

EXPLANATORY MEMORANDUM

THE BLUETONGUE (AMENDMENT) REGULATIONS 2012

2012 No. 1977

1. This explanatory memorandum has been prepared by Defra and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Purpose of the instrument**

The Bluetongue (Amendment) Regulations 2012 apply only in England and amend the Bluetongue Regulations 2008, (S.I. 2008/962 “the 2008 Regulations”). The main purpose is to substitute a new Part 3 to transpose Directive 2012/5/EU amending Council Directive 2000/75/EC as regards vaccination against bluetongue. In particular this will allow, on the basis of a risk assessment carried out by the Secretary of State, animal keepers the option to vaccinate their animals against bluetongue, which is an exotic (not normally found in England) notifiable animal disease that can affect ruminating animals. Inactivated vaccines will be available for voluntary vaccination by keepers in disease-free areas. England has been a disease-free area since 5 July 2011.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

None

4. **Legislative Context**

4.1 Directive 2012/5/EU came into force on 22 March 2012, and must be transposed by 24 September 2012. This instrument amends the 2008 Regulations.

4.2 The Appendix contains the Transposition Note.

5. **Territorial Extent and Application**

This instrument applies to England only.

6. **European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. **Policy background**

7.1 Member States are obliged to control and eradicate bluetongue virus. Council Directive 2000/75/EC requires measures to prevent the spread and eradication of the . The amendments to the 2000 Directive introduced by Directive 2012/5/EU enable Member States in disease-free areas to decide, following a risk assessment and notification to the Commission, to allow animal keepers to vaccinate their animals on a precautionary basis with approved inactivated vaccines.

7.2 The last outbreak of bluetongue in England occurred in 2007-2008, and the whole of the UK was declared disease-free on 5 July 2011. As we want to maintain this status, current policies and objectives are aimed primarily at reducing the risk of bluetongue outbreaks, and avoiding the consequential burden of animal movement controls and economic losses following export trade restrictions. Now that Directive 2012/5/EU allows Member States to provide for farmers the option to vaccinate their animals, thus giving them the freedom, as well as the responsibility, to take decisions which are appropriate for their businesses, rather than government taking such decisions on their behalf.

7.3 Amendment to the 2008 Regulations is required to transpose the Directive 2012/5/EU and thereby allow animal keepers in disease-free areas to vaccinate livestock with inactivated vaccines for the range of bluetongue virus serotypes. Where compulsory vaccination is required following an outbreak of the disease then a protection zone and vaccination zone must be declared, the Secretary of State, as was also the case with the 2008 Regulations and in line with published guidance, has again decided not to be constrained by the minimum depth of such zones. This will enable the Secretary of State to determine the depth of these zones as deemed to be appropriate to control the outbreak,

7.4 Although the UK and our North European neighbours are now all free from bluetongue, and therefore at a low risk of future disease incursion, the season when the midges that carry the disease are is already underway. Therefore, we propose to bring these amendment Regulations into force in August, instead of by 24 September, to provide the option for animal keepers to vaccinate if they so wish as early as possible so that their animals are protected in the midge-active season. Historically the south-east of England has been at most risk of disease incursion from infected midges being blown over the Channel in favourable meteorological conditions. This is the area where we expect that there may be most use of approved inactivated vaccines.

7.5 The Department chosen not to re-make the 2008 Regulations because there have only been minor earlier amendments and we expect that new legislation that is being negotiated within the EU will result in the need to re-make these Regulations once that new EU legislation is in place.

8. Consultation outcome

8.1 No formal consultation was undertaken as the amendment regulations do not require animal keepers or industry to do anything. When the requirements on the

Secretary of State have been met a general licence will be granted to enable farmers to vaccinate their animals with inactivated vaccine.

8.2 Industry and stakeholders have been kept informed of developments through the Bluetongue Virus Core Group, and the department's intentions were circulated in January 2012 to around 50 stakeholder organisations. This Core Group includes the National Beef Association, Livestock Auctioneers Association, British Veterinary Association, National Farmers' Union, and the National Sheep Association.

9. Guidance

Guidance, which had been agreed with the Core Group, was circulated to the stakeholders on 7 June, and a copy added to the Animal Diseases and Bluetongue pages on the Defra website. We also sent the guidance to vaccine producers and wholesalers so they could consider what preparations to make.

10. Impact

As it will be for the animal keeper and agricultural businesses (including micro-businesses) to decide whether the economic costs of vaccination are worthwhile, these amendment Regulations will not have a direct cost or impact on them. As a result an Impact Assessment has not been prepared for this instrument.

11. Regulating small business

The legislation does apply to small business. As it will be for them to decide whether the economic costs of vaccination are worthwhile, these amendment Regulations will not have a direct cost or impact on them.

12. Monitoring & review

No monitoring of the uptake of voluntary vaccination with inactivated vaccine is planned. However, in line with government policy, these amendment Regulations insert a requirement into the 2008 Regulations to require the Secretary of State to carry out a review of those Regulations in 2017.

13. Contact

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mark.cunningham@defra.gsi.gov.uk can answer any queries regarding the instrument.

Appendix

Transposition Note

This Note explains how the Bluetongue (Amendment) Regulations 2012 transpose Article 1 of Directive 2012/5/EU (OJ No L 81, 21.3.2012, p. 1) of 14 March 2012 that amends the Council Directive 2000/75/EC (laying down specific provisions for the control and eradication of bluetongue) as regards vaccination against bluetongue. Amendments are made to the Bluetongue Regulations S.I. 2008/962.

Article in Directive	Transposition	Objective
Article 1(1)	Regulation 2(2)	Adds new definition into the 2008 principal Regulations
Article 1(2) which substitutes a new Article 5 into the principal Directive 2000/75/EC.	Regulation 2(5) that substitutes a new Part 3 (vaccination) into the 2008 Regulations	The insertion of substituted Article 5 into the principal Directive 2000/75/EC enables the Secretary of State to allow the use of vaccines following a specific risk assessment and informing the EU Commission of the decision. It also provides that where live attenuated vaccine is required to be used during an outbreak then a vaccination zone must be declared. Such zone must consist of a protection zone that is surrounded by a surveillance zone.
Article 1(3)	No transposition required.	Article 1(3) deletes three lines from the existing Article 6(1)(d) of Directive 2000/75/EC, and has replaced this with the requirement in substituted Article 5(1) that obliges a Member State to inform the EU Commission of the decision to allow use of vaccines following a specific risk assessment carried out by the competent authority.
Article 1(4)	Regulation 2() that inserts paragraph (1A) into regulation 13 of the 2008 Regulations. Also transposed by regulation 2(5) with the substituted regulation 19(5)(b) in Part 3 of the 2008 Regulations.	Purpose is to ensure that the Surveillance zone does not have any risk of cattle that have received live attenuated vaccine hampering the eradication controls by masking the true extent of the disease.

Article 1(5)	Regulation 2(4) that inserts paragraph (1B) into regulation 13 of the 2008 Regulations. Also transposed by regulation 2(5) with the substituted regulation 19(6) in Part 3 of the 2008 Regulations.	Purpose is to ensure that the Surveillance zone does not have any risk of cattle that have received live attenuated vaccine hampering the eradication controls by masking the true extent of the disease.
Article 2	Does not require transposition	The text of our amendment Regulations will be communicated to the EU Commission before 23rd September.