STATUTORY INSTRUMENTS

2012 No. 1977

The Bluetongue (Amendment) Regulations 2012

Amendment of the Bluetongue Regulations 2008

- **2.**—(1) The Bluetongue Regulations 2008(1) 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—
 - "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(2);
 - (b) administration of a vaccine for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011(3).".
- (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.

⁽¹⁾ S.I. 2008/962, to which there are amendments not relevant to these Regulations.

⁽²⁾ S.I. 2008/944, to which there are amendments not relevant to these Regulations.

⁽³⁾ 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 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.
 - (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(4) 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.".

Changes to legislation:
There are currently no known outstanding effects for the The Bluetongue (Amendment)
Regulations 2012, Section 2.