



# SCOTTISH EXECUTIVE

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Agriculture Group

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Your ref:  
Our ref:

11 February 2002

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Dear Sir/Madam

## **THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (SCOTLAND) REGULATIONS 2002**

[Click here to view TSE \(Scotland\) Regulations Scotland Scottish Statutory Instruments](#)

1. This letter seeks your views on proposals for new domestic legislation to implement in Scotland EU-wide measures on Transmissible Spongiform Encephalopathies (TSEs). Parallel measures are proposed for the rest of the UK. This is a joint Scottish Executive/Food Standards Agency (Scotland) consultation.

### Background

2. New EU legislation for the prevention, control and eradication of certain TSEs has been in force since 1 July 2001 (EC Regulation 999/2001). This Regulation ("the Community TSE Regulation") was the subject of a consultation letter from this Department, which was sent to interested parties on 24 November 2000. Essentially, the Community TSE Regulation relates to all animal and public health risks resulting from animal TSEs, covering the whole chain of production and the placing on the market of live animals and products of animal origin. Its effect is to introduce measures to ensure that the full extent of the disease situation in all Member States is reliably ascertained, and that appropriate control measures are in place right across the Community.

3. The Community TSE Regulation is directly applicable in all Member States. Most of its provisions are already in force under current UK legislation. For the sake of clarity, however, we wish to consolidate and, where appropriate, amend UK legislation, ensuring that provisions for the administration and enforcement of the Community TSE Regulation are fully reflected in Scottish legislation. This will be achieved through the introduction of new Regulations under the European Communities Act 1972. In some respects the new Community rules go further than existing UK legislation and the proposed new domestic Regulations will deal with these aspects too.



4. The Community TSE Regulation specifies five categories into which Member States and third countries wishing to export into the Community will be placed, depending on their BSE risk. Until the categories of Member States are decided on, controls on animal feeding and on SRM are covered by transitional measures. The new Regulations make provision for the Community TSE Regulation and the Community Transitional Measures.

5. The new Regulations do not address those parts of the Community TSE Regulation, which relate to trade and exports of live animals or trading in products of animal origin. These aspects will be covered by separate legislation to be issued shortly.

6. As a result of the introduction of the new Regulations, many of the existing UK or Scottish legal instruments relating to BSE will be revoked. This is a formality designed to avoid duplication of legislation, and will not, of itself, lead to substantive changes in the control regime.

#### Draft legislation

7. Enclosed is a copy of the draft Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002.

8. In these draft Regulations, Part II sets out the arrangements for monitoring TSEs in bovine, ovine and caprine animals. There are requirements, in addition to current cattle testing arrangements, to test for TSEs a number of sheep and goats over the age of 18 months which would have been suitable for human consumption. There are further requirements in relation to testing a random sample of sheep and goats that have fallen on farm. The new Regulations provide enforcement powers to undertake this testing, which is currently underway on a voluntary basis.

9. Part III of the Regulations covers the Community transitional measures on animal feeding. When the Community Transitional measures lapse, after a maximum period up until July 2003, the restrictions will be limited to feeding mammalian protein to farmed animals, and to any mammal apart from cats and dogs. There will also then be a ban on feeding rendered ruminant fats to any ruminant. Meanwhile, the draft Regulations continue the controls currently set out in the Processed Animal Protein (Scotland) Regulations 2001 and the BSE (No. 2) Order 1996 (as amended). Extended controls are being introduced on the transport of feed materials, and there are additional enforcement powers which will enable officials to recall and dispose of processed animal proteins and feed containing them (similar to those in the BSE (No. 2) Order 1996 (as amended) which apply to mammalian meat and bonemeal).

10. Also, we are looking to implement Community requirements for premises manufacturing feed using fishmeal to be individually authorised. The draft SSI provides an opportunity to re-visit this issue: rather than visiting and authorising individual premises, a registration scheme is proposed. This will apply to those buying in fishmeal as a 'straight' ingredient to manufacture feed (i.e. mills/home-mixers).

11. Finally, part III of the Regulations makes provision for appeals against suspension and withdrawal of approvals of any premises (see paragraph 14 for further details).

12. Part IV of the draft Regulations deal with Specified Risk Material, largely mirroring the arrangements currently laid down in the Specified Risk Material Regulations 1997 (as amended) and the Specified Risk Material Order 1997 (as amended). A new prohibition is included here, requiring the collection and transport of SRM in separate vehicles from non-SRM material. Also, there are new licensing provisions to ensure the separation of live animals and products of animal origin in premises which are permitted to use SRM in production and live animals for research.

13. There is a continuing requirement that vertebral column from cattle over thirty months must be treated as SRM and removed in licensed cutting plants specifically designated for the purpose. This only affects members of the Beef Assurance Scheme (BAS), who can sell cattle for human consumption up to 42 months. Community law permits vertebral column removal at licensed cutting plants or, at the discretion of Member States, at licensed butchers' shops. However, there are clear problems with enforcement of such rules at these premises. We propose therefore that removal can only take place in licensed cutting plants specifically designated for the purpose, as is currently the case with imported carcasses. We would not insist on 100% MHS supervision, although MHS visits to cutting plants would check compliance with the legislation. Any additional costs associated with MHS supervision would be met by the FSA. The FSA will be writing separately to BAS producers to set out the proposed designation procedure.

14. This part of the Regulations also includes provisions for appeals to be made against suspension or revocation of licences of any premises. Although we are still considering the precise arrangements under which appeals should be heard, the aim is to develop an open, transparent and genuinely independent process. It is intended that decisions of the appeal tribunal (or other relevant body) should be binding on all parties. This approach is in line with expectations under the Human Rights Act 1998.

15. Part V sets out the measures for dealing with animals suspected of being affected by a TSE, including notification of animals, movement restrictions and compensation. These provisions largely mirror the existing UK rules.

16. Part VI of the Regulations deal with the placing on the market of first generation progeny, semen, embryos and ova of TSE suspect or confirmed animals.

17. The remaining provisions of the draft Regulations cover powers of entry, powers to take samples and other enforcement provisions, generally following the measures currently in force in the UK.

## **Timing**

18. It is intended that the new Transmissible Spongiform Encephalopathy (Scotland) Regulations should come into force in April 2002.

## **Impact on business**

19. A draft Regulatory Impact Assessment (RIA) is also enclosed. Your comments on this would also be particularly welcome.

20. The RIA explains that the compliance costs for the new Regulations in Scotland should be relatively modest. This is because many of the measures involved are already in place under existing UK or Scottish legislation. We would welcome views on any additional burdens on businesses.

### **England, Wales and Northern Ireland**

21. The attached draft legislation would only apply to Scotland. Agriculture Departments in England, Wales and Northern Ireland will be consulting separately on proposals for equivalent legislation.

### **Deadline for comments**

22. Normally twelve weeks is allowed for written consultation exercises, but certain exceptional circumstances may unavoidably require a shorter period. In this case we are driven by a timetable dictated by the EU, and we will need to have your comments by 14 March 2002.

### **The consultation process**

23. We intend to make available, at the end of the consultation process, copies of all the comments received. It will be assumed that your reply can be made publicly available in this way, unless you indicate clearly that you wish all or part of it to be excluded from this arrangement.

### **Other information**

24. A copy of this consultation letter has been put on the Scottish Executive website. The address is [<http://www.scotland.gov.uk>]. Further information about BSE can be viewed at the following address: <http://www.defra.gov.uk/animalh/bse/index.html>.

25. If you are aware of any organisations or individuals who might be interested in seeing this letter but have inadvertently been left off the circulation list, please contact Ian Murdoch (see contact details below) who will arrange for a copy to be sent to them.

Contact point for responses and enquiries

26. **Please send your comments to Mr Ian Murdoch, Scottish Executive, Environment and Rural Affairs Department, BSE, Scrapie and Animal Waste Branch, Pentland House, 47 Robb's Loan, Edinburgh, EH14 1TY (e-mail: [Ian.Murdoch2@Scotland.gsi.gov.uk](mailto:Ian.Murdoch2@Scotland.gsi.gov.uk) by no later than Thursday, 14 March 2002.** If you have any questions relating to this consultation exercise, please contact Ian at this address, or telephone him on 0131-244-6005.

Yours faithfully

M M Morgan

CONSULTATION LIST

All ABPO Approved Waste Food Processors in Scotland  
All Churches and Faith Groups  
All Local Authorities  
All Political Parties in Scotland  
All Scottish Hunt Kennels  
All Scottish Renderers  
All Scottish XAP Approved Plants  
All SRM Collection Centres in Scotland  
Association of Deer Management Group  
Association of Public Analysts  
Association of Scottish Chambers of Commerce  
Blackface Sheep Breeders Association  
Blair Drummond Safari Park  
Blue Faced Leicester Sheep Breeders Association  
Border Leicester sheep Breeders Association  
British Deer Society  
British Goat Society  
British Hospitality Association  
British Medical Association (Scottish Branch)  
British Veterinary Association  
British Veterinary Association (Scottish Branch)  
CBI Scotland  
Central Framers (2000) Ltd  
Central Framers Ltd  
Cheviot Sheep Society  
Convention of Scottish Local Authorities  
Crofters' Commission  
Deer Commission of Scotland  
East of Scotland Farmers Ltd  
East of Scotland Water Authority  
Edinburgh Zoo  
Environment Services Association c/o Shanks and McEwan (Waste Services Limited)  
Falkirk College (1)  
Federation of Small Businesses  
Federation of Wholesale Distributors  
Food and Drink Federation  
Glasgow Zoo  
Hannah Research Institute  
Health & Safety Executive  
Highlands and Islands Enterprise  
Highlands and Islands Livestock Ltd  
Hillend Horncraft  
Hospital Caterers Association (Scotland)  
Independent Farming Group  
Institute of Auctioneers and Appraisers in Scotland  
Institute of Waste Management (Scottish Contact)

MacSweens of Edinburgh  
McCauly Land Use Research  
Meat and Livestock Commission  
Meat and Livestock Commission (Scotland)  
Moredun Research Institute  
Mr B Flynn (Pakistan Society Edinburgh)  
National Cattle Association  
National Farmers Union of Scotland  
National Livestock Traders and Producers Association  
National Sheep Association (Scottish Branch)  
North Country Cheviot Sheep  
North County Cheviot Sheep Society  
North Eastern Farmers Ltd  
North of Scotland Water Authority  
NUFS Pig and Poultry Rep.  
Quality Meat Scotland  
R H Miller (Agricultural) Ltd  
Road Haulage Association Ltd (Scottish Branch)  
Rowett Research Institute  
Royal Dick Veterinary College  
Royal Environmental Health Institute of Scotland  
Royal Highland and Agricultural Society of Scotland  
Royal Zoological Society  
Scotch Quality Beef & Lamb Association  
Scottish Agricultural Organisation Society Ltd  
Scottish Agriculture Colleges Central Office  
Scottish Association of Master Bakers  
Scottish Association of Meat Wholesalers  
Scottish Beef Council  
Scottish Centre for Inspection and Environmental Health  
Scottish Chambers of Commerce  
Scottish Consumer Council  
Scottish Consumers Association  
Scottish Consumers Association for Natural Food  
Scottish Co-operative Wholesale Society Ltd  
Scottish Crofting Foundation  
Scottish Crookmakers Association  
Scottish Dairy Association  
Scottish Egg Producer Retailers Association  
Scottish Enterprise  
Scottish Environment Protection Agency  
Scottish Federation of Fishmongers  
Scottish Federation of Meat Traders Association  
Scottish Fish Merchants Federation  
Scottish Food and Drink Federation  
Scottish Food Trade Association  
Scottish Grocers Federation  
Scottish Knackery Representative – Douglasbrae Knackery  
Scottish Landowners Federation  
Scottish Licensed Trade Association  
Scottish Meat Industry Liaison Group  
Scottish Natural Heritage  
Scottish Quality Salmon



INVESTOR IN PE



Scottish Salmon Growers Association  
Scottish Trout Salmon Ltd  
Sheep Veterinary Society  
Shetland Agricultural Association  
Shetland Fish Products  
Shetland Flock Book Society  
Shetland Sheep Breeders Group  
Stackpole Farms Ltd  
UKASTA (Scotland)  
UKASTA (Scottish Representative)  
UKASTA Scottish Council  
United Fish Products  
United Molasses  
Waste Reduction Europe Ltd  
West of Scotland Water  
Wholesale Grocers' Association  
Women's Food and Farming Union



# **PARTIAL REGULATORY IMPACT ASSESSMENT**

## **1. Title**

Regulatory impact assessment of the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002.

## **2. Purpose and intended effect**

Regulation (EC) No. 999/2001 of the European Parliament and of the Council (the Community TSE Regulation) lays down rules for the prevention, control and eradication of certain Transmissible Spongiform Encephalopathies (TSEs) on an EU-wide basis. The Community TSE Regulation, which came into force on 1 July 2001, largely mirrors existing domestic controls.

## **3. Objective**

Against this background, and as part of its ongoing commitment to the eradication of BSE and the protection of human and animal health, the Executive wishes to ensure that the Community TSE Regulation is fully reflected in Scottish legislation. The proposed Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 would revoke and replace much of the existing legislation dealing with BSE issues and provide powers and penalties in order to effectively administer and enforce the Community TSE Regulation in Scotland. The proposed SSI does not cover trade aspects of the Community TSE Regulation, which will be addressed separately in the coming weeks.

## **4. Risk**

BSE in cattle is a terrible disease which has already cost the UK around £4.5 billion and, as a result of variant CJD, has led to the loss of over 100 lives. It has caused large-scale disruption in the livestock industry and loss of export markets, as well as major concern to consumers and in relation to the environment. And there is an acknowledged theoretical risk that BSE could be found in sheep. The incidence of BSE is increasing in other Member States, and it is clearly in the interests of the Community as a whole to put in place measures to ensure that appropriate measures to tackle TSEs are taken across the EU. The Executive needs to take powers to ensure that the new Community rules are fully implemented in this country.

## **5. Options**

EC Regulations are directly applicable and therefore Scottish Ministers have no other option but to implement them in full.

## **6. Costs and benefits**

The conditions set out in the Community TSE Regulation largely reflects the regime already in place in the UK, either under Community rules or under national legislation. This includes controls on animal feeding, removal and disposal of Specified Risk Material (SRM), notification and handling of

TSE suspect cases (including compensation) and rules for placing on the national market meat and other animal products. Accordingly, the introduction of the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 should, in most cases, impose no further costs on businesses.

The Community TSE Regulation introduces extended active TSE surveillance requirements (see paragraph 7, below), which will generate important information on the declining BSE epidemic in cattle. If the results of testing indicate that the measures put in place in 1996 (i.e. to make the feed ban fully effective) have largely been successful in controlling the disease, this will strengthen the case in seeking export markets with countries that at present refuse to import UK beef and beef products. Such benefits would, however, be longer term.

However, we might also discover more cases of BSE than anticipated. The number of cases of BSE in cattle born after the feed ban is particularly important. Whatever the results, they will provide useful information about the true levels of BSE in the UK and Scottish herds and will guide future decisions about maintaining and as necessary developing policies to ensure the continued reduction and eventual eradication of BSE in cattle. They will also provide important information for the Food Standards Agency's proposed review of the Over Thirty Month rule – due to be carried out later this year.

Requirements for additional testing of small ruminants will help us in applying measures under the National Scrapie Plan designed specifically to eradicate scrapie from scrapie-affected flocks.

## **7. Compliance costs**

As discussed, the domestic compliance costs for the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 as currently drafted are expected to be relatively modest since the measures required are already in place under existing national legislation. This is due to the fact that, in response to the BSE epidemic, we have already introduced many of the measures that are now included in the Community TSE Regulation.

The following parts of the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 are those which are likely to entail additional compliance costs:

- i). Part II of the Regulations consolidate and extend the existing major active TSE surveillance programme. There is a requirement additionally to test for TSEs a number of sheep and goats over the age of 18 months which would have been suitable for human consumption, as well as the extension of existing cattle testing requirements to fallen stock and casualty animals aged over 24 months, which was introduced last month. The Regulations provide enforcement powers to undertake this testing: including a requirement for abattoirs to co-operate with the testing requirements, and powers to identify, seize and slaughter animals for testing. There is also a requirement to test a random sample of sheep and goats that have fallen on farm. We are therefore proposing to introduce legal powers to allow us to require randomly selected keepers of sheep and goats to provide a fallen animal within a time limit (if available).

The compliance costs for a typical business, as a direct result of the Regulations, would be very small or negligible. The benefit of not having to pay for the collection of fallen animals will more than compensate. A typical business would be a farm. The only direct costs are the time it takes to telephone to notify SEERAD or its agents of fallen stock and, in the case of fallen sheep, the cost of the phone call (fallen cattle can be notified via a freephone helpline). There will also be the time it takes to accompany the haulier to the fallen animal(s) and to supply the necessary identification documents. This time equates to a few pounds per case and is not a regular cost.

The extended testing requirements will affect some businesses since carcasses that would normally be collected and retained by, say, a knackers' yard or hunt kennel, will be tested by SEERAD agents and incinerated. The requirement on farmers, if randomly selected, to supply a fallen animal may also involve limited and irregular costs. *What are these costs likely to be?*

The requirement on slaughterhouses to co-operate in the TSE surveillance programme may also give rise to limited compliance costs. These are likely to be associated with the loss of carcasses, disruption to the production line, disposal of SRM and blood. *Can the costs be estimated?*

ii). Under existing controls, SRM must be conveyed either in an impervious container that holds nothing but SRM, or in a part of the vehicle that is impervious and holds nothing but SRM. Provided these conditions are satisfied it is therefore currently permissible for an SRM load to be carried in the same vehicle as a non-SRM load.

The Community TSE Regulation requires that SRM is completely separated from other waste, and is collected separately. Part IV of the draft Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 therefore provides that SRM must be collected and transported in separate vehicles from non-SRM material. This will safeguard against any possible risk of cross-contamination. Separation of the material must be maintained at all times. The only exception to this rule is in a rendering plant, where non-SRM may be mixed with SRM providing that the entire mixture is treated to SRM specifications. Mixing at the rendering plant does not derogate from the requirement to transport SRM and non-SRM separately. *What are the costs likely to be for transporters, slaughterhouses, knacker's yards, hunt kennels and incinerators? What benefits is the permission to mix SRM and non-SRM at rendering plants likely to bring?*

iii) There is a continued requirement that vertebral column from cattle over thirty months must be treated as SRM and be removed in licensed cutting plants. This only involves members of the Beef Assurance Scheme (BAS). Member States have the option of allowing removal in licensed butchers' shops, but this option is not favoured in the UK for enforcement reasons. These continued measures, in place since April 2001 are not expected to involve additional compliance costs for members of the BAS.

iv). The TSE Regulation does not apply to cosmetic or medicinal products; products not destined for use in human food, animal feed or fertilisers; or products destined for exhibition,

teaching, scientific research, special studies or analysis; or live animals used or intended for research.

The Community TSE Regulation (Article 2), however, requires that these products and animals are kept separate from products of animal origin and animals that are within its scope, in order to avoid cross-contamination or substitution. The draft Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 enforce this requirement by introducing licensing for premises on which there are specified risk materials or infected animals for the purposes listed above. This continues and extends licensing requirements for technical uses in the SRM Order 1997 and, for exemptions from the feed ban for research purposes as outlined under the BSE (No. 2) Order 1996 (as amended). The conditions for the issue of a licence are strictly limited to demonstrating separation from animals and animal products that are not subject to the TSE Regulation from those which are. *Can the costs of fulfilling the separation requirement and demonstrating separation be quantified?*

v). If adopted as proposed, the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 will extend the enforcement powers available in the current BSE (No.2) Order 1996 (as amended) to recall and dispose of feed contaminated with meat and bonemeal. In the new legislation these powers will also apply to processed animal proteins and feed containing them. There will be no cost implications for those complying with the legislation.

The draft Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 also include provision for a scheme to register those premises which manufacture feed using fishmeal. The costs of a registration scheme to the 3-4,000 premises across GB involved should be minimal. This will address an existing Community requirement not included in the Processed Animal Protein (Scotland) Regulations 2001.

The draft regulations extend controls on transport of feedingstuffs covered by the Processed Animal Protein (Scotland) Regulations 2001. This is designed to ensure that the measures apply throughout the support network, to transport from intermediaries such as merchants and storage depots, rather than only to the premises of production or manufacture. The feed manufacturers' trade associations have already adopted a Code of Practice on, for example, separation of feedingstuffs during transport, and have assured us that their members are complying with the Code. Therefore, the impact on industry should be minimal.

## **8. Other costs**

The enhanced TSE testing programme for Great Britain will cost around £50 million annually.

## **9. Impact on small businesses**

If the Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 are adopted, they will apply across the industry, which includes small businesses. However, there will be no discrimination against small businesses.

## 10. Consultation

*A summary of replies received in response to the consultation exercise will be included here.*

This Department conducted an extensive public consultation during November 2000 on proposals for a Community TSE Regulation. It was made clear as part of this consultation exercise that the Community measures would have to be transposed into domestic legislation to allow us to enact national enforcement measures. Those consulted did not actively oppose this point.

## 11. Enforcement, sanctions, monitoring and review

The Transmissible Spongiform Encephalopathy (Scotland) Regulations 2002 apply to Scotland only. Parallel legislation is being introduced in England, Wales and Northern Ireland.

In premises licensed under the Fresh Meat (Hygiene and Inspection) Regulations 1995, enforcement will continue to be carried out by the Meat Hygiene Service. In relation to other premises, enforcement will remain the responsibility of Local Authorities. Inspections will be carried out to ensure compliance with the Regulations and in addition to carrying out the ad hoc inspections to meet EU requirements, complaints and allegations of irregularities will be followed-up.

In most instances it is anticipated that advice and warnings, with a time scale for compliance (followed-up as necessary), would be given before a decision was taken to initiate prosecution action. The offences and penalties under the Regulations are the maximum allowed under the parent legislation (the European Communities Act 1972). These penalties reflect the potentially serious nature of the offences. Failure to comply with the Regulations could have serious implications for human or animal health.

This legislation will be reviewed when necessary as it forms an integral part of the Executive's general policy on Transmissible Spongiform Encephalopathies.

## 12. Regulatory quality

**Declaration: I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.**

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**Ross Finnie**  
**Environment and Rural Development Minister**

## **Contact**

If you have any questions relating to this consultation exercise, please contact Mr Ian Murdoch, Scottish Executive, Environmental Rural Affairs Department, BSE, Scrapie and Animal Waste Branch, Pentland House, 47 Robb's Loan, Edinburgh, EH14 1TY, telephone him on 0131-244-6005 or e-mail him at [Ian.Murdoch2@Scotland.gsi.gov.uk](mailto:Ian.Murdoch2@Scotland.gsi.gov.uk)