

Title: Order under the Animal Health Act 1981 to make PED notifiable and enable Government to make public information on suspect or confirmed cases of disease IA No: Defra1910 Lead department or agency: Defra Other departments or agencies: Animal and Plant Health Agency (APHA)	Impact Assessment (IA)			
	Date: 9 December 2015			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Secondary legislation			
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Summary: Intervention and Options			RPC Opinion: fit for purpose	

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2014 prices)	In scope of One-In, Two-Out? Measure qualifies as In
£0.024m	£ 0.024m	£0.003m	Yes

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

Since 2012 a new highly pathogenic strain of Porcine Epidemic Diarrhoea (PEDV) (causing death of 80-100% of infected suckling piglets and production losses on growing pigs) has spread from China to the US, Canada, S America, Asia and the Ukraine. In addition, the "Ohio 851" strain of PEDV is circulating within the EU which can cause significant losses in affected pig herds. Infectious animal disease is a negative externality which can impose costs on farms in the sector as it spreads. Key pig industry groups want to take the lead and responsibility for controlling any PEDv incursion in England, using a pre-prepared Contingency Plan. However, they believe this will only be effective if Defra legislates to make PED notifiable (with a case definition for virulent strains) and shares reported data with AHDB Pork so they can give prompt support to pig keepers.

What are the policy objectives and the intended effects?

The policy objective is to facilitate the early detection and contingency planning for PEDV to control and slow down spread should the pathogenic agent be introduced to England and to help prevent PEDV from becoming endemic in England.

The intended effect is to provide early notification that disease is present on a farm so that voluntary follow up advice and support can be made available, enabling swift action to be taken to control the disease so that its spread (and cost to the sector) can be kept to a minimum.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: "Do nothing" i.e. just encourage voluntary reporting of the disease but do not make it compulsory. This option is rejected because a lack of compulsion could lead to belated reporting and/or non-reporting with serious implications for disease spread from farm to farm.

Option 1: (preferred option) make reporting of the disease compulsory throughout England, on suspicion or confirmation of disease presence on a holding and share notification details with industry (in practice AHDB Pork). This is the preferred option because it will enable an earlier and more rapid and effective attempt by industry to control the disease.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 11/2024					
Does implementation go beyond minimum EU requirements?			Yes		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: n/a	Non-traded: n/a	

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: _____ George Eustice _____ Date: 10th December 2015

Summary: Analysis & Evidence

Policy Option 1

Description: Amend legislation to make reporting of PED compulsory throughout England on suspicion or confirmation of disease and allow data sharing with industry (in practice AHDB Pork) so they can offer voluntary assistance to affected pig keepers.

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: 0.024

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-	-	-
High	-	-	-
Best Estimate	0.022	0.0	0.024

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

The total estimated cost to the (approximately) 7,800 pig holdings in England is around £24k for the first year (2015/16). This comprises: £22k (one-off) to familiarize themselves with the new provisions and an average of £210/year (potentially recurring) for estimated time required to notify the disease should 10% of the industry need to report suspicion or confirmation of the disease.

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

- None

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	-		
High	-		
Best Estimate			

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

- None

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

AHDB Pork would contact the keeper and surrounding farms to offer a voluntary package of support and advice which we expect them to embrace. This will lead to better control and slower spread of disease compared to what would occur in the absence of support. Also, making PED notifiable could facilitate export trade as Defra might be able to confirm officially that PEDv was "not present" in England or a particular region. It is not feasible to quantify these benefits as there are too many unknowns.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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Over the 10 years of the analysis the number (7,800) of pig holdings in England will remain constant. Pig keepers will comply with the legal requirement to report PED and chose to follow AHDB Pork's advice. AHDB Pork will continue to provide free support to affected farmers under its Contingency Plan during this period and will not run out of levy funds. Finally, it is assumed that any PEDV incursion would not spread so fast that the measures were unable to prevent it from becoming endemic.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OITO?	Measure qualifies as
Costs: 0.003	Yes	In
Benefits:		
Net: 0.003		

Evidence Base (for summary sheets)

Problem under consideration

1. For Government to find an effective and low cost way of helping the pig industry to take the lead on controlling and mitigating the spread of Highly Pathogenic Porcine Epidemic Diarrhoea (PEDV) should it arrive in England and thereby help prevent PEDV from becoming endemic in England.

Rationale for intervention

2. Infectious animal disease is a negative externality which can impose costs on farms in the sector as it spreads. The measure being introduced (disease notification) addresses the information asymmetry that exists between pig keepers and the authorities where pig keepers inevitably know more about the health status of their pigs than the authorities do.
3. The proposed measure will enable industry to take action to manage any PEDV outbreak more promptly and thereby reduce the likelihood of PEDV becoming endemic in our national herd. Experience from Canada, where there was a legal requirement to report PEDV before the first outbreak of the disease occurred, has shown that early identification of initial cases of disease suspicion or confirmation is a key part in slowing the spread of the disease to other units, thereby reducing the impact on PEDV on the wider industry.
4. By contrast, in the USA following identification of the first case, there was no legal requirement for disease outbreaks to be reported. The number of cases rose rapidly, and disease spread from coast to coast. Subsequently the United States Department of Agriculture developed a streamlined reporting process and implemented orders requiring new cases of the disease to be reported.

Background

5. Porcine Epidemic Diarrhoea (PED) is caused by a coronavirus that leads to severe gastrointestinal disease in pigs. PED is highly infectious and easily spread on fomites (any object or substance capable of carrying infectious organisms such as germs or parasites) but its spread can be controlled through scrupulous biosecurity measures. Infection spreads rapidly through a group or herd of pigs after the virus is introduced. Herds subsequently develop natural immunity, the duration of which is unknown at present. The original disease and PED virus were described in Europe, including the UK, in the 1970s.
6. However, in 2012 a new highly pathogenic strain of PED, causing a virulent form of PED (PEDV), was identified in China. This strain causes death in 80-100 percent of infected suckling piglets in naïve herds (i.e. herds not previously exposed to the virus). Infected older pigs do not generally die but the virus will affect growth rates and reproductive performance, therefore significantly impacting on herd productivity, health and welfare.
7. PEDV due to this new strain was first confirmed in the USA in May 2013 and has now been detected in 33 states with a loss of more than 10% of their National herd. The disease has spread across North America, into Canada and some South American countries, and is also widespread in Asia. More recently it was detected in the Ukraine bringing the threat much closer to home; the source of the virus in the Ukraine is still unknown. Although there are no reports of this particular PEDV virus strain in the European Union, including the UK, there are other strains (e.g. "Ohio 851") of PEDV circulating within the EU that also cause disease in all ages of pig and, in some breeding herds, piglet mortality.
8. Defra, Devolved Administrations and industry have taken a collaborative approach in reaction to these global developments. In May 2014 Defra set up and led the **PED Core Group** to identify policy options for the emerging threat. This comprised industry and veterinary representatives from BPEX (now AHDB Pork), the National Pig Association (NPA), the British Pig Association (BPA), the British Meat Processors Association (BMPA), the Pig Veterinary Society (PVS), NFU Scotland and (since December) Quality Meat Scotland (QMS). Independently, BPEX (with assistance from other industry bodies) developed a contingency plan for identifying PEDV incursion in the UK and actions to control its spread.

9. In March 2015 the PED Core Group concluded that BPEX's contingency plan would only succeed if there was early detection of disease and sharing of data with BPEX so they could support affected businesses. The Group agreed that Government and industry should take a novel partnership approach with Government legislating to make PED notifiable and sharing data with industry to enable industry to lead more effectively on disease control.
10. This impact assessment looks at two options. First, Government could take action only Government can take by amending legislation to make PED notifiable on suspicion and confirmation of disease and allowing notification details to be shared with industry, i.e. AHDB Pork. Second, Government could do nothing and simply allow a voluntary reporting of disease to AHDB Pork.
11. To achieve the preferred option 1 Defra intends to amend the Specified Diseases (Notification) Order 1996 (under Animal Health Act 1981 powers) as soon as possible in respect of England only to make Porcine Epidemic Diarrhoea notifiable to APHA on suspicion or confirmation of disease. The amended Order would also allow Defra to put the notified data (associated location and contact details) into the public domain. Defra would also provide a "case definition" in guidance to enable more virulent forms to be identified.

Policy objective

12. The agreed objectives of the joint Government-industry PED Core Group were to prevent the introduction of PEDV and, facilitate early detection and contingency planning to control spread should disease incursion occur, such that it could be detected at the earliest opportunity and onward spread prevented. The group supported UK industry being pro-active and prepared to respond to the disease threat
13. The policy objective introduces a **novel partnership approach** with Government legislating to make PED notifiable and sharing data with industry so industry can lead on disease control. This is a more cost-effective and proportionate way to control disease as Government is only facilitating notification and not requiring the more usual movement restrictions and slaughter/compensation which would be costly to Government. It will ensure a more appropriate level of cost and responsibility sharing in line with government policy.
14. This impact assessment considers the impact of the proposal to amend legislation to make PED notifiable and to allow data sharing with industry. The Scottish and Welsh Government are supportive of the Defra approach for England and are considering taking similar action for Scotland and Wales.

Options considered

15. **Option 0:** Our baseline option (do nothing) is the option against which all others have been appraised. This option would rely on voluntary reporting of suspicion or confirmation the disease to AHDB Pork. This is the approach which made up part of the suite of ineffective disease response measures in the USA. In the early stages of outbreak farmers may omit, through pressure of other management commitments, to carry out this voluntary action promptly meaning AHDB Pork support being delayed and opportunities to prevent disease spread being less effective or lost.
16. **Option 1:** The preferred policy option is to amend the Specified Diseases (Notification) Order 1996 under the Animal Health Act (1981) to:
 - make it a requirement for pig keepers, others (e.g. specialist pig veterinarians) who come into contact with pigs and laboratories carrying out testing for PED to report the suspicion or confirmation of the disease to Defra's Animal and Plant Health Agency and supply their location and contact details; and
 - permit the Secretary of State for Defra to make location and contact information of the unit reporting suspicion or confirmation of the disease public.
17. This preferred policy option would support industry surveillance activity by ensuring essential information regarding suspicion or confirmation of a disease outbreak is rapidly reported to Defra as the competent authority and communicated to AHDB Pork. AHDB Pork would then contact the affected farm to assist the operators and their veterinary surgeons in managing the outbreak and

importantly help prevent onward spread of the virus to other farms. It would also contact pig keepers within the vicinity of the outbreak site to offer advice on biosecurity and testing for PEDV. AHDB Pork would also support the wider industry through managing for example arrangements for supply of the affected farm with feed or other supplies and arrangements for stock movement or slaughter without compromising biosecurity or putting other units at risk. AHDB Pork would offer these services on a voluntary basis and so there would be no regulatory cost to business from their take up

18. **Option 1** is our preferred option. The principal purpose of this IA is to show the costs and benefits of this option to industry so that the EANCB can be verified. The costs and benefits to government are also set out.

Consultation

19. Early 2015 Defra set up a joint Working Group (WG) with industry (comprising APHA, AHDB Pork, NPA, PVS, BPA and AHWBE) to take forward the Core Group recommendations. In view of existing industry support for notification and data sharing, the WG agreed that a formal consultation exercise was not necessary. However, as the Core group was recommending a novel partnership approach between Government and industry, it was agreed that some consultation was necessary. Therefore, from 3 August – 1 September 2015 Defra hosted a 4 week on-line “conversation” using the Dialogue App to give wider industry bodies and pig keepers opportunity to comment on the proposals. This also enabled Defra to obtain evidence for RPC and Cabinet Committee clearance purposes. Defra sent the Dialogue App link to pig industry and veterinary bodies in the Working Group who extensively promoted the link and encouraged colleagues and members to post ideas and contribute to ideas initiated by others. In addition, industry representatives advertised the link through the specialist farming press (e.g. Pig World) and APHA tweeted the link widely.
20. The overall response to this extensive coverage was positive, with significant support for notification of suspect or confirmed disease and sharing of data with AHDB Pork. During the four week discussion period there were 81 page views. A total of 11 ideas were generated on the site which generally received positively support. Nearly all pig producers should have been aware of the App so we assume that those who did not reply (despite the opportunity) agree with the proposals.

Costs and Benefits of Option 1

Annual cost to business

21. There are approximately 7,800 pig holdings in England. As a result of the measure to make reporting PEDV compulsory there will be costs to industry associated with becoming familiar with the new regulation and then, in the event of a disease incursion here, there will be the costs of actually reporting the disease to the authorities. Virtually all pig farms are micro-businesses and so it would not be possible to grant an exemption to micro-businesses without the measures becoming ineffective.

Familiarisation Costs:

22. The concept of reporting a disease to the authorities is a familiar one to pig farmers as there are already so called notifiable diseases affecting pigs (e.g. foot and mouth disease, classical swine fever). Farmers will be informed about this new requirement by letter, websites and through articles in the trade press. It is reasonable to assume that it will not take more than 10 minutes for each farmer to become acquainted with who needs to be notified and what details to provide in the event of suspicion or confirmation of the disease on the holding. The costs also include familiarisation for specialist pig vets. These costs are one-off and for the industry in England would total about:

- Pig keepers: 7,800 holdings x £12.43/6 x 1.3 = £21,000
- Specialist pig vets: 175 x £20.79/6 x 1.3 = £790
- Total £21,790

Data and data sources:

23. According to the June Agricultural Survey (2014 provisional results) there are about 7,800 holdings in England with pigs.
24. The Annual Survey of Hours and Earnings (2014 provisional results, table 14.5a) puts the average (median) pay of managers and proprietors in agriculture at £12.43 per hour. This is divided by 6 to give pay costs for 10 minutes.
25. 30% is added to the pay rate to cover employers NI and pension contributions and holiday pay.
26. The number of specialist pig vets is the number of members and associate members of the Pig Veterinary Society.
27. The Annual Survey of Hours and Earnings (2014 provisional results, table 14.5a) puts the average (median) pay of veterinarians at £20.79 per hour. This is divided by 6 to give pay costs for 10 minutes.

Costs of reporting disease:

28. In the event of an outbreak the cost of reporting would be the cost of a phone call and the time that call takes multiplied by the number of holdings affected. It is difficult to know how many holdings that might be or when that would happen (i.e. starting in what year and spreading over how many years?) and it would be disproportionate to commission the epidemiological modelling needed to estimate this. Taking as an illustrative scenario a situation similar to that in the US where 10% of the herd has been affected and assuming the phone call takes 10 minutes the cost would be:

- $7,800 \times 0.1 \times £12.43/6 \times 1.3 = £2,100$

29. We have assumed there is an equal chance this occurs in each of the next 10 years and spread the reporting cost equally over this period.

Benefits:

30. Reports of disease suspicion or confirmation will be passed to AHDB Pork. As described above, AHDB Pork will contact the pig keeper and surrounding farms to offer a package of support and advice about controlling the disease and bio-security. Farmers do not have to act on this advice but it is expected that most will and the effect of this will be better control and slower spread of the disease (compared to what would occur in the absence of this advice). Both industry and government believe this will confer a benefit on the industry although it is not feasible to quantify this benefit as there are too many unknowns.

Summary of Monetised Costs and Benefits

31. To generate estimates over 10 years the cost and cost saving estimates above have been transferred to the tables below. The tables relate to calendar years and the measures are assumed to commence in April 2016. The number of pig producers is assumed to remain stable over this period.

Table 1: Costs to industry of Option 1 (additional to the baseline) by item (constant prices¹, £000)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Total
Industry											
Cost of familiarisation	21.8										21.8
Costs of reporting	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	2.1
Total costs (at 2014 constant prices)	22.0	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	23.9
Total costs (discounted at 3.5%)	22.0	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	23.6

¹ The figures in these tables are given in 2014 constant prices i.e. they exclude the effect of inflation over time.

RPC comments on RTA

32. When the RPC cleared (24 April 2015) the RTA they commented: “At validation stage the Department should provide further evidence or explanation to support the assumptions used for familiarisation costs, in particular on whether additional guidance will be needed on identifying PEDV and how this compares to the likely activity in the baseline. At validation stage the Department should explain further what actions will be undertaken in “*managing the outbreak and importantly help[ing] prevent onward spread of the virus to other farms*” to provide confirmation that the proposal will not result in any direct regulatory changes to the current biosecurity arrangements, or livestock tracking processes, that will impose additional costs on business.”
33. During the 4-week Dialogue App conversation with industry there was no challenge to Defra’s assertion that “benefits will outweigh burdens” which stated that the total national cost across England would be around £24,000. There were 17 “likes” for this idea. Notably £22,000 of this cost is for farmers to familiarise themselves with the new requirement to notify, which we assume to take 10 minutes. Farmers are already familiar with the notification procedure for other diseases such as classical swine fever and foot and mouth disease and are well aware of the proposal to make PED notifiable. Time taken for familiarisation is therefore expected to be negligible for most farmers and certainly no longer than 10 minutes.
34. Regarding additional guidance, a brief (half-page long) “case definition” of virulent strains of PED will be made widely available to farmers and veterinarians via literature and websites to help them identify PEDV clinical signs (essentially unusual or rapidly spreading diarrhoea in pigs of any age). However, in practice farmers would probably call a vet directly if pigs were dying or exhibiting diarrhoea without consulting this guidance which is therefore not expected to incur additional familiarisation costs.
35. In addition, the proposal will not result in any direct regulatory changes to the current biosecurity arrangement or livestock tracking processes that will impose additional costs on business. The follow up activity provided by AHDB Pork will be entirely voluntary and should help farmers to reduce their costs in tackling the disease as recommended biosecurity measures can be implemented sooner rather than later. Government does not propose introducing additional provisions employed for other notifiable diseases such as movement restrictions, cleansing and disinfecting requirements or culling/compensating affected animals.

Conclusion

36. Option 1 is the preferred option, with a total net present cost to industry over 10 years of £23,600. Using the BIS calculator the EANCB (at 2014 prices and 2015 present value base year) is estimated to be £2,650.

One-In-3-Out

37. This is a national measure which falls within the scope of One-In-3-Out (OI3O) rules.² The measure imposes some small costs on business. In the event of disease incursion there will be indirect benefits that arise from following the advice offered by AHDB Pork but these are not quantified. The measure should therefore be scored as an **IN**.

Small and Micro Business Assessment

38. The measures outlined in this Impact Assessment confer very low costs on the affected businesses. Virtually all pig farms are micro-businesses and so it would not be possible to grant an exemption to micro-businesses without the measures becoming ineffective.

² <https://www.gov.uk/government/policies/reducing-the-impact-of-regulation-on-business/supporting-pages/operating-a-one-in-two-out-rule-for-business-regulation>

Wider impacts

39. Greenhouse Gas: The preferred option would have no effect on gas emissions.
40. Wider Environmental issues - animal health and welfare: The prompt advice and support provided by AHDB Pork following any incursion of PEDV is expected to limit the spread of PEDV on both the original farm and surrounding premises. This should help prevent wide scale dissemination of infection (which reached 10% of the national herd in the US where notification was not compulsory).
41. Health and welfare: In the event that suspect disease is reported in a herd, APHA will immediately notify AHDB Pork so that they can contact the affected pig keeper without delay to offer relevant advice and support (in the form of proposed bio-security measures) should the disease subsequently be confirmed. This is expected to limit the number of animals affected by disease and to consequently mitigate animal suffering on individual farms.

42. Justice Impact:

Whilst the existing offence in the Specified Diseases (Notification) Order 1996 will be extended to include PED it is not anticipated that the change in policy approach will have an impact on the Courts and Tribunals Service or National Offender Management Service. This is because we consider the risk of non-compliance to be low - it is in farmers' interests to limit the spread of disease so that they do not experience high levels of piglet mortality and production losses.