Application for Bovine Spongiform Encephalopathy (BSE) Negligible Risk Status for Scotland

Scottish Government
Riaghaltas na h-Alba
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CONTENTS

Responding to this Consultation

This consultation starts on 26 August 2016 and closes on 30 September 2016. This consultation is for five weeks as there has already been extensive engagement on the issue.

Please respond to this consultation using the Scottish Government's consultation platform, Citizen Space. You can view and respond to this consultation online at https://consult.scotland.gov.uk/. You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of **30 September 2016**.

If you are unable to respond online, please complete the **Respondent Information Form** (see "Handling your Response" below) to:

Animal Health and Welfare Division – Disease Prevention Team
Scottish Government
P Spur
Saughton House
EDINBURGH
EH11 3XD

How to make an enquiry

Please contact Scottish Government Animal Health and Welfare Division (Disease Prevention Team) if you have any queries: Tel 0300 244 9813, or email BSEConsultation@gov.scot.

Handling your response

If you respond using Citizen Space (http://consult.scotland.gov.uk/), you will be directed to the Respondent Information Form. Please indicate how you wish your response to be handled and, in particular, whether you are happy for your response to be published.

If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form attached included in this document. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government is subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public at http://consult.scotland.gov.uk. If you use Citizen Space to respond, you will receive a copy of your response via email.

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so.

Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them to the address as above or email BSEConsultation@gov.scot.

Scottish Government consultation process

Consultation is an essential part of the policy-making process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.

You can find all our consultations online: http://consult.scotland.gov.uk. Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.

Consultations may involve seeking views in a number of different ways, such as public meetings, focus groups, or other online methods such as Dialogue (https://www.ideas.gov.scot).

Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

CONSULTATION ON APPLICATION FOR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) NEGLIGIBLE RISK STATUS FOR SCOTLAND

INTRODUCTION

Background

1.1 Transmissible Spongiform Encephalopathies (TSEs) are fatal diseases of the brain. TSEs include Bovine Spongiform Encephalopathy (BSE) in cattle and scrapie in sheep and goats. TSEs can be genetic, sporadic (atypical) or of infectious origin (classical). They are caused by pathogens known as prions which are an abnormal and infectious form of a natural protein that is abundant in the brain and spinal cord.

1.2 Transmission of these pathogens into the animal feed chain resulted in the emergence of classical BSE (cBSE) in the UK cattle herd in 1986 and in significant consequences for the global beef industry. This cBSE is now declining as a result of appropriate measures to control animal feed.

1.3 Due to its disease history, the United Kingdom as a whole is classified as having BSE Controlled Risk (CR) status. It will be 2020 before the UK could as a whole apply for BSE Negligible Risk (NR) status. The last animal born with BSE in Scotland was over 11 years ago. Scotland is now therefore eligible to apply for BSE NR status as a region of the UK. This status can be granted if particular tests can be met.

1.4 The Scottish beef sector take the view that BSE NR status would provide an improved global image for Scottish agriculture, which could offer a trade advantage in terms of gaining entry into new markets. The Scottish Government supports the making of this application in principle but is now seeking stakeholders' views. Any application would need to be carefully balanced to consider all the options and impacts on other sectors within Scotland and on a UK basis. A Business and Regulatory Impact Assessment also accompanies this consultation and is attached at Annex B**.**

Next steps

1.5 We are keen to hear views from as wide a variety of individuals and organisations as possible, in particular those involved or with an interest in the livestock, agricultural, food business operator, environmental and academic sectors.

1.6 This consultation is your opportunity to share your views on making an application to the World Organisation for Animal Health (OIE) for BSE NR status for Scotland. Following the closing date, all responses will be analysed and considered along with any other available evidence to help us reach a decision on whether a BSE NR application should be made. All documentation is then passed to the Department for Environment, Food and Rural Affairs (Defra), the competent authority in the UK, for onward transmission to the OIE.

CHAPTER 1 – OVERVIEW AND POLICY PROPOSAL

Current BSE Controls

1.7 Due to the strong evidence of a link between variant Creutzfeldt-Jakob Disease (vCJD) and cBSE, BSE was made a notifiable disease by the UK Government in 1988. Exposure to BSE through the consumption of infected or contaminated meat is believed to be the primary cause of vCJD in humans. The outbreak of BSE in the 1980s led to the removal of older cattle from the food chain, a greater burden of regulation on the food and feed chain and the 1996 beef export ban. The escalation in the disease in cattle continued until 1993 when the effect of policy interventions made by Governments began to be visible, and the number of cases in Scotland declined steadily from that time. **Scotland has been BSE-free since 2009.**

1.8 The pathogen which causes BSE is most commonly found in specific tissues of infected cattle. These include the brain, spinal cord, tonsils, vertebral column, mesentery, caecum and small intestine and are referred to as **Specified Risk Material (SRM)**. There are strict controls in place to protect consumers, including:

- a ban on the use of processed animal protein (PAP) in feed for farmed ruminants as a basic preventive measure against BSE transmission; and

- a requirement to remove SRM to minimise the risk of infective material entering the food chain from cattle in the early stages of BSE when disease is not otherwise apparent.

1.9 **Animal feed containing BSE-infected meat and bone meal (MBM),** a product derived from the processing of dead livestock and abattoir waste including dead livestock, was recognised at an early stage of the BSE epidemic as the major source of infection responsible for the spread of BSE among cattle. A ban on the feeding of ruminant-derived MBM to ruminants was introduced in the UK in 1988 (1989 in Northern Ireland). On 31 July 1996, this ban was reinforced and extended to the feeding of mammalian MBM to all farmed animals. In 2001, the EU introduced a ban on feeding animal protein to ruminants and processed animal protein to farmed animals. These feed bans, and their enforcement, have been highly effective in controlling the incidence of cBSE in the UK and across the EU.

1.10 **BSE testing of those cattle that were considered to pose a risk to human health, the feed ban and the removal and appropriate disposal of SRM are seen as the most important controls in place to protect consumers.**

1.11 In July 2010, the European Commission outlined future steps regarding BSE/TSEs in a plan known as the TSE Roadmap.[1] This initiative outlined

[1] A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015, July 2010: http://ec.europa.eu/food/safety/docs/biosafety_food_borne_diseases-tse_bse-roadmap_2_en.pdf

possible amendments to TSE rules with the objective of reviewing TSE control measures to ensure that they were proportionate to the risk, while ensuring a high level of food safety. Under this Roadmap, amendments to TSE rules have been made in the light of scientific evidence from the European Food Safety Authority (EFSA). EFSA has published opinions on risks of changing the BSE testing programme and also relating to reducing the SRM controls.[2]

1.12 As a result of amendments to the UK BSE testing programme, there is now no requirement to test healthy cattle slaughtered for human consumption for BSE. However fallen cattle (cattle that die on the farm), cattle slaughtered for welfare reasons and cattle showing signs of BSE at ante-mortem inspection, are all tested for BSE. In addition, awareness programmes, surveillance and monitoring, compulsory notification and investigation of suspects remain in place. This regime ensures that a robust programme is in place to detect any re-emergence of cBSE or the occurrence of sporadic cases.

Surveillance for BSE/TSEs

1.13 Surveillance for TSEs is carried out in the United Kingdom in livestock susceptible to the disease, including cattle, sheep and goats. All EU Member States carry out TSE surveillance in line with EU law. The main aim is to monitor trends in disease incidence and prevalence to evaluate the effectiveness of TSE disease controls. Surveillance is not in itself protection against disease, but supports essential control measures that exclude affected animals and remove designated high risk tissues from the food chain. The surveillance data also contributes to the TSE status of each country. There are two types of surveillance:

- **Passive surveillance** – animals with clinical signs suspicious of BSE or scrapie are reported to an Animal and Plant Health Agency (APHA) office and are investigated. Such cases are killed and the examination of the brain determines whether the animal was affected by BSE or scrapie. APHA has been recording and analysing data from cattle since the start of the BSE epidemic in 1986, and for scrapie in sheep and goats since this disease became notifiable in 1993.

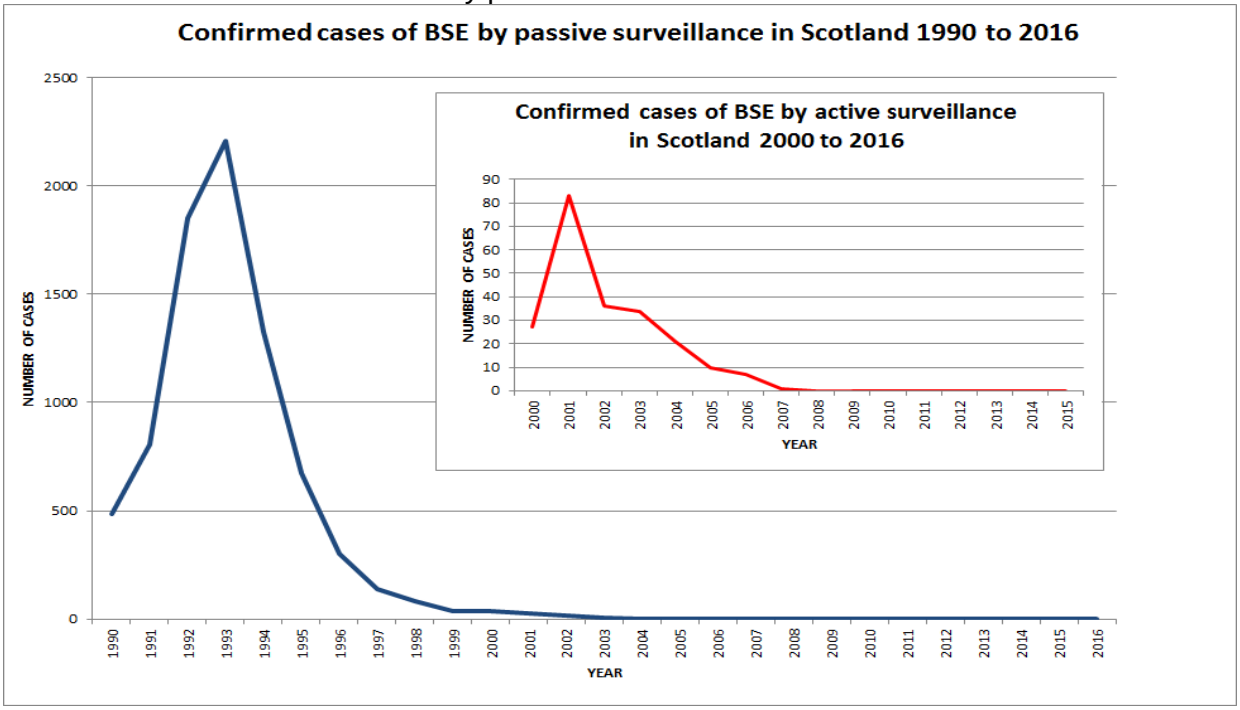
- **Active surveillance** – in addition to passive surveillance the EU requires all Member States to carry out active surveillance for TSEs:

  - cattle carcases have been subject to testing since July 2001; and
  - sheep and goat carcases have been tested since January 2002.

1.14 As predicted by epidemiological modelling, very few cases of BSE in cattle are now seen. Following a peak of over 36,000 clinical cases in the UK in 1992, the number of new cases detected by active and passive surveillance continues to decline year on year, with just 2 cases confirmed in the UK in 2015.

[2] https://www.efsa.europa.eu/en/topics/topic/bovinespongiformencephalopathy

Table 1: Confirmed cases of BSE by passive surveillance in Scotland 1990 to 2016[3]



1.15 As incidence of the disease in cattle continues to fall controls across the EU are reviewed in accordance with the Commission's TSE roadmap. Whilst making proportionate reductions in testing, it is important to maintain an appropriate level of surveillance as a safety measure against any unexpected re-emergence of the disease in cattle. For example, the criteria for inclusion in the testing programme have been changed over the years in response to regular risk assessments. With falling numbers of BSE cases across the EU, the requirement to carry out TSE testing on healthy slaughtered cattle was relaxed in 2013 and now only at 'risk cattle' such as fallen stock aged over 48 months, where BSE is most likely to be detected, are routinely tested under EU law.

1.16 Of the ~180,000 cases of BSE confirmed in the UK, only 164 were born after the introduction of the July 1996 feed control. These UK cases, born after 31 July 1996, are termed **BARBs** (Born After the Reinforced Ban).

1.17 Following a confirmed case of cBSE in Wales in June 2015, it will be 2020 before the UK as a Member State can make an application for BSE NR Status. Although it is anticipated that England could satisfy the requirements to apply for BSE NR status in 2018, Scotland is eligible to make an application on a more rapid timetable.

Question 1

Are you in favour or against an application for BSE NR status for Scotland? Please give reasons.

[3] Data supplied by the Animal and Plant Health Agency (APHA)

Classification of BSE Risk Status – The World Health Organisation for Animal Health (OIE)

1.18 The World Organisation for Animal Health (also known as the OIE (www.oie.int)) is the intergovernmental organisation responsible for monitoring and improving animal health worldwide. Complying with OIE requirements is the basis of all international trade and it is this body that classifies the BSE risk status of the cattle population of a country on the basis of a risk assessment. OIE classification criteria is taken into account by the Commission in arriving at a decision on an application for categorisation. The three categories of risk for countries or regions can be summarised as follows:

- **Negligible Risk (NR)** is defined as a country or region where the requisite risk analysis has been conducted, that has demonstrated that appropriate measures have been taken to manage the risks identified for the *relevant period of time* and that has demonstrated that there are sufficient surveillance and controls in place to meet a legislative "points target". The country or region must undertake awareness campaigns, notification and investigation and sampling. Neither meat and bone meal, nor greaves must have been fed to ruminants during the previous eight years. Further requirements depend on whether or not there have been indigenous BSE cases. If there have been, they must have occurred in an animal born at least 11 years ago, and the requirements are that BSE cases, bovine animals in contact with them and in some circumstances all bovine animals in the same herd and at-risk, must be identified, their movements restricted, and be destroyed on slaughter or death.

- **Controlled Risk (CR)** countries or regions are those where the required risk analysis has been conducted, that has demonstrated that appropriate measures are being taken to manage those risks identified but that a *longer* period is required for their application, and that has demonstrated that the surveillance and controls are in place to meet a legislative "points target". The country or region must undertake awareness campaigns, notification and investigation, and sampling, but in this category these activities have only been ongoing for less than 7 years, and/ or the country or region must be able to demonstrate that ruminants do not eat meat-and-bone meal or greaves but in this category these bans have not yet been demonstrably ongoing for 8 years. Further requirements apply where a country or region has had an indigenous case of BSE. In these cases, all BSE cases, bovine animals in contact with them and in some circumstances all bovine animals in the same herd and at risk, must be identified, their movements restricted, and be destroyed on slaughter or death.

- **Undetermined Risk (UR)** countries or regions are those whose BSE determination has not been concluded, or those not meeting the conditions applying to the other categories.

1.19 In applications for BSE risk categorisation, countries must demonstrate compliance with the provisions of the OIE Terrestrial Animal Health Code[4] – in particular, as they apply in the following areas:

- policies designed to protect animal and human health are based on an appropriate assessment of risk;
- BSE awareness, education and reporting programs have been implemented;
- an appropriate feed ban is in place;
- there is diagnostic competency within the laboratory system; and
- BSE surveillance has been conducted in accordance with the OIE's BSE guidelines.

Differing controls on Specified Risk Material (SRM) apply to NR and CR status

1.20 At the Standing Committee on Plant, Animals Food and Feed (SCoPAFF) on 17 March 2015[5], the Commission agreed proposals to relax Specified Risk Material (SRM) controls for Member States which have NR status. This brings EU rules more in line with the OIE requirements for non-EU countries. The change means that for Member States which have NR status:

- bovine material composed of those tissues at greatest risk of carrying potentially infective material (skull, brain, eyes and spinal cord of animals over 12 months of age) is still classified as SRM;
- all other bovine tissues would be able to enter food and feed chains; this includes the last 4 metres of the small intestine, the tonsils, vertebral column, mesentery and caecum.

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[4] http://www.oie.int/international-standard-setting/terrestrial-code/access-online/
[5] http://ec.europa.eu/food/safety/docs/reg-com_biosec_20150317_sum.pdf

Table 2: Category and designation of bovine tissues from CR and NR countries

Bovine Tissues	Member States and non - EU countries with CR or UR BSE risk	Member States with NR status
Skull, excluding the mandible, including the brain and eyes, of bovine animals over 12 months	SRM	SRM
Spinal cord of bovine animals over 12 months	SRM	SRM
Tonsils of all bovine animals	SRM	Food and feed
Vertebral column (backbone/spine) excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of bovine animals over 30 months	SRM	Food and Feed
Mesentery (fold attaching the small intestine to the posterior body wall), including mesenteric fat, mesenteric ganglion complex and mesenteric nerves, of bovine animals of all ages	SRM	Food and Feed
Caecum (part of the large intestine) of all bovine animals	SRM	Food and Feed
Last 4 meters of the small intestine of bovine animals of all ages (small intestine comprises of duodenum, jejunum and ileum)	SRM	Food and Feed

1.21 All SRM tissues are sent for destruction by incineration, or by rendering followed by incineration. In Scotland, as a CR region, SRM currently includes:

- in all cattle: the skull excluding the mandible but including the brains and eyes. The spinal cord of animals aged over 12 months;

- the vertebral column excluding the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of cattle aged over 30 months; and

- the tonsils, the last four meters of the small intestine, the caecum and the mesentery of cattle of all ages.

1.22 It is permissible to use parts of the intestine for feed and food. However, operators have not been able to realise all of the potential benefits due to the operational difficulty in separating the mesentery from that part of the intestine which is not SRM.

Question 2

Do you have any comments in relation to the benefits from the reduction in the volume of SRM? What advantages or disadvantages do you anticipate from the reduction in the volume of SRM?

A regional application for BSE Negligible Risk status?

Criteria for making an application

1.23 Applications by Member States (MSs) to be officially recognised as having a NR or CR BSE risk status are considered by the OIE (through the adoption of a resolution by the World Assembly of Delegates of the OIE) at the General Session in May every year. Under requirements defined by the OIE and the Commission Regulation (EC) No 999/2001 (the EU TSE Regulation), a country or region can apply for BSE NR Status provided they have:

- a surveillance programme to detect TSEs;
- the latest date of birth of a positive classical BSE case being at least 11 years ago: and
- a control strategy in place for positive BSE cases, SRM and feed.

Current Position in Scotland

1.24 A range of food safety controls have been in place to reduce the risk to consumers across the UK since the late 1980s. These controls reduce the potential for infection of cattle and include:

- surveillance for the prompt detection of BSE cases in cattle through the requirement to test certain categories of animal;
- animal feed controls; and
- controls on SRM.

1.25 The key food safety control is the removal of SRM. In countries with CR status (the current status in Scotland), SRM must be sent for destruction by incineration or by rendering followed by incineration. An outline of the current controls in Scotland is attached at Annex A.

Question 3

Do you have any comments to make from a public health perspective in relation to the relaxation of SRM-related controls?

Question 4

Do you have any comments from a consumer perspective?

What would change if Scotland achieved BSE NR status?

BSE Controls

1.26 If Scotland moved from CR to NR status, **BSE testing and feed and food safety arrangements for cattle would not change**, unless an OIE risk assessment indicated that this was appropriate, and then only in accordance with Regulation (EC) No. 999/2001. In the event of moving from CR to NR status, feed controls, surveillance etc. would continue to be carried out in accordance with the EU requirements.

1.27 The necessary official controls, therefore, would remain in place to deal with any residual risks associated with occasional cases of BSE. It is anticipated that existing food labelling rules, which are set out in legislation, would be unaffected and would continue to apply.

Benefits

1.28 Industry have argued that BSE NR status would contribute positively to Scotland's global image which will offer commercial benefits in terms of gaining entry into new markets.

1.29 Industry also take the view that there would be a reduction in the volumes of bovine tissues designated as SRM going for destruction which would reduce disposal costs for the red meat sector, and enable them to exploit new revenue streams.

Risks

1.30 The sporadic occurrence of BSE cases, means NR status could be lost as a result of a single case, thereby potentially generating considerable negative publicity.

1.31 There may also be implications for exports to non-EU countries which have agreed terms to trade based on a NR status basis. Should NR status be lost, there would likely be a requirement to renegotiate export conditions and this may lead to the loss of some important markets which were gained as a result of obtaining NR status.

1.32 There is also the risk that, with the reduction in the quantity of SRM for disposal, the rendering industry may be adversely affected, with the possibility that the rendering capacity in Scotland might reduce. Reduction in Scottish rendering capacity would result in reduced competition for material for disposal, with possible implications for increased disposal costs. This could impact on the disposal of fallen stock. The Scottish Government would have concerns if capacity in the fallen stock rendering industry was reduced, and especially in the context of an epizootic disease situation such as foot and mouth disease.

1.33 The implications of BSE NR Status are explored in more detail in Chapter 2.

CHAPTER 2 – IMPLICATIONS OF OBTAINING BSE NR STATUS: RISKS AND BENEFITS

2.1 There are a number of implications to be considered should Scotland acquire BSE NR status. As has been outlined earlier, industry has identified three potential key benefits:

- less tissue would be classified as Specified Risk Material (SRM), therefore less material would go for destruction, with consequent **reduced disposal costs for red meat establishments**;
- there would be an **opportunity for the red meat industry to generate new domestic and export revenue streams** by finding new markets for material previously classified as SRM; and
- there would be the potential for the **expanded utlilisation of other tissues** e.g. intestines for sausage casings and intestinal fat could also go into the food chain.

Disposal Costs

SRM

2.2 SRM is classified as *Category 1 Animal By-Product* (ABP) and is therefore only permitted to go for disposal at a cost currently of approximately £80 per tonne. Table 3 summarises which parts of the carcase are classified as SRM under the different regimes Negligible Risk and Controlled Risk. All disposal costs are borne by industry and through achieving negligible risk, the Scottish industry would be able to save on some of these costs.

Table 3: SRM Material under Controlled Risk and Negligible Risk Status*

Part of Carcase	Controlled Risk	Negligible Risk	Weight Per Head
Tonsil	SRM		0.02kg
Intestine and Intestinal Fat	SRM		30kg (Plus 25kg Contents)
Spinal Cord	SRM	SRM	0.2kg
Skull (excluding Mandible and including Meat)	SRM	SRM	8.67kg
Vertebral Column	SRM		19kg

* data from Scottish Association of Meat Wholesalers (SAMW)

2.3 In 2015, Scottish abattoirs slaughtered approximately 468,000 cattle with around 85,000 over 30 months (OTM) at slaughter[6]. Based on these figures, the savings on disposal costs would amount to approximately £1.3m per year (assuming that all the former SRM finds new markets and none is sent for disposal). If Scotland were to be upgraded to NR status 4 years ahead of the UK as a whole, this would mean a total saving of £5m for the Scottish industry assuming disposal costs are unchanged (see Table 4). This would be of benefit to the overall beef supply chain.

Table 4: Cost of disposing of intestine, intestinal fat and spinal column

	Under 30 months	**Over 30 months**	**Total**
Weight per Carcase	30.2kg	49.2kg	-
Scotland Production (tonnes)	11,566	4,182	15,748
Annual Disposal Cost Saving at current prices	£926,000	£335,000	£1,261,000
Projected Savings over 4 year period	£3.7m	£1.3m	£5m

2.4 By removing some parts of the carcase from the SRM list, an opportunity also emerges to generate an income stream. For example, there would be the potential for the use of intestines (average of 16.8kg per head in bovines) for sausage casings, and intestinal fat (13.4kg per head) could also go into the food-chain. This could potentially bring the total value to £12 -14m over four years. These figures are illustrative only and based on market prices in April 2015.

2.5 Projected figures assume unchanged disposal costs, although it is possible that these could rise on a per unit basis, due to the smaller volumes being rendered. Furthermore, the calculations are based on current approximated prices for ABPs which are subject to market variation. ABPs have had stronger values in the past and may rise or fall in the future.

2.6 The change from CR to NR status could mean the use of a different classification of SRM tissues. The European Commission recently agreed proposals to relax controls on SRM for those countries with NR status (bringing EU rules more in line with OIE requirements for non-EU countries). The classification of what is deemed to be SRM for these countries will change: **only the brain, skull, eyes and spinal cord of bovine animals aged over 12 months will remain classified as SRM**.

2.7 It should be stressed however that the reduction in SRM controls has only been applicable on a country (Member State), not regional basis in the past, so BSE NR status on a regionalised basis does not inevitably lead to a reduction in SRM controls.

[6] Data supplied by the Scottish Association of Meat Wholesalers (SAMW)

Question 5

In relation to the separation and disposal of SRM from CR and NR animals do you have any further comments?

2.8 The reduction in the volume of tissues designated as SRM would have the effect of reducing the quantity of material going for disposal by rendering. However the rendering sector in Scotland has reported that they fully support a BSE NR application, pointing out that the industry is constantly changing, and that the sector is already accustomed to adjusting to market pressures. It is actively seeking alternative methods of raising revenues in view of a possible reduction in Category 1 capacity, irrespective of whether or not Scotland is upgraded to BSE NR status. Category 2 ABP capacity will continue to be required for disposal of animals killed for control of notifiable diseases; at present category 2 disposal is provided by the existing category 1 rendering plants.

Question 6

Do you have any concerns that the reduction in the amount of SRM for disposal may reduce the capacity for disposal of SRM and fallen stock in Scotland, and may result in:

- increased costs for disposal of SRM and fallen stock of all species?
- disposal constraints in an epizootic disease outbreak?

Trade

2.9 The advantages of NR status for Scotland could provide an improved global image as there is a perception that NR countries have a higher general health status than those with CR status. Industry has argued that obtaining NR status conveys a disease-free image which would provide commercial benefits in terms of gaining entry into new markets and expanding current markets, especially where limited access currently exists. It is however difficult to quantify the impact that NR status would have on trade negotiations given they are contingent on a number of factors including but not limited to, health status across a range of diseases and the ability to comply with a particular importing country's standards.

Question 7

Do you have any comments on or any evidence to support the perception that countries with NR status have an improved global image?

2.10 The existing BSE CR status and the accompanying SRM controls should provide sufficient reassurances on the safety of exported Scottish beef; however, importing countries with BSE NR status are inclined to place further restrictions through various trade agreements. The achievement of BSE NR status would allow negotiations which could facilitate the removal of limiting

clauses, such as those which prohibit the export of products from animals over 30 months old.

Question 8

Do you have any comments on the issue of trade being negatively affected in existing markets should Scotland obtain NR status e.g. due to revision of existing export certificates?

2.11 In terms of the value of market opportunities, it is difficult to give a definite figure on what might be achievable if Scotland had full access to all the significant beef markets around the world. Should Scotland be successful in obtaining BSE NR status it would then become necessary to consider potential trade issues and re-negotiate or revise a number of existing health certificates, with the various authorities of the importing countries. Statements relating to BSE are found in a number of export certificates and these vary depending on the requirements of the importing country. The main certificates that would be affected by a change to our BSE status are those relating to beef products and hides and skins certificates. It is difficult to quantify how long these renegotiations would take and therefore, trade to existing markets may be disrupted for a time. Beef and beef products would still need to comply with existing labelling rules.

Question 9

If Scotland is upgraded to NR status can you provide examples of how/where trade will improve? This includes accessing new markets and negotiating existing ones.

Question 10

Do you have any comments on possible advantages or disadvantages to other sectors in Scotland? (i.e. dairy, sheep, pork, white meat, equine etc?)

Operational Controls

2.12 Food Standards Scotland (FSS) oversee the delivery of official controls in abattoirs and FSS officials have expressed support in principle for a NR status application as long as industry can provide appropriate assurances in relation to the separate handling of animals and abattoir processes, associated with cattle coming from a CR origin from those from a NR origin. Industry has confirmed that abattoirs already operate robust systems for the batching of animals of different jurisdictions or stock category and that receiving animals of differing BSE risk categorisations would not present any added difficulties for meeting regulatory controls in this area.

Livestock Identification and Traceability

2.13 The purpose of animal identification and movement notification is traceability, to enable efficient and effective disease control and protect public health. Maintaining a healthy cattle herd and supporting consumer confidence in milk and beef are essential for the industry to be successful. There are a number of well-established database systems across the United Kingdom for the registration of livestock keepers, agricultural land, the movement of livestock and for analysis. Many of these have been developed to meet European and domestic legislation and are subject to EU audit and strict veterinary controls.

2.14 The UK Cattle Tracing System (CTS) rules ensure cattle are individually identified throughout their lives. This is important for supporting the control and eradication of bovine diseases such as Tuberculosis (TB), Bovine Viral Diarrhoea (BVD) or Foot and Mouth Disease (FMD). It protects consumers by ensuring products going into the human food chain are fully traceable and safe. In Scotland the livestock markets support keepers by reporting cattle movements, on their behalf electronically to CTS. Work is ongoing to replace CTS links in Scotland and is taking a wide range of factors into account to design a system which suits industry requirements and enhances traceability.

2.15 For other livestock species significant progress has also been made in Scotland through a stepwise approach via the sheep, goat and pig movements systems developed on ScotEID, the BVD database and more recently the Beef Efficiency Scheme (BES). Building on this core capability has enabled industry developments such as the Scottish Eligibility Cattle Checker (SPECC) and work on Porcine Epidemic Diarrhoea (PED), all of which are accessible through www.scoteid.com.

Loss of NR Status – Publicity, Recall of Meat, Effects etc

2.16 The intermittent nature of BSE cases, both in terms of occurrence and the date of birth of the BSE case, could result in a situation where NR status is lost as happened recently in both the Republic of Ireland and in France.[7] This could generate considerable public concern and negative publicity. There is also the possibility that food and feed may need to be recalled, which would bring with it the expense and disruption caused to hard-won contracts, as well as the financial losses involved. The livestock sector is aware of this risk and whilst acknowledging it could cause difficulties, they take the view that they have the ability to deal with any recall situation which may be required and on balance, they do not think that it is sufficient justification not to proceed with an application.

Question 11

If Scotland were successful in achieving NR status, have you any comments on the impact to industry should NR status subsequently be lost?

[7] http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/lossreinstatement-of-status/

Question 12

Do you agree that, in order to mitigate the commercial risk in the event of loss of NR status, industry should work towards putting contingency arrangements in place?

ANNEX A

DETAILED OUTLINE OF BSE CONTROLS

BSE MONITORING AND SURVEILLANCE

The European Commission introduced the first Community legislation on BSE in July 1989. By the middle of 1990, basic Community legislation on BSE was in place concerning meat and live cattle. Regulation (EC) No. 999/2001 laying down rules for prevention, control and eradication of certain transmissible spongiform encephalopathies ("the Regulation") forms the legal basis for all legislative actions on TSEs. It gathers together all BSE measures adopted over the years into a single, comprehensive framework, and has been consolidated and updated in line with scientific evidence and international standards. It has been amended many times in response to the evolution of the BSE situation, new or updated scientific advice and technical developments. It applies both to live animals susceptible to TSEs (ruminants) and the animal products derived from them. The purpose of the TSE legislation is to protect the health of consumers and animals and to eradicate TSEs.

The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2010 SSI 2010/177 provide the powers to administer and enforce the provisions of Regulation (EC) No. 999/2001 in Scotland.

On 7 November 2005, cattle aged over thirty months and born on or after 1 August 1996 were allowed back into the food chain, subject to BSE testing. The requirement of BSE testing of these healthy cattle slaughtered for human consumption has gradually reduced since November 2005, with the age threshold being raised from 30 to 48 months on 1 January 2009 and again from 48 to 72 months on 1 July 2011.

From 1 March 2013, there was no longer a requirement to BSE test healthy cattle slaughtered for human consumption within the 28 Member States of the EU.

Current BSE Surveillance Requirements

Fallen cattle aged over **48 months** must be tested for BSE. Cattle keepers are required to make their own arrangements for the collection and disposal of fallen cattle that need to be tested for BSE. Carcases must be taken to an approved sampling site. The requirement to despatch bovine fallen stock aged over 48 months for BSE testing applies to all cattle keepers on the Scottish mainland and on the Isles of Bute and Skye.

Cattle Slaughtered for Human Consumption

In GB, the requirement to test healthy slaughtered cattle for BSE ended on 1 March 2013. This applies to cattle born in EU Member States (except Bulgaria and Romania). From 1 March 2013, the following cattle must still be tested for BSE:

- healthy cattle aged over 30 months slaughtered for human consumption which were born in Romania, Bulgaria and all non-EU countries;
- cattle subject to emergency slaughter for welfare reasons, cattle which are identified as sick at ante-mortem inspection, and fallen stock, i.e. cattle which die or are killed other than for human consumption;
- aged over 48 months if born in EU Member States (except Bulgaria and Romania); or
- aged over 24 months if they were born in Romania, Bulgaria and all non-EU countries.

Notification of suspicion of BSE

Over the last 30 years, the UK Government, Devolved Administrations and cattle industry have raised awareness of the signs of BSE with their stakeholders and members respectively. Suspicion of BSE as a result of clinical signs in a bovine animal must be notified to the Animal and Plant Health Agency (APHA) by law. This applies to cattle in private possession, or under supervised control at farms, markets, slaughterhouses or other places.

If an animal shows signs of BSE it is first reported to the Animal and Plant Health Agency (APHA). An APHA vet will visit the premises and carry out a veterinary assessment on the animal as soon as possible. If BSE is suspected APHA will issue a notice restricting the movement of the animal (movement restriction). The animal will either be culled on site or transported to an APHA laboratory for slaughter depending on the animal's condition. A herd restriction is then placed prohibiting the movement of cattle on and off the affected farm (whole herd restriction), and the suspect animal will be tested to find out if it has BSE. Once cohort and offspring animals are identified, notices will be issued restricting the movements of these animals only, and the whole herd restrictions are lifted. If BSE is suspected in a female animal, APHA will trace any of its offspring that were born up to 2 years before or after the mother showed signs of the disease. Movement restrictions are then put in place and the offspring will be slaughtered if BSE is confirmed in the mother.

Feed controls

In the UK, the original food ban was introduced in 1988 to prevent ruminant protein being fed to ruminants. In addition, it has been illegal to feed ruminants with all forms of mammalian protein (with specific exceptions) since November 1994 and to feed any farmed livestock, including fish and horses, with mammalian meat and bone meal (MBM) since 4 April 1996. Regulation (EC) No. 999/2001 introduced feed controls to combat the spread of BSE. Findings by the scientific committees linked the spread of BSE to the consumption of feed contaminated by the infected ruminant protein in the form of MBM.

The TSE feed ban applies to all ruminant animals, all non-ruminant farmed animals and to all pigs, poultry or horses, including those kept as pets, companion, performance or commercial animals. It does not apply to domestic pet rabbits or pet or ornamental fish. Under the TSE feed ban:

(i) ruminant and non-ruminant terrestrial farmed animals must not be fed the following prohibited derived products, either directly or in feeding stuffs:

- Processed Animal Protein (PAP)[8];
- collagen and gelatine from ruminants e.g. beef gelatine (including in surplus food);

(ii) ruminants must not be fed any animal protein – or any feeding stuff which contains animal protein – except the following permitted proteins (also permitted for non-permitted feed), when sourced and processed in accordance with the Animal By-Products (ABP) Regulations:

- milk, milk-based products and colostrum;
- eggs and egg-based products;
- hydrolysed proteins[9] derived from parts of non-ruminants or from ruminant hides and skins; and
- fishmeal, which is permitted only for use in milk replacer powder for feeding to unweaned ruminants[10] in liquid form but must not be fed to weaned ruminants.

For more information on the requirements of the TSE regulations and feed controls, the Animal and Plant Health Agency has produced a guidance note for industry and enforcement authorities.

[8] **Processed Animal Protein (PAP)** means animal protein derived entirely from *Category 3* material, which has been treated in accordance with the Animal By-Products Regulations (including blood meal and fishmeal) so as to render it suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium.

[9] **Hydrolysed proteins** means polypeptides, peptides and amino acids, and mixtures thereof, obtained by the hydrolysis of animal by-products in accordance with the Animal By-Products Regulations. Hydrolysed protein derived from ruminants must have a molecular weight below 10,000 Dalton.

[10] **Unweaned ruminant** means a ruminant that continues to receive liquid milk or liquid milk replacer in its diet.

Regulations controlling Cattle Movements

Live cattle are moved into Scotland every year. These animals originate from other parts of the UK, Ireland and other EU Member States. In 2015, the total number of recorded live cattle moved into Scotland was 71,560. The majority of these came from England.

From 1 August 1996, no cattle, whether born in the UK or imported, were permitted to be fed with feeding stuffs containing processed mammalian protein. This was the date from which the ban on the feeding of ruminants with mammalian protein (except milk) is considered by the UK authorities to have been fully effective.

Animals traded between EU Member States must be permanently identified in accordance with Regulation (EC) 1760/2000.

All cattle being imported must be accompanied by a veterinary health certificate which includes a certification requirement that each animal “comes from a holding of origin and an area/zone which is not subject to any prohibition or restriction for reasons of animal diseases affecting bovine animals”. The Scottish Government receives advance notification about consignments of live animals via the Trade Control and Expert System (TRACES).

Regulation (EC) 999/2001 provides the legislative basis to ensure that no animal imported from an EU Member State meets the definition of cohort or progeny of a BSE animal at the time of export as all cohort and progeny animals in EU Member States must be traced and destroyed.

ANNEX B

Partial Business and Regulatory Impact Assessment

Title of Proposal

The application for Bovine Spongiform Encephalopathy (BSE) Negligible Risk Status for Scotland.

Purpose and intended effect

- **Background**
  The Scottish Government is carrying out a 5 week consultation to seek views/comments on an application for BSE Negligible Risk status for Scotland. The World Organisation for Animal Health (OIE) classifies the BSE risk status of the cattle population of a country on the basis of a risk assessment and other criteria. The cattle population of a country can be classified into three categories: negligible BSE risk, controlled BSE risk or undetermined BSE risk (NR, CR and UR respectively). NR status is defined as a country or region where a risk analysis has concluded (and has been accepted by the OIE), that there are sufficient surveillance and controls in place *and* that either there has never been a case of BSE reported, *or* any reported BSE case was imported or that any positive BSE case was born at least 11 years ago. **As the required eleven years have now elapsed since the date of birth of the most recent born case, Scotland, as a zone of the UK, is in a position to apply for NR status.**

- **Objective**
  The policy objective is to ensure the supporting evidence and the implications this proposal will have for Scotland are fully explored in order that an informed decision can be made in relation to a BSE NR status application.

- **Rationale for Government intervention**
  At the Standing Committee on Plant, Animals Food and Feed (ScoPAFF) on 17 March 2015, the European Commission agreed proposals to relax Specified Risk Material (SRM) controls for Member States which have NR status. This brings EU rules more in line with the OIE requirements for non-EU countries. Scotland is now in a position to apply for BSE NR status and officials are assessing the benefits of an application with the aim of submitting a formal application to the OIE.

Consultation

- **Within Government**
  Food Standards Scotland (FSS) has been involved throughout the policy development to assess the implications of an application for BSE NR status. FSS has confirmed that it has no objection to any proposed application being made. If NR status is achieved it will need to be satisfied that all of the appropriate food safety controls are in place.

- **Public Consultation**
  A formal consultation will take place on the BSE NR status application from 26 August to 30 September 2016.

- **Business**
  Key stakeholders were consulted at a stakeholder engagement event in April 2016 to discuss the advantages and disadvantages and were fully supportive of a proposed application. Representatives included:

- Scottish Association of Meat Wholesalers (SAMW)
- Scottish Federation of Meat Traders Association (SFMTA)
- National Sheep Association (NSA)
- Scottish Beef Association (SBA)
- NFU Scotland
- Institute of Auctioneers and Appraisers in Scotland (IAAS)

A formal written public consultation exercise is being held to gauge wider sectoral views on the impact of the proposed application.

Options

- Option 1 – do nothing
- Option 2 – wait until an overall UK application is made
- Option 3 – consider making an application to the OIE to have Scotland classified as BSE NR status

Option 1 – Do nothing

This option means that Scotland would continue to be classified as BSE Controlled Risk (CR).

Option 2 – Wait until an overall United Kingdom application is made (not preferred)

This option means that Scotland would continue to be classified as BSE CR and form part of an overall UK application.

Option 3 – Consider making an application to the OIE to have Scotland classified as BSE NR status (preferred)

If Scotland was upgraded from CR to NR status, BSE testing and feed and food safety arrangements for cattle would not change, unless a risk assessment indicated that this was appropriate, and then only in accordance with Regulation (EC) No. 999/2001. In the event of moving from CR to NR status, feed controls, surveillance etc. would continue to be carried out in accordance with the EU requirements. The necessary official controls, therefore, would remain in place to deal with any residual risks associated with occasional cases of BSE.

Sectors and groups affected
The following sectors are likely to be affected by the proposals:

- Scottish farmers
- Scottish meat producers
- Scottish abattoirs & cutting plants
- Animal By-Product (ABP) renderers
- Meat Exporters
- Consumers
-

Benefits
Options 1 and 2 would see no change to current practices.

Under Option 3:
- Scotland would make a standalone application for BSE NR status which if accepted

would be of benefit to Scottish industry and see a marked change in SRM disposal methods.

It is argued that Scotland's reputation as being a disease-free region would be enhanced should NR status be achieved and this would provide a much stronger basis from which to develop a customer base in parts of the world where consumer opinion is highly sensitive to BSE. In terms of the value of market opportunities, it is difficult to put an exact figure on what might be achievable if Scotland had full market access to all significant meat-importing countries around the world.

Costs

There will be a cost to the rendering sector through loss of throughput material as there will be less SRM to be disposed of. If there is a reduction in Category 1 rendering capacity, it may result in increased disposal costs to livestock producers and meat establishments due to reduced competition, and increased transport costs.

There would be resource costs to the Scottish Government, the Department of Environment, Food and Rural Affairs (Defra) and the Foreign and Commonwealth Office (FCO) and non-EU countries to re-negotiate and agree export certificates. There is no direct cost to industry in making an application, however there could be cost implications should trade be disrupted where export conditions need to be re-negotiated.

The effect of achieving NR status on the domestic consumer is difficult to quantify. It can be argued that, on one hand, animals being slaughtered are of a higher health status compared to animals in CR status countries, however conversely it could be suggested that in NR status countries there is a reduction in controls over SRM. The responses to the consultation document will provide an insight into how this is viewed by the consumer and the retail trade, but at this stage, we cannot determine the costs or benefits to the domestic trade.

Scottish Firms Impact Test
This will be completed once the data from the consultation is collected and analysed.

Competition Assessment

There is risk that, with the reduction in the quantity of SRM for disposal, rendering capacity in Scotland may reduce. This could reduce in loss of competition for material for disposal and an increase in cost of future disposal, which would also affect the disposal of fallen stock. The Scottish Government would have concerns if capacity in the rendering industry was reduced, and especially in the context of an epizootic disease situation.

Test run of business forms

There will be no specific business forms involved with the implementation of the proposed legislation.

Legal Aid Impact Test

The proposal is unlikely to have an impact on the legal aid fund.

Enforcement, sanctions and monitoring

Countries that have been assessed as negligible risk or controlled risk must also:

- notify the OIE in writing during the month of November of each year that the epidemiological situation with respect to BSE has remained unchanged, and
- document their continued observance of OIE standards.

Failure to comply provides grounds for the OIE to revoke the given status.

Implementation and delivery plan

We will consider proposals for a Scottish application to the OIE for BSE NR status in light of the responses to this consultation. We are keen to hear views from as wide a variety of individuals and organisations as possible, in particular those involved or with an interest in the livestock, agricultural, food business operator, environmental and academic sectors.

Summary and recommendation

Option 3 is being recommended. This option allows Scotland to make an application to the OIE for BSE NR status. This option is of great economic, environmental and social benefit to both Scottish farming, food and rural industries as well as the Scottish Government.

Scottish Government
Riaghaltas na h-Alba
gov.scot

Application for Bovine Spongiform Encephalopathy (BSE) Negligible Risk for Scotland

A consultation

RESPONDENT INFORMATION FORM

Please Note this form **must** be returned with your response.

Are you responding as an individual or an organisation?

☐ Individual

☐ Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

☐ Publish response with name

☐ Publish response only (anonymous)

☐ Do not publish response

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

☐ Yes

☐ No

APPLICATION FOR BSE NEGLIGIBLE RISK STATUS FOR SCOTLAND – CONSULTATION QUESTIONS

Q1. Are you in favour or against an application for BSE NR status for Scotland?

Comments

Q2. Do you have any comments in relation to the benefits and from the reduction in the volume of SRM? What advantages or disadvantages do you anticipate from the reduction in the volume of SRM?

Comments

Q3 Do you have any comments to make from a public health perspective in relation to the relaxation of SRM-related controls?

Comments

Q4. Do you have any comments from a consumer perspective?

Comments

Q5. In relation to the separation and disposal of SRM from CR and NR animals do you have any further comments?

Comments

Q6 Do you have any concerns that the reduction in the amount of SRM for disposal may reduce the capacity for disposal of SRM and fallen stock in Scotland, and may result in:

- **increased costs for disposal of SRM and fallen stock of all species?**
- **disposal constraints in an epizootic disease outbreak?**

Comments

Q7. Do you have any comments on or any evidence to support the perception that countries with NR status have an improved global image?

Comments

Q8. Do you have any comments on the issue of trade being negatively affected in existing markets should Scotland obtain NR status e.g. due to revision of existing export certificates?

Comments

Q9. If Scotland is upgraded to NR status can you provide examples of how/where trade will improve? This includes accessing new markets and negotiating existing ones.

Comments

Q10. Do you have any comments on possible advantages or disadvantages to other sectors in Scotland? (i.e. dairy, sheep, pork, white meat, equine etc?)

Comments

Q11. If Scotland were successful in achieving NR status, have you any comments on the impact to industry should NR status subsequently be lost?

Comments

Q12. Do you agree that, in order to mitigate the commercial risk in the event of loss of NR status, industry should work towards putting contingency arrangements in place?

Comments

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