EXPLANATORY MEMORANDUM TO

THE VETERINARY SURGERY (VACCINATION OF BADGERS AGAINST TUBERCULOSIS) ORDER

2010 No. 580

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. Purpose of the instrument

2.1 This Order forms part of the plans to tackle bovine tuberculosis in Great Britain through a Badger Vaccine Deployment Project that will help address the problem of disease spread from badgers to cattle. The Order will allow an injectable BCG vaccine to be administered to badgers by persons other than veterinary surgeons, referred to hereafter as 'lay vaccinators'. The Order states that the person administering the vaccine must be 18 years old or over and either a) have successfully completed an approved course and hold a valid certificate of competence in the vaccination of badgers by injection, granted by the course provider; or b) carry out the vaccination as part of an approved course.

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

3.1 None

4. Legislative Context

4.1 The vaccination by injection of badgers against tuberculosis is an act of veterinary surgery, which normally has to be carried out by a veterinary surgeon, under the Veterinary Surgeons Act 1966. This Order is made under section 19(4)(e) of that Act, and allows suitably trained and certified people who are not veterinary surgeons to vaccinate badgers by injection.

5. Territorial Extent and Application

5.1 This instrument applies in Great Britain. Orders under section 19(4)(e) of the Veterinary Surgeons Act are made by the Secretary of State for the Environment, Food and Rural Affairs, the Secretary of State for Scotland, the

Secretary of State for Wales and the Department of Agriculture and Rural Development NI, acting jointly.

6. European Convention on Human Rights

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

7. Policy background

- 7.1 This Order forms part of the plans to vaccinate badgers against tuberculosis, following a commitment from the Secretary of State to fund an injectable Badger Vaccine Deployment Project (BVDP). An injectable BCG badger vaccine is expected to be licensed in 2010 and once it is licensed, vaccination will initially take place in six areas in England, each of up to 100km^2 , where there is high incidence of bovine tuberculosis in cattle. The deployment project will form part of a wider package of measures to tackle the problem of bovine tuberculosis in England, including the potential use of badger vaccination outside of the BVDP.
- 7.2 It is intended that the vaccination of badgers will be carried out by lay vaccinators, who will be trained by the Food and Environment Research Agency (Fera) or another institution approved by the Secretary of State, and licensed to trap badgers under the Protection of Badgers Act 1992. Vaccination of badgers by injection requires badgers to be cage trapped and injected *in situ* in the field. We do not propose that veterinary surgeons carry out vaccination of badgers; such an approach would require the presence of a veterinary surgeon in the field or transport of badgers to a different location, both of which would be impractical and expensive. Therefore, lay vaccinators are necessary to enable wide use of the injectable badger vaccine.
- 7.3 This Order permits lay vaccinators to vaccinate badgers. This will enable the BVDP, and also enable farmers outside the areas covered by the BVDP to have badgers on or near their land vaccinated if they wish. The lay vaccinators must carry out the vaccination as part of, or be certified as having successfully completed, a training course approved by the Secretary of State after consultation with the Royal College of Veterinary Surgeons (RCVS).
- 7.4 To be able to carry out the vaccination, lay vaccinators must be adequately trained and be deemed competent to do so. They will also need to be trained and licensed to take badgers under section 10(2)(a) of the Protection of Badgers Act 1992.
- 7.5 An amendment has been made to the Veterinary Medicines Regulations 2008 to allow vaccination of wild animals to be carried out

without the animals being under the care of a veterinary surgeon. The regulations under Schedule 3, Part 1, paragraph 4, state:

4.—(1) A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V must first carry out a clinical assessment of the animal, and the animal must be under that veterinary surgeon's care, and failure to do so is an offence.

In recognition of the fact that this would not be possible for a wild animal, the Veterinary Medicines Directorate (VMD) have added the following to this paragraph of the regulations:

—(2) This does not apply in relation to treatment of a wild animal where the treatment is authorised by the Secretary of State.

8. Consultation outcome

- 8.1 In response to the consultation, the requirement for lay vaccination of badgers to be "under the direction of a veterinary surgeon" has been added. The Royal College of Veterinary Surgeons defines "direction" as meaning the veterinary surgeon instructs the vaccinator as to the treatment to be administered but is not necessarily present.
- 8.2 Other consultation comments have fed into the application procedure for, and requirements of, the licence to take badgers, the content of the training course and audit process for vaccinators.

9. Guidance

9.1 Defra has provided guidance on the BVDP, including the role of lay vaccinators, to farmers and other stakeholders via public meetings, a booklet, and guidance on the Defra website. As soon as the injectable BCG vaccine for badgers is licensed by the Veterinary Medicines Directorate (VMD), Defra will issue joint advice to veterinary surgeons with the British Veterinary Association (BVA) and Royal College of Veterinary Surgeons (RCVS) on the veterinary surgeons' role in directing the lay vaccinators. This advice will also include guidance to veterinary surgeons on prescribing the injectable BCG vaccine for wild animals not in their care, and background to the lay vaccinator training course.

10. Impact

- 10.1 The impact on business, charities, or voluntary bodies is none, as it will not impose or reduce costs on any businesses or the third sector.
- 10.2 The impact on the public sector is none.
- 10.3 An impact assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring and review

- 12.1 The Food and Environment Research Agency (Fera), and any other body approved by the Secretary of State, will be required to put in place an auditing process to monitor vaccination conducted by lay vaccinators to ensure that it is being carried out correctly and in accordance with accreditation criteria.
- 12.2 Certification of lay vaccinators will be valid for one year, in the first instance, to allow the certification process to be reviewed. The duration of certification may be extended following a review by Defra. A register of certified persons will be maintained by the approved training body for auditing purposes and to allow the licensing authority to administer licenses. Any person who has been certified, who is not deemed to be competent in vaccinating badgers as part of the auditing process, will be taken off the register of certified lay vaccinators.
- 12.3 The success of this Order will be subject to internal review in light of the auditing process and the legislation may be amended accordingly.

13. Contact

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| Summary: Intervention & Options | | | | | |
|--|---|-----------------------|--|--|--|
| Department /Agency: Department for the Environment, Food and Rural Affairs | Title: Impact Assessment of amendments to legislation to allow the vaccination of badgers by persons other than veterinary surgeons | | | | |
| Stage: Final Proposal | Version: 1 | Date: 3 February 2010 | | | |
| Related Publications: | | · | | | |

Available to view or download at:

http://www.defra.gov.uk/

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

Under the Veterinary Surgeons Act (VSA)1966 it is prohibited for a non-veterinary surgeon to carry out an act of veterinary surgery, unless specified in an order made under section 19(4)(e) of the Act. The injection of badgers with vaccine to combat bovine TB would constitute an act of veterinary surgery for the purposes of the act, and therefore any vaccination of badgers would need to be carried out by a veterinary surgeon, which would be both impractical and expensive. As a result, Government proposes an exemption order under the VSA that will allow vaccination by suitably trained non-veterinary surgeons (hereafter referred to as 'lay vaccinators') to enable the use of injectable vaccine as a policy tool to tackle bovine TB.

What are the policy objectives and the intended effects?

The objective of the proposal is to allow for the deployment of an injectable badger vaccine in a practical and cost-effective way. Training lay vaccinators to trap and vaccinate badgers, who will need to be certified by an approved training provider to ensure their competence, would prevent the need to call out a veterinary surgeon to carry out the vaccination and make such use viable. Government is funding a deployment project that aims to test the practicality of deploying an injectable badger vaccine. The effect of the legislative change would be to see a dramatic reduction in costs of vaccination and increased capacity to vaccinate badgers by using lay vaccinators within the project and increase the likelihood of successful use of badger vaccine to tackle bovine TB in the long term.

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

Option 1: (Preferred) An exemption order is passed to allow vaccination of badgers by lay vaccinators. Option 2: No exemption, where veterinary surgeons accompany lay contractors who are trained to trap badgers for vaccination.

Option 3: No exemption, where veterinary surgeons are called out to vaccinate badgers already trapped by lay contractors.

Options 2 and 3 would be significantly more expensive than training lay vaccinators; both to government funding the deployment project and individuals wishing to fund vaccination privately. Training to trap and handle badgers (for licensing purposes) is still required for each option. Practically, it is also unrealistic that enough vets would be available to carry out vaccination for the deployment project and elsewhere.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The Food and Environment Research Agency (Fera) will put in place an auditing process to ensure vaccination is carried out competently and the policy will be reviewed after the first year to establish actual costs and benefits and on completion of the deployment project.

Ministerial Sign-off For final proposal stage Impact 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:

Summary: Analysis & Evidence

Policy Option: 1

Description: Passing an exemption order under the Veterinary Surgeons Act 1966 that will allow vaccination of badgers by non-veterinary surgeons.

Total Benefit (PV)

£ 1.19m

| | ANNUAL COSTS | | Description and scale of key monetised costs by 'main | costs by 'main |
|------|---|-----|--|----------------|
| | One-off (Transition) | Yrs | affected groups' | |
| | £0 | | | |
| OSTS | Average Annual Cost (excluding one-off) | | | |
| ၓ | £0 | | Total Cost (PV) | £0 |

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

| | ANNUAL BENEFITS | | Description and scale of key monetised benefits by 'main |
|---|--|------|---|
| | One-off | Yrs | affected groups' Government: i)Total vet call out charge (£10k over 6 years) ii)Total vet fee based on a per hour charge (£90k- |
| n | £0 | | £235k per annum) |
| | Average Annual Bene (excluding one-off) | efit | |

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

Key Assumptions/Sensitivities/Risks

Impact on Admin Burdens Baseline (2005 Prices)

Decrease of

Increase of

£ 90k-235k

| Price Base Year 2009 Time Period Years 6 Net Benefit Range (NPV) £ 1.09m NET BENEFIT £ 1.09m | | | | | | st estimate) | |
|---|----------------------|-------------------------|----------------|-------|-------------|--------------|--|
| What is the ge | eographic coverag | ge of the policy/option | ? | | GB | | |
| On what date | will the policy be | implemented? | | | 6 April 201 | 0 | |
| Which organis | sation(s) will enfor | ce the policy? | | | Fera | | |
| What is the to | tal annual cost of | enforcement for these | e organisation | s? | £ n/a | | |
| Does enforcer | ment comply with | Hampton principles? | | | Yes | | |
| Will implemen | tation go beyond | minimum EU requirer | ments? | | N/A | | |
| What is the va | lue of the propos | ed offsetting measure | per year? | | £ n/a | | |
| What is the va | lue of changes in | greenhouse gas emi | ssions? | | £ n/a | | |
| Will the proposal have a significant impact on competition? | | | | | | | |
| Annual cost (£ (excluding one-off) | £-£) per organisat | ion | Micro | Small | Medium | Large | |
| Are any of the | se organisations | exempt? | No | No | N/A | N/A | |

Key: Annual costs and benefits: Constant Prices

Net Impact

(Net) Present Value

(Increase - Decrease)

Summary: Analysis & Evidence

Policy Option: 2

BEN

Increase of

Description: No exemption order under the Veterinary Surgeons Act 1966 and vaccination of badgers is carried out by accompanying veterinary surgeons

£ 2.17m

| | ANNUAL COSTS | 5 | Description and scale of key monetised of | | |
|-------|---|---|--|---------|--|
| | One-off (Transition) Yrs | | affected groups' Government: i) Fees for veterinary surgeons to trap and vaccinate badgers (£0.45m-£1.17m) | | |
| | £ 0 | | | | |
| COSTS | Average Annual Cost (excluding one-off) | | | | |
| CC | £ 0.45-1.17m | | Total Cost (PV) | £ 5.87m | |

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

| | ANNUAL BENEFIT | ΓS | Description and scale of key monetised benefits by 'main |
|-----|--|-----|---|
| | One-off | Yrs | affected groups' Government: i)No vet call out charge (£10k over 6 years) ii) Cost saving on contractor fees (£0.17m-£0.43m); iv) |
| eo. | £0 | | training costs (£3k) |
| Т | Average Annual Benefit (excluding one-off) | | |

£ 0.17-£0.43m Total Benefit (PV)

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

Impact on Admin Burdens Baseline (Increase - Decrease)

Key Assumptions/Sensitivities/Risks

| Price Base Year 2009 Time Period Years 6 Net Benefit Range (NPV) £ -3.38m NET BENEFIT (NPV Best estimate) £ -3.38m | | | | | | | |
|---|---|-----------------------|----------------|-------|--------|-------|--|
| What is the ge | What is the geographic coverage of the policy/option? | | | | | | |
| On what date | will the policy be | implemented? | | | n/a | | |
| Which organis | sation(s) will enfor | ce the policy? | | | n/a | | |
| What is the to | tal annual cost of | enforcement for these | e organisatior | ıs? | £ | | |
| Does enforcement comply with Hampton principles? | | | | | | Yes | |
| Will implemen | tation go beyond | minimum EU requirer | ments? | | N/A | | |
| What is the va | alue of the propos | ed offsetting measure | per year? | | £ n/a | | |
| What is the va | alue of changes in | greenhouse gas emi | ssions? | | £ n/a | £ n/a | |
| Will the proposal have a significant impact on competition? | | | | | | | |
| Annual cost (£ (excluding one-off) | E-£) per organisat | ion | Micro | Small | Medium | Large | |
| Are any of the | ese organisations | exempt? | No | No | N/A | N/A | |

Net Impact

£

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. As part of the Bovine TB Vaccines Programme, which is dedicated to developing vaccines for both badgers and cattle, a Badger Vaccine Deployment Project (BVDP) is being funded to vaccinate badgers against bovine tuberculosis (bTB) in six areas of England with high bTB incidence in cattle. Vaccine deployment is expected to commence in summer 2010, when it is expected that the injectable BCG badger vaccine will be licensed, and the project aims to test the practicality of deploying the injectable vaccine. It is intended that this project will assess the practicality of injectable badger vaccination as a means of tackling bTB, potentially leading to wider, privately funded use and long term disease control benefits with consequential saving to Government.
- 2. Under the Veterinary Surgeons Act 1966, the practice of veterinary surgery by unqualified persons is restricted and most acts of veterinary surgery need to be carried out by a veterinary surgeon registered with the Royal College of Veterinary Surgeons (RCVS). Vaccinating badgers (by injection), constitutes an act of veterinary surgery for the purposes of this act and falls within this restriction.
- 3. The only vaccination of badgers in the past has been during a Badger Vaccine Study to test vaccine safety, which forms part of the Market Authorisation Dossier that has been sent to the Veterinary Medicines Directorate to inform the licensing process. This study was carried out by Food and Environment Research Agency (Fera) staff and under an Animal Test Certificate. We do not currently vaccinate badgers. Therefore, the current approach to badger vaccination cannot be used as a baseline to compare other options with. Option 3 (calling out a vet to vaccinate) has been used as the baseline in this impact assessment, as this is the most likely model that would be adopted to carry out the deployment project if the exemption order was not passed, by which option 1 (lay vaccinators) and option 2 (vets accompanying lay contractors) can be compared to.
- 4. Under all three options, the effectiveness of vaccination would be the same and badger welfare would be equally protected, as lay vaccinators would have to be deemed competent and licensed by Natural England in order to trap badgers for the purposes of vaccination. The different options can therefore be evaluated solely on cost grounds.

Option 1 – Passing the exemption order; training non-veterinary surgeons to vaccinate badgers

- 5. Vaccination of badgers to be carried out by lay vaccinators. All lay vaccinators will need to be fully trained to trap and vaccinate badgers by the Food and Environment Research Agency (Fera), with input from veterinary surgeons, and licensed under the Protection of Badgers Act by Natural England, or the appropriate licensing authority outside of England. Lay vaccinators will therefore need to be trained in sett surveying and identification; siting, pre-baiting and setting traps; and handling, transporting and administering the vaccine, with input from a veterinary surgeon in order to be deemed competent to vaccinate badgers.
- 6. With this option an exemption order under section 19(4)(e) of the Veterinary Surgeons Act will be required to allow the act of vaccination to be carried out by lay vaccinators. In order to meet the project aims, using lay vaccinators will be less expensive and more feasible than either having veterinary surgeons administer the vaccine, who would be teamed with

contractors trained to trap and handle badgers (option 2), or having contractors call out vets to administer the vaccine (option 3).

- 7. As there is currently no vaccination of badgers being carried out, veterinary surgeons will not lose any current income as a result of passing the exemption order.
- 8. The objective of the BVDP is to deploy an injectable badger vaccine in a practical and costeffective way. In a project that aims to test the practicality of deploying an injectable badger vaccine, the effect of training a lay vaccinator, instead of the need to call out a veterinary surgeon, would be to see a reduction in costs and increased capacity to vaccinate badgers.

Option 2 – No exemption order; training lay people to trap and handle badgers, and qualified vets to accompany them to administer the vaccine

- 9. If the exemption order under the Veterinary Surgeons Act was not passed, one option would be to have veterinary surgeons teamed up with people trained and licensed to trap badgers. Sixty people are required to vaccinate the project areas, with five teams of two people in each area. Of these teams of two, a person licensed to trap and handle badgers would be paired with a veterinary surgeon. Thirty lay people would therefore be trained to trap and handle badgers and licensed in accordance with the Protection of Badgers Act, and thirty veterinary surgeons would be required to accompany them in order to administer the vaccine. In all options, training to trap and handle badgers is required as even if a veterinary surgeon is to administer the vaccine, a trained person must still be present who is licensed under the Protection of Badgers Act to trap badgers for the purpose of vaccination.
- 10. This option would be practicably difficult as it is unlikely that veterinary surgeons would be willing or able to be involved with the project on the timescale that would be required.

Option 3 – No exemption order; training lay people to trap and handle badgers and having vets called out to administer the vaccine

11. If there were to be no exemption order, it is most likely that badgers will need to be vaccinated by veterinary surgeons called out to administer the vaccine in the field once they have already been trapped. The costs of this option are considerably more expensive than having non-veterinary surgeons administer the vaccine because they would still be required to be trained and licensed to trap badgers (in line with option 1). Again, as with option 2, this option would be practicably difficult and it is unlikely the number of veterinary surgeons available in each of the six deployment areas, would be sufficient to cover the demand required.

Costs and benefits

12. The deployment costs are based on a contractor daily rate of £200 (£26.67 per hour), with 10 people required for 72 days per 100km². These costs will be the same for options 1 and 3, where 60 people will be required to trap and vaccinate badgers (option 1) or trap badgers (option 3). For option 2, the deployment costs will amount to 30 people at the contractor rate of £26.67 per hour and 30 people at a veterinary surgeons hourly rate (based on the LVI rate of £72.53).

Table 1: Contractor costs of deploying traps, pre-baiting traps and vaccinating the 6 target areas for 6 years.

| | 2010/2011 | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 | 2015/2016 | Total |
|-------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Contractor costs for option 1 | £331,200 | £864,000 | £864,000 | £864,000 | £864,000 | £532,800 | £4,326,000 |
| Contractor costs for option 2 | £165,000 | £432,000 | £432,000 | £432,000 | £432,000 | £266,400 | £2,160,000 |
| Contractor costs for option 3 | £331,200 | £864,000 | £864,000 | £864,000 | £864,000 | £532,800 | £4,326,000 |

- 13. Vaccine deployment will be phased in over the first year, due to the need to train lay vaccinators to build up sufficient capacity to vaccinate badgers across the six 100 km² areas. Therefore, in 2010/2011 there will only be 100% vaccination taking place in one area, which will be used for training purposes; 50% of another area, where training will also be conducted; and 20% vaccination in the remaining four areas, amounting to 230km². There will then be full deployment in all areas during the following 4 years. There will also be vaccination during 2016/2017 in order to vaccinate the areas that were not vaccinated in year 1, amounting to 370km².
- 14. The scale of uptake of the injectable BCG vaccine outside the deployment project is currently unknown. These costs are minimum costs which will apply to vaccination of badgers within the BVDP only and will be borne by Government. The costs will increase dependent on uptake outside of these areas and any costs outside the deployment areas will be borne by industry.

Costs and benefits of option 1

Benefits

15. The benefits of option 1 is the cost savings made to government because they do not have to call out vets to vaccinate badgers and therefore, do not have to pay vet call out charges and the hourly fee for a vet call out. The vet call out charge is estimated to be £32 with an hourly fee for vet call out of £72.53. This is based on the Local Veterinary Inspector (LVI) rate.

Table 2 demonstrates how much the industry will save in vet charges if an exemption order is granted and the vaccination of badgers is carried out by trained lay vaccinators. In addition to the direct net benefits of option 1 relative to option 3, the wider net benefit derived if option 1 was carried out in high TB incidence areas of England and Wales, after the initial pilot period, have been considered. It is estimated that if an exemption order was granted and trained lay people were to vaccinate badgers in high TB incidence areas of England and Wales, the net benefit of this option relative to option 3 over a 10 year period would be over £100m, representing the costs of vet call-out costs that would not be needed under option 1. This assumes that vaccination is applied continuously in high incidence TB areas of England and Wales, over a 10 year period, once the initial pilot period has ended.

Table 2: Benefit of option 1 due to cost savings on vet charges

| | 2010/2011 | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 | 2016/2017 | Total |
|---|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Vet call out charge (£32) | £736 | £1,920 | £1,920 | £1,920 | £1,920 | £1,184 | £9,600 |
| Total vet call out fees (£72.53 per hour) | £90,082 | £234,997 | £234,997 | £234,997 | £234,997 | £144,915 | £1,174,986 |
| Total | £90,818 | £236,917 | £236,917 | £236,917 | £236,917 | £146,099 | £1,184,586 |

Costs

16. Relative to option 3, option 1 does not have any additional costs.

Costs and benefits of option 2

Benefits

- 17. Relative to option 3, option 2 has the same benefits as option 1. Option 2 exhibits a benefit of around £2.17m over the 6 year time period due to cost savings on contractor fees, training cost savings and no vet call out charges. Relative to option 3, option 2 has a benefit in deployment costs as only 30 trained lay people would be required at a daily rate of £200, instead of 60 people required. These trained contractors would then be accompanied by veterinary surgeons who would administer the injectable vaccine.
- 18. In addition to this benefit, under option 2, the training cost in terms of staff wages is only £3,000 as only 30 people would be required to be trained to trap and handle badgers (at a cost of £100 per person). Under option 1 and 3, staff wages are £6,000 as 60 people would need to be trained to handle badgers (in option 3) and handle and vaccinate badgers (in option 1). Therefore, there is an additional £3,000 benefit of option 2 compared to option 3. There is no call out fee for a veterinary surgeon in this option as the vets will be employed to carry out the trapping and vaccination procedure, rather than being called out to examine and vaccinate badgers outwith their veterinary surgery's working hours.

Costs

- 19. Though under option 2, there isn't a vet call out charge, there is still an hourly rate that industry is charged for vets to trap and vaccinate badgers, of £72.53 per hour for the thirty veterinary surgeons that will be required. These veterinary surgeons will replace thirty of the sixty lay people required in option 3. This hourly rate is based on the LVI rate. The total charge per year is shown in table 3 below.
- 20. In addition to the direct net cost of option 2 relative to option 3, the wider net cost derived if option 2 was carried out in high TB incidence areas of England and Wales, after the initial pilot period have been considered. It is estimated that if an exemption order was not granted and vets were trained to trap and handle badgers in order to vaccinate, it is estimated that there would be a net cost over a 10 year period of over £300m, representing the extra costs of vets over lay injectors over 10 years. This assumes that vaccination is applied continuously in high incidence TB areas of England and Wales, over a 10 year period, once the initial pilot period has ended.

Table 3: Cost of option 2 due to vet fees to vaccinate badgers

| | 2010/2011 | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 | 2016/2017 | Total |
|--|-----------|----------------|------------|------------|------------|-----------|------------|
| Total fees for vets to vaccinate badgers | £ 450,411 | £ 1,174,986 | £1,174,986 | £1,174,986 | £1,174,986 | £724,575 | £5,874,930 |

Recommendation

- 21. We do not propose that veterinary surgeons carry out the vaccination of badgers as such an approach would be both impractical and expensive over the six 100km² areas in England. Option 1 is recommended as under an exemption order where trained lay people vaccinate badgers, there are zero vet charges. Due to this, option 1 has a <u>net benefit</u> of £1.09m relative to option 3.
- 22. Option 2 is the least recommended option as despite having lower staff costs for the training period and lower contractor costs, the total vet fees paid over the 6 year period are far greater than the vet fees that would have to be paid under option 3. Due to this, option 2 has a <u>net cost</u> of £3.38m. In addition to the direct net benefit of option 1 relative to option 3, a wider <u>net benefit</u> of over £100m over a 10 year period has been estimated representing the costs of vet call-out costs that would not be needed under option 1. In addition to the direct net cost of option 2 relative to option 3, a wider <u>net cost</u> of over £300m, representing vet fees over a 10 year period has been estimated.
- 23. On behalf of the Chief Economist, the Deputy Director for Food and Animal Health Economics has been consulted on this Impact Assessment. He notes the efficacy of the vaccination is consistent between the three options, and that the cheapest option is therefore the most beneficial. He also notes the potential further benefits of this legislation if the vaccination programme is extended beyond the pilot. He approves the overall approach to the cost-benefit analysis and advises that, given the available evidence, the IA represents a reasonable view of the likely costs, benefits and impacts of the amendments of legislation.
- 24. It is recommended that an exemption order is passed under section 19(4)(e) of the Veterinary Surgeons Act to allow the vaccination of badgers against tuberculosis by lay people.
- 25. The Specific Impact Tests have been considered, but as this is not a regulatory requirement on business, but a change intended to facilitate a limited Government funded project to assess effective deployment of an injectable vaccine, there is no impact under any of the specific impact tests.
- 26. The scale of uptake outside the project is currently unknown. The project aims to support wider use of vaccines outside the deployment project areas and beyond the lifespan of the project. However, without lay vaccinators being able to administer the injectable vaccine, such widespread use is unlikely and the disease control benefits of vaccination would not be realised.

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 | No | No |
| Small Firms Impact Test | No | No |
| Legal Aid | No | No |
| Sustainable Development | No | No |
| Carbon Assessment | No | No |
| Other Environment | No | No |
| Health Impact Assessment | No | No |
| Race Equality | No | No |
| Disability Equality | No | No |
| Gender Equality | No | No |
| Human Rights | No | No |
| Rural Proofing | No | No |