

Assessment of the risk of use of inactivated vaccines against certain types of Bluetongue virus in Wales

Introduction

The European Directive 2000/75/EC that covers the official controls relating to the detection and control of Bluetongue virus (BTV) was changed in March 2012 to allow the use of vaccines outside a BTV restricted area. Previously, the use of vaccines (inactivated and modified live vaccines), were permitted only within a restricted area, and areas that gained freedom from disease status were required to prohibit the use of vaccine. Therefore, BTV vaccines were prohibited in the UK, after freedom from BTV-8 was declared in July 2011. Vaccine was used in Wales in 2008 and 2009, mostly in the South East area, which was the first area of Wales to receive vaccine.

The amendment by article 5 of Directive 2012/5/EU to the Directive 2000/75 EC stipulates that Member States may permit the use of vaccine provided that “such [a] decision is based on the result of a specific risk assessment carried out by the competent authority”.

The Risk Questions

1. Will allowing the use of inactivated vaccines against Bluetongue virus create risk of disease in areas free of disease restrictions?

Inactivated (killed) vaccines have been shown to provide adequate levels of immunity against specific types of BTV. There have been no significant adverse reactions to the use of the vaccine against BTV 8 since its introduction in the UK in 2008. Generally these vaccines require annual revaccination to ensure adequate immunity is maintained. Bluetongue Disease cannot be caused by killed virus.

Live vaccines on the other hand, while they tend to give much longer immunity (could be life long) can carry the risk of causing disease in some cases and would be inappropriate to use in areas without disease occurring naturally.

2. Will the use of vaccine interfere with the detection of new incursions of Bluetongue disease?

The inactivated vaccines are produced from killed virus. Disease cannot be caused by their use as above. Therefore clinical signs consistent with disease

caused by BTV would be indications that the virus is circulating within livestock.

Bluetongue is a notifiable disease, clinical signs suggesting infection should be investigated.

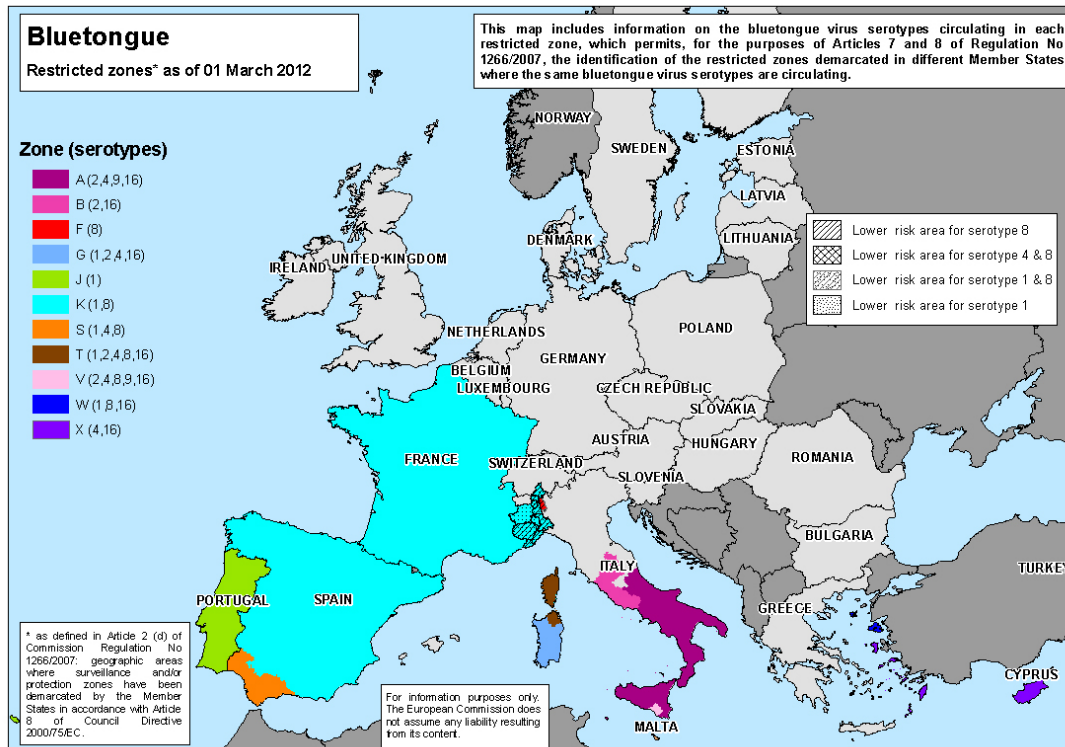
A standard test employed to detect current infection with BTV would be used to determine if the clinical signs were due to BTV (the PCR test). Animals vaccinated with killed virus do not produce a positive result to this type of test.

The Welsh Government and the other UK administrations have carried out a risk assessment based on advice from the BT National Experts Group, the BT core group and the Animal Health and Veterinary Laboratories Agency (AHVLA). Currently, there are several licensed inactivated BT vaccines that cover serotypes 1, 2, 4 or 8 (both monovalent and multivalent vaccines). These are authorised at the European level (via the European Medicines Agency).

Recommendation

The vaccines above should be permitted for use in Wales. The National Experts Group recommended in March 2011 that their use should be allowed in the UK.

Vaccination will be voluntary and should be made as a decision between the farmer and the private veterinarian. Time of year and the need for booster vaccinations should be considered as well as the risk of introduction. AHVLA will continue to monitor the international situation and update the risk assessments on <http://www.defra.gov.uk/animal-diseases/> to aid an individual's decision making. Currently, there are no reports of BTV in Northern Europe.



Source:

http://ec.europa.eu/food/animal/diseases/controlmeasures/Bluetongue_en.htm

The Animal Health and Veterinary Laboratories Agency (AHVLA) will continue to monitor the international threat of an incursion, and conduct risk based post-import testing and surveillance. Early reporting by the industry of illness consistent with the clinical signs of Bluetongue, irrespective of vaccination history, or perceived risk of an incursion of BTV, continues to be important.

Conclusion

Although the current risk of an incursion of Bluetongue appears to be low, we will, through a General Licence, permit the use of licensed inactivated vaccines in Wales for all the current serotypes. This will allow livestock keepers to protect the animals before there is any re-emergence of these types in Wales or the rest of the UK.

The situation concerning Bluetongue will continue to be monitored. Information e.g. international disease monitoring assessments will be made available on the Defra website at www.defra.gov.uk/animal-diseases/.

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