

# Final Business and Regulatory Impact Assessment

## **Title of Proposal**

The Bluetongue (Scotland) Order 2012 – consolidation of four Scottish Statutory Instruments, implementation of European Directive 2012/5/EU amending Council Directive 2000/75/EC and European Commission Implementing Regulation 456/2012 amending Commission Regulation 1266/2007.

## **Purpose and intended effect**

### **Background**

Bluetongue is a disease affecting ruminants (such as cattle, sheep and goats) and is transmitted by insect vectors that spread the virus from one animal to another. The new Directive provides Member States with more flexibility in dealing with the threat of a bluetongue incursion.

Vaccination is the preferred tool for bluetongue control and prevention of clinical disease in the EU. The use of vaccines has previously been limited by the EU to use only in areas where the disease occurred. Those rules were based on experiences with 'modified live vaccines' or 'live attenuated vaccines'. These live vaccines were the only vaccines available when the initial EU Directive was adopted over a decade ago. Live vaccines may lead to undesired circulation of the vaccine virus in unvaccinated animals in the areas where the vaccine has been used.

### **Objective**

To ensure that Scottish Government (SG) has effective measures to prevent, control and eradicate bluetongue underpinned by legislation that closely follows European legislation.

### **Rationale for Government intervention**

SG would support allowing the use of any available inactivated vaccine within a bluetongue free area as it is considered that livestock producers should have the opportunity to protect the health of their animals.

The bluetongue legislation meets the SG commitment for Principles of Better Regulation. It provides for clearer more effective disease prevention and control that should lead to the potential number and size of disease outbreaks being reduced. This will minimise disruption to the livestock sector and related industries, therefore benefiting those industries, Government, delivery partners and the wider economy in the event of a disease outbreak.

## **Consultation**

### **Within Government**

SG Legal Department – drafting of SSI

Rural and Environment Science and Analytical Services – economic impacts

Animal Health & Welfare Division – Veterinary advisors – veterinary information

### **Public Consultation**

No formal consultation has been undertaken for this Order as it consolidates previous legislation and transposes the principally deregulatory amendments to European legislation.

**Business**

Animal Health & Welfare Division has excellent communication and engagement with the livestock industry. Meetings occur frequently with key livestock producer organisations including the Scottish Animal Health & Welfare Stakeholder Meeting, most recently held on 30 April 2012. At that meeting SG invited industry views on the proposed amendments to both the European Directive and Regulation. There were no objections to SG's proposal to allow voluntary vaccination for bluetongue in Scotland.

The Scottish livestock industry has been actively lobbying for voluntary vaccination in a free area both domestically and at European level.

**Options**

Option 1 – do nothing

Option 2 - implement Directive 5/2012 by 24 September 2012

Option 1 – While doing nothing would save on the cost of producing a new SSI and familiarisation costs for businesses and enforcement authorities, continued reliance on the existing legislation is neither a transparent nor effective way of implementing disease prevention and control policy. SG needs to have appropriate controls in place to deal with any future outbreak swiftly and appropriately.

Option 2 - By transposing the European amendments SG will be fulfilling its European Community obligations and provide Scottish Ministers with more flexibility in dealing with the threat of disease. The new legislation will meet the EU obligations, and provide clarity as to the action which will be taken in the event of a disease outbreak. Clear definition will be provided to the basic principles of disease control:

- notification of suspect disease,
- veterinary investigation,
- controlling disease on infected premises, and
- imposition of wider movement controls to reduce the risk of disease spread.

In addition, we want to achieve consistency across the exotic notifiable animal diseases by ensuring standard procedures are in place wherever possible.

**Sectors and groups affected**

The legislation requirements only take effect when disease is suspected or confirmed. As with any outbreak of exotic notifiable animal disease the number of businesses affected depends on the nature of the outbreak and the animals involved.

An incursion of bluetongue is estimated to cost Scotland between £417 million and £476 million depending on time of incursion and the trajectory of the outbreak. Cost estimates include direct/on-farm costs (eg mortality, morbidity, veterinary costs) and indirect costs (mainly reduced demand for beef and hence lower beef prices).

The compulsory vaccination campaign in 2009 which was undertaken to prevent the spread of disease to Scotland when bluetongue was present in England cost Scottish farmers approximately £10 million.

The countryside will remain open, but tourism may be adversely affected due to a perceived health risk, a cost which is caused by the outbreak of disease itself and not the measures in the legislation. There are no provisions for the Scottish Ministers to close land.

Animal show organisers and zoo owners may lose revenue if they can no longer exhibit

animals at shows, zoos and gatherings in the zones. As the *Culicoides* midges which spreads bluetongue are mainly active between April to October, events like the Royal Highland Show which attracted over 5000 animals in 2011 would be affected. The cancellation such an event would be at a substantial cost to the area as it would also affect hotels, restaurants, shops etc.

### **Benefits**

Option 1 (do nothing)

There would be no costs i.e. not producing the new SSI, no familiarisation costs for businesses and enforcement authorities.

Option 2 (Transpose)

There is no economic impact unless disease is present. The new legislation will make the control strategy clearer, and ensure that the measures are fit for purpose, addressing the lessons identified from recent outbreaks of disease and uses the latest scientific knowledge.

Transposition of the Directive will give Scottish Ministers more flexibility in regard to vaccination. It allows the option of introducing vaccination on a voluntary basis in a free area using an inactivated vaccine. It also permits the use of a live attenuated vaccine but SG would be required to declare a Protection Zone. SG veterinary advice strongly recommends not permitting the use of a live attenuated vaccine and the Scottish Industry does not wish to use live vaccines.

The ability to allow voluntary vaccination in a free area provides livestock importers greater security with their purchases, and for livestock exporters more reassurance and possibly a better return that their product is disease free. For owners of valuable breeding stock vaccination could possibly be used as extra protection for their investment.

### **Costs**

Option 1 (do nothing)

No change to costs, but SG would likely face infraction proceedings and/or fines.

Option 2 (transpose)

When Scotland is disease free there is no impact on businesses and no mandatory costs to industry. However, there will be costs to livestock keepers who decide to vaccinate.

### **Scottish Firms Impact Test**

No specific face-to-face interviews were conducted for this assessment. As SG is in frequent communication with industry regarding bluetongue there have been many occasions where industry have put forward their views. The industry bodies referred to include National Farmers Union Scotland, National Sheep Association Scotland, National Beef Association Scotland, Scottish Dairy Cattle Association, Quality Meat Scotland, Institute of Auctioneers and Appraisers Scotland and Scottish Association of Meat Wholesalers.

### **Competition Assessment**

The legislation applies equally to all new and existing businesses and is similar to existing requirements for other serious diseases of livestock.

The Directive applies to all EU Member States, and therefore all UK administrations, so no country will have any competitive advantage.

### **Test run of business forms**

The consolidated legislation does not introduce any new business forms.

**Legal Aid Impact Test**

Existing disease control legislation already contains criminal sanctions and penalties, the new legislation will maintain these. In view of this there are no implications for legal aid.

**Enforcement, sanctions and monitoring**

Animal Health and Veterinary Laboratories Agency (AHVLA), and Local Authorities would continue to enforce the legislation as they do at present; there are no new burdens on these enforcement agencies.

The legislation does not introduce any new sanctions.

The legislation will be monitored by Scottish Government.

**Implementation and delivery plan**

It is anticipated that the Order will be laid in Parliament in June 2012 and come into force in September 2012.

**Post-implementation review**

Monitoring of the effectiveness of the legislation will arise from regular National Contingency Plan reviews and lessons identified following an outbreak of disease, the Order will also be reviewed if any further EU legislation is made.

**Summary and recommendation**

We recommend the transposition of Directive 5/2012. This includes all the essential measures for the prevention and control of bluetongue, which for relatively low cost provides net benefits to industry in term of controlling the spread of disease. This approach is in line with our disease control strategies for other exotic notifiable diseases.

**Declaration and publication**

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

**Signed:**

**Date:**

Richard Lochhead, Cabinet Secretary for Rural Affairs and the Environment

**Scottish Government Contact point:**

Angela Johnston  
Exotic Animal Disease Team  
P Spur  
Saughton House  
Broomhouse Drive  
Edinburgh  
EH11 3XD