

Summary: Intervention & Options

ANNEX A

Department /Agency:	Title: Impact Assessment of Amendment to the Specified Animal Pathogens Order 2008	
Stage: Final	Version: 3	Date: 2.11.09
Related Publications:		

Available to view or download at:

<http://www.defra.gov.uk/corporate/consult/foodfarming.htm>

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

Highly Pathogenic Porcine Reproductive and Respiratory Syndrome virus (HP-PRRSv), a variant of Genotype 2 PRRSv, is considered a new and emerging threat. Genotype 2 (PRRSv2) is not present in the UK. Introduction of the highly pathogenic form would have a devastating effect on the UK pig industry due to very high mortality in young pigs.

Government intervention is necessary to ensure proper control of a new and dangerous pathogen so that it is effectively contained in secure conditions in licensed research laboratories and is not accidentally released into the UK's pig population.

What are the policy objectives and the intended effects?

To prevent an outbreak of disease in the UK pig population by ensuring that PRRSv2 is contained and therefore only worked on in secure containment conditions in licensed laboratories.

Intended effects: to prevent PRRSv2 from infecting and thereby inflicting potentially devastating economic damage on the UK pig industry, and possibly adversely affecting international trade.

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

The only policy option available is to add Porcine Reproductive and Respiratory Syndrome virus (genotype 2) (PRRSv2) to the list of controlled pathogens in Part 1 of Schedule 1 to the Specified Animal Pathogens Order 2008.

Justification: PRRSv2 should be treated similarly to other dangerous animal pathogens and only worked on in licensed research laboratories in a biosecure way under appropriate containment conditions. Doing nothing risks severe economic consequences to the UK pig industry from an accidental release of the highly pathogenic form of this pathogen from an unlicensed laboratory.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? 2012

Ministerial Sign-off For Final Impact Assessment:

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:

..... Date:

Summary: Analysis & Evidence

Policy Option: Add PRRSv2 to SAPO 2008

Description: Amend SAPO 2008 by adding Porcine Reproductive and Respiratory Syndrome virus (genotype 2) to the list of controlled pathogens

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' No additional costs to Government. Minimal costs to laboratories that wish to work with the pathogen.
	One-off (Transition)	Yrs	
	£ 3k - 18k	1	
	Average Annual Cost (excluding one-off)		
	£ N/A		Total Cost (PV) £ 3k - 18k
<p>Other key non-monetised costs by 'main affected groups' The main cost would be for a laboratory without the appropriate containment facilities having to upgrade them in order to work with the virus.</p>			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' No expected monetised benefits, although expected to be significantly greater than the minimal costs highlighted above.
	One-off	Yrs	
	£ N/A	0	
	Average Annual Benefit (excluding one-off)		
	£ N/A		Total Benefit (PV) £ N/A
<p>Other key non-monetised benefits by 'main affected groups' Economic: A disease outbreak in pigs caused by the highly pathogenic form would cause very serious economic loss for the pig industry, both direct and indirect. The controls imposed by SAPO would minimise the risk of such outbreaks and consequential economic losses. Social: pet pigs would be similarly protected.</p>			

Key Assumptions/Sensitivities/Risks The HP form of this pathogen is regarded by the VLA Pig Group as the biggest non-notifiable disease threat currently facing the UK pig industry. Controlling the use of this pathogen under SAPO will greatly reduce the risk of accidental escape from a laboratory and will prevent its unlawful import for research.

Price Base Year 2009	Time Period Years 10	Net Benefit Range (NPV) £ N/A	NET BENEFIT (NPV Best estimate) £ N/A
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What is the geographic coverage of the policy/option?	England			
On what date will the policy be implemented?	2 December 2009			
Which organisation(s) will enforce the policy?	Health & Safety Exec.			
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 N/A	Medium N/A	Large N/A
Are any of these organisations exempt?	No	No	N/A	N/A

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

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

Evidence Base (for summary sheets)

Proposal

1. To amend the Specified Animal Pathogens Order 2008 (SAPO) (SI 2008 No.994) to add Porcine Reproductive and Respiratory Syndrome virus (genotype 2) (PRRSv2) to Part 1 of Schedule 1 to the Order.

Purpose and intended effect of the measure

2. The aim of SAPO is to provide controls against the outbreak of serious, predominantly exotic, diseases that can affect livestock and poultry and, in some cases, humans arising from an accidental release into the environment of an animal pathogen from a laboratory. The Department for Environment, Food and Rural Affairs (Defra) only issues licences authorising the possession of specified animal pathogens under SAPO where laboratories have the necessary operating procedures and containment facilities to ensure the secure containment, handling and disposal of the pathogens concerned. The objective of the proposed amendment to SAPO is to increase the level of protection provided in England to the pig population by extending the list of specified pathogens to include Porcine Reproductive and Respiratory Syndrome virus (genotype 2).

3. SAPO legislation prohibits the possession of certain animal pathogens causing serious, predominantly exotic, diseases that can affect livestock and poultry, and carriers of those pathogens, except under licence. It also prohibits the introduction of any of the pathogens into any animal except under licence.

4. The purpose of the Amendment Order is to prevent the accidental introduction and spread of an animal pathogen into the environment which could cause serious disease in animals and economic loss to the pig industry and possibly adversely affect international trade.

Background

5. Defra classifies animal pathogens into one of 4 Groups according to their type and the risks that they potentially pose to animal health, and sets minimum containment requirements for each category of pathogen. The Defra classification is made on the following basis:

Group 1 - Disease-producing organisms which are enzootic and do not produce notifiable disease (there are no specified animal pathogens in this category).

Group 2 - Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.

Group 3 - Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.

Group 4 - Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

Rabies - Special accommodation for Rabies and Rabies related viruses.

6. The independent Advisory Committee on Dangerous Pathogens (ACDP) was consulted on categorising PRRSv2 and suggested it should be listed under either Group 2 or 3. The pathogen has been classified in Group 3, unless Defra and the Health and Safety Executive (HSE) are satisfied that a particular strain has low pathogenicity, when it may be worked with under category 2 containment conditions. The Defra classification of animal pathogens, which

includes specified animal pathogens, is available of Defra's website at <http://www.defra.gov.uk/animalh/diseases/pathogens/index.htm>. Defra's containment requirements for Defra Classification of Groups 2, 3 and 4 animal pathogens are also published on the website. No pathogens are currently classified in Group 1.

7. Applications for a licence under SAPO are considered on a case by case basis taking account of risks. An inspection of the facilities where the work will be carried out is conducted by the Health and Safety Executive in every case to assess whether the facilities, management and documented procedures would be able to meet the licensing requirements to the required Defra containment level. If approved, a licence is issued which stipulates the way in which the specified animal pathogens covered by the licence must be handled to ensure their safe containment and disposal, the areas of laboratory in which various types of work may be done and the persons responsible for supervising the work. Periodic inspections of applicants' laboratories are carried out to assess continuing compliance with Defra containment and operating requirements.

Economic consequences

8. The UK pig population numbered 4.71 million in 2008 with pig meat production valued at £858 million. UK pigmeat production in the same year totalled around 800,000 tonnes from 13,500 holdings. Some 800,000 tonnes of pigmeat were imported in 2008 and 122,000 tonnes were exported to the EU. Live pig imports in 2008 totalled 415,500 and exports 18,800 pigs. The UK is the 10th largest producer of pigmeat of the 27 EU Member States.

9. HP-PRRSv is considered a new and emerging threat which poses significant risks to animal health and the UK pig industry. Economic losses would have a potentially devastating effect on the UK pig industry due to the very high morbidity and mortality in young pigs. Financial losses would be highly significant due to resulting death loss, poor reproductive performance of infected pigs, an increased significance and spread of other diseases, an increased use of vaccines and medications to try to contain the virus, and efforts to discover new cases could see a sharp increase in diagnostic and herd monitoring costs. Measures to control the virus could involve imposing and restricting pig movements in a worst case scenario, thereby disrupting trade in live pigs both nationally and internationally.

10. An outbreak of disease resulting from the accidental spread of this pathogen from a laboratory could therefore have potentially severe animal health and economic consequences to the UK pig industry. It is highly infectious, and is exotic i.e. it does not normally occur in this country. While this pathogen remains outside the controls imposed by SAPO, the risk of an accidental release from containment within a laboratory working on the virus would not be addressed.

11. Further background information on this pathogen and its potential effects is attached at Annex 2 to this IA. An unpublished paper "Highly pathogenic porcine reproductive and respiratory syndrome (HP-PRRS)" produced by Defra in collaboration with the VLA Pig Group was part of the evidence submitted to ACDP and is used as reference for some of the technical details and consequences of an outbreak in this impact assessment.

Rationale for Government intervention

12. Government policy is to control work on animal pathogens that pose a significant risk to livestock. Because of the need for the enforcement of strict risk management procedures and containment requirements within laboratories to prevent the accidental release of pathogens, and in the absence of any form of industry self-regulation, Government regulation is necessary. Alternatives will be considered when the policy is reviewed but it would not be appropriate to review policy in relation to the risks that this newly identified disease causes alone.

13. The Specified Animal Pathogens Order is in place to ensure as far as possible that the risk of an outbreak of a serious exotic disease of livestock or poultry being caused from the accidental spread of a pathogen from a laboratory is minimised. In order to maintain the level of protection from serious exotic animal disease that SAPO currently provides, it is necessary to update Part 1 of Schedule 1 to cover Porcine Reproductive and Respiratory Syndrome virus (genotype 2) which poses a significant level of risk to the UK pig population.

Consultation

Geographical coverage

14. Only laboratories in England that wish to work with this particular pathogen will be affected by the proposed amendment of SAPO as the Amendment Order will only extend to England.

Within Government

15. The Welsh Assembly Government, the Scottish Executive Environment and Rural Affairs Department and the Department for Agriculture and Rural Development Northern Ireland, which are responsible for administering similar controls in Wales, Scotland and Northern Ireland respectively, have been consulted on this proposal. All have confirmed that they intend to propose to similarly amend their own legislation in due course.

Public consultation

16. The holders of SAPO licences and interested stakeholders in England have been consulted about the proposal and about any costs they anticipate incurring as a result of the measure. Five responses were received. Two supported the proposal, one laboratory indicated that they may wish to work with the pathogen at some future time (but had no other comments), one said they were not intending to fund any research into the pathogen and one was a nil return.

Option

17. The only realistic option is to add Porcine Reproductive and Respiratory Syndrome virus (genotype 2) to Part 1 of Schedule 1 of SAPO.

18. This would extend SAPO controls to the pathogen causing this disease and ensure future work with the pathogen is carried out in a way that minimises risks of accidental release and protects animal health, the UK pig industry and international trade.

Benefits and costs

Benefits

19. Any outbreak of the disease in pigs caused by this pathogen could have serious economic consequences for the UK pig industry, both direct and indirect. The controls imposed under SAPO would minimise the risk of such outbreaks and consequential economic loss. It is difficult to estimate the magnitude of this potential benefit ex ante to any outbreak from these controls. Given the virulence and expected pig mortality level (as discussed in Annex 2), any outbreak could be very damaging to the pig industry.

20. Control of this pathogen under SAPO would reduce the risk of the disease being accidentally released and thus being spread by wild boar between commercial or domestic pigs. The spread of the disease to non-commercial pigs and wild boars could lead to the disease becoming endemic in the UK. The cost of controlling or eradicating endemic disease can be significant.

21. This disease affects pigs which are sometimes kept as pets. Control of the pathogen that causes this disease would help to protect these animals from the disease. This benefit is likely to be small in monetary terms, given the small number of pigs expected to be kept as pets in the UK.

Costs

22. It is not possible to specifically identify the laboratories that may wish to work with the pathogen we are proposing to add to the SAPO Schedule. However, while over 50 animal pathogens are currently controlled under SAPO, only 39 laboratories currently hold licences to work with specified animal pathogens. The number of laboratories likely to apply for a licence to work with this pathogen is therefore expected to be low.

23. For the purposes of cost calculation it is possible to define a range of costs based on the number of labs currently holding licences. At a maximum, all 39 current labs holding licences to work with specific animal pathogens could apply to hold a licence to work with this pathogen. At a minimum perhaps only 6 with current level 3 licences would apply for a licence. The consultation process did not provide any information to help us to refine the following estimates.

24. The costs to business associated with applications for licences under SAPO relate to:

(i) time taken to seek initial advice from Defra and obtain, complete and submit the SAPO licence application form. For the purposes of cost calculation this is assumed to be approximately 1 hour of a Senior Scientific Officer's (or equivalent) time at £30 per hour (including 30% overheads);

(ii) any work required to upgrade laboratory facilities to meet Defra's containment requirements (see "Background" above). This pathogen is classified in Group 3, unless Defra and HSE are satisfied that a particular strain has low pathogenicity, when it may be worked with under category 2 containment conditions. Laboratories wishing to work with this pathogen will therefore be required to demonstrate that their laboratories and facilities comply with Containment Level 2 or 3 requirements as appropriate. Containment requirements are available on Defra's website at <http://www.defra.gov.uk/animalh/diseases/pathogens/index.htm>. Putting an average monetary cost for these changes has been impossible as this information was not forthcoming through the consultation process;

(iii) time spent preparing or augmenting written Standard Operating Procedures (SOPs) related to the work to be undertaken with the pathogen. Again such augmentation is assumed to take approximately 14 hours of a Senior Scientific Officer's (or equivalent) time at £30 per hour;

(iv) time spent corresponding with Defra on the licence application or with the HSE on the laboratory's facilities etc, including attendance at the inspection of the laboratory. Given that the laboratories affected will already be facilitating such visits, it is not expected to take any significant additional time for facilitation;

(v) on-going costs of reviewing and maintaining compliance with SAPO licence conditions, including attendance during re-inspections of the laboratory. Again, this requirement is not expected to require further staff time due to the current practices already in place at laboratories that may wish to apply for licences.

25. The addition of this pathogen to Part 1 of Schedule 1 to SAPO is not expected to affect more than a very small number of laboratories. All applicants will have to complete SAPO

applications and be present, perhaps with other personnel, when their laboratory is inspected by HSE. Inspections may not, however, be required where applicants are planning to use laboratory facilities already licensed under SAPO to the appropriate level of containment. The additional costs of meeting Defra requirements under current SAPO arrangements, which focus on bio-containment and procedures to ensure that the pathogens are kept securely in the laboratory and disposed of safely, i.e. the costs related to items at points (ii), (iii), (iv) and (v) above, are therefore expected to be minimal.

26. Based on these estimates, laboratories wishing to apply for a licence to handle the new pathogen are expected to face a cost of around £450 per lab, based on 15 hours of staff time. This is a one-off administrative cost. At a maximum, therefore, the one-off costs to the industry will be approximately £18k; at a minimum the costs will be less than £3k. Note that these costs do not include those based on (iii) above, upgrading facilities, which could be significantly higher but which we have insufficient information about to form a reliable estimate.

27. Per annum costs are expected to be negligible to laboratories, given the inspection facilitation and review and compliance activities already carried out by labs. Although SAPO licences are valid for 5 years, all specified pathogens are covered on a single licence so there are no additional costs of having to reapply for the licence over and above what is already done.

Enforcement, sanctions and monitoring

Enforcement

28. Under SAPO, inspections of applicants' laboratories are carried out by HSE inspectors to assess compliance with Defra containment and operating requirements. It is not expected that there will be any significant cost implications for the Government as such inspections will be carried out already.

Sanctions

29. Licences can be withdrawn or revoked if breaches of licence conditions occur or laboratories fail to satisfy Defra requirements. Unlicensed specified animal pathogens and carriers can be seized, treated or destroyed and those convicted for committing offences under SAPO can be fined or imprisoned.

Monitoring

30. Licensed laboratories are inspected periodically by HSE to check that Defra containment requirements continue to be met and that licence conditions are being complied with.

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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
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

Competition assessment

The proposal is not expected to have any significant effect on competition.

The Small Firms Impact Test

All laboratories working with specified animal pathogens must be licensed by Defra 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 livestock, companion animals, wildlife and humans. No matter how large or small a laboratory establishment is, the risk must be controlled to minimise the likelihood of accidental release of the pathogen into the environment. The Defra licensing system made under SAPO therefore maintains equitable conditions under which all laboratories working with specified animal pathogens must operate.

Legal Aid

No new criminal sanctions or penalties are being introduced and there are no implications for legal aid.

Sustainable development

There will be no significant effect on sustainable development as the proposals are not expected to lead to any changes to the way laboratories currently operate.

Carbon Impact Assessment

The proposal will have no significant effect on carbon emissions, as the nature and scale of laboratory work is likely to remain the same.

Other Environment

As the nature and scale of laboratory work is likely to remain the same, the proposal has no implications in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.

Health Impact Assessment

The proposal will have no direct impact on health or well being and will not result in health inequalities. The pathogen is not zoonotic.

Race/Disability/Gender

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 laboratories involved in the activities covered by the proposal.

Human Rights

The proposal is consistent with the Human Rights Act 1998.

Rural Proofing

The proposal applies in the same way to rural and urban laboratories.

HIGHLY PATHOGENIC PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME (HP-PRRS)

Background

1. Porcine high fever syndrome (PHFS) emerged in Asia in 2006. This disease first caused devastating losses in China in 2006 and has since been identified in Vietnam and more recently confirmed in southern Russia, Bhutan and the Philippines, with other countries in the region also having suspect cases.
2. Epidemiological and virological investigations strongly indicate that a highly pathogenic form of Porcine Reproductive and Respiratory Syndrome virus (HP-PRRSv) is the causative agent of PHFS.
3. Porcine high fever disease affects pigs of all ages causing high fever, respiratory disease and reproductive disease, with high morbidity and mortality. Mortality rate in pigs less than 18 weeks of age is reported to be up to 100%, with death occurring within 7 days. In addition, high levels of abortion and neonatal deaths are seen on affected farms along with occasional losses in pigs over 18 weeks of age. Older pigs that survive carry the virus for extended periods (muscle is a significant source of virus).
4. HP-PRRSv is spread by direct contact (through infected pigs or infected semen) or indirect contact (via, for example, contaminated vehicles, personnel or other fomites).
5. The PRRS virus has evolved in a divergent fashion and two distinct lineages are now considered to exist: European/Genotype 1 and American/genotype 2 PRRSv (PRRSv2). Only European type PRRSv has been identified in the UK. PRRSv2 has been identified in some European countries but not the UK; incursion is thought to have been due to use of vaccine or infected semen.
6. European PRRS is considered endemic in UK and is not controlled under the Specified Animal Pathogens Order (SAPO). Infection with European PRRSv is often sub-clinical although the virus can exacerbate the effects of other pathogens. The high morbidity and mortality and severe clinical signs associated with the highly pathogenic form PRRSv2 is in direct contrast to the situation with European PRRSv. Therefore, for the purpose of disease containment, highly pathogenic PRRSv2 should be regarded as a new and emerging threat to the UK pig industry.
7. Vaccines against European PRRSv are available in UK. However these vaccines offer no protection against PRRSv2. Vaccines that are available against PRRSv2 are unlikely to be licensed in the UK due to problems with vaccine instability and virus reversion to wild-type. There are no vaccines available considered effective against PRRSv2.

Effect of introduction of PRRSv2 on UK pig industry

8. Within-herd mortality rates of 80-100% are reported in pigs less than 18 weeks of age when highly pathogenic PRRSv (a Genotype 2 variant) is introduced into a herd. In addition, high neonatal losses and abortions are also seen. It is thought that clinical signs associated with HP-PRRSv are often exacerbated by the presence of concurrent disease. It is unknown at this time whether the pathogens commonly seen in UK pigs (Salmonella, swine dysentery, etc) would exacerbate clinical signs in the same way as has been seen in Asia; however pig experts believe it is likely that HP-PRRSv would lead to significant losses in UK herds. On-farm

biosecurity on UK pig farms is generally not considered to be robust enough to prevent the spread of PRRSv through a holding; thus with currently available information we would expect that introduction of HP-PRRSv to a pig farm would result in significant mortality, abortions and neonatal losses. This would have a serious economic impact on the affected farm.

9. PRRSv2 is transmitted through direct and in-direct contact between pigs, through infected semen and through infected meat.

10. Overall, the introduction of HP-PRRSv into the UK pig herd would be expected to have significant economic impact on affected farms with slow transmission to other farms. In addition, it could result in restrictions to international trade from UK with significant economic implications for the industry.

11. The VLA Pig Group have identified HP-PRRSv as the biggest non-notifiable disease risk currently facing the UK pig industry.

Containment

12. Given the mechanisms of transmission outlined above, if not properly handled in a laboratory, PRRSv2 could be transmitted from a laboratory to a pig farm by fomites (human personnel, equipment etc). It is thus conceivable that, without controls, virus could easily be transmitted from laboratory to farm resulting in disease in pigs through indirect contact via a fomite.

13. Containment in a laboratory would be expected to be achievable through the application of appropriate containment techniques.

Summary

14. Spread of PRRSv2 from a UK laboratory to a pig farm is currently a risk due to lack of containment requirements. Spread of a highly pathogenic strain of this virus to a pig farm would have serious economic implications for the affected farm. In addition, slow spread to contact farms would be expected if disease was not controlled properly. PRRSv2 meets the reasons for government intervention identified in the Animal Health and Welfare Strategy. Intervention can be justified based on implications for animal welfare, economic effects and the potential impact on international trade.

15. It is recommended that PRRSv2 should be controlled under the Specified Animals Pathogen Order 2008.