

Title: Health Protection (Ships and Aircraft) Regulations IA No: 3019 Lead department or agency: Department of Health Other departments or agencies:	Impact Assessment (IA)	
	Date: 25/03/2013	
	Stage: Consultation	
	Source of intervention: International	
	Type of measure: Secondary legislation	
	Contact for enquiries: Tracy Owen 0113 25 45522	
Summary: Intervention and Options		RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, One-Out?	Measure qualifies as Zero Net Cost
£6.1m	£0m	£0m	Yes	Zero Net Cost

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

There is a need to ensure there is sufficient public health protection for UK borders, given the large numbers of people (and cargo) arriving from, or travelling to, destinations across the world, with the potential of an increased risk of infection or contamination spreading widely in a short space of time. As a State Party to the World Health Organisation's International Health Regulations (IHR), the UK has an obligation to recognise these risks. The Government is the only body that can implement international agreements that it has signed up to.

What are the policy objectives and the intended effects?

The policy objectives are to (i) ensure there is adequate public health protection at UK borders by ensuring Port Health Authorities can respond to new emerging infectious diseases and potential contamination (such as polonium 210); and (ii) to ensure the UK is compliant with the WHO's IHR "all hazards" approach. The intended effect is that England has an effective and proportionate legislative framework to prevent the spread of infection or contamination either into the country or abroad, which does not unduly hinder international travel or trade. The legislative framework will be consolidated and allow for more efficient use of resources that are overall cost-saving or cost-neutral.

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

Option 1 - No change to the current situation. Leave the existing regulations in place.

Option 2 - Introduce updated regulations to replace and repeal the existing aircraft and ship regulations. This is the preferred option as it achieves the policy objectives and creates the intended effects. The new regulations would also ensure we meet our international obligations in implementing the WHO's IHR and ensure that we comply with modern human rights requirements.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 11/2018

Does implementation go beyond minimum EU requirements?			N/A		
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: 0	Non-traded: 0	

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 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

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

These are defined to be zero.

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

These are defined to be zero.

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

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

These are defined to be zero.

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

These are defined to be zero.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Under option 1 England will not comply with the WHO's IHR, to which it is a State Party. Without the widening remit of current regulations the country and it's population are at greater risk of infection or contamination of new threats that have emerged since the regulations were introduced in 1979.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Update national health protection regulations for international travel via aircrafts and ships to reflect new infections and contaminations.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 6.1

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.008	0.017	0.152

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

Estimated costs include – providing a space to enable an individual to have a medical examination, enforcement of regulation costs, decontamination (if necessary) and training in the new regulations.

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

Costs also include implementation when required and imposing sanctions.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0.732	6.297

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

Benefits include avoided deaths, avoided treatment costs and wider impacts such as days off work.

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

Benefits also include avoided costs from individuals taking time off work and childcare, reduced costs to health services, prevented costs to public services and businesses in the event that non-co-operative infected or contaminated people spread their disease among the general population.

Key assumptions/sensitivities/risks

An assumption is made that a case of infectious disease occurs once every ten years. The same assumption is made for a case of contamination.

Discount rate (%)

3.5

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	Benefits:	Net:	Yes	Zero net cost

Evidence Base (for summary sheets)

Introduction

1. The International Health Regulations 2005 (the "IHR") were adopted by the World Health Assembly of the World Health Organisation (WHO) in 2005, and came into effect in June 2007¹. Article 2 of the IHR sets out their purpose and scope as being "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade".
2. The IHR represent an important international agreement that contributes to global health security and helps State Parties respond to public health threats. As a State Party to the IHR, the UK is committed to implementing them. In England, the Public Health (Ships) Regulations 1979 and the Public Health (Aircraft) Regulations 1979 were amended in 2007 to reflect aspects of the IHR, such as ship sanitation. However, they remain deficient in some respects, and notably do not provide a comprehensive "all hazards" approach in line with the IHR.
3. Within England, the Public Health (Control of Disease) Act 1984 ("the 1984 Act") provides the legal basis for health protection. Following a major review of health protection legislation, it was comprehensively updated by the Health and Social Care Act 2008 ("the 2008 Act") in order to provide a new, modern framework for the protection of public health from significant harm arising from infectious disease or contamination by chemical or radiological agents.
4. The 2008 Act replaced out-of-date provisions in the 1984 Act with new arrangements that:
 - take an "all hazards approach" to health protection, rather than focusing only on specified diseases. This enables a quick response to new or unknown diseases or threats (for example SARS or polonium 210),
 - take account of developing scientific understanding and provide for a more flexible and proportionate response to outbreaks of infectious disease or incidents of contamination,
 - clearly take into account the needs and rights of people who might be affected by them.
5. These updated provisions are contained in Part 2A of the 1984 Act, which came into force on 6 April 2010. Part 2A requires, or allows, a range of powers and duties in the new health protection framework to be delivered through regulations. Three sets of regulations covering the domestic, or "in-country", aspects of the new powers and duties were introduced along with Part 2A with effect from 6 April 2010. Only the "international travel" aspects (as the 1984 Act describes them) of the new provisions remain to be implemented.

Problem under consideration

6. The World Health Organisation (WHO) estimated in 2008 that over 20% of all deaths worldwide occur because of infectious disease. In the UK, about 7% of deaths can be attributed to this cause. The WHO has also said that new infectious diseases are emerging at a historically unprecedented rate. In addition, the world faces greater

¹ http://www.who.int/ihr/legal_issues/states_parties/en/index.html

than ever risks of chemical or radiological contamination, whether by accident, or by malign act.

7. The current regulations for health protection in relation to international travel do not cover all infectious diseases and contaminations that are a threat to the public health of England. They are considered inflexible and unclear in certain areas. With out of date regulations the threat posed is larger than if regulations were updated and made clearer for enforcement purposes.
8. International travel and trade by sea and air to and from the UK remains high and is set to increase, which means that the risk of the spread of infection or contamination to and from the UK, and the speed by which it may spread, is also high and likely to increase. Regulations need to be updated to reflect this. This is demonstrated via the following figures:
 - There were nearly 23 million international sea passenger journeys to and from the UK in 2010 - 21.1 million were short-sea ferry passengers, 1.6 million were cruise and other long-sea journey passengers. UK ports handled 519 million tonnes of freight traffic in 2010.²
 - There were 2 million international air transport movements to and from the UK in 2010, and 172.6 million terminal passengers on international services. Worldwide, Heathrow had the largest number of terminal passengers on international flights in 2010 at 61 million³.

Rationale for intervention

9. The particular circumstances of international ports and airports - with large numbers of people (and cargo) coming from, or travelling to, destinations across the world, mean an increased risk of infection or contamination spreading widely in a short space of time. There is therefore a need for effective controls at the border to prevent the spread of infection and contamination inside the country.
10. Without effective powers to respond to incidence of infectious diseases or contamination, there is a greater risk of suffering to individuals and families, and in extreme cases of damage to the UK's economy, businesses, and public services.
11. The World Health Organisation's (WHO) International Health Regulations (IHR) recognise the particular risks in a port or airport situation, and set out some specific requirements on State Parties, which should be reflected appropriately in national legislation.

Policy objectives

12. The overall aim is that England has an effective and proportionate legislative framework to prevent the spread of infection or contamination either into the country or abroad, which does not unduly hinder international travel or trade.
13. The objectives in developing new regulations are:

² <https://www.gov.uk/government/publications/tsgb-2011-maritime>

³ <https://www.gov.uk/government/publications/tsgb-2011-aviation>

- (a) to ensure there is adequate public health protection at UK borders by ensuring that Port Health Authorities can respond to:
- i. new emerging diseases such as Severe Acute Respiratory Syndrome (SARS); and
 - ii. potential contamination such as polonium 210
- (b) to ensure that the UK is compliant with the WHO's IHR "all hazards" approach.

14. The intended effect will be a set of simplified regulations that allow for more efficient use of resources and are overall cost-saving or cost-neutral.

Consultation

15. The evidence used to present costs and benefits of this policy will be further informed by responses to a public consultation.
16. The consultation will seek further evidence to better inform the analysis, via the following consultation question. Responses will provide valuable input into the policy analysis and development.

Consultation question: Do the assessments and assumptions in the Impact Assessments appear reasonable? Please give reasons if you do not consider this to be the case, with evidence if possible.

Options considered

17. The options considered are:
- Option 1 – No change to the current situation. Leave existing regulations in place.
 - Option 2 – Introduce updated regulations that replace and repeal the existing aircraft and ships regulations. The regulations must balance the need to protect public health, without hindering international travel or trade. Updated regulations would ensure England meets its international obligations in implementing the IHRs and that we comply with modern human rights requirements.

Description of options

Option 1

18. Option 1 involves continuing with current regulations. This would mean continuing with outdated provisions, which are inflexible and confusing. They apply only to a specific list of infectious diseases and they exclude contamination from scope. In addition, they do not fully implement the IHR, which England has an obligation to fulfil. Current regulations are also inconsistent with modern human rights requirements.

Option 2

19. Option 2 involves current regulations being repealed and replaced with up-to-date, appropriate and flexible provisions to protect public health in England. Option 2 ensures that obligations to implement the WHO's IHRs are met. The updated regulations aim to adopt a balanced approach between the need to protect public health in England and the need to avoid hindering international travel or trade. Whilst option 2 updates regulations to apply an "all hazards approach", it imposes fewer requirements on industry. Option 2 is the preferred option.
20. A detailed explanation of the current regulations and what changes to them as a result of option 2 is made in the consultation document that sits alongside this Impact Assessment. The proposed provisions made in the new regulations are outlined in Table 1.

The proposed new regulations make provision for;

- health protection functions to be carried out by local authorities or port health authorities through officers appointed for the purpose
- notification of a possible case of infection or contamination on board a ship
- harbour master to comply with local authority requests relating to accommodation, or location of an aircraft within the airport or port
- the provision of information to local authorities/port health authorities
- a risk assessment of a person on an inbound or outbound international journey suspected of being infected or contaminated
- a risk assessment of a ship or thing on board that ship on an inbound international journey suspected of being infected or contaminated
- detention of a person suspected of being infected or contaminated within the port for the purpose of the risk assessment or for an application for a Justice of the Peace's Order
- inspection of a ship or a thing on board that ship
- requirements to carry out health measures needed on the ship such as disinfection or decontamination of a ship, or a thing on board that ship
- local/port health authorities to recover the costs of measures if they undertake them
- requirements for the master to have regard to any guidelines issued by the Secretary of State and WHO guidelines about disinsection
- information to be sought from passengers to enable contact tracing
- ship sanitation certification and processes as per the IHR
- offences and penalties for non-compliance.

Table 1: Provisions made in new regulations

21. These provisions differ from the current regulations in a number of respects, outlined in Table 2.

1. Include all infectious diseases

The new regulations will apply in relation to any infectious disease, not just the list of diseases specified in the current regulations⁴. This will allow for appropriate health protection action to be taken in response to new or unknown diseases, which are emerging all the time. For example, SARS is not included in the list of diseases in the current regulations. If a person were to arrive at an English airport or port infected with SARS, there are no formal powers to prevent that person infecting others, potentially leading to fatalities. The new regulations will ensure the appropriate powers exist to deal with new and emerging threats, such as from SARS, therefore more fully

⁴ These are plague, cholera, yellow fever, smallpox and rabies or viral haemorrhagic fever.

protecting public health.

2. Include contamination

The current regulations also exclude contamination from scope. This gap in the current regulations means that the appropriate authorities are not fully equipped to take health protection action to combat contamination from chemicals or radiation. Legislation presently allows a local authority to apply for an order by a justice of the peace to deal with a threat from contamination posed by a person, or any thing. However, there are no powers to take swift action at the port or airport to prevent the spread of the contamination at point of entry if cooperation is not forthcoming. An example of contamination that would fall out of the reach of the authorities at the border would be if a case such as the major polonium 210 incident which occurred in London in 2006 were to arise at an airport or a port.

3. Adhere to modern human rights requirements

The new regulations remove provisions that do not comply with modern human rights requirements. For example, regulation 8 in the current regulations provide for detention of a person for the purpose of examination without any time limits. Subject to consultation, the new regulations will impose a strict six hour maximum time limit on the detention of persons (extendable to nine hours if it is necessary to apply to a justice of the peace for an order, for example, to admit the person to hospital). Any detention over two hours is only permitted if a medical examination is required, which must be carried out by a registered medical practitioner. The local authority/port health authority's officer will also be required to keep the need for detention under review throughout.

4. Remove surveillance and disinfecting

The current regulations allow a person to be placed under "surveillance" if they come from an "infected area" (regulation 20). There is no provision for this in the new regulations. The new regulations will also remove draconian powers such as disinfecting a person (regulation 8(2)(b)) or isolating a person for six days if they are suffering from pulmonary plague (schedule 2A(2)(b)).

5. Judicial oversight in relation to detention

The current regulations impose some restrictions that will not be retained as we feel it is more appropriate for such measures to be applicable only if ordered by a justice of the peace under the "domestic" legislation. An example would be when an assessment of the risk posed by a person is needed which requires a medical examination and will take longer than six hours. The current regulations do not impose any time limit on detention. In such a situation, when somebody's liberty is being curtailed for a substantial period, it is more appropriate that there is judicial oversight instead of relying on the judgement of the proper officer.

6. Simplify measures, making them clearer and more specific

The new regulations will simplify provisions, removing over-specific regulations, such as requiring specific measures to be applied in the event of plague, cholera, yellow fever, smallpox and rabies or viral haemorrhagic fever. The new regulations will allow the local authority/port health authority's officers greater discretion in decision-making – for example, it is their responsibility to decide if a person, aircraft/ship or anything on board presents a risk of spreading infection or contamination – rather than deciding if a specific disease is present.

The new regulations are clearer with regard to powers applying to “things” and aircraft and ships themselves in the event of infection or contamination. For example, instead of over-specific duties applying if rodents are suspected, or if an infected animal is found on board, there are more general requirements to undertake health measures as required by the local/port health authority's officer.

7. Include offences for non-compliance, with appropriate penalties

In line with good legislative practice, the new regulations will include offences for non-compliance and appropriate penalties. This is a necessary step in order to increase compliance and ensure that the regulations protect public health. The current regulations are hard to enforce, sometimes leading to non-compliance. For example, the current regulations place duties on different parties to provide information, to notify suspected disease on board and to disinfect an aircraft/ship if deemed necessary. However, without a clear offence and corresponding penalty for non-compliance, the current regulations have proved hard to enforce. We understand for example that under-reporting of illness on board aircraft as required under the current regulations does occur. It is hoped that appropriate offences with corresponding penalties will increase compliance – which ultimately benefits not only public health but all parties concerned.

A Justice Impact Assessment has been produced separately. Clearance from the Secretary of State for Justice will be sought for the new offences, in the light of the outcome of consultation, before laying the final new regulations.

Table 2: Changes to current regulations under option 2

Costs and benefits of option 1

22. Under option 1 there is no change to current legislation. The costs and benefits of this option are defined as zero as they provide the baseline against which to assess the impacts of options 2. The costs and benefits identified under option 2 are those that are realised in addition to those already experienced under option 1. It is important to stress that even though Option 1 is a ‘do nothing’ option, pursuing Option 1 will keep England in contravention of the WHO's International Health Regulations.

Costs and benefits of option 2

23. The analysis of costs and benefits under option 2 are separated and discussed in two parts:
- (a) Costs and benefits of the changes in the regulations that will be incurred each time an outbreak or a contamination take place.
 - (b) Costs and benefits will also occur outside of individual cases, that is, on an annual or one-off basis.

Illustrative costs and benefits of Option 2 in an outbreak or a contamination

24. Presently the incidence of outbreaks and contaminations (i.e. when the regulations will be used) is not fully known. Evidence from the Health Protection Agency suggests that the contingency which the existing regulations apply to has not occurred in the lifetime of the regulations (i.e. not since 1979.)
25. Given the scale of the international air and sea industries in England, the likelihood of one aircraft or one ship falling subject to these regulations is very rare. Under the current regulations, the diseases covered are of sufficient severity that almost all people with these diseases would be hospitalised and would not be travelling. Further, passengers may not be allowed to travel by the air/sea company for the sake of its own staff or other passengers.
26. Under option 2 the regulations take a wider definition of hazards. It follows that the likelihood of an outbreak or a contamination will be higher than under Option 1, but we consider the likelihood to remain very small. As the likelihood of an outbreak or a contamination is unknown, this analysis must show that in each scenario, the benefits of these regulations outweigh the costs.
27. The precise nature of the impact will depend on the type of threat. For example, it cannot be estimated with a degree of accuracy how often a worldwide SARS outbreak might occur. Whilst the frequency is unknown, when a situation arises under which these powers are exercised, both the costs and benefits are potentially large.

Prevention and control of the spread of infections and contaminations

28. In the event of an infectious disease or contamination that is not covered by current regulations, the impact on society could be substantial. The benefit of modernising the regulations to cover all infectious diseases and contaminations is that the risk of this substantial cost being incurred is very much reduced.
29. Preventing or controlling the spread of infection or contamination through these measures can result in:
 - (a) reduced morbidity and mortality, preventing unnecessary suffering in individuals and families,
 - (b) reduced cost to individuals, e.g. due to loss of income or childcare,
 - (c) reduced costs to the health services, e.g. inpatient or outpatient care,
 - (d) prevented disruption to public services and other businesses due to employee sickness.
30. Some of these benefits are captured in the tables above. Given the wide range of infectious disease that are possible, and the uncertainty about the frequency with which they occur, it would be misleading to provide one estimate of the health benefits arising from further prevention of the spread of infectious disease and contamination. It would be fair to say the benefits would be substantial in such a case.

Imposition of sanctions

31. Option 2 contains offences for non-compliance with the regulations. This is in line with good legislative practice to ensure good compliance with the regulations by placing a disincentive for non-compliance.
32. Some costs to industry (plane and ship businesses, but also some air and sea ports) are incurred in the event of a contingency. Sanctions will only be applied in the instance where a contingency has arisen *and* the company in question does not comply with the regulations. This places the probability of sanctions being imposed

as extremely small.

33. Serious breaches of the current regulations are rare and the introduction of sanctions will encourage greater compliance so that prosecutions will be rarely necessary. It is estimated that no more than 10 prosecutions will take place per year. It is not expected that this will have a discernible impact on the courts because the number of prospective cases is very low. There is no impact on Tribunals.

Scenario 1: An emerging infectious disease

34. An illustrative scenario showing possible benefits and costs of dealing effectively with a case of an emerging infectious disease are presented in Table 3. It presents the difference in scenarios as a result of option 2 compared to option 1 and therefore the impacts over and above those already experienced under the current situation.
35. This illustrative scenario is taken from an Impact Assessment for the Health and Social Care Act 2008, produced by DH⁵. As there was no evidence of estimated costs and benefits from a case of emerging infectious disease, the estimates are mainly driven by reasonable assumptions. We invite individuals responding to the consultation to comment on the assumptions made herein.
36. It is worth re-iterating these scenarios here, as the 2008 Act is the enabling legislation for these regulations. This illustrative scenario covers an emerging infectious disease that has not been seen before; it has a mortality rate of 4% and can be passed on from close contact with infected persons.
37. The table below shows the difference in response under the two options. The table also includes estimates for costs and benefits where practicable.

Co-operation from infected people

- The proportion of infected people who co-operate with the (air)port authorities is very high. It will be the same under Option 1 and Option 2.
- *Difference: None*

Non-co-operation from infected people

- Option 1: A few people will not co-operate. Unless their disease falls within the 1979 regulations they are free to leave.
- Option 2: A few people will not co-operate. They can be detained for the purposes of a medical examination, and at an earlier stage.
- *Difference: A few people will be detained earlier under Option 2. We assume 10 extra people will be detained in this scenario.*
- ***Benefit: If non-co-operative infected people are not detained, they are able to leave the [air]port and spread their infection among the general population. This creates a significant cost to human health (reduction in health or death, time off from work, use of health resource) among the general population that is avoided under Option 2. This cost is expected to be significant but as the impact depends on the type of infection it is unquantified.***

Cases to be treated

- Option 1: Assume 500 cases.
- Option 2: Assume 450 cases, due to the benefit of earlier tracing and treatment, and a reduction in the spread of infection.

⁵ "Impact Assessment of Public Health Protection Clauses of the Health and Social Care Act 2008"
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080455.pdf

<ul style="list-style-type: none"> • <i>Difference: 50 fewer cases to be treated.</i>
<u>Deaths avoided</u> <ul style="list-style-type: none"> • Option 1: [Status Quo] • Option 2: Assuming a 4% mortality x 50 people = 2 deaths avoided. • <i>Difference: 2 deaths avoided. These are valued at £1.8m each⁶.</i> • Benefit: £3.6m
<u>Costs of detention on authorities</u> <ul style="list-style-type: none"> • Option 1: N/A • Option 2: For each quarantined person, there are costs for arranging with the justice of the peace and also for making the case to the justice of the peace. • <i>Difference: Arranging with justice of the peace costs £415 each time. Making the case to the justice of the peace is assumed to cost £1,500. 10 x (£415 + £1,500) = £19,150</i> • Cost: £19,150
<u>Costs of treating infected individuals</u> <ul style="list-style-type: none"> • Option 1: Treatment of 500 cases • Option 2: Treatment of 450 cases • <i>Difference: 50 cases avoided at a cost of £1,800 per case⁷.</i> • Benefit (cost saving): £90,000
<u>Wider impacts</u> <ul style="list-style-type: none"> • Option 1: 500 people presumed unable to work for 10 days; half of these are work days • Option 2: 450 people presumed unable to work for 10 days, half of these are work days • <i>Difference: 50 people presumed unable to work for 10 days, half of these are work days. We assume society loses £100 for each work day they are absent⁸.</i> • Benefit (cost saving): £25,000
<u>Compliance with regulations (on business)</u> <ul style="list-style-type: none"> • Option 1: Business has a general duty to comply with the existing regulations • Option 2: Business has a general duty to comply with the existing regulations • <i>Difference: None.</i> • Cost: None.
<u>TOTAL</u> Quantified Costs: £19,150 Quantified Benefits: £3,715,000 Net benefit: £3,695,840

⁶ It is assumed in DH analysis that the impact of early death means the loss of 30 Quality Adjusted Life Years (QALYs) at £60,000 per QALY. This gives a value of £1.8m per life lost.

⁷ £1,800 is an approximate weighted average of HRG codes FZ36 (Intestinal Infectious Disorders), WA07 (Complex Infectious Diseases) and WA09 (Other non-viral infection) from 2011/12 NHS Reference Costs, source: <http://www.dh.gov.uk/health/2012/11/2011-12-reference-costs/>

⁸ Taken as an approximation of one day of mean weekly gross pay (£491.40), 2011, from Office for National Statistics, source: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-235202>

Table 3: Estimated costs and benefits from illustrative scenario of an emerging infectious disease

38. Under this illustrative scenario, the table shows there is a clear benefit from the draft regulations over and above the existing regulations. There is also a substantial unquantified benefit from the potential cost to human health that is foregone from requiring detention of non-co-operative infected individuals.

Scenario 2: A case of contamination

39. In this illustrative scenario, a new contamination risk has developed, posed by close proximity to the source of contamination and may have a high mortality rate for significant exposure.

<p><u>Co-operation from potentially contaminated people</u></p> <ul style="list-style-type: none"> The vast majority of people and contacts are ready to co-operate voluntarily, for instance with recommendations to have a medical examination. <i>Difference: none</i>
<p><u>Non-co-operation from potentially contaminated people</u></p> <ul style="list-style-type: none"> Option 1: A few people will not co-operate. There are no powers to act until their illness manifests Option 2: A few people will not co-operate. They can be required to have a medical examination (and a history taken). Decontamination of homes (or other sites) can be ordered. <i>Difference: Assume 10 people do not co-operate and 5 sites are identified.</i> Benefit: If non-co-operative contaminated people do not submit to medical examination, they are able to leave the [air]port and spread their contamination among the general population. This creates a significant cost to human health (reduction in health or death, time off from work, use of health resource) among the general population that is avoided under Option 2. The impact will depend on the specific type of contamination and therefore this benefit has not been quantified.
<p><u>Cases to be treated</u></p> <ul style="list-style-type: none"> Option 1: Assume 200 cases Option 2: Assume 250 cases, due to the benefit of earlier tracing and identification. <i>Difference: 50 more cases to be treated.</i>
<p><u>Deaths avoided</u></p> <ul style="list-style-type: none"> Option 1: 4% mortality x 200 cases = 8 deaths Option 2: 4% mortality x 250 cases = 10 deaths <i>Difference: 2 deaths avoided, valued at £1.8m per person.</i> Benefit: £3.6m
<p><u>Numbers to be examined and treated</u></p> <ul style="list-style-type: none"> Option 1: The existing regulations have no powers to deal with cases of contamination. Option 2: Voluntary and compulsory cases <i>Difference: 10 people to be examined</i>
<p><u>Costs of arranging examination and treatment for non-co-operative people</u></p> <ul style="list-style-type: none"> Option 1: N/A Option 2: For each detained person, there are costs for arranging with the justice of

<p>the peace and also for making the case to the justice of the peace.</p> <ul style="list-style-type: none"> • <i>Difference: Arranging with justice of the peace costs £415 each time. Making the case to the justice of the peace is assumed to cost £1,500. $10 \times (£415 + £1,500) = £19,150$</i> • Cost: £19,150
<p><u>Enforcement of extra examinations</u></p> <ul style="list-style-type: none"> • Option 1: N/A • Option 2: Assume 2 people require additional medical examination • <i>Difference: Assume 2 people require enforcement at cost of £2,000.</i> • Cost: £2,000
<p><u>Costs of examination and treatment on health authorities</u></p> <ul style="list-style-type: none"> • Option 1: Examination and treatment of 200 cases • Option 2: Examination and treatment of 250 cases • <i>Difference: 50 additional cases at £1,800 per case⁹.</i> • Cost: £90,000
<p><u>Cost of examination and treatment on non-co-operative contaminated individuals</u></p> <ul style="list-style-type: none"> • Option 1: N/A • Option 2: 10 extra people are examined and treated for (assumed) 7 days. It is assumed half of these people will also work, so the value of their lost output is included. • <i>Difference: 10 extra people are quarantined for 7 days. The 'nuisance' cost falling on the quarantined people is assumed to be £1,000 per person per week. For the five people who work, the value of their lost output is $5 \text{ people} \times 5 \text{ days} \times £100 \text{ per day}^{10} = £2,500$.</i> • Cost: £12,500
<p><u>Extra decontamination</u></p> <ul style="list-style-type: none"> • Option 1: The existing regulations have no powers to deal with cases of contamination • Option 2: 5 more sites are identified • <i>Difference: 5 more sites identified, at an assumed cost of £5,000 per decontamination.</i> • Cost: £25,000
<p><u>Compliance with regulations (on business)</u></p> <ul style="list-style-type: none"> • Option 1: The existing regulations have no powers to deal with cases of contamination • Option 2: Business must notify port authorities if they suspect a contamination on board their craft. • <i>Difference: Airplane pilot/sea commander must communicate their suspicion to port authority. There is no prescription on how they must communicate and could be done e.g. by radio.</i> • Cost: Equivalent to the cost of sending a radio message. Assumed to be negligible.

⁹ £1,800 is an approximate weighted average of HRG codes FZ36 (Intestinal Infectious Disorders), WA07 (Complex Infectious Diseases) and WA09 (Other non-viral infection) from 2011/12 NHS Reference Costs, source: <http://www.dh.gov.uk/health/2012/11/2011-12-reference-costs/>

¹⁰ Taken as an approximation of one day of mean weekly gross pay (£491.40), 2011, from Office for National Statistics, source: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-235202>

TOTAL
Quantified Costs: £148,650
Quantified Benefits: £3,600,000
Net benefit: £3,451,350

Table 4 : Estimated costs and benefits from an illustrative scenario of a contamination

40. In this illustrative scenario there is a clear net benefit from the draft regulations over and above those areas already covered under Option 1.

Annual/Transition costs and benefits incurred when there is no contamination or outbreak

Benefits of option 2

Flexibility of regulations for future contingencies

41. The benefits for enforcers are clearer powers, which allow officers to be certain about what the legislation allows and what their responsibilities are, without ambiguity. The regulations are clearer and easier to understand for business and enforcers. They will potentially increase compliance with health protection provisions, therefore exerting a downward pressure on costs of enforcement. In-country enforcement costs may also be potentially saved by catching threats at the border and preventing their spread.

Clearer powers of enforcement

42. Regulations under option 2 are clearer and easier to understand, making it easier for business to understand what is required and why. The benefits of option 2 for business are that with the means in place to tackle all infections or contamination presenting significant harm to human health, business is less likely to be disrupted. This benefit has not been monetised and is therefore unquantified.

Simplification and removal of some existing regulation

43. The provisions for ship sanitation certificates are to be essentially the same as they are now, with some simplification and removal of unnecessary elements. The benefits of this regime in securing effective hygiene standards in shipping will therefore be maintained.

44. The power in the current regulations of a local/port health authority officer to direct a ship to another port to obtain a certificate is not brought over to the new regulations. This could be seen as considerably reducing the potential costs to industry, but we understand that in practice this measure is not used, so the effect is neutral.

45. As mentioned above, regulations on individuals to be placed under surveillance if they come from an "infected area" will be repealed. Regulations on disinsecting individuals and a six day isolation for individuals suffering from pulmonary plague will be repealed and not replaced.

46. This benefit has not been monetised and is therefore unquantified.

A more human rights friendly approach

47. The draft regulation under Option 2 removes restrictions of indefinite detention for people where they are believed to have an infectious disease or a contamination. This approach is consistent with human rights legislation and ensures that individuals' human rights are not being curtailed. This benefit has not been monetised and is therefore unquantified.

Costs of option 2

48. Costs will be incurred owing to training (or informing) affected parties about the new regulations and from enforcement of the new regulations.

Training on the new regulations

Local authorities and Port Health Authorities

49. There will be an initial cost for training in the new provisions. Training itself will be shared between Local Authorities (LAs) and the Association of Port Health Authorities (APHA) and will be considered part of normal business.
50. There will be time costs for staff to attend the training. It is assumed that the costs of training will be similar to those arising from the implementation of the in-country legislation. We assume that approximately 75 local authorities send on average two people to half a day's training (at a cost of £50¹¹); this creates a total cost of £7,500. This will be a cost in year 1 only. Those local authorities that do not have a port or airport in their jurisdiction will incur no direct cost. The burden on each local authority is not a monetary cost; rather it is a reflection of the time local authority officials will need to complete training.

Plane and ship businesses, airports and sea ports

51. There are no direct training requirements to industry as the new requirements apply only in the case of a contingency. However, it is likely that industry will wish to ensure relevant staff are aware of the new provisions. Some minimal transition cost will therefore arise in the first year only, however, they are expected to be small. As there is substantially less burden on plane and ship businesses than on local authorities, the overall cost to the whole industry is likely to be much less than the cost estimate on local authorities estimated above.
52. Any refresher training after the initial period of transition is expected to be incorporated into the current regime of refresher training that is done. The content of the refresher training will be updated, which has minimal costs associated with it.

Enforcing regulations

53. The costs of enforcement may increase slightly because: (i) the remit is wider with all infections or contaminations which present or may present significant harm covered; and (ii) there are more offences. However, the clarity as to where an offence exists should help to increase compliance, so that there will be less need for local/port health authority officers to take action. Costs should therefore be reduced both for business and local/port health authorities. The net impact is likely to be neutral.
54. The existing regulations, which are to be repealed, contain some duties applying to operators of aircraft/ships in the event of specific circumstances. For example, an aircraft is to be "deratted" if rodents are suspected, and disinfected if an animal is found on board suspected of being infected with disease. These duties are to be

¹¹ £50 is equal to the mean daily earnings of an individual in the UK (used in Scenario 1 and 2) multiplied by one half.

replaced by a more general requirement to undertake health measures as required by the local/port health authority's officer. Overall, there will be fewer duties in the new regulations but the cost impact on industry is similar.

Summary of costs and benefits under option 2

55. Some of the costs and benefits estimated above are those accrued under a case of infectious disease or a case of contamination. However, these events occur incredibly rarely. In order to provide a time scale across which these costs and benefits are accrued, it is assumed that the probability of a case of infectious disease is 10%, that is, it occurs once every 10 years. The same probability is used in the scenario of a contamination¹². It is therefore possible to calculate annual costs and benefits, as well as the overall net benefit of option 2 across a chosen period. These are calculated by taking the costs and benefits outlined above and multiplying them by the probability of an event each year. The default period of 10 years is used for option 2. Total costs and benefits are given in Table 5.

Year(s)	0	1-9	Total
Costs			
Transitional	£7,500	£0	£7,500
Annual	£16,780	£16,780	£167,800
Benefits			
Transitional	£0	£0	£0
Annual	£731,500	£731,500	£7,315,000
Net Benefit	£707,220	£714,720	£7,139,700

Table 5: Illustrative total costs, benefits and net benefit for option 2.

Net Present Value of option 2

56. The costs and benefits across 10 years are discounted in order to give their present value. A discount rate of 3.5% is used for costs and benefits occurring in future years.

Year	Total	Average
Costs		
Transitional	£7,500	£750
Annual	£144,437	£14,444
Benefits		
Transitional	£0	£0
Annual	£6,296,523	£629,652
Net Benefit	£6,144,586	£614,459

Table 6 : Illustrative net present value for Option 2

57. Table 6 shows that option 2 has a positive illustrative NPV of £6.1m over the period of 10 years and is therefore shown to be beneficial.

¹² Though, as discussed already, evidence from the HPA suggests even a rate of infectious disease or contamination of once per 10 years is comparatively common given that since 1979 such a contingency has not arisen.

Risks and assumptions

58. Under option 1 the risk exists that an infectious disease or contamination that is not currently identified in existing health protection regulation arises and poses a serious and substantial cost to lives, health and the economy.
59. Under option 1, England is not adhering to the WHO's IHRs, of which it is a State Party as part of the UK. Continuing to use the existing regulations risks England failing to comply with international agreements.
60. The estimation of costs and benefits of option 2 on top of those existing under option 1 are based on the assumed probability of a case of infectious disease and contamination occur once every 10 years. However, the frequency of currently unknown future threats is inherently unpredictable.
61. The reduction in time allowed for medical examination and detention of non-co-operative individuals could be argued to raise the risk that if medical services could not be convened within the relevant timescales the regulations will not be effective. Detention of non-co-operative individuals arises in the instance of a contingency and it is very highly unlikely (almost impossible) that medical services could not be arranged within six hours of a request for medical assistance.

Direct costs and benefits to business calculations

One-In Two-Out

62. The draft regulations in Option 2 ensure compliance with the WHO's International Health Regulations. They additionally place offences on businesses that do not comply with the regulations, but these are incurred only in a contingency. It is considered good legislative practice to introduce penalties on businesses where a new duty places a requirement on them; this is the rationale behind including sanctions in Option 2.
63. On this basis, we consider these regulations to fall within the scope of the One In Two Out methodology as they go beyond the international agreement set by the WHO. We consider Option 2 to be classified as an IN.
64. While the introduction of offences may be seen as imposing a cost on business, these are only incurred in the instance where the air/sea transport company chooses not to comply with the regulations. But since compliance with the regulations is done at zero cost, we consider the net cost to business under Option 2 is zero.

Economic impacts: Competition

65. It has been argued by some representatives of the shipping industry that there are a higher number of provisions applying to ships compared to trains, and this may have an impact on competition between cross-channel ferries and trains. It is suggested that the reporting requirements will increase the burden on ferry companies and the information collection provisions may put passengers off ferry travel. The British Chamber of Shipping have argued that there is a high volume of short ferry journeys involving large numbers of people undertaking relatively short journeys, which means that any controls would be a major hindrance.
66. It is not accepted that this is a likely impact. There are no routine reporting requirements under option 2. Occasions when reports have to be made are rare, and there are already requirements to report in the current regulations. There is therefore

no appreciable change in impact. Similarly, the instances where passenger information is sought are also likely to be so rare that they are expected to have no meaningful impact. The provision will only require the master of the ship to use their 'best endeavours' to secure passenger and crew information. This takes into account that for some journeys it may not be practicable to secure this information. Furthermore, it is argued by others that passengers find it reassuring that measures are in place for cases of serious infectious disease, etc., and that most are content to be asked for their information.

Economic impacts: Small firms

67. In line with the Government's commitment to ensure the amount of new regulation affecting small businesses is reduced, it has been considered whether businesses with fewer than 10 employees should be exempted from the scope of these regulations. However, infectious diseases and contaminations pose the same threat to public health in England if entering the country through a small or large ship or aircraft. It is necessary that exactly the same regulations therefore apply to large and small companies. The regulations will apply to small shipping companies and airlines operating international flights and voyages as well as larger ones.
68. It is possible that the burden on smaller firms from complying with these regulations could be proportionally more significant than for larger firms. However, we do not envisage that there will be many small firms operating in this area given the large set up costs in the shipping and aircraft industries. In addition, we believe that any disproportionate impact would be outweighed by the fact that larger firms operating more flights or voyages, possibly with more passengers or cargo, would be more likely to be affected by these contingency provisions.

Wider impacts

Equality impact

69. An Equality Assessment has been conducted, outlining the impact of the policy on the equality characteristics defined in the Equality Act 2010. This Equality Assessment is attached alongside this Impact Assessment.
70. Ultimately, these regulations allow action to be taken to protect groups that might be particularly vulnerable to infectious disease, by allowing appropriate action to be taken to protect against an outbreak of these diseases.

Environmental impacts

71. The regulations include the collection of information about people on board ships and aircrafts (in particular) where a public health risk is possible. This may mean an increased use of paper forms by airlines and shipping companies.
72. For aircrafts, information may be collected on passenger locator cards (PLCs). These forms are currently in use and some airlines carry them already¹³. However, information can be collected on arrival, though this may cause some delay to travellers. Airlines will be free to decide whether to incur the minimal extra weight entailed. A similar situation will apply to ship companies.
73. The impact from increased paper in any event will be negligible as it is likely that PLCs will only be used very rarely and unused cards can be retained. It is hoped that

¹³ These are forms endorsed by the International Civil Aviation Organisation, a UN body which has worked with the WHO to produce a form which is internationally acceptable. The Card is one side of A4 paper.

air and sea companies would use recycled paper for PLCs.

74. Airlines and ferry companies that travel to other countries that implement the IHR will be subject to the 'collection of information' provisions in that country as well. Airlines and ferry companies may naturally seek to use one system for collecting passenger information, therefore the same process can be used for transport to England as well.

75. Other than the above potential impact, no environmental impact is anticipated.

Human rights

76. Regulations under option 2 seek to improve the existing regulations to ensure that human rights are not infringed without justification or safeguards, for example by placing a time limit on the power to detain.

77. The infringement of human rights can be justified if it is the consequence of a proportionate measure to achieve a legitimate aim. The protection of other people from infectious disease is recognised in the Human Rights Act as a legitimate aim. The regulations set strict criteria to ensure that the measures can only be lawfully used if they are the only means of achieving the health protection objective. That is, if it is proportionate to use them.

78. Some of the provisions in the regulations would impact on human rights to different degrees, from the provision of information to medical examination and detention.

79. The criteria for requesting passenger information could be seen as an infringement of privacy or liberty. The request would be on the basis that information could only be requested from those who may have been exposed, where the local authority has a reasonable suspicion that a person on board is suffering from an infectious disease or contamination. This is because there would be insufficient time to identify the condition and fully assess the risk to other people upon arrival at a destination. Gathering passenger contact details would enable those who may have been exposed to a health risk to be followed up, if necessary, once a diagnosis has been confirmed. It may be necessary to follow up those who have been exposed, but requiring their information is the lowest level of intervention possibly used to achieve that aim. Importantly, the regulations do not impose any requirement on a person to provide the information as it is purely voluntary. It is believed that most people will agree to give it as it is in their best interests to do so. The information sought would be the minimum necessary to allow the person to be contacted.

80. At the other end of the spectrum, the criteria for detaining a person would be high. The local authority/port health authority's officer must have reasonable grounds for believing that the person presents a risk of spreading infection or contamination and that detention is necessary to allow the risk to be assessed. The person can only be detained for two hours unless a medical examination is needed, in which case it must be carried out by a registered medical practitioner. The need for detention must be kept under review throughout this period, which can last for a maximum of six hours altogether. Once the examination is completed the person must either be allowed to leave or detained for a maximum of three further hours to allow an application for a justice of the peace order to be made. This could be needed if the examination confirms the risk and the person refuses to take action to protect others (such as agreeing to go to hospital). The time limits on detention are short. This is so that detention for a substantial period of time would only be possible under an order made by a justice of the peace under the "domestic" legislation (section 45G of the 1984 Act).

Justice system

81. The introduction of offences means there is the potential for an impact on the justice system. However, offences will arise only in a contingency and only when an air/sea transport company chooses not to comply with the regulations. Compliance with the regulations can be done at zero cost, so there is not expected to be an impact falling on the justice system.
82. A Justice Impact Assessment has been prepared and is subject to agreement with MoJ.

Summary

83. Option 2 is the preferred option. It has a positive net present value across 20 years. It provides an 'all hazards approach' that covers all infectious diseases and contaminations, reflecting the health protection threat from those that have been identified since the regulations were last updated in 1984. Option 2 ensures that England is adhering to the WHO's IHRs, to which it is a State Party as part of the UK.

Annex 1: Consultation questions

This Annex contains the questions that will be asked during the formal consultation process. These are below.

Q1. Do you agree that voyages from the Republic of Ireland should be included within the scope of these regulations? (para 2.7)

Q2. Is it necessary to place a legal duty on the crew to inform the master or commander of a case of infectious disease, or would this happen through standard procedures? (para 2.10)

Q3. Is the process for notification from in bound flights and voyages sufficient to ensure that the proper officer is alerted to a potentially serious case of infection or contamination? Are there any gaps? (para 2.15)

Q4. Is it reasonable to impose a duty on the aerodrome operator or harbour master to comply with a request to site a ship or aircraft somewhere suitable for risk assessment, subject to reasonable operational constraints? (para 2.19)

Q5. Are the provisions described a useful way of securing information? Should they be modified in any way? (para 2.26)

Q6. Are the proposed detention times sufficient to allow for a risk assessment and medical examination, if necessary? (para 2.49)

Q7. Is a detention time of three hours sufficient to allow for an application to be made to a JP? (para 2.52)

Q8. Are specific regulations required to deal with health protection issues related to cargo on ships and aircraft? (para 2.61)

Q9. Should the person accountable for implementation of any health measures be the aircraft operator, as defined in para 2.5. If not, who should be accountable? (para 2.65)

Q10. Do you agree that actual charges for health measures should conform to a previously published tariff and that charges should not exceed actual costs? (para 2.71)

Q11. Are the proposed offences and penalties a proportionate response to the risks posed to public health? If not, what approach would you suggest, bearing in mind that all duties should be associated with corresponding penalties for breach? (para 2.93)

Q12. Do the assessments and assumptions in the Impact Assessment appear reasonable? Please give reasons if you do not consider this to be the case, with evidence if possible. (para 3.1)