

2012 No. 2403 (W. 257)

ANIMALS, WALES

ANIMAL HEALTH

**The Bluetongue (Wales)
(Amendment) Regulations 2012**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Bluetongue (Wales) Regulations 2008 (S.I. 2008/1090 (W.116)) (“the 2008 Regulations”) by transposing Directive 2012/5/EU amending Council Directive 2000/75/EC as regards vaccination against bluetongue (OJ No L 81, 21.3.2012, p1).

Regulation 2(4) adds two new paragraphs to regulation 13 (restrictions in protection and surveillance zones) regarding requirements for surveillance zones.

Regulation 2(5) substitutes a new Part 3 (vaccination). Regulation 17 identifies the restrictions relating to obtaining vaccines. Regulation 18 provides a general prohibition on vaccination. Regulation 19 sets out the circumstances and conditions in which compulsory and voluntary vaccination against bluetongue can take place.

A regulatory impact assessment has not been produced for this instrument as no new impact on the private, voluntary or public sector is foreseen.

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**The Bluetongue (Wales)
(Amendment) Regulations 2012**

Made 15 September 2012

Laid before the National Assembly for Wales
19 September 2012

Coming into force 10 October 2012

The Welsh Ministers are designated for the purposes of section 2(2) of the European Communities Act 1972(1) in relation to measures in the veterinary and phytosanitary fields for the protection of public health(2).

The Welsh Ministers make the following Regulations in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972.

Title, application and commencement

1.—(1) The title of these Regulations is the Bluetongue (Wales) (Amendment) Regulations 2012.

(2) These Regulations apply in relation to Wales.

(3) They come into force on 10 October 2012.

Amendment of the Bluetongue (Wales) Regulations 2008

2.—(1) The Bluetongue (Wales) Regulations 2008(3) are amended as follows.

(2) In regulation 2 (interpretation) in the appropriate place in alphabetical order insert—

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- (1) 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a), and the European Union (Amendment) Act 2008 (c.7), Part 1 of the Schedule.
- (2) S.I. 2008/1792.
- (3) S.I. 2008/1090 (W.116).

““inactivated vaccines” (*brechlynnau anweithredol*)” means vaccines that are not live attenuated vaccines;”;

““live attenuated vaccines” (*brechlynnau byw a wanhawyd*)” means vaccines which are produced by adapting bluetongue virus field isolates through serial passages in tissue culture or in embryonated hens’ eggs;”.

(3) For regulation 3 (exemptions) substitute—

“3. These Regulations do not apply to—

- (a) anything a person is authorised to do by licence granted under the Specified Animal Pathogens (Wales) Order 2008(1);
- (b) administration of a vaccine for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011(2).”

(4) In regulation 13 (restrictions in protection and surveillance zones), after paragraph (1) insert—

“(1A) A surveillance zone declared by the Welsh Ministers must not contain any land where animals have been vaccinated with live attenuated vaccines against bluetongue within the last 12 months.

(1B) No person may vaccinate against bluetongue using live attenuated vaccine in a surveillance zone declared under this regulation.”

(5) For Part 3 (vaccination), substitute—

“PART 3

Vaccination

Obtaining vaccine

17. No person other than the holder of a marketing authorisation, a manufacturing authorisation or a wholesale dealer’s authorisation granted by the Secretary of State under the Veterinary Medicines Regulations 2011 may obtain vaccine except for the purpose of enabling the use of vaccines under regulation 19.

(1) S.I. 2008/1270 (W.129), to which there are amendments not relevant to these Regulations.

(2) S.I. 2011/2159.

Prohibition on vaccination

18. No person may vaccinate an animal against bluetongue except in accordance with regulation 19.

Use of vaccines

19.—(1) The Welsh Ministers may grant a specific or general licence permitting the use of inactivated or live attenuated vaccines against bluetongue in accordance with this regulation.

(2) The Welsh Ministers may declare a vaccination zone in which any occupier of premises or keeper of animals must ensure the vaccination of their animals with inactivated or live attenuated vaccines and comply with any other measures related to either vaccination or vaccine specified in that declaration.

(3) Where a zone is declared under paragraph (2), a veterinary inspector may serve a notice on the occupier of premises or the keeper of animals on premises requiring that occupier or keeper to ensure the vaccination with inactivated or live attenuated vaccines of animals at the premises.

(4) The Welsh Ministers may only grant a licence under paragraph (1) or declare a zone under paragraph (2) if—

- (a) the decision to use the vaccine is based on the result of a specific risk assessment carried out by the Welsh Ministers; and
- (b) the EU Commission is informed of that decision before such vaccination is carried out.

(5) Whenever live attenuated vaccines are to be used, the Welsh Ministers must declare—

- (a) a protection zone consisting of at least the vaccination area; and
- (b) a surveillance zone extending beyond the limits of the protection zone in which no animals have been vaccinated with live attenuated vaccines against bluetongue within the last 12 months.

(6) No person may vaccinate against bluetongue using live attenuated vaccine in a surveillance zone declared under this regulation.”

John Griffiths

Minister for Environment and Sustainable Development, one of the Welsh Ministers

15 September 2012

