. A quantitative assessment of the BSE risk associated with fly ash and slag from the incineration of meat-and-bone meal in a gas-fired power plant in Denmark. Preventive Veterinary Medicine, 68 (2-4), 263-275. doi: 10.1016/j.prevetmed.2005.01.010

Pritzkow S., Morales R., Moda F., Khan U., Telling G. C., Hoover E., and Soto C. 2015. Grass plants bind, retain, uptake, and transport infectious prions. *Cell reports,* 11(8):1168-1175. doi:10.1016/j.celrep.2015.04.036

Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. https://eur-lex.europa.eu/eli/reg/2001/999/oj

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). https://eur-lex.europa.eu/eli/reg/2009/1069/oj

Regulation (EU) No 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003. https://eur-lex.europa.eu/eli/reg/2019/1009/oj

Taylor D. M., Woodgate S. L., and Atkinson, M. J., 1995. Inactivation of the bovine spongiform encephalopathy agent by rendering procedures. *The Veterinary record*, *137*(24), 605–610.

Taylor D.M., Woodgate S.L., Fleetwood A.J., Cawthorne R.J.G., 1997. The effect of rendering procedures on scrapie agent. Veterinary Record, 141: 643-649.

Taylor D.M., Fernie K., McConnell I., Ferguson C.E. and Steele P.J., 1998. Observations on thermostable subpopulations of the unconventional agents that cause transmissible degenerative encephalopathies. Veterinary Microbiology, 64, 33–38. doi: 10.1016/S0378-1135(98)00257-0

Taylor D.M. and Woodgate S.L., 2003. Rendering practices and inactivation of transmissible spongiform encephalopathy agents. Scientific & Technical Review, 22 (1): 297-310. doi: 10.20506/rst.22.1.1400

US Code of Federal Regulations, 2024a. Title 9 Animals and Animal Products, Chapter III – Food Safety and Inspection Service, Department of Agriculture, Part 310.22 Specified materials from cattle and their handling and disposition: eCFR :: 9 CFR 310.22 -- Specified risk materials from cattle and their handling and disposition (Accessed online 16 May 2024).

US Code of Federal Regulations, 2024b. Title 21 Food and Drugs, Chapter I – Food and Drug Administration, Department of Health and Human Services, Subchapter E – Animal Drugs, Feeds, and Related Products, Part 589 – Substances prohibited from use in animal food or feed, Subpart B, § 589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy. eCFR :: 21 CFR 589.2001 -- Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy. (Accessed online 16 May 2024).

US Geological Survey (USGS) National Wildlife Health Center, 2024. Distribution of Chronic Wasting Disease in North America (map). Distribution of Chronic Wasting Disease in North America | U.S. Geological Survey (usgs.gov) (Accessed online 7 May 2024).

Wagner D., Neugebauer G., Kretschmer F. and Stoeglehner G., 2020. Integrating Life-Cycle Perspectives and Spatial Dimensions of Sewage Sludge Mono-Incineration. Water, 12 (5): 1267. doi: 10.3390/w12051267

WAHIS, 2024. Report preview: United Kingdom - Bovine spongiform encephalopathy - Follow up report 1. Report date: 17.05.2024. https://wahis.woah.org/#/in-review/5667

WOAH, 2022. Terrestrial Manual, Chapter 3.8.11. Scrapie. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/

WOAH, 2023a. Bovine spongiform encephalopathy. https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/. (Last update: 30.05.2023)

WOAH, 2023b. Terrestrial Animal Health Code, Article 4.13.6 Recommended methods for the disposal of dead animals. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_disposal.htm

Woodgate S.L., 2023. Meat industry by-products: a bio-refinery approach to the production of safe, value-added products for sustainable agriculture applications. Frontiers in Animal Science, 4: 1259200. doi: 10.3389/fanim.2023.1259200

Woodgate S.L. and Wilkinson R.G., 2021. The role of rendering in relation to the bovine spongiform encephalopathy epidemic, the development of EU animal by-product legislation and the reintroduction of rendered products into animal feeds. Annals of Applied Biology, 178 (3), 430-441. doi: 10.1111/aab.12676

Appendices

Appendix 1 - Regulatory definitions (extracts from European Legislation)

In: **Regulation (EC) No 1069/2009** of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

Animal By-Products (Chapter I, Section 1, Article 3):
'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;

Category 1 material (Chapter I, Section 3, Article 8):
Category 1 material shall comprise the following animal by-products:

(a) entire bodies and all body parts, including hides and skins, of the following animals:
  (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed;
  (ii) animals killed in the context of TSE eradication measures;
  (iii) animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;
  (iv) animals used for experiments as defined by Article 2(d) of Directive 86/609/EEC without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;
  (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

(b) the following material:
  (i) specified risk material;
  (ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal;

(c) animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;

(d) animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;

(e) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:
  (i) from establishments or plants processing Category 1 material; or
  (ii) from other establishments or plants where specified risk material is being removed;

(f) catering waste from means of transport operating internationally;

(g) mixtures of Category 1 material with either Category 2 material or Category 3 material or both.

Disposal and use of Category 1 material (Chapter II, Section 2, Article 12):
Category 1 material shall be:

(a) disposed of as waste by incineration:
  (i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(b) recovered or disposed of by co-incineration, if the Category 1 material is waste:

(i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(c) in the case of Category 1 material other than material referred to in Article 8(a)(i) and (ii), disposed of by processing by pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill;

(d) in the case of Category 1 material referred to in Article 8(f), disposed of by burial in an authorised landfill;

(e) used as a fuel for combustion with or without prior processing; or

(f) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

In: **Regulation (EC) No 999/2001** of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

"CATEGORIES" below refer to the category of EU Member State, i.e. Category 1 is a country or region free of BSE; Category 2 is a BSE provisionally free country or region where no indigenous case has been reported; Categories 3 and 4 are countries with one or more reported indigenous case(s) and low incidence, and Category 5 is for countries with high BSE incidence, which does not currently apply.

SPECIFIED RISK MATERIAL (SRM) (Annex V)

1. The following tissues shall be designated as specified risk material depending on the category of the Member State or third country of origin or residence of the animal, determined in accordance with Article 5:

CATEGORIES 1 AND 2

None.

CATEGORIES 3 AND 4

(a) the skull including the brain and eyes, the tonsils and the spinal cord of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum of bovine animals of all ages;

(b) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

The following material is currently designated as **SRM** in accordance with point 1 of Annex V of EC Regulation 999/2001 (as amended):

Cattle

• All ages – the tonsils, the last four metres of small intestine, the caecum, and the mesentery. • Over 12 months – skull excluding the mandible but including the brains and eyes, and spinal cord. • Over 30 months – vertebral column, excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae, the median sacral crest and the wings of the sacrum, but including the dorsal root ganglia.

Sheep and goats

• All ages – the spleen and the ileum. • Over 12 months (or have a permanent incisor erupted) – skull including the brains and eyes, tonsils, spinal cord.

Appendix 2 - Occurrence of animal TSE and human vCJD in the European Union and selected countries, 2000-2023.

Table A.1: Number of Bovine Spongiform Encephalopathy (BSE) cases by country and year, 2004–2023

Classical BSE Cases						Atypical BSE Cases				
Country	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023**	**Total**	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023**	**Total**
Austria	4	0	0	0	**4**	1	2	0	0	**3**
Belgium	15	0	0	0	**15**	0	0	0	0	**0**
Czechia	19	2	0	0	**21**	1	0	0	0	**1**
Germany	118	2	0	0	**120**	1	0	2	1	**4**
Denmark	1	1	0	0	**2**	1	0	0	0	**1**
Greece	0	0	0	0	**0**	0	0	0	0	**0**
Spain	370	36	1	0	**407**	4	8	6	6	**24**
Finland	0	0	0	0	**0**	0	0	0	0	**0**
France	95	11	1	0	**107**	11	10	11	10	**42**
Ireland	284	15	1	0	**300**	0	3	1	1	**5**
Italy	24	1	0	0	**25**	1	2	0	0	**3**
Luxemburg	1	0	0	0	**1**	0	0	0	0	**0**
Netherlands	14	2	0	0	**16**	0	1	0	1	**2**
Poland	47	5	0	0	**52**	8	6	0	1	**15**
Portugal	203	17	1	0	**221**	6	1	0	0	**7**
Romania	0	0	0	0	**0**	0	0	2	0	**2**
Sweden	0	0	0	0	**0**	1	0	0	0	**1**
Slovenia	5	0	0	0	**5**	0	0	1	0	**1**
Slovakia	13	1	0	0	**14**	0	0	0	0	**0**
Total EU27	**1'213**	**93**	**4**	**0**	**1'310**	**35**	**33**	**23**	**20**	**111**
UK	765	30	3	1	**799**	9	6	1	1	**17**
Canada	14	3	1	0	**18**	0	0	0	1	**1**
Switzerland	11	0	0	0	**11**	0	3	0	3	**6**
USA	2	0	0	0	**2**	0	1	2	1	**4**
Total non-EU	**792**	**33**	**4**	**1**	**830**	**9**	**10**	**3**	**6**	**28**

Table A.2: Number of Scrapie cases in goats by country and year, 2004–2023.

Classical Scrapie Cases in Goats						Atypical Scrapie Cases in Goats				
Country	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023[1]**	**Total**	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023[1]**	**Total**
Austria	0	0	0	0	**0**	0	0	1	0	**1**
Bulgaria	0	4	10	20	**34**	0	0	0	0	**0**
Cyprus	3'190	4'239	3'722	813	**11'964**	0	0	3	1	**4**
Germany	0	0	0	0	**0**	0	0	2	1	**3**
Denmark	0	0	0	0	**0**	0	0	0	1	**1**
Greece	160	313	108	88	**669**	0	1	4	0	**5**
Spain	35	26	166	127	**354**	15	17	21	9	**62**
Finland	4	0	0	0	**4**	0	1	0	0	**1**
France	43	61	45	0	**149**	20	23	15	7	**65**
Hungary	0	0	0	1	**1**	0	0	0	0	**0**
Italy	25	36	59	70	**190**	10	7	9	11	**37**
Poland	0	0	0	0	**0**	0	0	0	1	**1**
Portugal	0	0	0	0	**0**	2	10	1	2	**15**
Romania	2	4	10	10	**26**	0	0	0	0	**0**
Slovenia	4	0	0	0	**4**	0	0	1	0	**1**
Total EU27	**3'463**	**4'683**	**4'120**	**1'129**	**13'395**	**47**	**59**	**57**	**33**	**196**
UK	116	60	55	2	**233**	0	0	0	0	**0**
USA[2]	6	14	11	0	**31**	NA	NA	NA	NA	**NA**
Canada[2]	1	1	132	0	**134**	NA	NA	NA	NA	**NA**
Total non-EU	**123**	**75**	**198**	**2**	**398**	**0**	**0**	**0**	**0**	**0**

[1]Data on scrapie cases in 2023 for the EU-27 Member States were not available at the time of this report.
[2]Case classifications for classical and atypical cases unavailable.
NA = not available

Table A.3: Number of Scrapie cases in sheep by country and year, 2004-2023.

Classical Scrapie Cases in Sheep						Atypical Scrapie Cases in Sheep				
Country	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023[1]**	**Total**	**2004-2008**	**2009-2013**	**2014-2018**	**2019-2023[1]**	**Total**
Austria	0	0	0	0	**0**	0	9	6	1	**16**
Belgium	12	0	0	0	**12**	7	0	0	2	**9**
Bulgaria	2	6	9	14	**31**	2	2	2	0	**6**
Cyprus	2'896	263	51	7	**3'217**	0	0	0	0	**0**
Czechia	27	0	0	0	**27**	1	0	7	0	**8**
Germany	79	1	1	0	**81**	37	58	33	24	**152**
Denmark	0	0	0	0	**0**	5	7	2	1	**15**
Estonia	0	0	0	0	**0**	0	2	0	0	**2**
Greece	1'207	3'377	1'461	671	**6'716**	6	17	9	1	**33**
Spain	559	334	722	857	**2'472**	74	97	52	35	**258**
Finland	0	0	0	0	**0**	5	5	5	5	**20**
France	1'089	44	31	0	**1'164**	424	115	24	25	**588**
Croatia	0	0	0	0	**0**	0	1	1	4	**6**
Hungary	7	2	1	0	**10**	16	54	86	66	**222**
Ireland	335	109	33	0	**477**	4	16	24	9	**53**
Italy	1'081	875	915	591	**3'462**	59	19	24	22	**124**
Netherlands	260	8	0	0	**268**	4	14	0	0	**18**
Poland	0	0	0	0	**0**	0	17	43	24	**84**
Portugal	12	14	7	6	**39**	338	203	137	93	**771**
Romania	38	427	547	273	**1'285**	0	0	0	1	**1**
Sweden	0	0	0	0	**0**	13	15	17	4	**49**
Slovenia	169	7	0	0	**176**	0	4	6	3	**13**
Slovakia	86	8	34	0	**128**	1	15	22	22	**60**
Total EU27	**7'859**	**5'475**	**3'812**	**2'419**	**19'565**	**996**	**670**	**500**	**342**	**2'508**
UK	948	158	2	9	**1'117**	176	115	71	45	**407**
USA[2]	1'317	206	31	1	**1'555**	NA	NA	NA	NA	**NA**
Canada[2]	31	346	32	0	**409**	NA	NA	NA	NA	**NA**
Total non-EU	**2'296**	**710**	**65**	**10**	**3'081**	**176**	**115**	**71**	**45**	**407**

[1] Data on scrapie cases in 2023 for the EU-27 Member States were not available at the time of this report.
[2] Case classifications for classical and atypical cases unavailable.
NA = not available

SAFOSO

Because Animal Health Matters.

SAFOSO AG
Waldeggstrasse 1
3097 Liebefeld
Switzerland

phone +41 31 544 25 00
info@safoso.ch

www.safoso.ch