EXPLANATORY MEMORANDUM TO

THE SPECIFIED ANIMAL PATHOGENS ORDER 2008

2008 No. 944

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs. The Statutory Instrument is not subject to any parliamentary procedure, being an order made by Ministers under the Animal Health Act 1981. However, the Department voluntarily subjects such orders to Parliamentary scrutiny for a 21-day period

2. Description

2.1 The Statutory Instrument replaces the Specified Animal Pathogens Order 1998 (SAPO). This instrument provides a new enforcement framework for SAPO to enable the HSE to become the lead inspection and enforcement body for specified animal pathogens under a separate agency agreement. It provides additional powers for inspectors similar to those which HSE currently have under the Health and Safety at Work Act, when carrying out an inspection or investigation. It also provides for appeals against Improvement and Prohibition notices.

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

None

4. Legislative Background

4.1 The Specified Animal Pathogens Order 1998 is made under the Animal Health Act. Its purpose is to prevent the release of dangerous animal pathogens into the environment where they may cause serious animal or human disease.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the Specified Animal Pathogens Order does not amend primary legislation, no statement is required.

7. Policy background

7.1 The investigations into the outbreaks 2007 Foot and Mouth Disease (FMD) outbreak concluded that the most likely cause was an accidental release of virus from Pirbright. The Secretary of State commissioned Sir Bill Callaghan to lead a review of the regulatory framework for handling animal pathogens and recommend changes to

strengthen the regulation of animal pathogens. The Report of this Review was published in December 2007.

7.2 One of the Review's recommendations was that the responsibility for inspection and enforcement functions in respect of animal pathogens should move to an independent and expert body; namely the HSE.

8. Impact

8.1 A partial Impact Assessment has been prepared and is published with this document.

8.2 In February 2008 a total of 93 key stakeholders, including licensees (mainly academic and research institutions, including government laboratories), were informed of the forthcoming amendments to the legislation and given an opportunity to comment on a draft Impact Assessment. No comments or feedback were received.

9. Contact

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Summary: Intervention & Options

Department /Agency:	Title:	
Defra	Impact Assessment of Changes to Arrangements for Inspection and Enforcement of Specified Animal Pathogen Requirements.	
Stage: Final	**Version:** 1	**Date:** 26 March 2008
Related Publications: Review of the Regulatory Framework for Handling Animal Pathogens, Written Statement to Parliament, Summary of Review Recommendations.		

Available to view or download at:

http://www. www.defra.gov.uk/animalh/diseases/fmd/investigations/index.htm

Contact for enquiries: **Telephone: 08459 33 55 77**

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

A Review of the Regulatory Framework for Handling Animal Pathogens was led by Sir Bill Callaghan, following the foot and mouth disease outbreaks in Surrey in 2007. The Review concluded that Defra should no longer be regulator, licensor and inspector under SAPO as well as a major customer of animal pathogens research and diagnostics and set out a 3 phase approach to deliver its recommendations by the end of 2008. This IA covers transitional changes expected to apply from April to meet the phase 2 recommendation to designate HSE as inspection and enforcement body as a first stage in separating regulator and customer functions. Government intervention is needed to provide public reassurance as to the independence of inspection and enforcement activities by making changes to legislation and other arrangements to improve regulation in the short term, while consideration is given to implementing wider recommendations of the review.

What are the policy objectives and the intended effects?

To transfer current inspection and enforcement responsibilities for facilities handling specified animal pathogens from DEFRA and local authorities to the HSE for the period April to December 2008. This is a temporary measure whilst consideration is given to more wide ranging measures.

Intended effect: Provide public reassurance as to the independence of inspection activities and strengthen enforcement mechanisms whilst providing access to the range of technical expertise needed to carry out the regulation of specified animal pathogens. HSE to carry out inspection and enforcement functions for facilities handling specified animal pathogens with additional powers for inspectors e.g. formal improvement and prohibition notices, sampling.

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

Only one option has been considered as the Government has accepted all of the Review's recommendations. There are therefore no alternative options to implementation. The review spoke to a range of relevant individuals before making its recommendations.

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

These changes will be reviewed in 2009.

Ministerial Sign-off For Final 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:

Jeff Rooker

.....Date: 1.04.2008

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 80k	<1
Average Annual Cost (excluding one-off)	
£ N/A	

Description and scale of **key monetised costs** by 'main affected groups' All costs relate to government as this is primarily a transfer of inspection and enforcement activities from DEFRA and Local Authorities to the HSE. It is estimated inspections will cost £80k more to December 2008.

There should be no increased costs to licensees which are

Total Cost (PV) **£ 80k**

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

N/A

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ N/A	
Average Annual Benefit (excluding one-off)	
£ N/A	

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

Licensees: there are no changes for licensees, so there will be no new monetised benefits

Total Benefit (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' Public and farming industry: Reassurance that issues identified by investigations into FMD outbreaks and reviews are being addressed. Reduced risk of accidental release of animal pathogen by application of additional technical expertise and enforcement powers. Due to the uncertainty regarding the potential cost of any outbreak and the effect on the probability of an outbreak we have not sought to monetise this benefit. Licensees: in line with Hampton principles of inspection and enforcement.

Key Assumptions/Sensitivities/Risks

The cost given assumes that arrangements will be in place by April 2008 to enable HSE to carry out the inspection and enforcement work.

Price Base Year 2008	Time Period Years <1	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ -80k**

What is the geographic coverage of the policy/option?	England
On what date will the policy be implemented?	April 2008
Which organisation(s) will enforce the policy?	HSE
What is the total annual cost of enforcement for these organisations?	£ 0
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?	£ N/A
What is the value of changes in greenhouse gas emissions?	£ 0
Will the proposal have a significant impact on competition?	No

Annual cost (£-£) per organisation (excluding one-off)	Micro **N/A**	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease £ 0 **Net Impact** **£** 0

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

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.]

Background

The investigations into the outbreaks of Foot and Mouth Disease (FMD) in Surrey in August 2007, concluded that the most likely cause was an accidental release of virus from the laboratory complex at Pirbright. The Government commissioned two reviews of biosecurity arrangements which were published on 7 September 2007. These were the Health and Safety Executive (HSE) Final Report on potential breaches to biosecurity at the Pirbright site and Independent Review of the safety of UK facilities handling foot and mouth disease virus, chaired by Professor Brian Spratt. The reports are available from the Defra website at: www.defra.gov.uk/animalh/diseases/fmd/investigations/index.htm.

Responding to these, the Government agreed that a review of the regulatory framework for animal pathogens should be undertaken, and that the position of Defra as regulator, licensor and inspector under the Specified Animal Pathogens Order 1988 (SAPO) and as a major customer of animal pathogens and diagnostics should be reviewed. In September 2007, the Government asked Sir Bill Callaghan to carry out this review of the regulatory framework for handling animal pathogens and to make recommendations for changes that would strengthen their regulation. His report was published on 13 December 2007. The Government accepted all the recommendations in the report including the proposed timetable for achieving them. The Review and Government written statement to Parliament are available from the Defra website at: www.defra.gov.uk/animalh/diseases/fmd/investigations/bill-callaghan.htm

Key recommendations of the report

- Responsibility for inspection and enforcement functions in respect of animal pathogens should move from Defra to a body that is not subject to the same conflict of interest and which has access to the range of technical expertise needed to carry out the full regulatory function.
- The Health and Safety Executive (HSE) should become the single regulatory body for both animal and human pathogens with resources, expertise and legal powers to carry out its function effectively.
- Until the regulatory role has passed to HSE, inspections under SAPO should continue to be conducted by Defra, with HSE support.
- Defra, Department of Health, HSE and other interested parties should work together to develop by the end of 2008 a single regulatory framework to govern work with human and animal pathogens. This will be subject to a separate IA.
- Risk assessment should be a key element of the single regulatory framework for handling human and animal pathogens.
- The Advisory Committee on Dangerous Pathogens (ACDP) should be tasked with formulating a common set of containment measures to apply to both animal and human pathogens, to complement the single regulatory framework.

- Defra, Department of Health, HSE and other interested parties should work towards the introduction of cost recovery in the new regulatory framework.

The Callaghan report proposed that their recommendations be carried out in three phases, which are being addressed concurrently.

Phase 1: Defra should enter into immediate discussions with HSE to formalise HSE's support of SAPO inspections by 1 January 2008.

The programme of inspections of SAPO licensees (and new applications) are being conducted by Defra, Veterinary Laboratories Agency and HSE inspectors acting on behalf of Defra until phase 2 comes into effect.

Phase 2: Changes should be made to SAPO to designate HSE as the inspection and enforcement body under the Order by April 2008. Defra would continue to be the licensing authority until the end of 2008. (see detail below)

Phase 3: Defra, Department of Health, HSE and other interested parties should begin work urgently to bring in the single regulatory framework by the end of 2008.

This final phase will involve a significant change in the way in which animal pathogens are regulated. Defra, HSE and other Departments are considering the options to give effect to these changes.

Objective

To implement the recommendations of phase 2 of the Callaghan report within the proposed timescales.

Phase 2 - detail

In **phase 2**, an amendment to SAPO legislation and arrangements with HSE have been prepared to allow HSE to become the inspection body for SAPO. HSE will also take on enforcement responsibilities. The SAPO amendment provides inspectors that are appointed under SAPO with powers similar to those which HSE inspectors currently have under the Health and Safety at Work Act. These include:

- Formal Improvement notices: corrective action within a specified time where non compliance(s) with licence conditions are encountered during inspections.
- Formal Prohibition notices: would prevent work being carried out on pathogens with immediate effect where a serious level of non compliance is found.
- Allowing inspectors to ask veterinary or other experts to accompany them on inspections, as considered necessary on case by case basis.
- Allowing inspectors or those accompanying them to take on to the premises equipment and other things necessary to carry out the inspection.
- Allow inspectors to take samples, photographs or make recordings.
- Require the production and inspection of records.

- Require premises or equipment to remain undisturbed while an examination is carried out
- Provide for equipment or materials to be dismantled or be subjected to tests.
- Require people to give information, answer questions and provide assistance to inspectors.
- Appeals against improvement and prohibition notices.

There are no changes affecting licensees themselves.

Costs

Inspection responsibility is being passed from the VLA to the HSE so there will be a transfer of funds from Defra and HSE to meet HSE costs of carrying out inspection and enforcement activity under SAPO.

The Callaghan Review reported that Defra spent of the order of £100k per year on inspection of SAPO laboratories and issuing licences. This was comprised of:

£ 70k – licensing activity (including technical advice and support on inspections, consideration of applications for licences and renewals, administration of licensing process. ;
£30 k – inspections.

Under phase 2 arrangements the inspection element is transferred to the HSE and the cost is estimated to be:

£110k – inspections.

For the period April to December 2008, based on Review recommendations

Therefore costs to HM Government will increase by £80 k.
There were 37 SAPO licensed laboratories in England at December 2007. There should be no additional costs to businesses already complying fully with SAPO licence conditions.

Benefits

We would expect implementation of phase 2 to give reassurance to the public and farming industry that concerns identified by investigations into the foot and mouth disease outbreaks are being addressed.

Additional technical expertise will be available for inspections and the HSE will have the power to issue formal improvement and prohibition notices, this may reduce the risk of future accidental release of animal pathogens. It is difficult to quantify the benefits of this, due to the uncertainty as regards the risk and the scale of any potential disease outbreak.

For licensees, the approach to streamlining inspection and enforcement with HSE carrying out this role is in line with Hampton principles, though most of the benefits of applying these principles are expected to be realised in phase 3.

Stakeholder Communications

A wide range of stakeholder organisations have been informed of progress and plans concerning implementation of the recommendations of the review. They were given a very brief opportunity to comment on a draft of the Impact Assessment.

Administrative Burdens

These proposals are not expected to have any significant overall net affect on the administrative burden because there are no changes for licensees.

Phase 3 will be subject to a separate impact assessment as well as a public consultation. Defra, HSE and DH are working together to develop the proposed single regulatory framework envisaged for phase 3. This will include risk assessment as a key element and the introduction of cost recovery.

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

Annexes

Annex I: Outcome of Impact Tests not referred to in the Evidence Base

Specific Impact Tests

Competition Assessment

These changes will not have an impact on competition because the regime for licensing is not changing.

Small Firms Impact Test

All laboratories working with specified animal pathogens must be licensed under SAPO legislation. Defra classifies animal pathogens according to their type and the risks that they potentially pose to animal health. Everyone applying for a licence under SAPO must demonstrate that their laboratory and facilities meet the containment requirements relevant to the pathogen with which they wish to work. The level of containment required is proportionate to the level of risk to laboratory workers, other workers, people, and animals in the outside environment. No matter how large or small a laboratory establishment is, the risk must be controlled to minimise the likelihood of an escape into the environment.

Legal Aid

These changes do not create new criminal sanctions or civil penalties.

Sustainable Development

These changes comply with sustainable development principles.

Carbon

These changes will have no significant effect on carbon emissions.

Environmental Issues

These changes may have some effect on environmental issues. If an animal pathogen found its way into the environment, this may contribute to its onward transmission to other animals including man. Enhanced control of the pathogens under SAPO is likely to reduce the risk of this happening and help to protect wildlife and public health as well as the health of farmed livestock.

Health Impact Assessment

These proposals will not directly impact on health and wellbeing and will not result in health inequalities.

Race/Disability/Gender/ Equality

These changes apply
equally to all individuals and businesses working with specified animal pathogens. .

Human Rights

These proposals are consistent with the Human Rights Act 1998.

Rural Proofing
These changes do not have a different impact in rural areas.