
WELSH STATUTORY INSTRUMENTS

2007 No. 2803 (W.236)

ANIMALS, WALES

ANIMAL HEALTH

**The Diseases of Animals (Approved
Disinfectants) (Wales) Order 2007**

Made - - - - - *25 September 2007*

Coming into force - - - - - *15 October 2007*

The Welsh Ministers, in exercise of their powers under section 1 of the Animal Health Act 1981⁽¹⁾, make the following Order:

Title, application and commencement

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(1) The title of this Order is the Diseases of Animals (Approved Disinfectants) (Wales) Order 2007:

- (2) This Order applies in relation to Wales.
- (3) This Order comes into force on 15 October 2007.

Approvals

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

Approval of disinfectants

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

- (2) The Welsh Ministers may only approve a disinfectant if they are satisfied-
 - (a) as to its efficacy and quality; and

⁽¹⁾ 1981 c. 22; see section 86(1) for definition of “the Ministers”. The functions of “the Ministers” insofar as exercisable in relation to Wales, were transferred to the National Assembly of Wales by virtue of S.I. 1999/672 and S.I 2004/3044 and are exercisable by the Welsh Ministers by virtue paragraph 30 of Schedule 11 to the Government of Wales 2006.

- (b) that it complies with the Biocidal Products Regulations 2001⁽²⁾.
- (3) The approval—
 - (a) must specify the dilution rate; and
 - (b) may contain conditions to which the approval is subject.
- (4) The Welsh Ministers may test the disinfectant at any time, and must test it before approving it unless—
 - (a) the disinfectant has the same formulation as another disinfectant manufactured by the manufacturer whose application it is;
 - (b) that other disinfectant is an approved disinfectant; and
 - (c) approval is sought only for use in one or more of the circumstances in respect of which the other disinfectant is approved.
- (5) The Welsh Ministers must publish a list of approved disinfectants.
- (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 lasts for two years, and may be renewed within 3 months prior to its expiry.
- (2) If a renewal is applied for, the approval continues to be valid up to the date on which the applicant is notified of the decision to renew or to refuse to renew.

Amendment, suspension and revocation of approvals

- 6.—(1) The Welsh Ministers may amend, suspend or revoke the approval or refuse to renew the approval if production of the disinfectant has ceased or if the disinfectant—
 - (a) is no longer efficacious or of suitable quality;
 - (b) does not comply with any condition of the approval; or
 - (c) does not comply with the Biocidal Products Regulations 2001.
- (2) The Welsh 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.

Representations to the Welsh Ministers

- 7.—(1) A manufacturer may make representations against—
 - (a) a refusal to grant or renew an approval;
 - (b) an amendment, suspension or revocation of an approval; or
 - (c) any condition of an approval,
- to a person appointed by the Welsh Ministers.

(2) S.I. 2001/880, as amended by S.I. 2003/429, 2005/2451 and 2005/2759.

(2) The manufacturer must notify the Welsh Ministers of his or her intention to make such representations to the appointed person within one month of receiving notice of the refusal to grant or renew the approval or the amendment, suspension or revocation of the approval.

(3) The appointed person must consider the representations and report in writing to the Welsh Ministers within one month of receiving the representations.

(4) The Welsh Ministers must give written notification of their final determination and the reasons for it to the applicant within one month of receiving the report from the appointed person.

(5) Unless the Welsh Ministers direct otherwise, the refusal to renew an approval or an amendment, suspension or revocation of an approval shall continue in force until they make their final determination.

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

8.—(1) If the Welsh 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 he or she has supplied the disinfectant in the previous 6 months.

(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 place on the market 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. Any reference in an order under the Animal Health Act 1981 to a disinfectant approved under the Diseases of Animals (Approved Disinfectants) Order 1978⁽³⁾ or listed in a Schedule to that Order is a reference to a disinfectant approved under this Order.

Provision of information and samples

11.—(1) The Welsh Ministers may, at any time, 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 Welsh Ministers within the time period set by them.

(3) At the request of the Welsh Ministers, the manufacturer must provide his or her technical expertise to facilitate any analysis of the samples.

(3) [S.I.1978/32](#), as amended by [S.I. 2006/3166](#).

Enforcement

12.—(1) This Order is enforced by the local authority.

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

Revocations

13. The following are revoked—

- (a) the Diseases of Animals (Approved Disinfectants) Order 1978⁽⁴⁾; and
- (b) the Diseases of Animals (Approved Disinfectants) (Amendment) (Wales) Order 2006⁽⁵⁾.
- (c) the Diseases of Animals (Approved Disinfectants) (Amendment) (Wales) Order 2007⁽⁶⁾.

25 September 2007

Elin Jones
Minister for Rural Affairs, one of the Welsh
Ministers

⁽⁴⁾ S.I. 1978/32, as amended by S.I. 2006/3166.

⁽⁵⁾ S.I. 2006/3166.

⁽⁶⁾ S.I. 2007/2494.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order revokes and remakes the Diseases of Animals (Approved Disinfectants) Order 1978 (S.I.1978/32).

Article 3 provides that a manufacturer of a disinfectant may apply to the Welsh Ministers to have that disinfectant approved for use when an order under the Animal Health Act 1981 (c. 22) 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 lasts for two years but may be renewed. Article 6 provides that the Welsh Ministers may amend, suspend or revoke an approval or refuse to renew an approval. Article 7 provides a procedure for a manufacturer to make representations against any such amendment, suspension or revocation or a refusal.

Article 8 provides that a manufacturer or supplier must take reasonable steps to notify any person in the United Kingdom to whom he or she 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 11 provides that the Welsh Ministers may at any time require information about a disinfectant, or samples of that disinfectant, to be provided to them.

The Order is enforced by the local authority (article 12). 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.

A Regulatory Impact Assessment has been produced for this instrument. Copies are available from the Office of the Chief Veterinary Officer, Welsh Assembly Government, Cathays Park, Cardiff CF10 3NQ.

Office of the Chief Veterinary Officer.