

2008 No. 219

ANIMALS

ANIMAL HEALTH

**The Diseases of Animals (Approved Disinfectants) (Scotland)
Order 2008**

Made - - - - *2nd June 2008*

Coming into force - - *23rd June 2008*

The Scottish Ministers make the following Order in exercise of the powers conferred by section 1 of the Animal Health Act 1981(a) and all other powers enabling them to do so.

Citation, commencement and extent

1.—(1) This Order may be cited as the Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008 and comes into force on 23rd June 2008.

(2) This Order extends to Scotland only.

Interpretation

2.—(1) In this Order—

“approved disinfectant” means a disinfectant approved by the Scottish Ministers under this Order; and

“supplier” means a person supplying disinfectant in the course of carrying on a business.

(2) Any approval under this Order or any renewal, amendment, suspension or revocation of an approval must be in writing.

(3) Any reference in this Order to anything done in writing or produced in written form includes a reference to an electronic communication, as defined in the Electronic Communications Act 2000(b), which has been recorded and is consequently capable of being reproduced.

Approval of disinfectants

3.—(1) The manufacturer of a disinfectant may apply to the Scottish Ministers for the approval of that disinfectant for use in cases where an order or regulations under the Animal Health Act 1981 specifies that an approved disinfectant must be used.

(2) The Scottish Ministers may only approve a disinfectant if they are satisfied—

(a) as to its efficacy and quality; and

(a) 1981 c.22. The functions of “the Ministers” and “the appropriate Minister” (each as defined in section 86 of the Animal Health Act 1981), in so far as exercisable within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

(b) 2000 c.7; section 15(1) contains a definition of “electronic communication” and is amended by paragraph 158 of Schedule 17 to the Communications Act 2003 (c.21).

- (b) that it complies with the Biocidal Products Regulations 2001(a).
- (3) The approval—
 - (a) must specify the dilution rate; and
 - (b) may contain other conditions to which the approval is subject.
- (4) The Scottish Ministers—
 - (a) may test the disinfectant at any time; and
 - (b) must test it before approving it unless—
 - (i) the disinfectant has the same formulation as another disinfectant manufactured by the manufacturer whose application it is;
 - (ii) that other disinfectant is an approved disinfectant; and
 - (iii) approval is sought only for use in one or more of the circumstances in respect of which the other disinfectant is approved.
- (5) The Scottish Ministers must publish a list of approved disinfectants specifying the dilution rate.
- (6) In this article, “dilution rate” means the number of parts of water with which one part of an approved disinfectant is to be diluted.

Use of the disinfectant

4. An approved disinfectant may only be used in accordance with the conditions of its approval or as directed by an inspector.

Duration of approval and renewal

5.—(1) An approval is for a period of 2 years and may be renewed within 3 months prior to its expiry.

(2) An approval which is the subject of an application for renewal is valid up to the date on which the applicant is notified of the decision to renew or to refuse to renew the approval.

Amendment, suspension and revocation of approvals

6.—(1) The Scottish Ministers may amend, suspend or revoke the approval or refuse to renew the approval if—

- (a) production of the disinfectant has ceased; or
- (b) the disinfectant—
 - (i) is no longer efficacious or of suitable quality;
 - (ii) does not comply with any condition of the approval; or
 - (iii) does not comply with the Biocidal Products Regulations 2001.

(2) The Scottish Ministers may also suspend an approval pending investigation of any disinfectant if they have reasonable grounds to suspect that any of the grounds in paragraph (1) apply.

Review of a decision by the Scottish Ministers

7.—(1) A manufacturer may apply in writing to the Scottish Ministers for a review of a decision.

(2) An application for review—

- (a) must be made within 28 days after the date on which notice of the decision is received by the applicant; and
- (b) may include any written explanation that the applicant considers appropriate.

(a) S.I. 2001/880; as amended by S.I. 2003/429, 2005/2451 and 2759 and 2007/293.

(3) A decision which is the subject of an application for review shall, unless the Scottish Ministers direct otherwise in writing, have effect until the date of determination of that application.

(4) The application for review shall be determined by the Scottish Ministers, in accordance with paragraphs (5) to (9).

(5) The Scottish Ministers shall name an appointed person.

(6) The Scottish Ministers shall inform the applicant in writing—

- (a) of the name and address of the appointed person;
- (b) of the role of that person; and
- (c) that the applicant may give a written explanation (or further explanation) to that person.

(7) Any written explanation referred to in paragraph (6) shall be given to the appointed person within 14 days after the date of intimation to the applicant under that paragraph.

(8) The appointed person shall—

- (a) examine the merits of the decision;
- (b) consider any written explanation given by the applicant;
- (c) report to the Scottish Ministers following that examination; and
- (d) include in that report such recommendation (if any) for determination of the application as the appointed person shall think fit.

(9) The Scottish Ministers shall consider the report of, and any recommendation by, the appointed person.

(10) The Scottish Ministers shall inform the applicant in writing of the result of the determination of the review.

(11) In this article, “decision” means the—

- (a) determination of an application for approval;
- (b) decision to attach a condition to an approval;
- (c) amendment, suspension or revocation of an approval; or
- (d) refusal to renew an approval.

Duties of manufacturers and suppliers in relation to amended, suspended or revoked approvals

8.—(1) If the Scottish Ministers amend, suspend or revoke the approval of a disinfectant or refuse to renew an approval, the manufacturer, and any supplier who becomes aware of the fact, must take all reasonable steps to notify every person in the United Kingdom to whom the manufacturer or supplier has supplied the disinfectant in the previous 6 months of that fact.

(2) Such notification must be given within one month of the manufacturer or supplier becoming aware of the amendment, suspension or revocation of the approval, or the refusal to renew the approval.

Placing disinfectant on the market

9. No person may sell, or offer to sell, any disinfectant that is labelled or otherwise represented as an approved disinfectant if—

- (a) it is not approved under this Order; or
- (b) the formula for it has changed since its approval was granted.

References to disinfectants in Orders under the Animal Health Act 1981

10.—(1) Any reference in an order or regulations under the Animal Health Act 1981 to a disinfectant approved under the Diseases of Animals (Approved Disinfectants) Order 1978(a) (“the 1978 Order”) or listed in a Schedule to that Order is a reference to a disinfectant approved under this Order.

(2) Any reference in an Order or Regulations under the Animal Health Act 1981 to the concentration or dilution rate specified in the 1978 Order is a reference to the concentration or dilution rate specified in the list of approved disinfectants published under article 3(5).

Provision of information and samples

11.—(1) The Scottish Ministers may, at any time, for the purposes of this Order require the manufacturer of a disinfectant for which approval is sought or granted, or any person in possession of such a disinfectant, to—

- (a) provide samples of that disinfectant for testing; or
- (b) provide any information relating to that disinfectant.

(2) The samples or information must be provided to the Scottish Ministers within the time period set by them.

(3) At the request of the Scottish Ministers, the manufacturer must provide that manufacturer’s technical expertise to facilitate any analysis of the samples.

(4) Nothing in this article shall be construed as requiring any person to answer any question or to provide any information if to do so might incriminate that person.

Offences by a body corporate

12.—(1) Where a body corporate is guilty of an offence under this Order, and that offence is shown to have been committed with the consent or connivance of, or to have been attributable to any wilful neglect on the part of—

- (a) any director, manager, secretary or other similar office bearer of the body corporate; or
- (b) any person who was purporting to act in such a capacity,

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

(2) If the affairs of a body corporate are managed by the members of that body, the provisions of paragraph (1) shall apply in relation to the acts and omissions of a member in connection with a management function of that member as if the member were a director of a body corporate.

(3) In this article—

“director” in relation to a body corporate whose affairs are managed by the members of that body means a member of the body; and

“body corporate” includes a partnership in Scotland, and in relation to such a partnership, a reference to a director or other officer of a body corporate is a reference to a partner.

Enforcement

13.—(1) This Order shall be enforced by the local authority.

(2) The Scottish Ministers may direct, in cases of a particular description or any particular case, that they will enforce this Order instead of the local authority.

(a) S.I. 1978/32; relevantly amended by S.I. 1978/934 and 1999/919 and S.S.I. 2001/45 and 51, 2003/334, 2004/537, 2005/99 and 587 and 2006/352.

Revocations

14. The enactments specified in the first column of the Schedule are revoked to the extent specified in the corresponding entry in the third column of the Schedule.

St Andrew's House,
Edinburgh
2nd June 2008

RICHARD LOCHHEAD
A member of the Scottish Executive

SCHEDULE

Regulation 14

Revocations

The Diseases of Animals (Approved Disinfectants) Order 1978	S.I. 1978/32	In so far as it extends to Scotland
The Diseases of Animals (Approved Disinfectants) (Amendment) Order 1999	S.I. 1999/919	In so far as it extends to Scotland and is not already revoked
The Diseases of Animals (Approved Disinfectants) Amendment (Scotland) Order 2001	S.S.I. 2001/45	In so far as not already revoked
The Diseases of Animals (Approved Disinfectants) Amendment (Scotland) Order 2003	S.S.I. 2003/334	In so far as not already revoked
The Diseases of Animals (Approved Disinfectants) Amendment (Scotland) Order 2006	S.S.I. 2006/352	The whole Order
The Foot-and-Mouth Disease (Scotland) Order 2006	S.S.I. 2006/44	Article 59
The Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006	S.S.I. 2006/336	Article 87(2)

EXPLANATORY NOTE

(This note is not part of the Order)

This Order revokes and remakes the Diseases of Animals (Approved Disinfectants) Order 1978 in so far as it relates to Scotland.

Article 3 provides that a manufacturer of a disinfectant may apply to the Scottish Ministers to have that disinfectant approved for use when an Order under the Animal Health Act 1981 specifies that an approved disinfectant must be used.

Article 4 provides that an approved disinfectant may only be used in accordance with the conditions of the approval or as directed by an inspector.

Article 5 provides that an approval is granted for two years but may be renewed.

Article 6 provides that the Scottish Ministers may amend, suspend or revoke an approval or refuse to renew an approval.

Article 7 provides a procedure for a manufacturer to apply for a review of any decision made by the Scottish Ministers.

Article 8 provides that a manufacturer or supplier must take reasonable steps to notify any person in the United Kingdom to whom the manufacturer has supplied a disinfectant in the previous 6 months if its approval has been amended, suspended or revoked, or if a renewal of the approval has been refused.

Article 9 prohibits the placing of any disinfectant on the market that is labelled or otherwise represented as an approved disinfectant if it is not approved under this Order or if the formula for it has changed since approval was granted.

Article 10 makes provision in connection with references in existing legislation.

Article 11 provides that the Scottish Ministers may at any time require information about a disinfectant, or samples of that disinfectant, to be provided to them.

Article 12 provides for offences by a body corporate.

Article 13 provides that the Order shall be enforced by the local authority.

Article 14 revokes earlier legislation as set out in the Schedule.

Breach of the Order is an offence under section 73 of the Animal Health Act 1981, punishable in accordance with section 75 of that Act.

This Order has been notified in draft to the European Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council (O.J. No. L 204, 21.7.98, p.37) laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, as amended by Directive 98/48/EC of the European Parliament and of the Council (O.J. No. L 217, 5.8.98, p.18).

A regulatory impact assessment has not been produced for this instrument because it has no impact on the costs of business.

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£3.00

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