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ANIMALS, ENGLAND

ANIMAL HEALTH

The Bluetongue (Amendment) Regulations 2012

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| <i>Made</i> | - - - - | <i>25th July 2012</i> |
| <i>Laid before Parliament</i> | | <i>30th July 2012</i> |
| <i>Coming into force</i> | - - | <i>24th August 2012</i> |

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972^(a) in relation to measures in the veterinary and phytosanitary fields for the protection of public health^(b).

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Citation, commencement and application

1. These Regulations—

- (a) may be cited as the Bluetongue (Amendment) Regulations 2012;
- (b) come into force on 24th August 2012;
- (c) apply in England.

Amendment of the Bluetongue Regulations 2008

2.—(1) The Bluetongue Regulations 2008^(c) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) after the definition of “control zone” insert—

““inactivated vaccines” means vaccines that are not live attenuated vaccines;”;

(b) after the definition of “inspector” insert—

““live attenuated vaccines” 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—

^(a) 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.
^(b) S.I. 1999/2027.
^(c) S.I. 2008/962, to which there are amendments not relevant to these Regulations.

“3. These Regulations do not apply to—

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

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

“(1A) A surveillance zone declared by the Secretary of State 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.

Prohibition on vaccination

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

Use of vaccines

19.—(1) The Secretary of State 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 Secretary of State 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 Secretary of State 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 Secretary of State; and
- (b) the EU Commission is informed of that decision before such vaccination is carried out.

(a) S.I. 2008/944, to which there are amendments not relevant to these Regulations.

(b) S.I. 2011/2159.

(5) Whenever live attenuated vaccines are to be used, the Secretary of State 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.”.

(6) After regulation 29 (revocation) insert—

“Review of these Regulations

30.—(1) The Secretary of State must from time to time—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Council Directive 2000/75/EC laying down specific provisions for the control and eradication of bluetongue(a) is implemented in other member States.

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.”.

25th July 2012

Taylor of Holbeach
Parliamentary under-Secretary of State
Department for Environment, Food and Rural Affairs

(a) OJ No L 327, 22.12.2000, p. 74.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Bluetongue Regulations 2008 (S.I. 2008/962) (“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.

Regulation 2(6) inserts a new regulation 30 into the 2008 Regulations which requires the Secretary of State to review the operation of those Regulations and publish a report within five years after these Regulations come into effect and within every five years after that.

An 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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