#### EXPLANATORY MEMORANDUM TO

#### THE BLUETONGUE REGULATIONS 2008

#### 2008 No. 962

1. This Explanatory Memorandum has been prepared by The Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

#### 2. Description

2.1 The Regulations have been made to allow implementation of controlled vaccination in England. They are due to come into force on 26th April.

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

3.1 These Regulation were made on 2 April and come into force on 26 April 2008.

# 4. Legislative Background

- 4.1 The Bluetongue Order 2007 implemented Council Directive 2000/75/EC on the control and eradication of bluetongue, as amended by Commission Regulation 1266/2007 published on 27 October 2007. The draft Regulations revoke the 2007 Order apart from article 17 which provides for the slaughter powers under the Animal Health Act 1981 to be retained.
- 4.2 The draft Regulations retain the necessary provisions of the old Order, deal with some technical matters that were not sufficiently clear and, importantly, add provisions relevant to vaccination. They are Regulations made under the European Communities Act 1972 as the 1981 Act does not provide all the powers necessary for the vaccination provisions.

#### 5. Extent

5.1 This instrument applies to England.

#### 6. European Convention on Human Rights.

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

#### 7. Policy background

- 7.1 Since the emergence of Bluetongue serotype 8 (BTV-8) in Northern Europe and now in certain areas of England control of the disease has been largely based on movement restrictions. However, even strict enforcement of these restrictions is no guarantee against disease spread as it is not possible to control the midge vector. The implementation of a vaccination programme could therefore significantly reduce Bluetongue virus circulation and limit its geographical distribution, contributing to its control and potential eradication, and prevent losses by minimising the impact of clinical disease.
- 7.2 The current powers do not provide sufficient flexibility or control to implement a Bluetongue vaccination programme in line with the plan agreed with the industry. Under current powers, it is not possible to control the distribution of vaccine or, if necessary, require compulsory vaccination without considerable disproportionate costs. As a result, we are introducing appropriate provisions to allow vaccination to be delivered under suitably controlled programmes.

#### 8. Impact

- 8.1 The new provisions will ensure that the Bluetongue legislation provides the necessary powers to enable the implementation of suitably controlled Bluetongue vaccination programmes, so that the farming industry can better control the disease through vaccination.
- 8.2 Those provisions (i) introduce controls on obtaining vaccine; (ii) introduce powers to require vaccination either on individual premises or a zone; and (iii) clarify that the use of vaccine is prohibited except under licence.
- 8.3 A full impact assessment has been prepared, in which a full cost benefit analysis is contained. Importantly, the inclusion of vaccination provisions to allow vaccination under a suitably controlled programme is recognised as a positive step, supported by farming and veterinary organisations and the wider industry, and gives greater flexibility in controlling of disease.

#### 9. Contact

Andrew Clayton at the Department for Environment, Food and Rural Affairs can answer any queries regarding this instrument:

Address: Area 5A Nobel House, 17 Smith Square, London SW1P 3JR

Tel: 0207 238 6137

Email: Andrew.clayton@defra.gsi.gov.uk

**ANNEX: Impact Assessment** 

Summary: Intervention & Options				
Department /Agency: Department for the Environment, Food and Rural Affairs	Title: Impact Assessment of amending the Bluetongue Order 2007 to include provisions on vaccination.			
Stage: Implementation	Version: Final	<b>Date:</b> 01 April 2008		
Related Publications: Council Directive 2000/75/EEC and Commission Regulation 1266/2007				

#### Available to view or download at:

http://www.

Contact for enquiries: Marian Dunlop Telephone: 0207 238 6191

#### What is the problem under consideration? Why is government intervention necessary?

The Government needs to revise its powers under the Bluetongue Order 2007 to enable the implementation of suitably controlled Bluetongue vaccination programmes, so that the farming industry can better control the disease through vaccination. Intervention is necessary because government, through licensing powers, is best placed to control the distribution and use of the currently limited supply of vaccine that has been ordered by the Government on behalf of the industry. When a livestock keeper vaccinates stock against Bluetongue there are benefits to other livestock keepers and this means that a completely uncoordinated private approach is not likely to yield the most effective

#### What are the policy objectives and the intended effects?

A vaccination programme could significantly reduce the circulation of Bluetongue and limit its distribution, contributing to its control, and potential eradication in the longer term. The provisions for vaccination being introduced in this legislation will permit the implementation of a Bluetongue vaccination programme which has been developed in conjunction with the industry. That programme involves a voluntary approach to vaccination in order to allow the rapid roll-out of vaccination, targeted at the areas of greatest risk. However, we need to provide for wider compulsory powers for any future vaccination planning, should this also be required on the basis of veterinary risk analysis and cost-benefit analysis. Such planning would be published.

#### What policy options have been considered? Please justify any preferred option.

Continuing to rely on present powers would not provide sufficient flexibility to implement a Bluetongue vaccination programme in line with the plan agreed with the industry. Under those powers, it is not possible to control the distribution of vaccine or, if necessary, require compulsory vaccination without considerable disproportionate costs. As a result, we are recommending introducing appropriate provisions to allow vaccination to be delivered under suitably controlled programmes.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Bluetongue policy is subject to ongoing review, including by cost benefit analysis.

Ministerial Sign-o	ff For fi	inal ni	roposal/imp	lementation	stage 1	Impact A	Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

#### Signed by the responsible Minister:

Jeff Rooker

Date:	1 st	April 2008
Date.	1.	April 2000

Summary: Analysis & Evidence				
Policy Option:	Description:			

	ANNUAL COSTS		
	One-off (Transition)	Yrs	
	£0		
SISO	<b>Average Annual Cost</b>		
SC	(excluding one-off)		
<u>ٽ</u>	£0	1	

Description and scale of **key monetised costs** by 'main affected groups'

Cost to farmers of purchasing and administering vaccine. Total vaccine use is the same (~20 m doses) under both baseline and proposed policies, therefore there are no additional costs.

Total Cost (PV) £ 0

Other key non-monetised costs by 'main affected groups'

Cost to government of administering licensing scheme assumed to be negligible as it will consist of general licences published on the Defra web site.

# ANNUAL BENEFITS One-off Yrs £0 Average Annual Benefit (excluding one-off) £1m - £30m 1

Description and scale of **key monetised benefits** by 'main affected groups'

Benefit to cattle and sheep farming industry of avoiding larger disease outbreak that could occur under baseline conditions, as a result of more effective targeting of vaccine.

Total Benefit (PV) £1m to £30m

NET RENEFIT (NPV Rest

Other key non-monetised benefits by 'main affected groups'

#### Key Assumptions/Sensitivities/Risks

Time Period

Price Race

(i) Vaccine efficacy assumed to be 90% (ii) Number of animal movements out of PZ assumed to stay constant under both policy scenarios (iv) For other assumptions regarding disease transmission and disease outbreak, see evidence base

Net Renefit Range (NPV)

Year 2008	Years 2008	£1m to £30m	(111 1)	estimate)	)		
What is the ge	ographic coverag	e of the policy/option	?		England	England	
On what date	will the policy be	implemented?			April 2008	April 2008	
Which organis	sation(s) will enfo	orce the policy?			Local Auth	orities / AH	
What is the tot	tal annual cost of	enforcement for these	organisations	?	No extra cost in 2008		
Does enforcen	Does enforcement comply with Hampton principles?					Yes	
Will implementation go beyond minimum EU requirements?					No		
What is the value of the proposed offsetting measure per year?				£			
What is the value of changes in greenhouse gas emissions?				£			
Will the proposal have a significant impact on competition?				No			
Annual cost (£	C-£) per organisati	ion	Micro	Small	Medium	Large	
Are any of the	se organisations	exempt?	Yes/No	Yes/No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices)				(Increase - Decrease)
Increase of	£0	Decrease of £0	Net Impact	£0

#### **Evidence Base (for summary sheets)**

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

#### 1. Proposal

- 1.1 We need to revise our powers under the Bluetongue Order 2007 to incorporate more specific vaccination provisions. These provisions will enable the implementation of suitably controlled Bluetongue vaccination programmes, so that the farming industry can better control the disease through vaccination. A new Statutory Instrument is being made under the European Communities Act 1972 and the Bluetongue (No. 2) Order 2007 is being revoked.
- 1.2 In this revoke and remake we are also taking the opportunity to make a number of technical amendments. These do not have a regulatory impact.

#### 2. Purpose and intended effect of measures

# (i) The objective

- 2.1 To ensure that the Bluetongue legislation provides the necessary powers to enable the implementation of suitably controlled Bluetongue vaccination programmes, so that the farming industry can better control the disease through vaccination. Under the current powers, it is not possible to control the distribution of vaccine or, if necessary, require compulsory vaccination without considerable disproportionate costs.
- 2.2 Specifically, the new provisions will effectively:
  - Clarify that the use of Bluetongue vaccine will only be allowed under licence (enabling controls on the use of vaccine geographically);
  - Introduce controls on obtaining vaccine (to target the distribution of vaccine to areas which are at greatest risk from the disease); and
  - Enable compulsory vaccination, either on an individual premises or in a zone

#### (ii) Background

- 2.3 Since the emergence of Bluetongue serotype 8 (BTV-8) in Northern Europe (and now in certain areas of England) control of the disease has been largely based on movement restrictions. However, even strict enforcement of these restrictions is no guarantee against disease spread as it is not possible to control the midge vector. The implementation of a vaccination programme could therefore significantly reduce Bluetongue virus circulation and limit its geographical distribution, contributing to its control and potential eradication, and prevent losses by minimising the impact of clinical disease.
- 2.4 To that end, in December 2007, Defra placed an order with pharmaceutical company Intervet to supply 22.5 million doses of BTV-8 vaccine for use in England and Wales. 20 million doses are reserved for use in England and 2.5 million doses are reserved for potential use in Wales. Intervet has indicated that the first batches of vaccine are expected to be ready for use from early May 2008.
- 2.5 Under European Community law, Bluetongue vaccination can only be carried out in a Protection Zone. As vaccine is delivered and once vaccination is progressing across the Protection Zone, the current Bluetongue vaccination programme outlines an intention to extend or modify the Protection

Zone in order to permit further vaccination, allowing a phased approach as vaccine comes onstream. However, when vaccine first becomes available from May, it will be delivered in relatively small batches. It may therefore be necessary to limit vaccine availability within the Protection Zone in accordance with the supply of vaccine and the epidemiological situation. The distribution of vaccine therefore needs to be controlled.

2.6 The vaccination programme also involves a voluntary approach to vaccination in order to allow the rapid roll-out of vaccination, targeted at the areas of greatest risk. However, we need to provide for wider compulsory powers for any future vaccination planning, should this also be required.

#### 3. Options

#### Option 1

To continue to rely on present powers. Under these powers, it would not be possible to control the distribution of vaccine (and therefore target vaccine at the areas of greatest risk) or, if necessary, require compulsory vaccination without considerable disproportionate costs.

#### Option 2

To introduce the necessary powers to enable the implementation of a suitably controlled Bluetongue vaccination programme, so that the farming industry can better control the disease through vaccination.

#### 4. The key changes compared to existing legislation

- 4.1 We will (i) introduce controls on obtaining vaccine; (ii) introduce powers to require vaccination either on individual premises or in a zone; and (iii) clarify that the use of vaccine is prohibited except under licence.
- 4.2 Under the present powers, there are no controls on obtaining vaccine. As, from a legislative point of view, we are required under European Community law to ensure that vaccination is only carried out in a Protection Zone, and, from a disease control point of view, vaccine will be delivered in relatively small batches and we need to target the distribution of vaccine to areas which are at the greatest risk, we need to introduce controls on the distribution of vaccine.
- 4.3 The current powers in relation to compulsory vaccination would require notices to be issued to individual premises and would necessarily involve on-site visits from Animal Health to carry out vaccination where keepers were not willing to do it themselves, and so could not be used without considerable disproportionate costs. We are introducing powers which would require livestock keepers to vaccinate their own animals and would be able to target those powers either at individual premises or in a specific zone.

#### 5. Comparison of the costs and benefits of proposed versus existing regulation

#### Introduction

5.1 The current bluetongue vaccination plan<sup>1</sup> envisages a voluntary vaccination programme and a gradual rollout of vaccination. Under EU law, vaccination can only take place in the PZ. When the first batches of the vaccine become available probably in May, the PZ will be maintained in its current form (provided no additional cases occur that necessitate an expansion), and vaccination will take place within the PZ. As subsequent batches of the vaccine become available, the PZ will be extended (eventually covering the whole of England) in order to permit further vaccination. So at each stage the available vaccine will be targeted to the areas of highest disease risk.

<sup>&</sup>lt;sup>1</sup> See http://www.defra.gov.uk/animalh/diseases/notifiable/bluetongue/pdf/vaccinationplan.pdf

- 5.2 As stated above, the following key amendments to the existing vaccination programme are proposed:
- (i) Use of bluetongue vaccine only to be allowed under licence. This would enable geographical controls on the use of the vaccine, i.e. ensure that vaccination is only carried out in the PZ.
- (ii) Introduce controls on obtaining vaccine, in order to prevent stockpiling or potential anti-competitive action, and target the distribution of vaccine to areas that are at greatest risk from the disease.
- (iii) Enable compulsory vaccination, either on an individual premises or in a zone (although the vaccination programme will initially progress on a voluntary basis).
- 5.3 A simple cost benefit analysis (CBA) of the proposed legislation is presented here. A one-year time horizon (2008/09) is used.

# Vaccination coverage in option 1 (baseline scenario)

- 5.4 It is assumed that, under the existing regulations, the vaccine would be initially administered to 65% of the cattle and sheep stock in the PZ. Higher uptake of vaccine in the PZ is prevented as a result of less stringent controls on obtaining and distribution of the vaccine, e.g. failure to control stockpiling leads to some farmers in the PZ being unable to vaccinate their animals or to initial high prices that deter early vaccination. Two alternatives are considered:
- (i) The additional (stockpiled) vaccine is ultimately used by farmers in the PZ, and vaccination coverage in the PZ rises to about 80%. However, the additional vaccine becomes available in the PZ so late in the vector season that it has little impact on the spread of the disease. When the PZ is extended to cover all England, there is 75% vaccination coverage in the SZ and the FZ. In total, around 20 m doses of vaccine are administered.
- (ii) The additional (stockpiled) vaccine is used by farmers in the old SZ and FZ, and not in the PZ where disease incidence is highest. Therefore, vaccination coverage in the PZ remains at 65%, but rises slightly in the SZ and FZ when the PZ is extended to cover all England. In total, around 20 m doses of vaccine are administered.

# <u>Vaccination coverage in option 2 (proposed scenario)</u>

- 5.5 By introducing controls on obtaining vaccine, the proposed policy will ensure that vaccine supply is targeted more effectively within the voluntary vaccination regime, so that all keepers who want to vaccinate their animals can purchase the vaccine. It is therefore assumed that, under the proposed policy, the vaccine will be administered in a timely manner to 80% of the cattle and sheep stock in the PZ. When the PZ is extended to cover all England, vaccine coverage in the new area is 75% as before. As in the baseline scenario, the total number of vaccine doses administered is about 20 m.
- 5.6 The additional benefit of the proposed regulation therefore comprises the following:
- (i) The avoided cost of a larger disease outbreak that could be expected to occur under the existing policy, as a result of lower vaccination coverage or delayed vaccination in the PZ. Disease cost is expected to be higher under the existing programme, as there would be more unprotected animals in the PZ from which disease could spread to the rest of the country via either midges or movements of undetected infected animals.
- (ii) Without vaccination, animals are not allowed to move out of the PZ (except to approved slaughterhouses). Moves of vaccinated animals would however be allowed. It is possible that the proposed regulation would lead to a higher number of moves taking place, as more animals would be vaccinated in the PZ. However, this effect is minor as the number of additional moves would be small and it is likely that owners who wanted to move their animals would vaccinate them in either scenario.
- 5.7 There is no difference in vaccination cost between the two policy options, as approximately 20 m doses of vaccine are used in both scenarios. Although the market price of vaccine can be expected to be

higher if stockpiling takes place, the overall quantity of vaccine purchased is assumed to be the same. The higher prices will therefore represent a transfer from buyers to sellers of the vaccine. The additional costs to government of administering the licensing procedure under the proposed policy are negligible and assumed to be zero.

#### **Assumptions**

- 5.8 The proportion of the animal population in any zone that is effectively protected from Bluetongue through vaccination is the product of vaccination coverage (coverage rates under the two policy scenarios described above) and vaccine efficacy (proportion of vaccinated animals that develop resistance to bluetongue). A relatively high vaccine efficacy of 90% is assumed here. For the existing regulation scenario, this implies an effective protection rate of 58.5% for the PZ<sup>2</sup> and 67.5-68.4% for the SZ and FZ. For the proposed regulation scenario, it implies an effective protection rate of 72% for the PZ and 67.5% for the SZ and the FZ.
- 5.9 It is assumed that Bluetongue can be transmitted from the PZ (where the disease is already known to be) to the SZ, and from the SZ to the FZ via midges and via moves of undetected infected animals. We lack detailed quantitative epidemiological knowledge of the possible disease transmission patterns under different vaccination scenarios. Therefore a range of values is used for transmission rates in order to estimate the potential impact of greater (and timely) vaccination coverage in the PZ on the size and cost of a disease outbreak in England under alternative assumptions about the scale of the threat.
- 5.10 It is assumed that the maximum possible scale of a Bluetongue outbreak in 2008 would be similar to the Belgian outbreak of 2007. In an outbreak of this scale, 12% of cattle herds and 60% of sheep flocks would be affected. Assumptions about the disease outbreak are in table 1. Mortality rates are assumed as reported from Belgium in 2007 and lead to complete loss of the animal's value plus cost of disposal of the carcass. Sick animals require treatment and may lose productivity (milk yield, fertility and/or growth rate) assumed to average 20% of the value of the animal.

Cattle Sheep 30% Morbidity rate 6% Cost due to morbidity (as % animal value) 20% 20% Mortality rate 0.3% 27% Cost of carcass disposal £75 £20 Market value of average healthy animal £500 £60

Table 1. Assumptions about disease outbreaks

5.11 The cost of a voluntary vaccination programme comprises the cost of purchasing and distributing the vaccine and the cost of time spent administering the vaccine on farm. The vaccine will be available in 56,250 20 ml (20 dose) and 427,500 50 ml (50 dose) bottles. The final on-farm price is likely to be around 55-66 p/ml for the 50 ml bottles, and 82-98 p/ml for the 20 ml bottles. The average cost of vaccine at the point of delivery to the farmer is therefore estimated to be about £0.62 per dose. Sheep require a single dose of vaccine and cattle require two doses. Complete vaccination courses are delivered for all animals on vaccinating holdings.

# Cost benefit analysis

5.12 As stated above, the cost of the vaccination programme is the same under the existing and proposed regulations. The benefit is likely to be higher under the proposed regulation, as a result of higher

<sup>&</sup>lt;sup>2</sup> The effective protection rate is assumed to be 58.5% even when vaccination coverage in the PZ eventually rises to 80%, because it is assumed that the additional uptake of vaccination occurs too late in the vector season.

vaccination coverage in a timely manner in the PZ. Using a range of assumptions regarding the transmission of disease from the PZ to the SZ and FZ, the additional benefit of the proposed policy (over and above the baseline) is estimated to be in the range of £1 million to £30 million. The low estimate represents the situation in which the risk of disease transmission from the PZ to the rest of England is low, so that higher vaccination coverage in the PZ cannot be expected to yield significant benefits in the form of avoided disease costs. The high estimate represents the situation in which there is a relatively high risk of disease spread from the PZ to the rest of England and potential for major disruption of early delivery of vaccine to the most affected areas. In such a situation, achieving higher vaccination coverage in the PZ would be expected to yield significant benefits by avoiding a larger scale outbreak.

- 5.13 The "best estimate" of benefit is believed to be at the lower end of this range perhaps around £5 million. However it is important to industry that the proposed policy reduces the risk of the most serious outcomes, so the high end of the benefits range is also important despite its low probability.
- 5.14 Given the lack of knowledge of disease transmission and the range of possible disease scenarios in 2008, this analysis must be considered to be illustrative and must not be taken to represent a firm forecast of future net benefits. It must also be noted that there is no certainty that the stockpiling or other distortions of vaccine distribution would in fact occur under the existing regulation. However, it certainly represents a potential risk, which is addressed by the proposed policy assessed in this IA.
- 5.15 The benefit estimates reported above are for an incremental change in vaccination policy, and do not represent the overall benefits of bluetongue vaccination. In the absence of vaccination, an outbreak similar to the Belgium 2007 outbreak could lead to disease losses in the region of £400 million across England. National vaccination to protect against that potential loss would cost less than £20 million.

#### 6. Will implementation go beyond EU requirements

Our implementation facilitates vaccination programmes in the Protection Zone as necessary for movements as anticipated in the EU legislation. It does not go beyond these requirements.

#### 7. Other

#### Business sectors affected

7.1 Any keepers of Bluetongue susceptible animals may be affected. Other farming businesses, such as veterinary practices, may also be affected.

# Expected environmental and social costs

7.2 There would be no additional costs in disposing of carcases and other contaminated materials and treating waste waters, as the new legislation makes no changes in this area.

#### Issues of equity and fairness including distributional issues

- 7.3 The new legislation is an improvement over the existing controls in terms that it can be seen as providing more effective disease control, and more choice for farmers wishing to protect their animals against the introduction of disease on their premises.
- 7.4 EU legislation only prohibits vaccination in the Surveillance Zone. Vaccination can therefore take place in a Protection Zone, which currently extends across the south and east of England, but may expand with the detection of new cases in previously disease-free areas, or under the Bluetongue Control Strategy agreed with industry.

#### 8. Outcome of other Impact Tests

a) Legal Aid

- 8.1 The proposal does not create new criminal sanctions or civil penalties.
- b) Carbon Impact Assessment
- 8.2 The proposal will have no effect on carbon / greenhouse gas emissions, as the nature and scale of the livestock and related industries remain the same.
- c) Other Environmental Issues
- 8.3 The proposal has no implications in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.
- d) Health Impact Assessment
- 8.4 The proposal will not directly impact on human health or well being and will not result in health inequalities.
- e) Race/Disability/Gender
- 8.5 There are no limitations on meeting the requirements of the proposal on the grounds of race, disability or gender. The proposal does not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposal.
- f) Human Rights
- 8.6 The proposal is consistent with the Human Rights Act 1998.
- g) Rural Proofing
- 8.7 The majority of producers and many suppliers are based in rural areas and the proposal is designed to facilitate their ability to control disease. The policy does impact the rural community as it affects controls to prevent the spread of disease, but these are expected to give greater flexibility to farmers in how they control introduction of disease.
- h) Small Firms Impact Test
- 8.8 All cattle and sheep farms in England are small firms. The proposed policy on vaccination will affect the entire cattle and sheep farming industry in England. It could be of particular benefit to smaller farms by preventing situations such as stockpiling, which create an artificial scarcity and push up the market price of vaccine, as high vaccine prices may be expected to have a disproportionate effect on the ability of smaller farmers to vaccinate their animals.

# 9. Competition Assessment

The proposed policy is not expected to have any negative impact on competition compared to existing regulation. By targeting the distribution of vaccine to those areas that are at greatest risk of the disease, the proposed policy will ensure that the costs of a potential bluetongue outbreak are kept to a minimum. This would benefit the competitiveness of the cattle and sheep farming industry in England, both in the domestic (UK) and international markets.

#### 10. Enforcement and Sanctions

- 10.1 In the event of a disease outbreak, Animal Health and Local Authorities will enforce the legislation as they do at present; there are no significant new burdens on these agencies.
- 10.2 The effectiveness of UK enforcement procedures is kept under ongoing review. Any evidence of failure to enforce by other Member States is drawn to the attention of the Commission.
- 10.3 Possible use of the power of compulsion in future years would increase enforcement costs and the burden on those farmers who did not choose to vaccinate voluntarily. These costs will be taken fully into account in cost-benefit analysis of the compulsion option prior to any decision to use it.

#### 11. Monitoring and review

11.1 Legislation and policy are subject to ongoing review. The legislation will also be reviewed if any further Commission Directives or Decisions are made.

#### 12. Consultation

12.1 We have engaged in continual consultation with a Core Group of representative industry stakeholders, with whom we have developed our vaccination and disease control strategies. We have consulted the Core Group on the proposed changes and they support the proposals fully.

#### 13. Summary

13.1 We recommend Option 2: the introduction of the necessary powers to enable the implementation of a suitably controlled Bluetongue vaccination programme, so that the farming industry can better control the disease through vaccination.

# **Specific Impact Tests: Checklist**

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	Yes	No
Sustainable Development	Yes	No
Carbon Assessment	Yes	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No