SCOTTISH STATUTORY INSTRUMENTS

2008 No. 417

ANIMALS

ANIMAL HEALTH

The Transmissible Spongiform Encephalopathies (Scotland) Amendment (No. 2) Regulations 2008

Made - - - -	*16th December 2008*
Laid before the Scottish Parliament - - - -	*17th December 2008*
Coming into force - -	*1st January 2009*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**) and all other powers enabling them to do so.

The Scottish Ministers have carried out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**2**).

Citation and commencement

1. These Regulations may be cited as the Transmissible Spongiform Encephalopathies (Scotland) Amendment (No. 2) Regulations 2008 and come into force on 1st January 2009.

Amendment of the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006

2.—(1) The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006(**3**) are amended in accordance with the following paragraphs of this regulation.

(2) At the end of the definition of "inspector" in regulation 2(1) (interpretation) insert– "or

(c) a person appointed as such for the purposes of these Regulations by the Food Standards Agency in relation to its enforcement responsibilities under these Regulations;".

(**1**) 1972 c. 68. Section 2(2) was amended by the Scotland Act 1998 (c. 46) ("the 1998 Act"), Schedule 8, paragraph 15(3), and the Legislative and Regulatory Reform Act 2006 (c. 51), section 27(1). The functions conferred upon the Minister of the Crown under section 2(2) of the European Communities Act 1972, insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.

(**2**) O.J. No. L 31, 1.2.02, p.1, as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.03, p.4), Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 8.4.06, p.3) and Commission Regulation (EC) No. 202/2008 (O.J. No. L 60, 5.3.08, p.17).

(**3**) S.S.I. 2006/530; amended by S.S.I. 2007/357 and 2008/166.

(3) In regulation 5 (the Schedules), for "restrictions on dispatch to other member states and to third countries", substitute "restrictions on placing on the market and export".

(4) In regulation 12 (appointment of inspectors), after "local authority", insert "and the Food Standards Agency".

(5) In regulation 20(3) (enforcement) after "Schedule 6", insert "and paragraphs 1 and 3 of Schedule 7".

(6) For Schedule 2 (TSE monitoring), substitute–

"SCHEDULE 2 Regulation 5

TSE monitoring

CONTENTS

PART 1

Monitoring for TSE

Interpretation

1. In this Schedule–

"Amended Community TSE Regulation" means the amended Community TSE Regulation as further amended by Commission Regulation (EC) No. 571/2008 amending Annex III to Regulation (EC) No. 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE(**4**), and as read with Commission Decision 2008/908/EC of 28th November 2008 authorising certain Member States to revise their annual BSE monitoring programme(**5**);

"approved sampling site" means a sampling site approved under paragraph 13 or a sampling site in another part of the United Kingdom approved by the competent authority in that part of the United Kingdom to carry out sampling for the same purpose;

"approved testing laboratory" means a laboratory approved under paragraph 14 or a laboratory in another part of the United Kingdom approved by the competent authority in that part of the United Kingdom to carry out the test; and

"no test result" means a sample that an approved testing laboratory has certified cannot be tested for any reason.

Notification of the body of a goat for the purpose of monitoring under Article 6 of the Community TSE Regulation

2. For the purpose of monitoring under Article 6 of the Community TSE Regulation, a person who has possession or control of the body of a goat aged 18 months or over at death, must–

(a) within 24 hours from the time when the animal dies or is killed or the body comes into that person's possession or control notify the Scottish Ministers; and

(b) where the Scottish Ministers direct, detain it until it has been collected by or on behalf of the Scottish Ministers,

and failure to do so is an offence.

(2) This paragraph does not apply in relation to goats slaughtered for human consumption or killed in accordance with Schedule 4.

Delivery of the body of a bovine animal for the purposes of monitoring under Article 6 of the Community TSE Regulation

3.—(1) For the purpose of monitoring under Article 6 of the Amended Community TSE Regulation, a person who has possession or control of the body of a bovine animal over 48 months of age must, unless directed otherwise by the Scottish Ministers, within 24 hours either–

(a) make arrangements with another person for that other person to collect it and deliver it to an approved sampling site; or

(b) identify an approved sampling site that will carry out the sampling and deliver the animal to that site so as to arrive at the site within 72 hours,

and failure to do so is an offence.

(**4**) O.J. No. L 161, 20.6.08, p.4.
(**5**) O.J. No. L 327, 5.12.08, p.24.

(2) The periods of 24 and 72 hours referred to in sub paragraph (1) run from the time when the animal died or was killed or came into the possession or control of the person to whom the requirements of that sub paragraph apply.

Consignment and slaughter of over-age bovine animals

4. If a bovine animal was born or reared in the United Kingdom before 1st August 1996, it is an offence–

(a) to consign it to a slaughterhouse for human consumption (whether the animal is alive or dead); or

(b) to slaughter it for human consumption in a slaughterhouse.

Brain stem sampling of bovine animals

5.—(1) The occupier of a slaughterhouse in which a bovine animal which must be tested in accordance with point 2(1) or 2(2) of Part I of Chapter A of Annex III to the Amended Community TSE Regulation is slaughtered shall–

(a) take a sample of brain stem in accordance with point 1 of Chapter C of Annex X to the Community TSE Regulation; and

(b) arrange for it to be delivered to an approved testing laboratory,

and failure to do so is an offence.

(2) The Scottish Ministers must, by means of a notice, notify the occupier of a slaughterhouse if a bovine animal comes into the categories specified in point 2(1) of Part I of Chapter A to Annex III to the Amended Community TSE Regulation (except in the case of a dead animal consigned to a slaughterhouse with a written declaration from a veterinary surgeon that it falls into one of those categories).

(3) In accordance with point 5 of Part I of Chapter A of Annex III to the Community TSE Regulation, the Scottish Ministers may serve a notice on the occupier of a slaughterhouse requiring the occupier to sample and send for testing in accordance with sub paragraph (1) any bovine animal slaughtered there.

Slaughter of bovine animals over 30 months of age

6.—(1) It is an offence for the occupier of a slaughterhouse to use the slaughterhouse to slaughter for human consumption a bovine animal aged over 30 months unless the Scottish Ministers have approved the Required Method of Operation (referred to in this Schedule as "RMOP") for that slaughterhouse and that occupier.

(2) The RMOP shall, as a minimum–

(a) describe the procedures that will be followed to comply with Part 1; and

(b) describe all the systems and procedures specified in Part 2.

(3) The Scottish Ministers shall approve the RMOP if they are satisfied that all the requirements of the Amended Community TSE Regulation and these Regulations will be complied with, and the occupier shall demonstrate this by means of an assessment of 2 days duration in which bovine animals are slaughtered (using bovine animals under 30 months old unless the slaughterhouse is operating for the purposes of Commission Regulation (EC) No. 716/96 adopting exceptional support measures for the beef market in the United Kingdom(**6**)).

(**6**) O.J. No. L 99, 20.4.96, p.14, as last amended by Commission Regulation (EC) No. 2109/2005 (O.J. No. L 337, 22.12.05, p.25).

(4) If a bovine animal aged over 30 months is slaughtered for human consumption other than in accordance with the RMOP, the occupier of the slaughterhouse is guilty of an offence.

Retention of products and disposal

7.—(1) In relation to any sampled bovine animal, the occupier of a slaughterhouse, hide market or tannery shall, for the purpose of point 6(3) of Part I of Chapter A of Annex III to the Community TSE Regulation and pending receipt of the test result, either–

(a) retain all carcases and all parts of the body (including the blood and the hide) that will have to be disposed of in the event of a positive result; or

(b) dispose of them in accordance with sub paragraph (2).

(2) For the purposes of points 6(4) and 6(5) of that Part, if a positive result is received for a sampled bovine animal, the occupier of the slaughterhouse shall immediately dispose of–

(a) the carcase and all parts of the body of that animal (including the blood and the hide); and

(b) unless a derogation has been granted under point 6(6) of that Part, the carcase and all parts of the body (including the blood and the hide) of the animal immediately preceding that animal on the slaughter line and the 2 animals immediately following it,

in accordance with point 6(4) of that Part.

(3) If no sample has been sent to an approved testing laboratory for testing in accordance with paragraph 5, or if a no test result is received, in respect of a bovine animal required to be tested under this Schedule, the occupier of the slaughterhouse shall immediately dispose of–

(a) the carcase and all parts of the body (including the blood and the hide) of that animal; and

(b) unless a derogation has been granted under point 6(6) of Part I of Chapter A of Annex III to the Community TSE Regulation, the carcase and all parts of the body (including the blood but not the hide) of the animal immediately preceding that animal on the slaughter line and the 2 animals immediately following it,

in accordance with point 6(4) of that Part.

(4) The Scottish Ministers may grant in writing a derogation under point 6(6) of Part I of Chapter A of Annex III to the Community TSE Regulation if they are satisfied that there is a system in place that prevents contamination between carcases.

(5) In relation to any sampled sheep or goat, the occupier of a slaughterhouse, hide market or tannery shall–

(a) for the purposes of point 7(3) of Part II of Chapter A of Annex III to the Community TSE Regulation, retain the carcase and all parts of the body (including the blood and the hide) pending receipt of the test result; and

(b) in the event of a positive result, immediately dispose of the carcase and all parts of the body (including the blood and the hide) in accordance with point 7(4) of that Part.

(6) Any person who fails to comply with sub paragraphs (1) to (3) or (5) is guilty of an offence.

Compensation

8.—(1) If a bovine animal slaughtered for human consumption tests positive, the Scottish Ministers shall pay compensation for the carcase and all parts of the body (including the blood and the hide) of–

(a) that animal; and

(b) if they are destroyed because of that positive result, the animal immediately preceding it on the slaughter line and the 2 animals immediately following it.

(2) In the case of a bovine animal for which a no test result is received the Scottish Ministers shall–

(a) inform the owner in writing whether they intend to pay compensation for–

(i) the carcase and all parts of the body (including the blood and the hide) of that animal; and

(ii) if they are destroyed because of that no test result, the carcase and all parts of the body (including the blood but not the hide) of the animal immediately preceding it on the slaughter line and the 2 animals immediately following it; and

(b) if they do not intend to pay compensation, give their reasons in writing, and the appeals procedure in regulation 10 applies.

(3) The compensation is the market value, established under the procedure in regulation 11, with the occupier paying any fee arising for nominating and employing a valuer.

(4) Compensation is not payable in any other case.

Persons collecting and delivering

9. A person with whom arrangements are made under paragraph 3(a) for the delivery of a body to an approved sampling site must, unless directed otherwise by the Scottish Ministers, within 48 hours of the time when the body comes into that person's possession or control–

(a) identify an approved sampling site that will carry out the sampling; and

(b) ensure it is delivered to that site,

and failure to do so is an offence.

Destruction without sampling

10. Any person who destroys the body of a bovine animal to which paragraph 3 applies before it has undergone sampling at an approved sampling site, except in accordance with a direction of the Scottish Ministers, commits an offence.

Retention of bodies of bovine animals pending test results

11. An approved sampling site to which the body of a bovine animal has been sent for sampling in accordance with this Part must retain it in accordance with point 6(3) of Part I of Chapter A of Annex III to the Community TSE Regulation, and failure to do so is an offence.

Island areas

12.—(1) The requirements of paragraphs 2 and 3 do not apply in an island area.

(2) In this paragraph, "island area" means–

(a) islands in the area of the Argyll and Bute Council, excluding the island of Bute;

(b) the area of Comhairle nan Eilean Siar;

(c) islands in the area of the Highland Council, excluding the island of Skye;

(d) the area of the Orkney Islands Council; and

(e) the area of the Shetland Islands Council.

Approved sampling sites

13. The Scottish Ministers must on application approve a sampling site to sample animals to which paragraph 3 applies if satisfied that the sampling site has adequate control procedures to carry out the sampling.

Approval of laboratories

14.—(1) The Scottish Ministers must approve laboratories to test samples taken under paragraph 5 if the Scottish Ministers are satisfied that the laboratory–

(a) will carry out the testing in accordance with Chapter C of Annex X to the Community TSE Regulation;

(b) has adequate quality control procedures; and

(c) has adequate procedures to ensure the correct identification of the samples and notification of the test results to the consigning slaughterhouse and to the Scottish Ministers.

(2) The Scottish Ministers may charge the fees set out in the following table for the initial approval and ongoing quality assessment of a laboratory–

Fees for laboratory approvals and quality assessment

	Fee (£)
Initial approval	29,770
Annual proficiency testing and follow up inspection for the first year after approval	8,834
Annual proficiency testing from the second year after approval	4,135
Single proficiency test (in the event of a failure in the annual proficiency testing)	1,385
Hourly rate of an inspector (for any additional inspections that are necessary to check for compliance with the matters set out at sub paragraphs (1)(a) to (c))	87.24

PART 2

Contents of a RMOP

Animal identification and separation

15.—(1) The RMOP shall describe the system that–

(a) enables bovine animals born or reared in the United Kingdom before 1st August 1996 to be identified and ensures that they are not slaughtered for human consumption; and

(b) enables bovine animals born on or after 1st August 1996 which must be tested in accordance with point 2(1) or 2(2) of Part 1 of Chapter A of Annex III to the Amended Community TSE Regulation to be identified and ensures that they are sampled in accordance with this Schedule.

(2) It shall also describe the system that ensures that bovine animals which must be tested in accordance with point 2(1) or 2(2) of Part 1 of Chapter A of Annex III to the Amended Community TSE Regulation are batched together before slaughter.

Brain stem sampling

16.—(1) The RMOP shall describe how the slaughterhouse occupier will ensure that there are–

(a) sufficient staff trained and competent in the taking, labelling, packaging and dispatch of brain stem samples;

(b) hygienic facilities for sampling; and

(c) sampling procedures that do not jeopardise the hygienic production of meat intended for human consumption.

(2) It shall describe how health and safety guidelines designed to minimise the risk of exposure of staff to BSE during brain stem sampling and packaging will be complied with.

Correlation of sample to carcase and all other parts of the body

17. The RMOP shall describe the system linking the brain stem sample of each bovine animal which must be tested in accordance with point 2(1) or 2(2) of Part 1 of Chapter A of Annex III to the Amended Community TSE Regulation to the carcase of that animal and all parts of the body of that animal (including the blood and the hide).

Retention of carcases

18.—(1) The RMOP shall describe the system that ensures that all carcases retained in accordance with paragraph 7(1) are retained in slaughter order either in a sealed or locked chiller or on a sealed or locked rail in an unsealed chiller pending the receipt of the test result.

(2) It shall describe how the occupier will ensure that there is suitable and sufficient chiller space for retaining carcases for the purposes of this Schedule.

Retention of parts of the body

19. The RMOP shall describe the system that ensures that all parts of the body (including the blood and the hide) are retained in accordance with paragraph 7(1).

Disposal before receipt of the result

20. The RMOP shall describe the disposal arrangements for all carcases and all parts of the body (including the blood and the hide) retained pending receipt of a test result but disposed of before the test result is received.

Other measures following sampling

21. The RMOP shall describe the systems in place that ensure that–

(a) brain stem samples are packaged in accordance with packaging instructions P650 of the European Agreement Concerning the International Carriage of Dangerous Goods by Road (version applicable as from 1st January 2005)(**7**);

(b) test results are received, either by fax or by other electronic means; and

(**7**) ISBN 92-1-139097-4.

(c) following a positive or a no test result everything required to be disposed of in accordance with point 6(4) or 6(5) of Part I of Chapter A of Annex III to the Community TSE Regulation or under this Schedule is identified and disposed of accordingly.

Removal of vertebral column

22. The RMOP shall describe the system that ensures that, in the case of a bovine animal for which a negative test result has been received–

(a) those parts of the vertebral column that are specified risk material are not removed in the slaughterhouse; and

(b) the meat containing that specified risk material is consigned to a cutting plant authorised under paragraph 12 of Schedule 6 to remove it.".

(7) For Schedule 7, substitute–

"SCHEDULE 7 Regulation 5

Restrictions on placing on the market and export

Placing on the market or export to third countries of bovine products

1.—(1) It is an offence for any person to place on the market or to export (or offer to export) to third countries, any products consisting of or incorporating any material (other than milk) derived from a bovine animal born or reared within the United Kingdom before 1st August 1996.

(2) The prohibition in sub-paragraph (1) does not apply to the hides of bovine animals born or reared within the United Kingdom before 1st August 1996 (including hides from bovine animals referred to in the third indent of point 1(a) of Annex VII to the Community TSE Regulation) that have been used for leather production in accordance with Article 1(3) of Commission Decision 2007/411/EC(**8**).

Placing on the market or export to third countries of bovine animals

2.—(1) It is an offence for any person to place on the market or to export (or offer to export) to third countries contrary to Part II of Chapter A of Annex VIII to the Community TSE Regulation bovine animals born or reared in the United Kingdom before 1st August 1996.

(2) The prohibition in sub-paragraph (1) does not apply to the placing on the market of such animals for sale or supply to any person in the United Kingdom.

Exports to third countries of products containing specified risk material

3. Any person who fails to comply with point 10(3) of Annex V to the Community TSE Regulation is guilty of an offence.

Functions of the Food Standards Agency

4.—(1) The Food Standards Agency shall carry out the duties of the Member State in relation to paragraphs 1 and 3 within a slaughterhouse or cutting plant.

(2) The Food Standards Agency may appoint as inspectors such persons (whether or not officers of the agency) as they consider necessary for the purpose of enforcing paragraphs 1 and 3 within a slaughterhouse or cutting plant.

(**8**) O.J. No. L 155, 15.6.07, p.74.

(3) An appointment as an inspector may be limited to powers and duties specified in the appointment.".

Consequential amendment

3. For regulation 3(3)(b) of the Animal By Products (Identification) Regulations 1995(**9**), substitute

"(b) any bovine carcase or body part which must be disposed of in accordance with paragraph 7(2) of Schedule 2 to the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006(**10**);".

Transitional provision

4. Notwithstanding regulation 2(6), paragraph 1 of Schedule 2 to the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 shall continue to have effect until 12th January 2009 as if the substitution of that Schedule by these Regulations had not been made.

St Andrew's House,
Edinburgh
16th December 2008

RICHARD LOCHHEAD
A member of the Scottish Executive

(**9**) S.S.I. 1995/614.
(**10**) S.S.I. 2006/530; amended by S.S.I. 2007/357 and 2008/166.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 ("the principal Regulations") which enforce Regulation (EC) No. 999/2001 of European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (O.J. No L 164, 26.6.07, p.7), as amended ("the Community TSE Regulation").

Regulation 5 (the Schedules) of the principal Regulations is amended to refer to the new title of Schedule 7.

Schedule 2 (monitoring for TSE and contents of a RMOP) of the principal Regulations is replaced.

The substituted Schedule 2 provides at paragraphs 2 and 9 for bovine animals that die or are killed to be delivered to an approved sampling centre as defined in paragraph 13, unless the animals dies or is killed at a slaughterhouse, or in an Islands area as defined in paragraph 12.

The substituted Schedule 2 also–

(a) gives effect in Scotland to Commission Decision 2008/908/EC (O.J. No L 327, 5.12.2008, p.24), which authorises certain Member States (including the UK) to revise the annual monitoring programmes provided for by Article 6 of the Community TSE Regulation, by providing in paragraph 5 for the testing at slaughterhouses of brain stems that must be tested in accordance with the Community TSE Regulation as read with that Decision; and

(b) making consequential changes to the provisions carried forward from the replaced Schedule 2, including changes to the Required Method of Operations provided for by paragraph 6 and Part 2 of the substituted Schedule.

Failure to comply with these provisions is an offence.

Schedule 2 is also amended to create new offences of failing to notify the Scottish Ministers of the death of an animal that must be delivered to an approved sampling centre, failing to deliver the body of such an animal to the centre, destroying the body before it has been sampled, and failing to retain the body at the centre until a negative test result has been obtained.

Schedule 7 (restrictions on placing on the market and export) of the principal Regulations is replaced.

The substituted Schedule 7 makes it an offence to place on the market and export live bovine animals and products derived from them to other Member States and to third countries, and provides that paragraphs [1 and 3] of the Schedule shall be enforced by the Food Standards Agency.

Amendments are also made to the definition of "inspector" and regulations 12 and 20 of the principal Regulations in relation to the enforcement by the Food Standards Agency.

Offences are punishable in accordance with regulation 18 of the principal Regulations by–

(a) on summary conviction, a fine not exceeding the statutory maximum or imprisonment for a term of three months or both, or

(b) on conviction on indictment, a fine or imprisonment for a term not exceeding two years or both.

Regulation 3 provides for a consequential amendment to the Animal By-Products (Identification) Regulations 1995.

Regulation 4 of these Regulations saves the effect of paragraph 1 of the replaced Schedule 2 of the principal Regulations so far as they related to bovine animals that die or are killed other than at a slaughterhouse until 12th January 2009.

A Regulatory Impact Assessment has not been produced for this instrument but the impact assessment for the March 2008 Responsibility and cost sharing consultation will be updated to reflect the proposed increase in the testing ages for cattle.