# 2012 No. 383

# **ANIMALS**

#### ANIMAL HEALTH

# The Bluetongue (Amendment) Regulations (Northern Ireland) 2012

Made - - - - 22nd October 2012

Coming into operation - 19th November 2012

The Department of Agriculture and Rural Development, is designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b), in relation to the common agricultural policy of the European Community.

The Department of Agriculture and Rural Development, makes the following Regulations in exercise of the powers conferred upon it by section 2(2) of the European Communities Act 1972.

### Citation, commencement and application

**1.** These Regulations may be cited as the Bluetongue (Amendment) Regulations (Northern Ireland) 2012 and shall come into operation on 19th November 2012.

## Amendments to the Bluetongue Regulations (Northern Ireland) 2008

- **2.**—(1) The Bluetongue Regulations (Northern Ireland) 2008(**c**) are amended as follows.
- (2) In regulation 2 (interpretation)—
  - (a) after the definition of "Divisional Veterinary Officer" insert—
    - ""inactivated vaccines" means vaccines that are not live attenuated vaccines;";
  - (b) after the definition of "keeper" 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 (Northern Ireland) 2008(d);

<sup>(</sup>a) S.I. 2000/2812

**<sup>(</sup>b)** 1972 c. 68

<sup>(</sup>c) S.R. 2008 No. 275

<sup>(</sup>d) S.R. 2008 No. 336 as amended by S.R. 2010 No. 24.

- (b) administration of a vaccine for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011(a).".
- (4) In regulation 10 (restrictions in protection and surveillance zones) after paragraph (1) insert—
  - "(1A) A surveillance zone demarcated by the Department shall not contain any animals that have been vaccinated with live attenuated vaccines within the last 12 months.".
  - (5) For regulation 18 (obtaining vaccine) substitute—
    - "18. 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 a vaccine except—
      - (a) a person obtaining such a vaccine following a decision of the Department under regulation 19A (decision to allow the use of such vaccines) within an area not subject to any bluetongue restrictions; or
      - (b) under the authority of a licence granted by the Department.".
  - (6) For regulation 19 (prohibition on vaccination) substitute—
    - "19.—(1) Except where regulations 19A (decision to allow the use of vaccines) or 20 (compulsory vaccination) apply, a person shall not vaccinate an animal against bluetongue except under the authority of a licence granted by the Department.
    - (2) Any vaccination against bluetongue using live attenuated vaccines is prohibited in the surveillance zone.".
  - (7) After regulation 19 (prohibition on vaccination) insert—

#### "Decision to allow use of vaccines

- **19A**.—(1) The Department may decide to allow the use of inactivated or live attenuated vaccines against bluetongue provided that—
  - (a) such decision is based on the result of a specific risk assessment; and
  - (b) the EU Commission is informed of that decision before the vaccination is carried out.
  - (2) When live attenuated vaccines are used, the Department must declare—
    - (a) a protection zone consisting of at least the vaccination area; and
    - (b) a surveillance zone extending beyond the limit of the protection zone.".

Sealed with the Official Seal of the Department of Agriculture and Rural Development on 22nd October 2012



C. McMaster

A senior officer of the Department of Agriculture and Rural Development

#### **EXPLANATORY NOTE**

(This note is not part of the Regulation)

These Regulations amend the Bluetongue Regulations 2008 (S.R. 2008 No.275) ("the 2008 Regulations") by transposing Directive 2012/5/EU of 14 March 2012 amending Council Directive 2000/75/EC as regards vaccination against bluetongue (O.J. No L 81, 21.3.2012, p1). The main purpose of Directive 2012/5/EU, as transposed by these amendment Regulations, is to provide a mechanism for inactivated vaccine to be allowed to be used in areas no longer subject to bluetongue restrictions.

Regulation 2(4) adds a new paragraph to regulation 10 (restrictions in protection and surveillance zones) regarding requirements for surveillance zones.

Regulation 2(5) amends regulation 18 (obtaining vaccine) to add to the circumstances in which vaccine may be obtained.

Regulation 2(6) amends regulation 19 (prohibition on vaccination) to add the further exception following a decision of the Department in accordance with the new regulation 19A. It also prohibits the use of live attenuated vaccines in the surveillance zone.

Regulation 2(7) inserts a new regulation 19A (decision to allow use of vaccines) into the 2008 Regulations to allow the use of bluetongue vaccine once certain steps have been taken by the Department. Where a decision has been taken to allow live attenuated vaccine to be used then the Department must declare a protection zone that consists of at least the vaccination area, and a surveillance zone surrounding that area.

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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