SCOTTISH STATUTORY INSTRUMENTS

2007 No. 473

The Import and Export Restrictions (Foot-and-Mouth Disease) (Scotland) (No. 5) Regulations 2007

Citation, commencement, cessation and extent

- 1.—(1) These Regulations may be cited as the Import and Export Restrictions (Foot-and-Mouth Disease) (Scotland) (No. 5) Regulations 2007, and come into force at 2200 hours on 19th October 2007.
 - (2) These Regulations cease to have effect on 15th November 2007.
- (3) These Regulations extend to Scotland and, in so far as they extend beyond Scotland, do so only as a matter of Scots law.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"approved" means approved in accordance with regulation 3;

"the Decision" means Commission Decision 2007/554/EC concerning certain protection measures against foot-and-mouth disease in the United Kingdom and repealing Decision 2007/552/EC(1), as amended from time to time;

"dispatch" means dispatch from a place within the restricted area to a place outside the restricted area and includes consigning for dispatch;

"Directive 2002/99" means Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption(2);

"export" includes consigning for export;

"inspector" means a person appointed by the Scottish Ministers or a local authority to be an inspector for the purposes of—

- (a) these Regulations;
- (b) the Animal Health Act 1981(3);
- (c) the Products of Animal Origin (Import and Export) Regulations 1996(4);
- (d) the Products of Animal Origin (Third Country Imports) (Scotland) Regulations 2007(5); or
- (e) the Animals and Animal Products (Import and Export) (Scotland) Regulations 2007(6);

O.J. No. L 210, 10.8.2007, p.36, as amended by Commission Decisions 2007/588/EC, 2007/608/EC, 2007/663/EC and 2007/664/EC.

⁽²⁾ O.J. No. L 18, 23.1.2003, p.11.

^{3) 1981} c. 22.

⁽⁴⁾ S.I. 1996/3124, as amended by S.I. 1997/3023, 1998/994, 1999/663, 2000/656 and, as regards Scotland, S.S.I. 2000/62, 171, 288 and 2001/169 and 257.

⁽⁵⁾ S.S.I. 2007/1, as amended by S.S.I. 2007/304.

⁽⁶⁾ S.S.I. 2007/194.

"HACCP" means Hazard Analysis at Critical Control Points, which is a system in which the critical points of the manufacturing process have been identified, assessments have been made of the potential risks at those points, and necessary steps have been taken to minimise those risks;

"local authority" means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994;

"official veterinarian" means a veterinarian who is-

- (a) qualified in accordance with Part A of Chapter IV of Section III of Annex I to Regulation 854/2004 to carry out the controls required of an official veterinarian under that Regulation; and
- (b) appointed by the Scottish Ministers.
- "Regulation 1774/2002" means Regulation (EC) No. 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption(7);
- "Regulation 853/2004" means Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(8);
- "Regulation 854/2004" means Regulation (EC) No. 854/2004/EC of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption(9); and
- "restricted area" means Great Britain; and
- (2) An approval under these Regulations shall be in writing, may be made subject to conditions and may be amended or revoked by notice in writing at any time.

Approvals

3. The Scottish Ministers or a local authority may approve cutting plants, establishments or slaughterhouses for the purposes of these Regulations if satisfied that the occupier of the premises will comply with the conditions of these Regulations.

Importation of live animals

4. No person shall import any live animal of a bovine, ovine, caprine, porcine or other biungulate species into Scotland from another member State.

Dispatch, transit and export of live animals

- **5.**—(1) No person shall dispatch any live animal of a bovine, ovine, caprine, porcine or other biungulate species.
- (2) By way of derogation from paragraph (1) of this regulation, the Scottish Ministers may authorise export of an animal originating outside Great Britain if that animal has made a direct and uninterrupted transit of through the restricted area travelling only on main roads or railway lines in that area.
- (3) No person shall dispatch a biungulate animal originating outside the restricted area to another member State unless at least three days before dispatch the Scottish Ministers have notified that State of the intended dispatch, and in the case of—

⁽⁷⁾ O.J. No. L 273, 10.10.2002, p.1 as last amended by Regulation (EC) No. 829/2007.

⁽⁸⁾ O.J. No. L 139, 30.4.2004, p.55.

⁽⁹⁾ O.J. No. L 139. 30.4.2004, p.206 as last amended by Regulation (EC) No. 1791/2006.

- (a) a bovine, porcine, ovine and caprine animal, the health certificate accompanying the animal bears the words—
 - "Animals conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom"; and
- (b) any other animal, the health certificate accompanying the animal bears the words—
 - "Live biungulates conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".

Export of fresh meat, minced meat, mechanically separated meat and meat preparations

- **6.**—(1) No person shall export any meat of an animal of a bovine, ovine, caprine, porcine or other biungulate species coming from the restricted area or obtained from an animal originating in that area.
- (2) The prohibition in paragraph (1) does not apply in relation to meat bearing the health mark in accordance with Chapter III of Section I of Annex I to Regulation 854/2004 provided that the meat—
 - (a) is clearly identified, and has since the date of production been transported and stored separately from meat which is not eligible for export; and
 - (b) complies with-
 - (i) paragraph (3); or
 - (ii) paragraphs (4) and (5).
 - (3) The meat referred to in paragraph (2)(b)(i) must-
 - (a) have been obtained before 15th July 2007; or
 - (b) be derived from animals reared outside of the restricted area for at least 90 days prior to slaughter, and slaughtered, outside the restricted area, or in the case of meat obtained from wild game species susceptible to foot-and-mouth disease, killed, outside the restricted area.
- (4) The meat referred to in paragraph (2)(b)(ii) must be obtained from domestic bovine, ovine, caprine or porcine animals that—
 - (a) were kept for at least the past 90 days on holdings situated within the areas specified in the Schedule, where there has been no outbreak of foot-and-mouth disease for 90 days;
 - (b) during the 30 days prior to transport to the slaughterhouse, remained under the supervision of the Scottish Ministers on a single holding—
 - (i) situated in the centre of a circle of at least 10 km radius in which there was no outbreak of foot-and-mouth disease during at least the past 30 days; and
 - (ii) where no animal of a species susceptible to foot-and-mouth disease was introduced during the 21 day period prior to loading, except in the case of pigs when that period is 7 days;
 - (c) were transported under control of the Scottish Ministers in means of transport that were cleaned and disinfected before loading from the holding referred to in sub-paragraph (b) directly to the approved slaughterhouse; and
 - (d) were slaughtered less than 24 hours after arrival at the slaughterhouse separately from animals the meat of which is not eligible for export.
 - (5) The meat referred to in paragraph (2)(b)(ii) must-
 - (a) be obtained in an approved slaughterhouse situated within the areas specified in the Schedule;

- (b) be inspected, along with the animal from which it derived, post-mortem by an official veterinarian in the slaughterhouse with no clinical signs or evidence of foot-and-mouth disease identified;
- (c) remain in the slaughterhouse for at least 24 hours after that post-mortem inspection; and
- (d) not be exported where obtained from a slaughterhouse where foot-and-mouth disease has been diagnosed unless—
 - (i) the conditions specified in paragraph (6) are met; and
 - (ii) 24 hours have expired following completion of the cleansing and disinfection required by sub-paragraph (6)(c).
- (6) The occupier of a slaughterhouse where foot-and-mouth disease has been diagnosed must ensure that—
 - (a) all animals present at the date of diagnosis are slaughtered;
 - (b) all meat and dead animals are removed; and
 - (c) the slaughterhouse is cleansed and disinfected under the control of an official veterinarian.
- (7) Any person consigning an animal to a slaughterhouse to produce meat as referred to in sub-paragraph (2)(b)(ii) must–
 - (a) make a written declaration that the animal complies with each of the conditions contained in sub-paragraphs (4)(a) to (d); and
 - (b) ensure that the declaration accompanies the consigned animal.
- (8) The prohibition in paragraph (1) does not apply in relation to fresh meat obtained from an approved cutting plant situated in the restricted area if—
 - (a) only fresh meat as described in sub-paragraph (2)(b) is processed in the cutting plant in any one day;
 - (b) cleansing and disinfection is carried out after processing any meat not meeting the requirement in the preceding sub-paragraph;
 - (c) the meat bears the health mark in accordance with Chapter III of Section I of Annex I of Regulation (EC) No 854/2004;
 - (d) the cutting plant is operated under strict veterinary control;
 - (e) the meat is clearly identified; and
 - (f) the meat has been transported and stored separately from meat which is not eligible for export.
- (9) Meat exported to another member State must be accompanied by a certificate from an official veterinarian which bears the words—
- "Meat conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
- (10) In this regulation and in regulation 8, references to "meat" includes (unless the context requires otherwise) fresh meat, minced meat, mechanically separated meat and meat preparations as defined in points 1.10, 1.13, 1.14 and 1.15 of Annex 1 to Regulation 853/2004.

Export of fresh meat from animals reared outside, and slaughtered in, the restricted area

- 7.—(1) The prohibition in paragraph (1) of regulation 6 does not apply to fresh meat obtained from animals specified in that paragraph—
 - (a) reared outside the restricted area; and

(b) transported directly and under official control in sealed means of transport through the restricted area to an approved slaughterhouse situated in any part of that area,

provided first that the meat is only placed on the market in the restricted area, and second that the conditions specified in paragraph (2) are met.

- (2) The specified conditions are that the-
 - (a) meat is marked in accordance with-
 - (i) the second sub-paragraph of Article 4(1) of Directive 2002/99; or
 - (ii) Commission Decision 2001/304/EC on the marking and use of certain animal products(10);
 - (b) slaughterhouse is operated under strict veterinary control;
 - (c) meat is clearly identified; and
 - (d) meat is transported and stored separately from meat in the restricted area that is not eligible for export.

Meat not eligible for export to another member State

- 8. Meat not eligible for export to another member State must be marked in accordance with-
 - (a) the second subparagraph of Article 4(1) of Directive 2002/99; or
 - (b) Commission Decision 2001/304/EC.

Export of meat products

- **9.**—(1) No person shall export meat products of an animal of a bovine, ovine, caprine, porcine or other biungulate species coming from the restricted area, or prepared using meat obtained from such an animal originating in that area.
- (2) The prohibition in paragraph (1) does not apply to meat products that have been transported and stored since the date of production separately from other meat products not eligible for export, provided that the first mentioned meat products—
 - (a) are clearly identified;
 - (b) bear the health mark in accordance with Chapter III of Annex I to Regulation 854/2004; and
 - (c) are-
 - (i) made from meat described in regulation 6(2)(b); or
 - (ii) have undergone at least one of the relevant treatments laid down for foot-and-mouth disease in Part 1 of Annex III to Directive 2002/99.
- (3) Meat products exported to another member State must be accompanied by a certificate from an official veterinarian which bears the words—
- "Meat products (including treated stomachs, bladders and intestines) conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
 - (4) Paragraph (3) does not apply to meat products which-
 - (a) comply with paragraph (2);
 - (b) have been processed in an establishment operating HACCP and an auditable standard operating procedure that ensures that standards for treatment are met and recorded; and

- (c) are on export accompanied by a commercial document endorsed in accordance with regulation 16 which states that the product has been treated in accordance with sub paragraph (2)(c)(ii).
- (5) Paragraph (3) does not apply to meat products treated in accordance with paragraph (2)(c)(ii) and stored in hermetically sealed containers in such manner as to ensure that they are shelf stable, if the treatment applied is stated in the commercial document accompanying the dispatch of such products.
- (6) In this regulation, the reference to meat products includes treated stomachs, bladders and intestines.

Export of milk

- **10.**—(1) No person shall dispatch milk produced or prepared in the restricted area.
- (2) The prohibition in paragraph (1) does not apply to milk produced in the restricted area which has been subjected to a treatment in accordance with—
 - (a) Part A of Annex IX to Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease(11) (milk intended for human consumption); or
 - (b) Part B of Annex IX to Directive 2003/85/EC, if the milk is not intended for human consumption or is intended for feeding to animals of species susceptible to foot-and-mouth disease.
- (3) The prohibition in paragraph (1) does not apply to milk prepared in an approved establishment in the restricted area if—
 - (a) all milk used in the establishment has been treated in accordance with paragraph (2), or has been obtained from animals reared and milked outside the restricted area;
 - (b) the establishment is operated under strict veterinary control;
 - (c) the milk is clearly identified;
 - (d) the milk is transported and stored separately from milk and dairy products which are not eligible for export; and
 - (e) raw milk from outside the restricted area is carried to the establishment in vehicles which-
 - (i) are cleansed and disinfected prior to carriage; and
 - (ii) have no contact during carriage with any holding in the restricted area on which an animal of a species susceptible to foot-and-mouth disease is kept.
- (4) Milk exported to another member State must be accompanied by an official certificate which bears the words—
- "Milk conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
 - (5) Paragraph (4) does not apply to milk which—
 - (a) complies with paragraph (2);
 - (b) has been processed in an establishment operating HACCP and an auditable standard operating procedure that ensures that standards for treatment are met and recorded; and
 - (c) is on export accompanied by a commercial document endorsed in accordance with regulation 16 which states that the milk has been treated in accordance with paragraph (2).

(6) Paragraph (4) does not apply to milk treated in accordance with paragraph (2) and stored in hermetically sealed containers in such manner as to ensure that they are shelf stable, if the treatment applied is stated in the commercial document accompanying the export of such milk.

Export of dairy products

- 11.—(1) No person shall export a dairy product produced or prepared in the restricted area.
- (2) The prohibition in paragraph (1) does not apply to a dairy product—
 - (a) produced before 15th July 2007;
 - (b) prepared from milk complying with the provisions in regulation 10(2) or (3); or
 - (c) for export to a third country where import conditions permit a product to be subject to treatment, other than as laid down in regulation 10(2), that ensures the inactivation of the foot-and-mouth disease virus.
- (3) The prohibition in paragraph (1) does not apply to a dairy product intended for human consumption produced from—
 - (a) milk of a controlled pH less than 7.0 and subject to a heat treatment at a temperature of at least 72°C for at least 15 seconds, on the understanding that such treatment is not necessary for a finished product the ingredients of which comply with the respective animal health conditions laid down in these Regulations;
 - (b) raw milk-
 - (i) of a bovine, ovine or caprine animal which has been resident for at least 30 days on a holding within the restricted area and situated in the centre of a circle of at least 10 km radius in which no outbreak of foot-and-mouth disease has occurred during the 30 days prior to the date of production of the raw milk; and
 - (ii) subjected to a maturation or ripening process of at least 90 days during with the pH is lowered below 6.0 throughout the substance, and the rind of which has been treated with 0.2% citric acid immediately prior to wrapping or packaging.
 - (4) The prohibition in paragraph (1) does not apply to a dairy product—
 - (a) prepared in an approved establishment in the restricted area if—
 - (i) all milk used in the establishment conforms to the conditions of regulation 10(2) or is obtained from animals outside the restricted area;
 - (ii) all dairy products used in the final product conform to the conditions of paragraph (2)(a) or (b) or (3) or are made from milk obtained from animals situated outside the restricted area;
 - (iii) the establishment is operated under strict veterinary control;
 - (iv) the product is clearly identified; and
 - (v) the product is transported and stored separately from milk and dairy products which are not eligible for export;
 - (b) prepared in a part of the United Kingdom outside the restricted area using milk obtained before 15th July 2007 from the restricted area if the product is—
 - (i) clearly identified; and
 - (ii) transported stored separately from milk products not eligible for export.
- (5) A dairy product exported to another member State must be accompanied by an official certificate which bears the words—

[&]quot;Dairy products conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".

- (6) Paragraph (5) does not apply to dairy products which-
 - (a) comply with paragraphs (2)(a) or (b), (3) or (4);
 - (b) have been processed in an establishment operating HACCP and an auditable standard operating procedure that ensures that standards for treatment are met and recorded; and
 - (c) are on dispatch accompanied by a commercial document endorsed in accordance with regulation 16 which states that the product complies with the requirements of paragraphs (2)(a) or (b), (3) or (4).
- (7) Paragraph (5) does not apply to dairy products treated in accordance with paragraphs (2)(a) or (b), (3) or (4) and stored in hermetically sealed containers in such manner as to ensure that they are shelf stable, if the heat treatment applied is stated in the commercial document accompanying the dispatch of such products.

Export of semen, ova and embryos

- **12.**—(1) No person shall export semen, ova or embryos of an animal of a bovine, ovine, caprine, porcine or other biungulate species, produced in or coming from the restricted area.
 - (2) The prohibition in paragraph (1) does not apply to-
 - (a) Semen, ova and embryos produced before 15th July 2007; and
 - (b) frozen semen of a bovine, ovine, caprine or porcine species, or frozen embryos of a bovine, ovine or caprine species, imported into the United Kingdom in accordance with the conditions in—
 - (i) Council Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species(12);
 - (ii) Council Directive 89/556/EEC on animal health conditions governing intra Community trade in and importation from third countries of embryos of domestic animals of the bovine species(13);
 - (iii) Council Directive 90/429/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species(14); or
 - (iv) Council Directive 92/65/EEC laying down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules(15),

and which since introduction into the United Kingdom have been stored and transported separately from semen, ova and embryos from the restricted area not eligible for export.

- (3) Frozen bovine semen exported to another member State must be accompanied by a health certificate bearing the words—
- "Frozen bovine semen conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
- (4) Frozen porcine semen exported to another member State must be accompanied by a health certificate bearing the words—

"Frozen porcine semen conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".

⁽¹²⁾ O.J. No. L 194, 22.7.1988, p.10 as last amended by the Act of Accession of Austria, Finland and Sweden.

⁽¹³⁾ O.J. No. L 302, 19.10.1989, p.11 as last amended by Act of Accession of Austria, Finland and Sweden.

⁽¹⁴⁾ O.J. No. L 224, 18.8.1990, p.62 as last amended by Council Decision 2001/36/EC (O.J. No. L 13, 19.1.2000, p.21.

⁽¹⁵⁾ OJ No. L268, 14.09.1992, p.54 as last amended by Council Decision 2007/265/EC.

- (5) The health certificate accompanying frozen ovine or caprine semen exported to other member States must bear the words—
- "Frozen ovine/caprine semen conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
- (6) The health certificate accompanying frozen ovine or caprine embryos exported to other member States must bear the words—
- "Frozen ovine/caprine embryos conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
- (7) Frozen bovine embryos exported to another member State must be accompanied by a health certificate bearing the words—
- "Bovine embryos conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".

Export of hides and skins

- **13.**—(1) No person shall export hides and skins of animals of a bovine, ovine, caprine, porcine or other biungulate species, produced in or coming from the restricted area.
 - (2) The prohibition in paragraph (1) does not apply to hides and skins which—
 - (a) were produced before 15th July 2007; or
 - (b) conform to the requirements of point (c) or (d) of paragraph 2 of Part A of Chapter VI of Annex VIII to Regulation 1774/2002; or
 - (c) were produced outside the restricted area in accordance with the conditions laid down in Regulation 1774/2002, and since introduction into the United Kingdom have been transported and stored separately from hides and skins from the restricted area not eligible for export,

provided that treated hides and skins are separated from untreated hides and skins.

- (3) Hides and skins exported to another member State must be accompanied by an official certificate which bears the words—
- "Hides and skins conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
 - (4) Paragraph (3) does not apply to hides and skins which conform to the requirements of either-
 - (a) Points (b) to (e) of paragraph 1 of Part A of Chapter VI of Annex VIII to Regulation 1774/2002; or
 - (b) Points (c) or (d) of paragraph 2 of Part A of Chapter VI of Annex VIII to Regulation 1774/2002,

if compliance with those conditions is stated in the commercial document accompanying the consignment, endorsed in the case of sub-paragraph (b) in accordance with regulation 16.

Export of other animal products

- **14.**—(1) No person shall export an animal product of a bovine, ovine, caprine, porcine or other biungulate species not otherwise mentioned in these Regulations—
 - (a) produced after 15th July 2007 in the restricted area; or
 - (b) obtained from animals originating in the restricted area.

- (2) No person shall export any dung or manure from an animal of a bovine, ovine, caprine, porcine or other biungulate species.
 - (3) The prohibition in paragraph (1) does not apply to-
 - (a) animal products that-
 - (i) have been subject to a heat treatment in a hermetically sealed container with a Fo value of 3,00 or more;
 - (ii) have been subject to a heat treatment in which the centre temperature of the product is raised to at least 70oC; or
 - (iii) were produced outside the restricted area in accordance with the conditions laid down in Regulation 1774/2002, and which since introduction into the United Kingdom have been stored and transported separately from animal products not eligible for dispatch;
 - (b) blood and blood products as defined in paragraphs 4 and 5 of Annex I to Regulation 1774/2002-
 - (i) which have been subjected to one of the treatments provided for in paragraph 3(a) (ii) of Part A of Chapter IV of Annex VIII to that Regulation, followed by an effectiveness check; and
 - (ii) that have been imported in accordance with Part A of Chapter IV of Annex VIII to Regulation 1774/2002;
 - (c) lard and rendered fats which have been subjected to the heat treatment prescribed in point 2(d)(iv) of Part B of Chapter IV of Annex VII to Regulation 1774/2002;
 - (d) animal casings that comply with the conditions in Part A of Chapter 2 of Annex I to Directive 92/118/EC laying down animal health and public requirements governing trade in and imports into the Community of certain products(16), and which are cleaned and scraped and then—
 - (i) salted, bleached or dried; and
 - (ii) subject to effective steps taken to prevent recontamination of the casings;
 - (e) sheep wool, ruminant hair and pig bristles which have undergone factory washing or have been obtained from tanning;
 - (f) unprocessed sheep wool, ruminant hair and pig bristles which are securely enclosed in packaging and in a dry state;
 - (g) pet food conforming to the requirements of paragraphs 2 to 4 of Part B of Chapter II of Annex VIII to Regulation 1774/2002;
 - (h) composite products containing products of animal origin not subjected to further treatment provided that the treatment was not necessary for finished products the ingredients of which comply with the respective animal health conditions laid down in these Regulations;
 - (i) game trophies in accordance with paragraphs 1, 3 or 4 of Part A of Chapter VII of Annex VIII to Regulation 1774/2002;
 - (j) any packed product intended for use as an in-vitro diagnostic or laboratory reagent; or
 - (k) medicinal products as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to medicinal products for human use(17), non-viable medical devices as defined in Article 1(5)(g) of Council Directive 93/42/EEC of 14th June 1993 concerning medical devices(18), veterinary

⁽¹⁶⁾ O.J. No. L 62, 15.3.1993, p.49.

⁽¹⁷⁾ O.J. No. L 311, 28.11.2001, p.67.

⁽¹⁸⁾ O.J. No. L 169, 12.7.93, p.1.

medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to veterinary medicinal products(19) and investigational medicinal products as defined in Directive 2001/20/EC of the European Parliament and of the Council of 4th April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the conduct of clinical trials on medicinal products for human use(20).

- (4) A product specified in paragraph (3) exported to another member State must be accompanied by an official certificate which bears the words—
- "Animal products conforming to Commission Decision 2007/554/EC of 9th August 2007 concerning certain protection measures against foot-and-mouth disease in the United Kingdom".
- (5) Paragraph (4) does not apply to a product specified in sub-paragraphs (a) to (d) and (g) of paragraph (3) accompanied by a commercial document endorsed in accordance with regulation 16 of these Regulations.
- (6) Paragraph (4) does not apply to a product specified in sub-paragraph (e) or (f) of paragraph (3) accompanied by a commercial document stating that the product—
 - (a) has undergone factory washing or have been obtained from tanning; or
 - (b) complies with the conditions laid down in paragraphs 1 and 4 of Chapter VIII of Annex VIII to Regulation 1774/2002.
- (7) Paragraph (4) does not apply to a product specified in sub-paragraph (h) of paragraph (3) produced in an establishment operating HACCP and an auditable standard operating procedure which ensures that pre-processed ingredients comply with the requirements of these Regulations accompanied by a commercial document endorsed in accordance with regulation 16.
- (8) Paragraph (4) does not apply to a product specified in sub-paragraph (j) or (k) of paragraph (3) accompanied by a commercial document stating that the product is for use as in-vitro diagnostic or laboratory reagent or medical products or medical devices, provided that the product is clearly labelled "for in-vitro diagnostic use only", or "for laboratory use only", or as "medical products" or "medical devices".
- (9) Paragraph (4) does not apply to composite products that fulfil the conditions set out in Article 6(1) of Commission Decision 2007/275/EC concerning lists of animals and products to be subject to controls at border inspection posts(21), if they are accompanied by a commercial document which bears the words—

"These composite products are shelf stable at ambient temperatures or have clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance so that any raw material is de-natured".

Exemptions

- 15. The prohibitions in regulations 9, 10, 11 and 14 do not apply to a product—
 - (a) not produced in the United Kingdom and which remains in the original packaging indicating country of origin; or
 - (b) which is-
 - (i) produced in the restricted area in an approved establishment from pre-processed products originating outside that area which, since introduction into the United Kingdom, were transported, stored and processed separately from products not intended for export; and

⁽¹⁹⁾ O.J. No. L 311, 28.11.2001, p.1.

⁽²⁰⁾ O.J. No. L 121, 1.5.2001, p.34.

⁽²¹⁾ O.J. No. L 116, 4.5.2007, p.9.

(ii) accompanied by a commercial document or official certificate as required by these Regulations.

Endorsement of commercial documents

- **16.**—(1) Where reference is made to a commercial document being endorsed in accordance with this regulation, the document must have attached to it a copy of the official certificate which—
 - (a) states that the production process has been audited and found to be-
 - (i) in compliance with the appropriate requirements in Community animal health legislation; and
 - (ii) suitable to destroy the foot-and-mouth disease virus; or
 - (b) states that the product or products concerned have been produced from pre-processed materials which have been certified in accordance with paragraph (a), and that provisions are in place to avoid possible re-contamination with the foot-and-mouth disease virus.
- (2) The certificate shall bear a reference to the Decision, shall be valid for 30 days, shall state the expiry date and shall be renewable after inspection of the establishment.
- (3) In case of products for retail sale to the final consumer, a consolidated consignment other than fresh meat, minced meat, mechanically separated meat and meat preparations, each of which is eligible for export in accordance with these Regulations, may be exported if sent from an approved establishment accompanied by a commercial document endorsed by the attachment of a copy of an official veterinary certificate which—
 - (a) confirms that the establishment of export has in place a system to ensure that goods can only be exported if they are traceable to documentary evidence of compliance with these Regulations;
 - (b) confirms that this system has been audited and found satisfactory;
 - (c) refers to the Decision;
 - (d) is valid for 30 days;
 - (e) states the expiry date; and
 - (f) is renewable only after the establishment had been audited with satisfactory results.

Personal exports

17. No person travelling out of Scotland to a place outside the restricted area shall take with them in any personal luggage or on any other non-commercial basis anything prohibited from being dispatched or exported by these Regulations.

Offers to dispatch or export

18. No person shall offer to dispatch or export, or accept orders for the dispatch or export of, anything prohibited from being dispatched or exported by these Regulations, whether on the internet or otherwise.

Cleansing and disinfection

19.—(1) Any person in charge of a vehicle used to transport any live animal of a bovine, ovine, caprine, porcine or other biungulate species shall cleanse and disinfect that vehicle after the transport of the animal is completed.

(2) That person shall ensure that a record is kept of the date and place of the cleansing and disinfection, in accordance with Article 12(2)(d) of Council Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine(22).

Powers of an inspector

- **20.**—(1) An inspector shall, on producing, if required to do so, some duly authenticated document showing his authority, have the right to enter any land or premises at all reasonable hours for the purpose of ascertaining whether there is or has been on the land or premises any contravention of these Regulations.
- (2) An inspector shall have powers to carry out all checks and examinations necessary for the enforcement of these Regulations, and in particular may—
 - (a) detain any vehicle, vessel, container or anything which the inspector reasonably suspects to contain animals or products controlled by these Regulations and intended for dispatch or export for as long as is reasonably necessary to determine whether the consignment complies with the conditions for dispatch or export;
 - (b) search any premises;
 - (c) carry out inspections of any processes used for the marking and identification of animals, any premises and any installation;
 - (d) examine documentary or data processing material relevant to the checks carried out under these Regulations, including any import or export manifesto; and
 - (e) take with him a representative of the European Commission acting for the purposes of the Decision.
- (3) In this regulation "premises" includes any place, installation, vehicle (including any container, trailer, semi-trailer, caravan or other thing which is designed or adapted to be towed by another vehicle), train, ship, vessel, boat, craft, hovercraft or aircraft.

Illegal export of products

- **21.**—(1) An inspector who has reasonable grounds to suspect that any product other than an animal is intended to be exported in contravention of these Regulations may seize and remove the product.
 - (2) An inspector who has seized and removed a product shall forthwith-
 - (a) apply to the sheriff for an order under paragraph (3); and
 - (b) intimate that application to any person appearing to the inspector to be in charge of the product.
- (3) The sheriff, if satisfied that it was intended to export the product in contravention of these Regulations, shall-
 - (a) if satisfied that the product can be returned to the owner without a significant risk of a further attempt to export it in contravention of these Regulations, order that it is so returned; or
 - (b) if not satisfied that the product can be returned in accordance with sub-paragraph (a), order that is to be put into storage (if practicable) or destroyed.
- (4) The owner and any person in charge of a product destroyed or disposed in accordance with an order under paragraph (3) shall be jointly and severally liable for the costs incurred in the return to the owner, removal to storage, storage or destruction or disposal.

- (5) An inspector may apply to the sheriff for the destruction of a product stored in accordance with an order under paragraph (3), and the sheriff shall order that it is to be destroyed if satisfied that the owner cannot—
 - (a) be found; or
 - (b) pay the costs associated with storage of the product.

Obstruction

- 22. No person shall—
 - (a) intentionally obstruct any person acting in the execution of these Regulations;
 - (b) without reasonable cause, fail to give to any person acting in the execution of these Regulations any assistance or information which that person may reasonably require for the purposes of their functions under these Regulations.

False information

23. No person shall provide to any person acting in the execution of these Regulations any information which the first mentioned person knows to be false or misleading.

Offences by bodies corporate

- **24.**—(1) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of—
 - (a) any director, manager, secretary or other similar officer of the body corporate, or
 - (b) any person who was purporting to act in any such capacity,

that officer or person as well as the body corporate, shall be guilty of the offence and be liable to be proceeded against and punished accordingly.

(2) For the purposes of this regulation, "director" in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

Penalties

- 25. A person contravening any provision of these Regulations is guilty of an offence and liable—
 - (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months, or to both;
 - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years, or to both.

Approvals issued and things done in another part of the British Islands

- **26.**—(1) Where these Regulations require any approval to be issued or granted by the Scottish Ministers, an equivalent document issued in another part of the British Islands by a competent authority in that part is valid in Scotland.
- (2) Where these Regulations require that any declaration is made, an equivalent document made in another part of the British Islands is valid in Scotland.
- (3) Where these Regulations require anything to be done in an approved establishment, slaughterhouse or cutting plant in Scotland, anything done in premises approved for the same purpose in another part of the British Islands shall be treated as if it had been approved in Scotland.

(4) Where these Regulations require anything to be done under the supervision or control of the Scottish Ministers, anything done under the supervision or control of the equivalent authority in another part of the British Islands shall be treated as if it had been done by the Scottish Ministers.

Sharing of information

- **27.**—(1) The Scottish Ministers and any local authority may exchange information for the purposes of these Regulations, and may disclose information to an enforcement authority in another part of the British Islands.
- (2) Paragraph (1) is without prejudice to any other power of the Scottish Ministers or any local authority to disclose information.

Enforcement

28. These Regulations shall be enforced by the Scottish Ministers or the local authority.

Revocation

29. The Import and Export Restrictions (Foot-and-Mouth Disease) (Scotland) (No. 4) Regulations 2007(**23**) are revoked.

Pentland House, Edinburgh 19th October 2007

NEIL RITCHIE
A member of the staff of the Scottish Ministers