



SAFOSO

Because Animal Health Matters.

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



Project report - DRAFT

Safety of Category 1 animal by-products ash for use as fertiliser



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

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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
EFRA	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)



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, 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 produced to fertiliser. The current regulation on fertilising products (Regulation (EU) 2019/1009) does not mention Cat 1 ABP ash but mentions Cat 2 and Cat 3 ABP ash as a potential source of elements for 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 using Category 1 ABP ashes as a source of recycled Phosphorus for fertilisers. The European Sustainable Phosphorus Platform (ESPP) asked SAFOSO for a risk appraisal report which could potentially guide ESPP's narrative when communicating with EFSA 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 material with Categories 2 and/or 3 is classified as Category 1.

The disposal of Cat1 ABP and SRM (that are not treated) 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 Category 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 (Specified risk materials from cattle and their handling and disposition, 9 CFR 310.22). 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. C.R.C. c. 296, Part I.1). 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. C.R.C. c. 296, Part II).

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 can be registered by the authorities to provide both types of treatment. The term *pre-rendering* was found in the grey literature and is assumed to refer to a size reduction step before they can be further processed (e.g. cutting up of large carcasses, crushing to compact volumes). If undertaken at a slaughterhouse, such pre-rendering would have to be approved by the relevant authorities. 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.

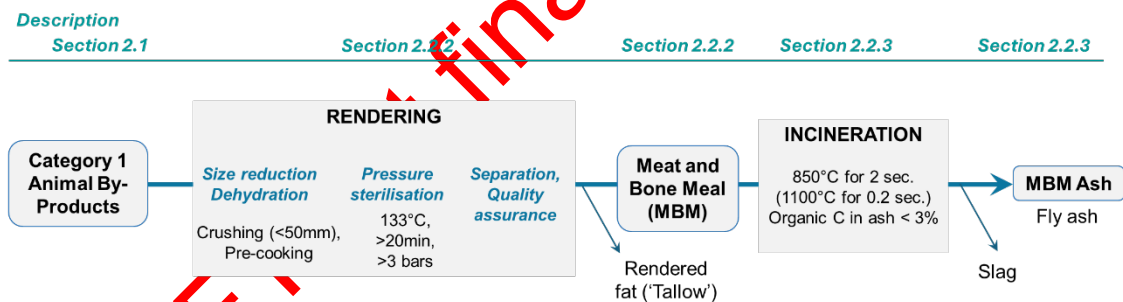


Figure 1a: Processing steps of Category 1 Animal By-Products into ash with reference to relevant report sections.



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 Cat1 ABPs, usually a mix of Cat1 and Cat2 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, Animal by-products
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. 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 Cat 1, Cat 2 and partly Cat 3 ABPs (EFPRA, pers. comm.).

Rendering consists in applying both heat and pressure 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. The treatment then breaks open the cell structures and facilitates the separation of fat from protein, all sterilised in the process (Woodgate, 2023). The final end-products are water, meat and bone meal (MBM) and rendered fat (tallow).

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”. The other four methods are variations from Method 1.

Method 1 is compulsory in some Member states (e.g., Germany, Austria). 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 (EFPR, 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** prior to incineration (EFPR, pers. comm.).

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 oxidation 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 (EFPR, 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 (EFPR, pers. comm.).

The most common type of incinerators is a rotating kiln, in which the material is burnt in a rotating chamber (EFPR, pers. comm.). The conditions used by industry for waste incineration are 850 °C 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, 1100°C for 0.2 sec is an option but in practice it is only used to process fats, not MBM (EFPR, 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 collected at the bottom of the incineration grate. It consists 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 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.

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 (EFPR, 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 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 Cat1 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 a 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 was considered by EFSA in assessing the risk of BSE contaminated processed animal proteins (PAP) entering cattle feed in the EU-28 and potential new BSE cases (EFSA Panel on Biological Hazards, 2018). One of the model scenarios assumed the absence of controls at abattoirs to remove SRM and the absence of BSE infectivity reduction through rendering followed by the use 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 EU and the UK is highly unlikely.

Consideration of TSE infectivity in **incineration** products should take into account the difference in composition between slag, bottom ash and fly ash. For example, these differences in BSE risk were modelled in the study by Paisley & Hostrup-Pedersen (2005) for fly ash and slag.

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 conservative scenario

To illustrate the reduction of BSE infectivity of Cat 1 ABP resulting from rendering and incineration processes, a conservative scenario 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 followed by incineration in line with required parameters.

Rationale and assumptions

- 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
- 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, which amounts to 49 350 BoID50 for our estimation scenario (5 infected cows).

- 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 is recognised to be "not less than 10^3 " (EC, 1999). Therefore after rendering the scenario batch, the remaining infectivity is: $49\,350 \times 10^{-3}$ BoID50. The volume of Cat 1 MBM is reduced down to 30% of the initial theoretical volume, i.e. 3 000 kg (DNV, 1997c). The infectivity is $49.35 \text{ BoID50} / 3\,000 \text{ kg}$ (or $16.45 \times 10^{-3} \text{ BoID50} / \text{kg}$).

- Batch infectivity after incineration:

As per DNV (1997a, b), the risk reduction for BSE infectivity after incineration 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). The infectivity therefore becomes: $49.35 \times 10^{-6} \text{ BoID50} / 300-900 \text{ kg}$ of MBM ash, or $5.5-16.4 \times 10^{-8} \text{ BoID50/kg}$.

The overall infectivity reduction factor is in the order of 10 to 30 million from the initial scenario batch of 5 infected cows in a single 10000 kg batch for rendering to the resulting ash after incineration (per kg unit).

Contextualisation of BSE risk exposure to cattle

The level of exposure ($5.5-16.4 \times 10^{-8} \text{ Bo ID50/kg}$ of Cat 1 MBM ash) suggests that a cattle would need to consume significantly large volumes of ash to become infected. This situation is highly improbable, especially if the ashes were used as fertilizer or in fertilising products, and dispersed across a grazing field.

We considered the probability of cattle ingesting the needed amount of Cat 1 MBM ash (hypothetically used directly as fertiliser) to become infected with BSE, when the fertiliser would be applied at a standard rate on

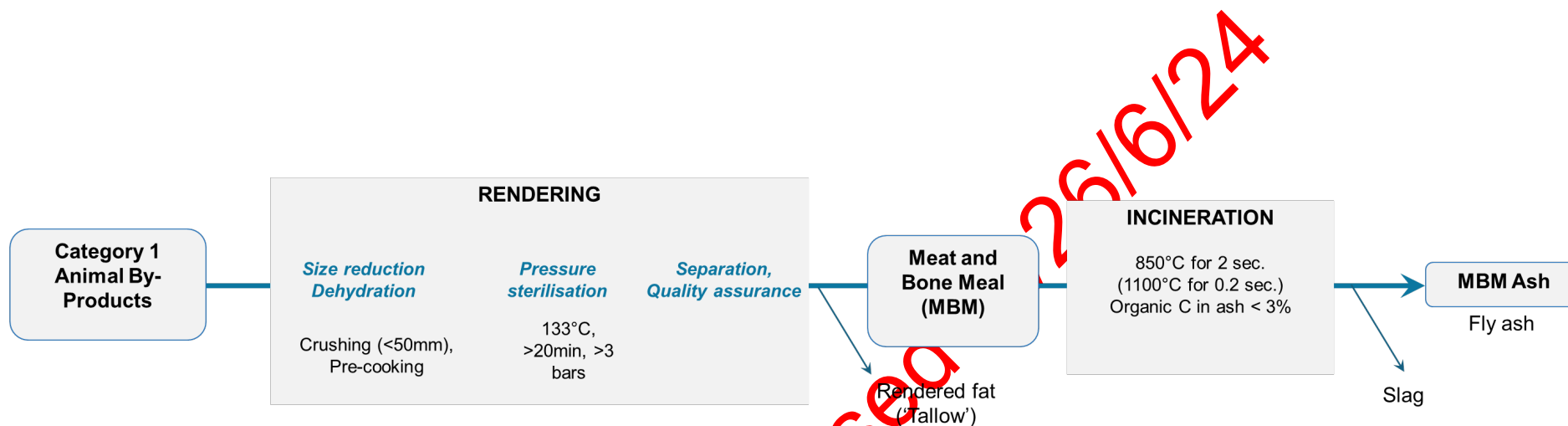


grazing fields. However, given the scale of dilution of the infectivity risk and the uncertainty and multiplicity of environmental and management factors, it was decided not to pursue the estimation.

The review of risk of BSE infectivity 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).

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Risk reduction scenario

- 5 BSE-infected cows
- Single batch (10 000 kg)
- Batch infectivity at start:
 $9\,870 \times 5 \text{ (Bo)ID}_{50}/10\,000\text{kg}$
 = **49 350 (Bo)ID₅₀/10 000kg**

Rendering

- Risk reduction: 10^3
- Volume after rendering: 3 000 kg
- Batch infectivity after rendering:
49.35 (Bo)ID₅₀/3 000kg

Incineration

- Risk reduction: 10^6
- Volume after incineration: 300-900kg
- Batch infectivity after incineration:
 $49.35 \times 10^{-6} \text{ (Bo)ID}_{50}/300\text{-}900\text{kg}$
 = **5.5-16.4 x 10^{-8} (Bo)ID₅₀/kg of MBM ash**

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

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 (and sequestered in concrete) or used in power stations using coal or partly other wastes. While landfill of Cat 1 MBM is an option, the use of MBM in cement kiln incinerators presents major economic and logistic advantages as all the MBM is disposed of, leaving no residue for disposal to landfill (Department of Agriculture, 2023).

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 can be treated as municipal waste from incineration or whether they should be directed to dedicated landfills (there is no evidence of such landfill existence). There may be variations of interpretation and directions at local level.

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

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 (ORRChem, 2016 Ref).

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.).

To provide some context around volumes of Cat 1 MBM incinerated each year in the UK (for energy production), the ash produced from five plants average 70 thousand tons per year. The volume associated with production of cement is negligible. The vast majority of Cat 1 MBM ash is used as arable fertiliser under an “End of Waste” status or in fertilising products (SARIA UK, pers. comm.).

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Example of the commercial product range Kalfos® (<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 at an approved facility dedicated to processing Cat 1 ABP. 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 (EFPPA, 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 (Code of Federal Regulations, §589.2001).

There are no official standards for processing conditions for rendering or incineration (EFPPA, 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 (EFPPA, pers. comm.).

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 (EFPPA, 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 (EFPPA, 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 (EFPR, pers. comm.).

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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 WOA'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 WOA 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. 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 2: 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 (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 3: 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

To be added.

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Appendices

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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
Luxembourg	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
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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





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