

**EXPLANATORY MEMORANDUM TO THE  
VETERINARY SURGERY (TESTING FOR TUBERCULOSIS IN BOVINES)  
ORDER 2005**

**2005 No. 2015**

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

**2. Description:**

2.1 This Order will permit, during the proposed pilot programmes, non-veterinarians to carry out tuberculin testing of cattle. This will be restricted to (i) State Veterinary Service Animal Health Officers, and (ii) technical staff from the Department of Agriculture and Rural Development (Northern Ireland), acting under the direct supervision of Veterinary Officers.

**3. Matters of Special Interest to the Joint Committee on Statutory Instruments**

None

**4. Legislative Background:**

4.1 Tuberculin testing of bovines constitutes ‘an act of veterinary surgery’ as defined in Section 27 of the Veterinary surgeons Act 1966. However, Section 19(4)(e) of the Act allows Ministers, after consultation with the Royal College of Veterinary Surgeons, to introduce Exemption Orders to permit a minor treatment, test or operation to be carried out by people who are not veterinary surgeons.

4.2 This Order specifies tuberculin testing of bovines as a test for the purposes of section 19(4)(e) of the Act 1966.

4.3 We have noted an error in the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794). The original section 27 of the Veterinary Surgeons Act 1966 c.36 read, ""the Ministers" means the Minister of Agriculture, Fisheries and Food, the Secretary of State and the Minister of Agriculture for Northern Ireland acting jointly."

4.4 This was textually amended by paragraph 1 of Schedule 5 to the Transfer of Functions (Wales) (No. 1) Order 1978, which provides that, for the words “the Secretary of State” there are substituted the words “the Secretary of State for Scotland and the Secretary of State for Wales”.

This means that, following the amendment, the text reads,

“the Ministers” means the Minister of Agriculture, Fisheries and Food, the Secretary of State for Scotland and the Secretary of State for Wales and the Minister of Agriculture for Northern Ireland acting jointly."

4.5 This change is not printed in the bound volume of Halsbury's Statutes, although it appears in Butterworths. The bound version of Halsbury's is accordingly wrong. For the record, the bound version refers to article 4(1) of the Order, which transfers functions "exercisable by the Minister of Agriculture, Fisheries and Food acting alone". This applies to the reference to the Minister in section 8 of the Act but not the reference to the Minister in section 27 of the Act.

## **5. Extent:**

This Order applies to the UK.

## **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 There is currently a backlog of 1750 outstanding TB tests. This undermines the effectiveness of our TB controls and places unnecessary burdens on farmers.

7.2 The Government consulted publicly, in 2003, on proposals to introduce legislation that would permit TB testing by technical staff of the State Veterinary Service, and other non-veterinarians (i.e. Veterinary Nurses) employed by Local Veterinary Inspector (LVI) practices. In areas where there are few large animal practices, the introduction of lay testers would ensure sufficient flexibility to meet the expected increased demand for testing, and to help cope with present testing demands. There would be no obligation for practices to employ lay testers.

7.3 This is a sensitive issue for the veterinary profession, who have raised a number of valid concerns on the principle of introducing lay TB testing and on the legal and practical implications of the Department's approach. Many of their concerns related to the longer-term application of lay TB testing. The Department considered the options available and sought advice from the EU commission on using lay testers.

7.4 In order to address these concerns the Government are proposing to run a pilot programme in England and Wales in order to identify all the issues and find appropriate solutions, before considering whether the procedure could be rolled-out to other non-veterinarians. The pilots will last approximately 12 months and involve around 11,000 tests.

7.5 The pilot programmes will include training to determine the competence of the lay testers, and continuous evaluation with the help of supervising veterinary officers, the farmers whose animals are being tested, and members of the veterinary profession. The pilots will be carefully monitored and take place under strictly controlled conditions.

7.6 Final decisions on the possible introduction of lay TB testing will depend on the results of the pilot.

**8 Impact:**

A Regulatory Impact assessment has been prepared and a copy is attached to this Explanatory Memorandum.

**9. Contact:**

Paul McDonald, Veterinary Services Team, Defra, Area 711, 1A Page Street, London SW1P 4PQ. Tel: 020 7904 6588. Fax: 020 7904 8200.

## **REGULATORY IMPACT ASSESSMENT**

### **1. Title of proposed measure**

The Veterinary Surgery (Testing for Tuberculosis in Bovines) Order 2005.

### **2. Purpose and Intended Effects**

#### **Issue**

2.1 The Veterinary Surgeons Act 1966 reserves most minor surgery and procedures requiring entry into a body cavity to registered veterinary surgeons. The introduction of this Order will permit (i) Senior Animal Health Officers (SAHO) and Animal Health Officers (AHO) of the State Veterinary Service (SVS); and (ii) technical staff of the Department of Agriculture and Rural Development (Northern Ireland) to administer the tuberculin test under the direction of a veterinary surgeon.

2.2 In relation to TB, the historic trend has been towards year on year increases in the amount of testing needed – and there are no reasons to believe that this pattern will change. Indeed, all the evidence suggests that if anything we will, in the next few years, see a steeper rise in testing requirements. The new TB controls announced in November 2004 resulted in significantly increased levels of testing. Similarly, the possible introduction of pre-movement testing (in England and Wales) and post movement testing (in Scotland) would add further pressure on our already stretched testing resources.

2.3 It is also borne in mind that the recently introduced ‘zero tolerance’ measure (i.e. herd movement restrictions applied immediately a routine TB test becomes overdue) means that the implications of failing to complete a test on time are now more significant than ever. It is vital, therefore, that all parties are assured that sufficient testing capacity is available for future years – though we accept that it is extremely difficult to predict what the required future capacity will be.

#### **Objective**

2.4 The objective is to permit, during the proposed pilot programmes, (i) SVS (S)AHOs and (ii) technical staff from DARD(NI), under the direct supervision of Veterinary Officers, to carry out tuberculin testing of cattle. The results of the pilot will be evaluated and a decision taken on whether to extend the exemption to carry out TB testing to any suitably trained lay person.

#### **Risk Assessment**

2.5 There are associated risks for the Department's, the SVS, cattle owners, and private veterinarians:

- **Agriculture Departments** – would incur damage to their reputations if cattle owners are not able to meet new policy requirements due to factors outside their control, i.e. non availability of sufficient numbers of 'approved' Bovine TB testers.
- **SVS** – there may be increased calls on SVS staff which compromises its ability to complete the pilot programme.
- **Cattle owners** – farms could lose their officially TB free status as a result of uncompleted tests. The consequent herd movement restrictions would have financial implications for affected cattle owners.
- **Private veterinarians** – relationship with farmer customers might be adversely affected if they are not able to cope with increased testing demands (i.e. if farms are, as a result, placed under restrictions).

### 3. Options

#### Options identified

3.1 Three options have been identified as possible ways forward.

**Option 1** is to do nothing and continue to rely on veterinary surgeons to carry out tuberculin testing of cattle.

**Option 2** would be to permit technical staff of the SVS and DARD(NI) (non-veterinarians) to carry out the procedure during a pilot programme, before considering whether to extend the procedure to other competent and trained non-veterinarians (i.e. Veterinary Nurses).

**Option 3** would be to permit all suitably trained and competent non-veterinarians to perform tuberculin testing of cattle.

#### Issues of Equity and Fairness

3.2 The introduction of this new legislation would initially only affect areas covered by the SVS Divisions in Carmarthen and Caernarfon in Wales and Reading and Reigate Divisions in the South East of England.. Participation in the pilot programme will be limited to experienced (S)AHOs, with support from Veterinary Officers who have a designated role in the pilot Animal Health Divisional Offices. Whilst we recognise that using experienced SVS technical staff will not entirely replicate the use of lay testers in LVI practise, we believe the pilot will provide a valid basis for evaluating and determining the feasibility of extending the principles of lay testing. The use of experienced SVS staff simply reflects our concern that we proceed carefully and under controlled conditions.

3.3 This pilot programmes are designed to test the effectiveness of a key change to a major disease control policy. Involvement in the pilot will be voluntary, both for trainees and those whose animals are to be tested by the

trainees. No one is being treated unfairly. We consider, in the circumstances, it is prudent to trial these arrangements within the SVS under close supervision.

#### **4. Benefits**

##### **Identify the benefits**

**Option 1** - would maintain the status quo, but would result in a continued backlog of overdue tests. The Royal College of Veterinary Surgeons, the British Veterinary Association and others have expressed reservations during and subsequent to the department's consultation (see Section 6). The main advantage of this Option is that it has the support of some key stakeholders.

**Options 2 and 3** – We believe that lay TB testing would make a valuable contribution to improving the efficiency of the delivery of TB controls. It would also provide the additional capacity to meet the likely increase in demand for TB testing. The introduction of pilot programmes would help us determine the effectiveness of lay TB testing and help us to determine whether lay testing could be extended to other suitably trained and competent non-veterinarians.

The welfare of cattle will be protected, as only trained and competent lay testers will be permitted to carry out the procedure, under direct veterinary supervision.

##### **Environmental benefit**

**4.1** There is a need to ensure that there is sufficient testing capacity available that will help to protect the business interests of cattle owners by reducing the risk of their herds being placed under movement restrictions.

#### **5. Costs**

##### **Compliance costs for Businesses, Charities and Voluntary Organisations**

**5.1** TB testing during the proposed pilot programmes would be carried out by trained and competent technical staff of the SVS and DARD(NI) only. The funding will be from Defra and SVS budgets. There will be no costs to businesses, charities or organisations.

**5.2** There would be no additional costs for farmers associated with the pilot. However, in the longer term, it is proposed that the costs of pre-movement testing (and post movement testing in Scotland) would be met by cattle owners. The availability of lay testers may give farmers the opportunity to reduce the cost impact of these new measures.

## **Implementation Costs of the SVS pilot programme**

5.3 The estimated costs in the following paragraphs only relate to the SVS pilot programme. The proposed pilot programme is at a very early stage of development and figures are not yet available.

5.4 The SVS pilot programme will take place in the Carmarthen and Caernarfon Divisions in Wales, and the Reading and Reigate Divisions in the South East of England. Participation in the programme will be limited, in the preliminary stages of the pilot, to experienced SVS (S)AHOs, with direct supervision from SVS Veterinary Officers. The main cost associated with the pilot programme is related to the training programme and the setting up of the pilot programme.

5.5 Training will consist of both theoretical and practical elements, with emphasis on practical experience and understanding. Following completion of the training, the trainee will undertake an examination in order to assess competence. The initial pilot programme will include 20 (S)AHOs (7 in Wales and 13 in South East England). Each trainee will test at least 500 animals, under direct veterinary supervision. In addition, each trainee must have seen and recorded at least 30 reactors and 30 inconclusive reactors during the training.

5.6 It is estimated that the total cost per trainee will be £8,700. This includes costs for detached duty, travel and subsistence, accommodation and veterinary supervision. On the basis that the pilot programme will initially involve 20 trainees, the total training cost will be estimated as £174,000.

5.7 In addition to the training costs, there have been costs associated with the preparation of the pilot and training programme. This is estimated at £6,659. Therefore, the total cost of setting up the pilot and running the training programme for the 20 (S)AHOs is estimated at £180,659.

5.8 There will also be costs associated with the evaluation of the pilot programme. At this stage it is impossible to estimate these. The evaluation will include continuous review in the light of customer reaction and feedback from Veterinary Officers involved in supervision; issues encountered during the pilot; and the impact of the pilot. In addition an exercise will be undertaken to assess the perception of farmers who have their animals tested by the lay testers, either by telephone or by provision of a feedback questionnaire. The relevant Divisional Veterinary Manager (DVM) will handle local co-operation and communication. Local Veterinary Inspector's (LVI's) will be kept informed, and their opinions sought, either by telephone or direct contact. Representatives from the Royal College of Veterinary Surgeons (RCVS), British Veterinary Association (BVA) and the British Cattle Veterinary Association (BCVA) will also be encouraged to participate in the impact assessment of this pilot programme.

## **6. Results of the Consultation**

6.1 The Partial RIA was included in the Department's public consultation on its proposals to introduce lay TB testing in 2003. The consultation was on behalf of all devolved departments in the UK. The suggested options included (1) doing nothing and continue to rely on veterinary surgeons to carry out testing; and (2) introduce legislation that would permit suitably trained and competent non-veterinarians to perform the test. This included Animal Health Officers of the SVS and other non-veterinarians (i.e. Veterinary Nurses) that would be employed by a Local Veterinary Inspector (LVI) practice. We suggested that permitting such non-veterinarians to perform the test would provide additional resources for an increasing test programme and would more rapidly identify positive reactors. We clearly stated that we would not force LVI practices to employ lay TB testers, but should they chose to do so there would be a reduced rate. It was also suggested that there would be an initial cost to the practice for training the lay tester.

6.2 The results of the consultation were disappointing. Of the 88 responses received 62% disagreed with the proposal. Forty-six of these were from the veterinary profession. The reasons included (i) a concern that the proposal would mean less veterinary visits to farms and, therefore, a reduction in veterinary surveillance; (ii) considered that TB testing included a clinical examination which should not be carried out by non-veterinarians; and (iii) a perceived threat to the viability of rural veterinary practices.

6.3 Following the results of the consultation, we considered the options further. We held meetings with the RCVS and BVA to discuss the possibility of a further option - a pilot programme using SVS trained and competent technical staff – and the concerns the profession had raised in the consultation.

### **Recognition of clinical signs and practical arrangements for veterinary attendance**

6.4 The veterinary profession had concerns that interpretation of the TB test, as set out in EU Directive 64/432/EEC, is based on 'clinical observations' as well as the skin fold test. Any such clinical observations should be interpreted by a veterinary surgeon.

6.5 The EU Commission have confirmed that lay persons could be used to perform the test, but not interpret the results of the test. The circumstances we can use lay testers are:-

- Pre and post movement testing; and
- Periodic herd testing and check testing.

It has, however, been made clear that if cattle are being tested prior to export, any TB test required by the recipient country must be carried out by a veterinary surgeon.

6.6 During the first stages of the proposed pilot only experienced technical staff of the SVS will be used. They will undertake comprehensive theoretical



and practical training, which will include recognition of circumscribed reactions and reactions with oedema – the most commonly observed reactions at a tuberculin test under UK conditions. The lay tester will also be trained to recognise the abnormal reactions (exudation, necrosis and lymphangitis) and if such reactions occurred then we would expect them to call a veterinary surgeon to attend the animal. The formal training and subsequent practical training will emphasise and embed the importance of lay testers recognising the expected reactions (that is, absence of reaction, circumscribed reaction and some degree of oedema), and being certified as capable of doing this. When an unusual reaction occurs, that is exudation or necrosis, then lay testers must call for a veterinary surgeon's opinion immediately.

6.7 During the proposed pilot all tests will be fully supervised by a veterinary surgeon. One of the objectives of the pilot is to identify whether or not these lay staff are, indeed, capable of identifying situations where a veterinary opinion is required. The results of the pilot would need to be fully evaluated before any detailed proposals were developed to extend the principle of lay testing beyond the SVS.

### **Impact on disease surveillance and rural practices**

6.8 A particular concern of the veterinary profession was the expected impact of lay testing on disease surveillance. It is argued that the TB test is often one of the few occasions veterinarians have to assess disease status and animal welfare on the farm as a whole. It also provides the opportunity to discuss management systems over and above the technical aspect of the TB test. There is also considerable concern that the proposal could adversely affect rural mixed and large animal practices. It is argued that the proposal would result in a significant reduction in the number of vets, especially newly qualified vets, employed in large and mixed practices. This would have a knock-on effect on the provision of essential expertise, 24-hour cover and cover in the event of emergencies. However, there is no requirement for rural vets to change their current working practices or hire lay TB testers. In addition, the opportunity to employ lay testers at some time in the future will allow practices to target their veterinary expertise at some farms when testing is due, allowing lay testers, for example, to test at farms where management and welfare are already known to be good.

6.9 In order to take forward the Animal Health and Welfare Strategy (AHWS), Defra is working closely with the Devolved Administrations, the veterinary profession and other interested parties, to put in place a number of initiatives to promote farm health planning and improve training and advice. Farm health planning is one way that higher standards can be achieved. It is already being used successfully by many livestock keepers and their vets to identify disease risks and essential problems on the farm so that action can be targeted in a cost-effective way.

## **7. Competition Assessment**

7.1 The competition filter looks at the impact regulation has on various sectors of an industry. It tries to ensure that no firm gains or loses disproportionately as a result of new legislation. The Veterinary Surgery (Tuberculin Testing of Cattle) Order 2005 will not have a negative impact on competition. Tuberculin testing of cattle will continue, as now, to be carried out by LVIs and paid for by Agricultural Department in the UK. The Competition Assessment will be considered further should it be decided to roll-out lay testing to other non-veterinarians (i.e. Veterinary Nurses at LVI practices) following the pilot.

## **8. Enforcement, sanction, monitoring and review**

8.1 There will be a continuing need for quality assurance of the work of the lay testers. The technical staff will be under continuous supervision by a Veterinary Officer during the pilot programme. Any lay tester that is not competent will not be permitted to perform the tests and their approval will be suspended pending re-training.

### **Trainee evaluation of the SVS pilot programme**

8.2. The designated Veterinary Officer will directly supervise all work done by trainees, including practical technique and completion of paperwork, and provide regular reports to the Project Manager, who will monitor both qualitative and quantitative aspects of performance. Following authorisation, Veterinary Officers will be expected to carry out comprehensive and unannounced spot checks, both on farm and on paper. In this way, any deterioration in performance should be identified quickly, and remedial action taken.

8.3 An interim report, scheduled for Autumn 2005, will be produced indicating the issues encountered during the pilot, and the impact of the project. This report will also make recommendations for future action, including modification to training provided and expansion of the project.

### **SVS Pilot programme evaluation**

8.4 The pilot will be subject to continuous review in the light of customer reaction, trainee feedback and feedback from veterinary officers involved in supervising the activity and other veterinarians who may be affected by the outcome of this pilot.

8.5 In addition, an exercise will be undertaken to assess the perception of farmers who have their animals tested by lay testers, either by telephone or by provision of a feedback questionnaire.

8.6 Local co-operation and communication will be handled by the relevant DVM; LVIs will be kept informed, and their opinions will be sought, either by

telephone or direct contact. Representatives from the RCVS, BVA and BCVA will also be encouraged to participate in the impact assessment of this pilot programme and have been invited to attend the training courses.

## **9. Summary and recommendations**

9.1 We consider that the injection of tuberculin and the reading and recording of results is essentially a technical operation that, for the most part, does not require veterinary expertise. The interpretation of reaction is tightly prescribed in Annex B of Directive 64/432/EEC. The EU Commission has confirmed the circumstances in which we can and cannot use lay testers.

9.2 At present Agricultural Departments only see the level of TB testing increasing. The introduction of lay testers will provide another tool in ensuring that there is sufficient flexibility to meet expected increased demand. It not appropriate to do nothing (Option 1). We do not propose to progress with Option 3 immediately, because we recognise the range of concerns expressed by the veterinary profession require careful monitoring under controlled conditions. It is, therefore, recommended that Option 2 be adopted. This will permit the introduction of tuberculin testing of cattle by only properly trained and competent technical staff of the SVS and DARD(NI) for the duration of the pilot programmes. These programmes will be evaluated throughout. Following the pilot, expected to take approximately 1 year, we will consider whether to extend (i) extend the pilot programmes; (ii) cease lay testing; or (iii) extend lay testing to other experienced non-veterinarians (i.e. Veterinary Nurses). The veterinary profession will be fully involved in the evaluation and in discussion in the next steps.

## **10. Ministerial declaration**

I have read this Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister:  
Ben Bradshaw  
Parliamentary Under-Secretary of State  
Department for Environment, Food and Rural Affairs

.....  
Date...20th July 2005.....

### **Contact Point**

Paul McDonald  
Veterinary Surgeons Act Team  
Area 711  
1A Page Street  
London SW1P 4PQ

Tel: 020 7904 6588

Email: [Paul.A.McDonald@defra.gsi.gov.uk](mailto:Paul.A.McDonald@defra.gsi.gov.uk)

