EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (PART 2A ORDERS) REGULATIONS 2010

2010 No. [XXXX]

THE HEALTH PROTECTION (LOCAL AUTHORITY POWERS) REGULATIONS 2010

2010 No. [XXXX]

THE HEALTH AND SOCIAL CARE ACT 2008 (CONSEQUENTIAL AMENDMENTS) ORDER 2010

2010 No. [XXXX]

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instruments

2.1 The Health Protection (Part 2A Orders) Regulations 2010 ("the Part 2A Orders Regulations") supplement the provisions in Part 2A of the Public Health (Control of Disease) Act 1984 ("the 1984 Act") by which Justices of the Peace (JPs) may by order impose restrictions and requirements on people, or in relation to premises or things, for health protection purposes. These regulations set out requirements as to the evidence a JP must have before making an order, provide safeguards for people who might be affected by an order, and make provision for monitoring of orders and some procedural matters.

2.2 The Health Protection (Local Authority Powers) Regulations 2010 ("the Local Authority Powers Regulations") give local authorities discretionary powers to take action to protect public health, by allowing them to impose restrictions or requirements in certain limited circumstances, and through formal powers to request cooperation for health protection purposes and to disinfect or decontaminate things or premises on request.

2.3 The Health and Social Care Act 2008 (Consequential Amendments No.2) Order 2010 ("the Order") makes a small consequential amendment to the Water Industry Act 1991.

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

3.1 None.

4. Legislative Context

4.1 The Public Health (Control of Disease) Act 1984 ("the 1984 Act") and regulations made under it have provided a legislative framework for health protection in England and Wales for many decades (the 1984 Act is itself a consolidation of legislation dating back to 1936).

4.2 The 1984 Act has recently been substantially updated through amendments made by the Health and Social Care Act 2008 ("the 2008 Act"). The updated legislation is mostly contained in a new Part 2A of the 1984 Act, and the existing Part 2 is repealed.

4.3 Part 2A of the 1984 Act provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation, and includes powers to impose restrictions or requirements on people, and in relation to things and premises, for use in rare circumstances where voluntary cooperation cannot be obtained. Overall, the amended 1984 Act sets out a framework for health protection which requires much of the detailed provisions to be

delivered through regulations. For England, it is proposed that the regulation-making powers will be exercised in two tranches: the first tranche will make domestic or 'in-country' provision; and the second will make provision in relation to England's international borders, that is, at ports, airports and international train stations.

4.4 Along with the Health Protection (Notification) Regulations 2010 ("the Notification Regulations"), these regulations together comprise the first tranche. The Notification Regulations are negative resolution and will be brought forward shortly. It is proposed that the three sets of regulations are made and come into force on the same date (with the exception of regulation 4 of the Notification Regulations which is to come into force 6 months later).

4.5 Further regulations relating to the protection of public health at England's international borders, constituting the second tranche, will be brought forward in due course.

4.6 The Order makes a small amendment as a consequence of the repeal of Part 2 of the 1984 Act.

4.7 A number of commitments relating to the use of the regulation-making powers in Part 2A of the 1984 Act were made in the House of Lords during the passage of the 2008 Act, all of which have been met:

- to consider adding to the list of affected persons (*21 May 2008: Column GC591*) – see regulation 6 of the Part 2A Orders Regulations;
- to carry out a full 12-week consultation (*21 May 2008: Column GC592*) – see section 8 of this Memorandum;
- to require that the local authority report the making of an order to the Health Protection Agency (HPA) (*24 June 2008: Column 1390*) – see regulation 10 of the Part 2A Orders Regulations;
- that guidance will be produced (*24 June 2008: Column 1390*) – this is underway;
- that the regulations will ensure a person who has an order made against him is aware of his rights, relevant support services and how to access them (*24 June 2008: Column 1391*) – see regulation 8 of the Part 2A Orders Regulations;
- to require local authorities to endeavour to notify the next of kin where an order involves a dead body (*24 June 2008: Column 1391*) – see regulation 3 of the Part 2A Orders Regulations;
- to add "next of kin" to the list of affected persons who can apply for variation or revocation of a JP order involving a dead body (*24 June 2008: Column 1391*) – see regulation 6 of the Part 2A Orders Regulations.

5. Territorial Extent and Application

5.1 Each of these instruments extend to England and Wales.

5.2 The Part 2A Order Regulations and the Local Authority Powers Regulations apply in relation to England only.

5.3 The Order applies in relation to England and Wales.

6. European Convention on Human Rights

6.1 The Minister of State for Public Health, Gillian Merron, has made the following statement regarding Human Rights:

"In my view the provisions of the Health Protection (Part 2A Orders) Regulations 2010, the Health Protection (Local Authority Powers) Regulations 2010 and the Health and Social Care Act 2008 (Consequential Amendments) Order 2010 are compatible with the Convention rights."

7. Policy background

- ***What is being done and why***

7.1 The health protection provisions in the 1984 Act (and regulations made under it) were substantially out of date prior to their amendment by the 2008 Act. They applied only to specific infectious diseases, and took no account of new or emerging diseases nor of threats from contamination, for example by chemicals or radioactive materials. The requirements for notification of specific diseases were out of date and inadequate to ensure identification of new micro-organisms or pathogens which could endanger human health. The powers of JPs to make orders were inflexible, being applicable only to medical examination, or removal to or detention in hospital; and many of the local authority powers dated back to Victorian society, and failed to meet the needs of the modern world. In addition, there were insufficient safeguards for people who might be affected by the use of the powers.

7.2 The amendments to the 1984 Act introduced in 2008 comprehensively modernised the legal framework for health protection. The new Part 2A takes an "all hazards" approach to health protection, where the criterion for action is based on the potential of an infection or contamination to present significant harm to humans, rather than on specific infectious diseases. It provides a system where local authorities must in most cases apply to a JP for an order if it is necessary to impose restrictions or requirements on people, or relating to things or premises, thereby better protecting individual rights. JPs' order-making powers can be used in a range of situations, from (for example) requiring a person to attend training, to detention in hospital; and can be applied to people, things or premises. The powers are therefore more flexible, allowing orders to be better targeted to the problem at hand.

7.3 Part 2A requires regulations to be made relating to some aspects of JP orders, and also provides powers to make regulations concerning duties on registered medical practitioners and others to notify cases of infection or contamination; various other matters relating to JP orders; and the functions of local authorities relevant to their health protection role. Much of the detail of health protection powers and duties is, therefore, to be set out in regulations.

7.4 The regulations provide a three-way approach to protecting public health in England, complementing the primary legislation. The new provisions for dealing with health protection problems on a contingency basis, through JP orders or local authority action, will be supported by updated requirements for notification, allowing identification of threats at an early stage. The updated framework for health protection in England which the 1984 Act and the regulations provide will enable local authorities, JPs, the Health Protection Agency (HPA) and the NHS to make a swift response to infection or contamination presenting significant harm to human health, while providing safeguards for anyone who might be subject to the new powers.

<u>Health Protection (Part 2A Orders) Regulations 2010</u>

7.5 These regulations are intended to promote high quality decision-making by JPs and to protect the interests of people who might be the subject of an order. They aim to achieve this by:

- setting evidential requirements to assist the JP in reaching a decision on applications from local authorities for any order relating to a person. This should ensure that JPs have all the relevant information available, while being sufficiently flexible to allow an order to be made in an emergency;
- specifying who must be notified about an application for an order and who can apply for variation or revocation - ensuring that those who need to know are informed and can take action;
- imposing a time limit of 28 days on all orders relating to a person, as an extra safeguard;
- protecting vulnerable people by requiring local authorities to help people who are the subject of an order to understand the order and their rights, to give information about relevant support

services, and in certain cases to have regard to the impact of the order on the person's welfare or that of any dependents;
- allowing local authorities to charge for the costs of measures required under an order but undertaken by them, if appropriate and necessary - this will help ensure that local authorities take prompt action if this is needed to protect public health;
- requiring all applications for orders to be reported to the HPA, so enabling the use of orders to be monitored.

Health Protection (Local Authority Powers) Regulations 2010

7.6 The aim of these regulations is to provide a set of health protection powers that local authorities can exercise without recourse to a JP, which are potentially useful to protect public health, proportionate, and accompanied by appropriate safeguards. Our consultation exercise asked for views about the need for certain powers that are currently available, and the regulations reflect the outcome of this. The regulations provide powers similar in some respects to those currently in force, but redundant powers have been removed and the remainder updated.

7.7 The regulations therefore provide powers to keep children off school; to require a list of pupils attending a school; to disinfect or decontaminate on request; to request that action is taken, or not taken, as the case may be, to protect public health; and to prohibit contact with dead bodies that pose a risk.

7.8 We have reviewed the offences and fines associated with these powers and believe it is right to retain them as an incentive to comply. We have made some adjustments to the level of fines to ensure that they are proportionate yet meet that objective. As is the case under the current Act, it will be an offence to breach the regulations about keeping a child off school; providing details of pupils attending a school; and restricting contact with a dead body.

The Health and Social Care Act 2008 (Consequential Amendments) Order 2010

7.9 This Order amends paragraph 4 of the Schedule to the Water Industry Act 1991 as a consequence of the repeal of section 11 (which falls within Part 2) of the 1984 Act by the 2008 Act.

7.10 Schedule 4A lists premises which are not to have their water supply disconnected for non-payment of charges. The list includes a reference at paragraph 4 to "A hospital within the meaning of section 11 of the Public Health (Control of Disease) Act 1984".

7.11 In light of the repeal of section 11 of the 1984 Act, the intention is to amend paragraph 4 in order that it retains a reference to a "hospital"; but a "hospital" is now to be defined by reference to the National Health Service Act 2006 (in relation to England) and the National Health Service (Wales) Act 2006 (in relation to Wales), both of which contain identical and extant definitions of "hospital".

- ***Consolidation***

7.12 This is not relevant as these are not amending regulations.

8. Consultation outcome

8.1 We consulted formally on draft versions of these Regulations, together with a draft version of the Health Protection (Notification) Regulations. The consultation ran for 12 weeks between July and September 2009. Consultees included local authorities, NHS organisations, public and independent sector microbiology laboratories that test human samples, the Health Protection

Agency (HPA), the Chartered Institute of Environmental Health, the Local Government Association (LGA), the Local Authorities Coordinators of Regulatory Services (LACORS), the National AIDS Trust and Liberty. The consultation document is available at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_102134

8.2 Sixty-eight responses were received. The majority of respondents broadly supported the regulations. The consultation response document, which includes a full list of consultees, is available on the Department of Health's website at: http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_111046

8.3 The main issues arising in respect of the Part 2A Orders Regulations and the Local Authority Powers Regulations, and how we dealt with them, are summarised below.

Health Protection (Part 2A Orders) Regulations 2010

8.4 *People with HIV or other sexually transmitted infections* - Sixteen respondents feared that JP powers could be used routinely and inappropriately as a means of preventing the spread of HIV or other sexually transmitted infections. They argued that HIV and sexually transmitted infections should be explicitly excluded from the scope of JP orders (although, because of the way the 1984 Act is framed, we cannot exclude any particular kind of infection or mode of transmission from the scope of JP orders). It was also suggested that the regulations might set higher standards for the evidence needed to satisfy a JP of the necessity of an order in relation to a person with HIV or a sexually transmitted infection. However, the evidential standard is already high for all orders and we do not think it is appropriate to differentiate in this way. The provisions for JP orders should not be a cause for concern for people with HIV or another sexually transmitted infection, as they are only intended for possible use in rare and exceptional cases where interventions to achieve voluntary action by an individual are not successful. An order could certainly not be made solely on the basis that an individual had HIV or another sexually transmitted infection.

8.5 Relevant stakeholders in the field are contributing to guidance on the use of Part 2A orders, which should help to put the above beyond doubt. We will also ensure that information about the use of orders, required to be supplied under the Part 2A Orders Regulations, will be published annually, to help reassure stakeholders by allowing transparency.

8.6 *Charges for costs of measures* – A major stakeholder was concerned that we had not included in the draft regulations a power for a local authority to charge for the costs of any measures it carries out as a consequence of a JP order. In response, we carried out a short additional consultation of stakeholders with an interest in this issue, to ascertain their views on whether we should include a regulation to this effect. As a result we have added a regulation (regulation 7) allowing local authorities to make a charge at their discretion, which must be reasonable and not exceed the actual costs incurred. This should remove any barriers to the local authority's taking health protection measures, while being fair to those affected.

8.7 *Rights of people affected by a JP order* - Some respondents thought the regulations did not go far enough to protect the rights of people who might be the subject of an order. In response, we have clarified the evidential requirements (regulation 4); introduced a new limit of 28 days on all orders relating to a person (regulation 5); and provided that a parent need not be notified if a child under 18 is the subject of an order, if it would not be in the child's best interests (regulation 3).

Health Protection (Local Authority Powers) Regulations 2010

8.8 *Extent of local authority powers* - Three respondents, including the CIEH and LACORS, were concerned that the new provisions will no longer allow a local authority to require a food handler who has food poisoning to stop working, but only to request that the person do so. This reflects the new balance in health protection legislation between local authority powers and those requiring judicial oversight. We consider this balance to be right, and that the local authority's

ability to back any formal request by an application to a JP if necessary is adequate to deal with this situation. In addition, food hygiene legislation places a duty on an infected food handler to notify the food business operator of his or her illness.

8.9 *Keeping a child off school* - While the regulations allowing a local authority to keep a child off school provide a right to a review (regulation 2), five respondents argued that we should add measures to guarantee the independence of the review. However, after further consultation with LACORS we believe this to be impracticable. In practice, liaison with professionals in the HPA and the relevant primary care trust provides an element of independence in both the original decision and in the review.

9. Guidance

9.1 The Department of Health and the HPA, in collaboration with the CIEH, LGA and LACORS, and organisations in the field of HIV and sexually transmitted diseases, will make available guidance setting out the detail of the new legislative requirements, including operational guidance to assist those who will be responsible for putting the new legislation into practice.

10. Impact

10.1 The regulations are estimated to impose a minimal extra burden in applying for JP orders on local authorities. The cost of training staff is estimated to be small.

10.2 An Impact Assessment, covering these regulations as well as the Notification Regulations, is attached to this memorandum.

10.3 No impact assessment has been prepared in respect of the Order as no impact on the private or voluntary sector is foreseen.

11. Regulating small business

11.1 The regulations do not apply to small business.

12. Monitoring & review

12.1 These instruments, along with the Notification Regulations, will be reviewed against their objectives in April 2015, in line with the timing for the review of relevant provisions of the Health and Social Care Act 2008. We will also ensure that information from the reports to the HPA of applications for JP orders (required under the Part 2A Orders Regulations) will be published annually. This will allow the use of applications for orders to be monitored and provide transparency about the reasons for them.

13. Contact

Janet Whybrow at the Department of Health (tel: 020 7972 4358 or email: janet.whybrow@dh.gsi.gov.uk) can answer any queries regarding the instruments.

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of regulations to be made under the Public Health (Control of Disease) Act 1984, as amended**	
Stage: Implementation	**Version:** 1.0	**Date:** 26 November 2009

Related Publications: Response to the consultation on health protection regulations; Impact Assessment of Public Health Protection Clauses of the Health and Social Care Bill; Health and Social Care Act 2008

Available to view or download at:
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/

Contact for enquiries: Janet Whybrow **Telephone:** 020 7972 4358

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

Protecting the public against infectious disease and contaminations has public good attributes, suggesting a role for government. The Public Health (Control of Disease) Act 1984 ("the 1984 Act") provides for action to be taken to protect public health. The provisions of the Act currently in force, however, lack flexibility to respond to new threats, and provide insufficient safeguards for those who might be affected by the use of health protection measures. The Health and Social Care Act 2008 ("the HSC Act") began the process of addressing this problem by amending the 1984 Act. The HSC Act requires, or allows, some specific powers and duties to be delivered through regulations. Regulations are therefore essential to provide a comprehensive health protection framework. This impact assessment is for three sets of regulations made under this updated legislation. They complete the process of modernising the domestic aspects of public health protection legislation.

What are the policy objectives and the intended effects?

The new provisions of the Public Health (Control of Disease) Act 1984 take an "all hazards" approach to health protection rather than focussing on specific infectious diseases. They allow a swift response to infection or contamination presenting significant harm to human health while providing safeguards for anyone who might be subject to the new powers. The policy objectives of these regulations are to modernise out-of-date requirements and to complete the picture of safeguards, powers and duties applying to public health protection.

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

The policy options considered for each of the three sets of regulations proposed are set out in the "Evidence base" section below. For each, we proposed the option which allows modernisation of out-of-date provisions, using some, but not all, of the regulation-making powers available. Responses to the consultation were broadly supportive of this approach. Some specific concerns were raised, which we have taken account of in finalising the regulations.

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

April 2015, in line with the timing for review of the impact of the relevant provisions of the Health and Social Care Act 2008.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Gillian Merron.....Date:***14th December 2009***

Summary: Analysis & Evidence

Policy Option:	Description:
Main	**Regulations made under powers in the amended Public Health (Control of Disease) Act 1984**

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 26,000	1
Average Annual Cost (excluding one-off)	
£ 220,000	10

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

Regulations impose some new, minor requirements on doctors, laboratories, Local Authorities, and the Health Protection Agency. Most of the cost is due to changes in notifying infectious disease (costs predominately to doctors and laboratories). (See summary of costs and benefits at page 26.)

Total Cost (PV) **£ 1.92 million**

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

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	1
Average Annual Benefit (excluding one-off)	
£ 240,000	10

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

PCTs benefit from saved administration costs. Since the regulation changes i) are applicable only rarely, or ii) formalise best practice, any further benefits have not been monetised.

Total Benefit (PV) **£ 2.07 million**

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

With respect to changes around notification of infectious disease, in the event of an outbreak the benefits could be substantial (reduced mortality/morbidity, improved surveillance, etc.).

Key Assumptions/Sensitivities/Risks

Uncertainties have been reflected in the ranges of figures that we have used, and many of the uncertainties relate to the time needed to make or deal with notifications.

Price Base Year 2009	Time Period Years 10	**Net Benefit Range** (NPV) **-£1.15m to +£0.31m**	**NET BENEFIT** (NPV Best estimate) **£0.15 million**

What is the geographic coverage of the policy/option?				England	
On what date will the policy be implemented?				6 April 2010, except for laboratory provisions which is 1 October 2010	
Which organisation(s) will enforce the policy?				L.A.s and DH	
What is the total annual cost of enforcement for these organisations?				£ nil additional	
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?				£ 0	
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	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

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

Increase of £ Decrease of £ 215,000 **Net Impact** **£215,000 decrease**

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

1. Introduction

These regulations take forward the process which began with the Health and Social Care Act 2008 (HSC Act) of providing a new, modern framework for the protection of public health from significant harm arising from infectious disease or contamination by chemical or radiological agents.

The HSC Act replaces out-of-date provisions in the 1984 Public Health (Control of Disease) Act with new arrangements which:

- 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.

The updated legislation is contained in a new Part 2A of the Public Health (Control of Disease) Act 1984. Part 2A requires, or allows, a range of powers and duties in the new health protection framework to be delivered through regulations. These regulations are the first of a planned package of such regulations, and cover the domestic, or "in-country", aspects of the new powers and duties. Further regulations will be brought forward in due course relating to international travel to modernise the framework for protection of public health at England's ports and airports.

Many of the powers in the new Part 2A are contingent powers to be used in the event of a threat to public health emerging and a refusal by someone to take voluntary action to address the threat. This combination of circumstances can be expected to arise only rarely, so that the need to use statutory powers to address the threat to public health will occur infrequently. The "Part 2A orders" regulations, and the "Local Authority Powers" regulations, discussed below, are examples of contingent powers (or matters associated with the use of such powers).

Part 2A also allows requirements to be imposed with regard to the recording, notifying and monitoring of public health risks arising from infection or contamination. The "Notification" regulations (see below) address this aspect.

We are introducing three sets of regulations:

i) Health Protection (Notification) Regulations

Currently there are provisions in the Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988 for statutory notification of specified infectious diseases by registered medical practitioners to the proper officer of the local authority. The new regulations will improve and strengthen these provisions by (a) updating the current list of notifiable diseases (b) introducing provision for notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health and (c) introducing statutory notification of specified infectious microorganisms by laboratories testing human samples.

ii) Health Protection (Part 2A Orders) Regulations

These impose some requirements on local authorities in connection with applications to a Justice of the Peace (JP) for an order under Part 2A to protect the public from infection or contamination. These regulations will provide safeguards for people who might be subject to an order. The regulations cover the evidence to be produced; who must be notified about an application and who can appeal; the person's rights to information and help to access support if needed; a local authority's power to charge for the costs of any measures it undertakes as a result of a Part 2A order about a "thing" or premises; and proposals for reports to the Health Protection Agency.

iii) Health Protection (Local Authority Powers) Regulations

These cover the range and scope of powers local authorities have, relating to their health protection role, without needing recourse to a JP. The regulations replace existing powers in the 1984 Act and include powers to keep children off school; to disinfect or decontaminate on request; to request action to protect public health; and to prohibit contact with dead bodies that pose a risk.

From July to September 2009 we carried out a consultation on these three sets of regulations. In view of the responses received, we have now finalised the regulations as discussed below.

2. Information gathering

The formal consultation ran from 8 July to 30 September 2009. We invited comments on the draft regulations, and in particular, responses to specific questions set out in the consultation paper. We also sought views on an accompanying set of draft impact assessments.

The following organisations were made aware by email of the consultation:

- chief executives of NHS organisations and the chief executives of local authorities, for cascade within their organisations (via the NHS chief executive's weekly bulletin, *the week*);
- public and independent sector diagnostic laboratories which test human samples;
- the Health Protection Agency (HPA);
- other selected stakeholder organisations (for example, the Chartered Institute of Environmental Health, the National AIDS Trust).

Before drafting and consulting upon the regulations, we aimed to capture a wide range of expert input. In particular, a meeting held in early 2009 with a range of stakeholder organisations directly contributed to the content of the draft regulations. Subsequent to this stakeholder meeting, two focus group meetings were held with health protection consultants from various English regions, to gather evidence from front line professionals to inform further policy development. Separate stakeholder consultation meetings were also held with two independent laboratories, including one of the major independent UK providers.

A number of further activities also took place during the consultation period:

- A poster was displayed at the HPA Annual Conference encouraging individuals to respond to the consultation, and distributed as a leaflet at the Chartered Institute of Environmental Health's (CIEH) Annual Conference.
- We had informal discussions with a limited number of organisations who wished to ask us questions arising from the consultation.

Sixty-eight responses to the consultation were received.

The majority of respondents broadly supported our proposed option for each set of regulations, which was to modernise out-of-date provisions using some, but not all, of the regulation-making powers available. There were however some notable concerns, in particular about the position of people with HIV or other sexually transmitted infections (STIs). Other themes concerned human rights issues; the lists of notifiable diseases and microorganisms; the impact on local authorities' powers and duties in health protection; and the practical effect on day-to-day health protection measures of increased judicial oversight. We also undertook a further, limited consultation on a provision for local authorities to charge for measures they need to undertake as a result of a JP order. These issues and how we have dealt with them are addressed at the relevant points in this impact assessment and in more detail in the consultation response document.

We have endeavoured to meet respondents' concerns where possible. In some instances we think the issue is better covered in guidance than in regulation, which has been produced to accompany the regulations.

One issue that the consultation highlighted is that the draft regulations omitted to make provision for local authorities to make a charge for measures they may need to undertake as a result of a JP order about a

"thing" or premises. We therefore undertook a further, limited consultation involving only those organisations with an interest in this issue.

We asked consultees if they thought that the assumptions in our Impact Assessment appeared reasonable. Most of those who answered this question (18 out of 26) agreed that they were. Four of those who disagreed considered that the Equality Impact Assessment (EqIA) had not adequately addressed the impact on people with HIV or another STI. We cover this point in the revised EqIA, which is available on the Department of Health website. We have reviewed all the representations made and are satisfied that the impact of the final regulations will, as far as can be assessed, be in line with the figures in the impact assessment produced when the draft regulations were put out for public consultation.

This is a Department of Health policy area. Other Government departments with an interest are the Ministry of Justice, the Department for Communities and Local Government, and the Department for Children, Schools and Families. All of these have been consulted.

The public bodies that will be affected by these powers include the Health Protection Agency, local authorities, NHS laboratories, and to a minor extent Justices of the Peace and legal clerks.

There are also implications for private laboratories and registered medical practitioners.

This impact assessment draws greatly upon the impact assessment produced when the draft regulations were put out for public consultation in July 2009 (available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433).

3. Health Protection (Notification) Regulations

3.1 Background

The statutory notification of infectious diseases has been a mainstay of the health protection "armoury" in England since the late 19th century. Many countries have statutory notification systems in place e.g. France, Germany, the Netherlands, Sweden, USA, Canada, Australia and New Zealand.

The notification system enables prompt investigation and risk assessment of cases of serious disease so that measures can be taken to protect public health. Such measures may include tracing and screening of people who have been in close contact with someone who has a specified infectious disease, ensuring appropriate treatment, immunisation or prophylaxis; or disinfection and decontamination of objects or premises. Currently there are provisions for statutory notification of specified infectious diseases in the Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988.

3.2 Reason for updating regulations

The current notification provisions regulations were updated most recently in 1988. In the light of public health developments in the last two decades, they require updating to reflect current threats and opportunities for action to prevent and control infection and contamination that presents or could present significant harm to human health. For example, the list of notifiable diseases dates back originally to the 1880s, and so does not cover some of the important public health threats today, such as botulism, Legionnaires' disease or diseases caused by exposure to chemicals or radiation. There is also no clear timescale for notifying in the current legislation, which may result in missing the window of opportunity for responding effectively to a health threat. Inclusion of all notification requirements in regulations, rather than splitting them between primary legislation and regulations as is the case now, means that they can be amended quickly in future, if necessary, to protect public health.

3.3 Policy objectives

The main aim of the new regulations is to ensure that there is a comprehensive and reliable system for notification of important public health threats from infection or contamination in England to enable local authorities, the Health Protection Agency and the NHS to respond promptly to such threats and control their spread.

The objectives of the proposed changes are:

a. to ensure that registered medical practitioners notify the local authority of suspected or diagnosed cases of notifiable diseases caused by infectious agents, or by other infection or contamination by chemicals or radiation that present or could present significant harm to human health, to enable prompt investigation and response to prevent or control spread of infection or contamination;

b. to ensure timely notification to the Health Protection Agency of infectious diseases caused by specified microorganisms diagnosed by laboratories testing human samples so that spread of disease can be prevented or controlled;

c. to ensure all notifications are made in a timely manner that allows preventive or control measures to be taken.

3.4 Options

Three policy options were considered:

1- To repeat the current legislative provisions in the new regulations.
2- To update the list of infectious diseases to be notified by registered medical practitioners.
3- To proceed as in option 2, and also to introduce:

- statutory notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health; and
- statutory notification of specified infectious microorganisms by diagnostic laboratories testing human samples.

For the reasons already explained, current provisions need updating and we consulted on option 3, as it provides a more comprehensive and robust notification system that can be updated easily in the future as necessary. The outcome of the consultation supported this approach, with a number of respondents making specific comments which are considered below.

3.5 Summary of proposed regulations

These draft regulations make provision for the statutory notification of specified infectious diseases in humans by registered medical practitioners and of specified infectious microorganisms by laboratories for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England. The regulations also make provision for statutory notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health.

These new regulations will replace the current provisions by:

a. updating the current list of notifiable diseases;

b. introducing a requirement on registered medical practitioners to notify cases where a patient has died with (but not necessarily because of) a notifiable disease, or other infection or contamination that presents or could present significant harm to human health, unless this has already happened when the patient was alive;

c. introducing provision for notification by registered medical practitioners of other infections or chemical or radiological contamination that presents or could present significant harm to human health;

d. introducing statutory notification of specified infectious microorganisms by diagnostic laboratories testing human samples;

e. providing timescales for notification by registered medical practitioners and laboratories;

f. removing provision for nominal payment for notifications by registered medical practitioners, on the basis that the provision of information needed to protect public health is an intrinsic part of the professional duty of a registered medical practitioner, and therefore should be provided without payment.

Overall, the majority of respondents to consultation agreed with the above proposed changes. However, there were some specific comments and suggestions about the lists of notifiable diseases and organisms and other related issues, which we considered before finalising our response.

3.6 Benefits

Notifications are primarily information to enable prompt investigation and action. They enable local authorities, the Health Protection Agency (HPA), primary care trusts (PCTs) and other agencies to take necessary actions to prevent further spread of infection or contamination.

In the consultation document we proposed removing two diseases currently notifiable by registered medical practitioners from the list - relapsing fever, which is mainly diagnosed by laboratory tests and should be reported by the diagnostic laboratory; and ophthalmia neonatorum, which is usually associated with gonococcal or chlamydial infections and is managed by sexual health rather than health protection services.

Following consultation, we removed leptospirosis from Schedule 1, as the diagnosis on the basis of clinical signs and symptoms is unlikely. We also removed human influenza caused by a new sub-type of the human influenza virus, as arrangements for notification of cases in the mitigation phase of a pandemic may change according to a range of factors and are, therefore, not suited to a standing statutory requirement.

We proposed adding botulism, brucellosis, invasive group A streptococcal disease, Legionnaires' Disease and SARS to the Schedule 1. There were no disagreement with these additions from respondents.

The additional list of infectious diseases that will require notification by registered medical practitioners under the proposed regulations and estimate of their incidence can be found in Annex 3. Most of these infectious diseases occur very rarely. In taking an "all hazards" approach, the draft regulations also require notification by registered medical practitioners of cases of other infections (e.g. new or emerging infections that are not notifiable) or chemical or radiological contamination that present or could present significant harm to human health.

Although the potential incremental benefits of the regulations could be relatively small for much of the time, in the event of a case or outbreak the impact could be substantial in:

a. reducing morbidity and mortality
b. preventing unnecessary suffering in individuals and families
c. reducing cost to individuals, e.g. due to loss of income or childcare
d. reducing costs to the health services, e.g. inpatient or outpatient care
e. preventing disruption to public services and other businesses due to employee sickness.

As a secondary benefit, data on notifications are also used for surveillance purposes, which provides information that may be relevant, for example, for:

a. reviewing and updating immunisation programmes
b. planning targeted and/or specialist health services, e.g. outreach services or disease-specific clinics designed for high risk groups
c. planning primary care services such as travel health advice.

Without detailed analysis of the incidence (and diagnosis) of the proposed additional notifiable diseases and associated benefits and costs, it is not possible to explicitly quantify these benefits. As we estimate that the additional burdens on registered medical practitioners, laboratories, local authorities and the

Health Protection Agency are likely to be small, it would be disproportionate to carry out such detailed analysis.

However, we briefly describe two examples of such benefits, in Italy and in the UK. In Italy there were two outbreaks of hepatitis A reported, which showed clearly that a timely notification, followed by health protection measures (such as immunisation) can help to prevent a considerable number of cases[1]. In the UK, an assessment of Legionnaires' disease outbreaks investigations and control measures suggests that such investigations are good value for money[2].

(Note that there are also administrative cost savings to Primary Care Trusts, described in Section 3.7.1 and summarised in Section 3.8.)

3.7 Costs

Costs of updating and extending the current legislative provisions fall on four groups: (i) registered medical practitioners; (ii) laboratories (NHS and private); (iii) local authorities; and (iv) the Health Protection Agency. Costs are considered for each group in this section separately.

3.7.1 Impacts on registered medical practitioners and Primary Care Trusts

Currently, registered medical practitioners (RMPs) are required to notify diseases based on the current list of notifiable diseases. The average annual number of notifications of infectious diseases (NOIDs), between 1994 and 2006 in England, was approximately 120,000. None of consultation respondents objected to the removal of notification fees during the consultation. Since RMPs currently receive £3.36 per notification, the removal of the nominal payments made to RMPs for notifying diseases is likely, therefore, to reduce such payments by about £0.40 million nationally per annum which is directly equivalent to the savings for the Exchequer. The impact of these provisions on RMPs has already been considered in the context of the Impact Assessment for the Health and Social Care Bill and is not discussed further here. This earlier Impact Assessment can be viewed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433

There would also be savings to PCTs in administration costs associated with these payments. We estimate that providing fees for each notification takes approximately 5 to 15 minutes for a PCT to process. Assuming an hourly cost of £12 for an administrative worker (see section 3.7.4), we might estimate that PCTs would save £120,000 to £360,000 nationally per annum.

Some of the additional diseases to be made notifiable are already being reported regularly on a voluntary basis by registered medical practitioners (e.g. Legionnaires' disease, botulism and diseases caused by exposure to chemicals). In addition, most diseases that we propose to add to the list of notifiable diseases, although of significant public health impact, are very rare (e.g. botulism, brucellosis and diseases caused by radiation). We estimate that the total incidence of these diseases is approximately 5,520 cases per year in England (see Annex 3).

We estimate that 50 to 75% of these diseases are currently being reported by registered medical practitioners on a voluntary basis. The relatively high estimated percentage of voluntary reporting is based on the fact that these conditions are rare but of public health importance, and clinicians regularly seek expert health protection advice. We, therefore, anticipate a minimal increase in the workload for reporting clinicians and, at the receiving end, for local authorities and the Health Protection Agency (see 3.7.3 and 3.7.4). We estimate that in total an additional 1,380 to 2,760 notifications will be made by registered medical practitioners annually in England; this assumes that an additional 25 to 50% notifications of diseases will be made under the new regulations compared to the number of voluntary notifications made now (for details of estimate, see Annex 3).

We assume that each additional notification requires 5 to 15 minutes of a RMP's time to either complete a written form or to give the required information verbally over the telephone if notification should be made urgently. RMPs include both GPs and hospital doctors (junior doctors and consultants). We therefore take the cost of a RMP's time to be the average of the different costs of GPs and hospital

[1] Bonanni P, et al. Vaccination against hepatitis A during outbreaks starting in schools: what can we learn from experiences in central Italy? Vaccine. 2005 Mar 18;23(17-18):2176-80

[2] Lock K, et al. Public health and economic costs of investigating a suspected outbreak of Legionnaires' disease. Epidemiol Infect. 2008 Oct;136(10):1306-14. Epub 2007 Dec 19

doctors (which is, again, taken to be the average cost of the whole range of hospital doctors)[3]. In addition, we inflate the cost of a RMP's time by 30% (in line with advice from the Better Regulation Executive)[4]. We can, therefore, estimate that an additional £13,800 to £88,320 will fall on RMPs per year for England (see following table).

Table 1: Total additional costs to RMPs

	Lower estimate: 25% increase in notifications	Mid estimate: 35% increase in notifications	Upper estimate: 50% increase in notifications
Number of additional notifications by RMPs	1,380	1,932	2,760
Cost of a RMP's time (per 5/10/15 minutes)	£10	£21	£32
Total additional cost falling on RMPs	£13,800	£40,572	£88,320

We did not receive any comments to challenge the above assumptions and estimates during the consultation.

3.7.2 Additional costs to laboratories (both NHS and private)

Approximately 95% of NHS laboratories currently report voluntarily a wide range of identified micro-organisms for surveillance purposes to the Health Protection Agency. In the majority of cases, reporting is carried out by electronic extraction of data from laboratory computer systems, and is likely to be complete. We therefore think that it is unlikely that the numbers reported from 95% of NHS laboratories would increase, so that the only increase in notifications from NHS laboratories is likely to be due to more laboratories reporting rather than improved completeness.

There are also local arrangements in most regions for the laboratories to report identified microorganisms with significant public health impact to the Health Protection Agency's local Health Protection Units urgently, i.e. on the same day. All the proposed infectious microorganisms to be notified to the Health Protection Agency under the draft regulations are already included in the voluntary system, apart from viruses causing viral haemorrhagic fever, which are only identified by specialist Health Protection Agency laboratories in England. We therefore expect the additional burden on NHS laboratories to be minimal.

However, the new regulations will also require private laboratories to notify the specified diseases. According to the Directory of Microbiology Laboratories published by the Department of Health's Inspector of Microbiology and Infection Control Office, there are approximately 212 NHS and 40 independent laboratories operating in England[5]. NHS laboratories participating in voluntary reporting to the Health Protection Agency reported an average of 137,000 diagnoses of organisms on the proposed list per year between 2006 and 2008[6]. We do not assume that private laboratories will identify a proportionate number of microorganisms compared to NHS laboratories. This is for two reasons:

i. Private laboratories are sometimes sub-contracted by NHS laboratories to carry out diagnostic tests. The proposed regulations require the primary laboratories (those receiving samples directly from clinicians), and not sub-contractors, to notify identification of a specified microorganism to the Health Protection Agency. This means that some of the organisms identified by private laboratories are already being reported by NHS laboratories.
ii. Our understanding is that private laboratories are generally smaller than NHS laboratories, so that they are likely to report less disease.

[3] The cost of a minute of an RMP's time is taken from the Unit Costs of Health and Social Care 2008, found at http://www.pssru.ac.uk/uc/uc2008contents.htm. See page 109 for the cost of a GP and pages 156-160 for the costs of different hospital doctors time.

[4] BRE advise that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.**uk**/files/file44503.pdf

[5] www.dh.gov.uk/en/Publichealth/Patientsafety/Microbiologyandinfectioncontrol/DH_4135669

[6] Personal communication: Erol Yusuf, Surveillance Systems manager, I.M.& T Department, Centre for Infection, Health Protection Agency

We, therefore, assume that reports by private laboratories will lead to an increase of 10 to 25% on the 137,000 already reported by NHS laboratories.

In addition, we assume a 5% increase in reporting by NHS laboratories, some of which are currently not reporting voluntarily but are expected to start notifying following implementation of the new regulations, so that there would be an additional 6,850 notifications per year by NHS laboratories. This means a total increase in private and NHS laboratory notifications of 20,550 to 41,100 per year.

We assume that each notification will require 5 to15 minutes of an employee's time. We take the cost of an employee's time here from the *Administrative Burdens Measurement Exercise*[7]. This estimates that the hourly wage rate of an internal professional, including those working in science and technology, was £18, in 2005 prices. We have updated this estimate to 2008 figures using the Average Earnings Index produced by the Office for National Statistics[8], giving an hourly wage rate for an employee in 2008 of £20.16. In addition, the Better Regulation Executive advises that employers' overheads are included when considering the cost of administrative time[9], providing an overall hourly cost estimate of £26.20. The cost estimates are, therefore, as in the table below.

Table 2: Total additional costs to laboratories

	Lower estimate 15% increase	Mid estimate 20% increase	Upper estimate 30% increase
Number of additional notifications by NHS and private laboratories	20,550	27,400	41,100
Administration costs falling on laboratories (per notification)	£2.18	£4.37	£6.55
Total additional cost falling on laboratories	£44,799	£119,738	£269,205

One professional body that responded on behalf of microbiologists queried the above estimates. They commented that private laboratories and a small number of NHS laboratories did not have access to computer systems or programmes to extract laboratory data automatically and those who did have such systems needed to develop them further to be able to notify within the required time limit. However, they did not offer any alternative estimate of impact.

The assumptions in this impact assessment are based on notification of individual cases on paper which is the most time-consuming option and likely to represent the highest estimate.

Following consideration of the consultation responses, we revised the time limit for non-urgent notification by laboratories to 7 days, from the original proposal of 3 days, to make it practicable for laboratories.

3.7.3 Additional costs to local authorities

In 3.7.1, we have estimated that there will be in the region of 1,380 to 2,760 additional notifications from RMPs to the proper officer of the local authority. However, more than 95% of local authorities in England have appointed an employee of the Health Protection Agency as their proper officer. Therefore, additional notifications will probably be received directly only by a minority of local authorities. Moreover, local authorities are no longer required to collate aggregated weekly and quarterly reports throughout the year to send to the Health Protection Agency.

We consulted on the requirement for the proper officer of the local authority to send copies of individual notifications to the PCT and, as a result of responses we received, we have decided not to introduce such a requirement.

[7] See, in particular, the *Administrative Burdens Measurement Exercise – Technical Summary*, page 20 for details on hourly wage rates of internal professional staff. (Both the full report and technical summary can be found at http://www.berr.gov.uk/whatwedo/businesslaw/better-regulation/simpplan/page35599.html.)
[8] http://www.statistics.gov.uk/StatBase/tsdataset.asp?vlnk=392&More=Y
[9] BRE advice that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.uk/files/file44503.pdf

We also removed the requirement for the local authorities to send the new regulations to RMPs in their area, following the consultation, as it is likely to be impracticable. Neither will the Health Protection Agency be required to send copies of the regulations to laboratories. Non-statutory methods of disseminating the regulations will be used instead.

Therefore, we estimate that there would be zero additional cost or a net saving to the local authorities arising from the proposed notification regulations.

FF3.7.4 Additional costs to the Health Protection Agency

As mentioned in part 3.7.3 the Health Protection Agency receives the majority of notifications from RMPs currently as they provide proper officers for the vast majority of local authorities. The number of notifications received may increase by 1.1 to 2.2% as a result of proposed new notifiable diseases.

In 3.7.2, we estimate an additional 20,550 to 41,100 notifications per year from laboratories which will be received by the Health Protection Agency only.

As mentioned above, the Health Protection Agency already runs a voluntary laboratory surveillance scheme, based mainly on automatic extraction of data from laboratories information management systems for a wide range of organisms, including those proposed by the Health Protection (Notification) Regulations[10]. Therefore, the additional burden of receiving reports from laboratories not currently reporting is estimated as around 25% of current reporting rates.

To estimate the additional burden on the Health Protection Agency from RMP and laboratory notifications, we might assume that each notification requires 5-15 minutes of administrative time. We take the cost of administrative time here again from the *Administrative Burdens Measurement Exercise.* This estimates that the hourly wage rate of an administrative or clerical worker was £8.28, in 2005 prices. Again, we have updated this estimate to 2008 figures using the Average Earnings Index produced by the Office for National Statistics, and added an additional 30% for employers' overheads, providing an overall hourly cost estimate of administrative time of £12. The cost estimates are as follows.

Table 3: Total additional costs to Health Protection Agency

	Lower estimate	Mid estimate	Upper estimate
Number of additional notifications by RMPs and laboratories	21,930	29,332	43,860
Administration costs to HPA (per notification)	£1	£2	£3
Total additional cost to HPA	£21,930	£58,664	£131,580

[10] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947381307

3.8 Summary of costs for Health Protection (Notification) Regulations

Additional costs to…	**Lower estimate**	**Mid estimate**	**Upper estimate**
Registered medical practitioners	£13,800	£40,572	£88,320
NHS and private laboratories	£44,799	£119,738	£269,205
Local authorities	<0	<0	<0
Health Protection Agency	£21,930	£58,664	£131,580
Total Incremental Cost of Option 3	**£80,529**	**£218,974**	**£489,105**
Administrative savings to Primary Care Trusts	-£120,000	-£240,000	-£360,000
Net cost	-£39,471	-£21,026	£129,105

The preferred option (Option 3) therefore costs between £39,471 less and £129,105 more than option 1 (no changes option).

3.9 Risks

There is already a long-standing requirement on registered medical practitioners to report notifiable diseases and a well-established national voluntary surveillance system run by the Health Protection Agency, in which around 80% of all laboratories in England participate.

Therefore, the risk of the new notification provisions not being implemented effectively are probably low. This risk will be mitigated by the provision of information and advice from Department of Health and the Health Protection Agency about the new requirements and associated training (see section 6 on the costs associated with this training).

The risk of the new notification system not being sensitive to new and emerging infections or contamination by chemicals or radiation has been addressed by including provision for reporting by registered medical practitioners of non-notifiable diseases or disease caused by chemicals or radiation that could present or present a significant risk to human health. Having the list of notifiable diseases in regulations rather than primary legislation makes it straightforward to update the list in future if necessary.

3.10 Data burdens on the public sector

As mentioned above (section 3.7.1) we anticipate a relatively small increase (1,380 to 2,760 cases per year in England) in the workload for reporting clinicians and those receiving this information (local authorities and Health Protection Agency).

As mentioned above (section 3.7.2) we anticipate that 20% of laboratories will be affected by the requirements in the new regulations (the majority of these being private laboratories).

4. Health Protection (Part 2A Orders) Regulations

4.1 Background

An order made under the new Part 2A of the Public Health (Control of Disease) Act may require a person to be detained, isolated or quarantined, or impose other restrictions on them; or may require a person to do, or not do, certain things, in order to protect public health. A Justice of the Peace (JP) may also make an order about things or premises, for example that they be seized or disinfected, or that a premises be closed. In all cases, the JP must be satisfied that clear criteria as to the type and degree of risk, and the necessity for an order, as laid down in the Act, are met. The impact of these provisions has been considered in the context of the Impact Assessment for the Health and Social Care Bill and is not repeated here. This Impact Assessment can be viewed at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433.

4.2 Reason for intervention

We are required to make regulations on some aspects of the new arrangements for Part 2A orders and may do so on others (see 4.4.1. below). We are using these powers to provide increased safeguards for individuals affected by the new arrangements.

4.3 Policy objectives

Our objectives are to:

- set evidential requirements which assist JPs to reach a decision on applications for orders, while being sufficiently flexible to allow applications to be made in an emergency when some details of the circumstances may not be known;
- protect interests of people affected by a JP order, without jeopardising necessary action to protect public health;
- ensure vulnerable people are supported by an obligation on local authorities to provide information or in certain cases to have regard to their welfare;
- allow monitoring of orders made or applied for by instigating a system of reporting applications for orders.

4.4 Options

We considered three options for these regulations.

Option 1 - regulate only on things which the Act requires us to regulate about
Option 2 - use all the Act's relevant powers to make regulations
Option 3 - regulate on things which the Act requires us to regulate about, and also on some, but not all, of the matters where we have powers to do so.

We proposed, and consulted on, Option 3.

4.4.1 Option 3

Part 2A **requires** regulations to be made on a limited number of matters, and **allows** regulations to be made on a range of others.

The Secretary of State **must** make regulations about the evidence to be available to a Justice of the Peace (JP) before the JP can be satisfied that the criteria for an order restricting a person, or imposing any requirements on him or her, are met. Part 2A also requires regulations to be made about who must be notified that an application for an order is being made.

Part 2A allows (rather than requires) regulations to be made about the following matters relevant to JP orders:

- the evidence to be available for orders about things or premises;

- any other persons, in addition to those specified in the Act, who are “affected persons” (that is, who can apply for variation or revocation of an order by virtue of being personally affected);
- the measures to be taken in connection with Part 2A orders. This could cover anything relevant to the taking of measures, including what investigations might be made as part of a medical examination, the manner in which measures are to be taken, who is responsible for execution and enforcement, liability for costs and payments of compensation or expenses.

Regulations may also be made conferring functions on local authorities or other persons in relation to monitoring of public health risks.

We considered that it was not necessary to use all the powers available and that this would incur unjustified expense. Therefore, we proposed that the regulations should cover the topics we are required to regulate about together with those which Ministers have made a commitment to include in regulations, or which we think are needed to provide a further safeguard for individuals.

We proposed that the regulations should cover:
- the evidence to be available to a JP before making an order about a person;
- that the next of kin of the deceased is an “affected person” if an order involves a dead body or human remains;
- who must be notified of application for an order - to include the next of kin of the deceased if an order is made involving a body or human remains;
- a local authority duty to provide information to people subject to an order;
- a local authority duty to report applications for orders to the Health Protection Agency;
- a local authority duty of care for anyone whose liberty is restricted by an order so that they cannot care for themselves or any dependents.

The outcome of the consultation supported this approach, with a number of respondents making particular points which are considered below.

4.5 Benefits & Costs

We believe that there will be no impact on the voluntary sector. The estimated impact on business and the public sector is discussed below.

4.5.1 Evidence that a JP must have before making an order about a person

a) Benefits

We proposed that the regulations should require evidence to be given by a suitably qualified person on the key aspects of the statutory criteria, for all orders relating to a person. In brief, the evidence must give the reasons for believing that the person is infected or contaminated; summarise the characteristics and effects of the infection or contamination; assess the risk the person poses to others; and assess the options available to deal with the risk, to show why an order is necessary.

Some respondents to the consultation argued for more stringent evidential requirements to apply if an application were made for an order in respect of a person with HIV or another sexually transmitted infection. However we have declined to do this, because the requirements already set a high standard of evidence for all applications.

The benefits are:
- an increased safeguard for an individual who might be subject to an order, to ensure that an order cannot be made without clearly identifiable grounds;
- JPs will be assisted in reaching their decision, because the grounds for an order will be clearly specified.

Since it is likely that this part of the regulations will formalise what is already best practice, we have assumed that no monetary benefit arises as a result.

b) Costs

The requirement will impose a minimal extra burden on local authorities in applying for an order. We believe that the requirements formalise what is done now in the course of usual good practice. (This is borne out by the actual content of applications made available to the Department in anonymised form for information.)

In addition, the number of applications for orders are low and expected to remain so. In the IA for the Health and Social Care Bill, we estimated the number of JP orders to be around 10 nationally per annum. We have reviewed this figure and in the light of our conversations with health protection consultants, we consider a range of the number of potential orders, from 5 to 15 per annum.

The IA for the Health and Social Care Bill assessed the cost of making an application to a JP at £1,500. We assume an additional cost of between 5 to15% for each order to comply with these evidential requirements (and for the sake of argument, that all orders will involve a person).

Using a standard cost model this shows additional costs in the range as follows:

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**5**	**10**	**15**
Additional cost	**5%**	**10%**	**15%**
Total costs	**£375**	**£1,500**	**£3,375**

4.5.2 Affected persons

a) Benefits

An "affected person" has the right to apply for variation or revocation of an order. As a result of the consultation we are using the power to regulate about who is to be an affected person to prescribe that, where a person subject to an application for an order has a "decision-maker" (a donee of lasting power of attorney, or enduring power of attorney, under the Mental Capacity Act, or any deputy appointed by the Court of Protection, who is authorised to act for them in that respect), that person is to be an affected person. We are also, as proposed in the consultation, prescribing the next of kin of the deceased person in respect of orders involving a dead body or human remains.

The benefit is therefore:

- it is put beyond doubt that any decision-maker for a person has a clear legal right to challenge an order made against a person they are authorised to represent;
- the next of kin will have the opportunity to influence decisions regarding their relative's final arrangements, which could be of considerable significance to that person.

b) Costs

We do not think any costs apply to the designation of a decision-maker as an affected person. This situation would arise very rarely, and it is likely that a formal decision-maker would, in practice, be entitled to represent the person in any event - the regulations simply put that beyond doubt.

A next of kin might exercise the right to apply for variation or revocation, therefore impacting on the work of local authorities and JPs. However, an order involving a body or human remains - for example, for burial or cremation - would be a rare occurrence. We might assume one a year. It would be inappropriate to assume that the deceased person would have a next of kin, or that the next of kin would always apply for variation or revocation. The impact, therefore, is likely to be somewhat less than one extra application a year nationally, and so can be regarded as having no significant impact or costs.

4.5.3 Persons to be notified of an application for an order

a) Benefits

For orders relating to people, notification is to be made to the person concerned, or their parent in the case of a child, or any "decision-maker" (as above), where decisions about orders are within the scope of that person's authority. Should an application be made for an order involving a dead body or human remains (see above), the next of kin must be notified. For orders relating to things or premises, the owner, or person with custody or control, or occupier, as the case may be, must be notified. The duty will not apply if there are good reasons why the relevant person should not, or cannot, be notified.

The benefits are therefore:

- those most directly affected by an application for an order will be aware of it and in a position to represent their interests to the JP, or, if an order is made, to apply for variation or revocation if they wish (by virtue of being affected persons under the legislation).

b) Costs

We do not think that this duty imposes a significant burden on local authorities. In practice, anyone involved in an order in this way would be sure to be notified, unless there were good public health reasons for not doing so. The extra costs would therefore be minimal. One respondent to the consultation thought that the bulk of this work would be carried out by a professional officer, but we do not think this should be necessary and we therefore assume the costs are attributable to administrative time. We might assume between 2 and 6 hours of administrative time per order. We take the cost of administrative time here, and throughout when looking at the general administrative burden on local authorities under the Part 2A regulations, from the *Administrative Burdens Measurement Exercise*[11]. This estimates that the hourly wage rate of an administrative or clerical worker was £8.28, in 2005 prices. We have updated this estimate to 2008 figures using the Average Earnings Index produced by the Office for National Statistics[12], giving an hourly wage rate for administrative and clerical staff in 2008 of £9.29. In addition, the Better Regulation Executive advises that employers' overheads are included when considering the cost of administrative time[13], providing an overall hourly cost estimate of administrative time of £12. Assuming that there are between 5 and 15 orders per year, the cost range is therefore as follows.

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**5**	**10**	**15**
Cost of administrative time per order	**£24**	**£48**	**£72**
Total costs	**£120**	**£480**	**£1,080**

4.5.4 Duty to report applications for orders to the Health Protection Agency

a) Benefits

During the passage of the Health and Social Care Bill the Minister agreed that all orders should be reported to the Health Protection Agency. We are extending this requirement for local authorities to report all applications for orders as well as orders made, and in addition, any variations or revocation of an order.

The benefits are:

- to allow transparency as to the extent of the use of the powers when the new Part 2A comes into force;
- potentially provides a fuller picture of health protection activity than reporting of orders alone.

[11] See, in particular, the *Administrative Burdens Measurement Exercise – Technical Summary*, page 20 for details on hourly wage rates of administrative and clerical staff. (Both the full report and technical summary can be found at http://www.berr.gov.uk/whatwedo/businesslaw/better-regulation/simpplan/page35599.html.)
[12] http://www.statistics.gov.uk/StatBase/tsdataset.asp?vlnk=392&More=Y
[13] BRE advice that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.**uk**/files/file44503.pdf

b) Costs

Information we have obtained from health protection consultants about current practice shows that there have been no known instances of any applications that did not result in an order (although the order might have differed in some respects from what was applied for). We do not therefore consider that requiring reporting of applications, rather than of orders actually made, imposes any significant further burden on local authorities. Variations or revocations of an order should not be frequent events and we do not think a requirement to report these will add any significant costs.

This duty will entail the local authority copying the application and the order (with all details of individuals who are the subject of the application removed), together with some relevant administrative details, to the Health Protection Agency. Should an order not be made, the reasons for this are to be given.

We estimate that this would require somewhere in the region of 4 to 8 hours of administrative time by the local authority, at a cost of £12.00 per hour.

Using the standard cost model, this shows costs in the range as follows.

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**5**	**10**	**15**
Cost of administrative time per order	**£48**	**£72**	**£96**
Total costs	**£240**	**£720**	**£1,440**

4.5.5 Duty to provide information

a) Benefits

The regulations will require the local authority to give information about how the order works, the reasons for it, the person's rights to apply for variation and revocation, and any relevant services available, to anyone who is the subject of an order (one person only per order).

The benefits are:

- the person understands the reasons for the order and what it does and why, and how to apply for variation and revocation if they wish;
- public health protection is improved, because a person who does not understand what an order does will not be a position to comply.

b) Costs

This duty should not impose a significant burden on the local authority. It requires the authority only to take all reasonable steps to ensure the person understands the reasons for the order and what it does and why, and how to apply for variation and revocation. Nor does it require the authority to provide any particular service; the duty relates to information, not provision. We consider that the requirement formalises good practice, and that no significant extra costs therefore accrue.

4.5.6 Duty of care

a) Benefits

The need for this duty was supported by respondents to the consultation. The local authority is to be required to have regard to the welfare of any individual who is placed under detention, isolation or quarantine by a JP order, and of any dependents.

The benefit is:

- an extra safeguard for people whose liberty is restricted by an order, to ensure that this does not impact on the person's or dependents' needs for care or essential services.

b) Costs

The need for action under this duty is likely to arise only rarely. The local authority may charge for any services provided, using their powers in section 93 of the Local Government Act 2003, and will therefore often be able to recoup any costs. We do not consider that any additional costs can be identified as arising as a result of this requirement.

4.5.7 Local authority power to charge for measures taken under a JP order

A matter was raised in the consultation that we had not addressed, namely that the legislation does not provide for local authorities to make a charge for the costs of any measures it needs to carry out as a result of a JP order. This could arise, for example, if an order were made for a premises to be disinfected or decontaminated, but the owner of the premises was unable or unwilling to carry out the measures required. We agree that this issue has some importance for effective public health protection.

We therefore conducted an additional, smaller scale consultation of key organisations with an interest, as follows:

- Chartered Institute of Environmental Health;
- Local Authorities Coordinators of Regulatory Services;
  Local Government Association;
  Association of British Insurers;
- Confederation of British Industry;
- Federation of Small Businesses;
- Liberty;
- The UK Faculty of Public Health;
- James T H Button & Co, Solicitors.

We proposed that local authorities should be able to make a reasonable charge for reimbursement of costs they might incur if it fell to them to carry out any measures required under a JP order relating to things or premises (not those relating to people). We asked whether there were any circumstances in which such a charge should not be made, and invited any further comments on the issue.

We received five responses. The majority felt that local authorities should be allowed to make a charge, although there were some concerns that the individual's or business' ability to pay should be taken into account.

As a result of this consultation we have included in the regulations (under powers in local government legislation) a power for local authorities to levy a discretionary charge where it becomes necessary for them to take the required action, because the person to whom the order is directed cannot or will not do so. This will apply only to orders in relation to things or premises, not to people.

The amount of the charge must be reasonable, and not exceed the actual costs to the authority. Where the person or business concerned would have difficulty in paying the charge the authority might choose not to levy a charge, as they have discretion not to do so. In any event, the authority must act reasonably, in accordance with the standard principles applying to public bodies.

a) Benefits

The circumstances in which this situation might arise will be rare. However, if those rare circumstances do arise, as has happened in the past, this provision will help to ensure there is no disincentive for local authorities to take health protection measures. Public health should therefore be safeguarded.

b) Costs

We do no think any appreciable costs arise to local authorities or business. The power to levy a charge allows a local authority to recoup costs in the rare circumstances where the expenditure needed might cause problems. To some extent this provision mirrors current powers, which allow a local authority to disinfect articles or premises at an occupier's cost to prevent the spread of disease. The main differences are that this new power to charge applies only in the case of a relevant JP order, and the scope is wider, covering cases of contamination as well as infection. However, the need to use this provision will arise only rarely, so that the impact on business interests or individuals is unquantifiably small.

4.5.8 Time limit for JP orders about a person

The consultation raised the question of whether the regulations should place a time limit on JP orders, over and above the 28-day limit placed in the Act on orders imposing detention, isolation or quarantine. The regulations therefore impose a 28-day time limit on all orders made in respect of a person. This might apply, for example, if an order were made for a person to stay off work, or requiring their health to be monitored. It could also mean that a one-off event imposed under a JP order - such a medical examination - had to take place within 28 days.

The regulations will not set a time limit for an order about "things" or premises, which will be a matter for the JP.

a) Benefits

This measure provides an extra safeguard for an individual subject to an order.

b) Costs

We do not think this measure entails any extra costs. JP orders will be rare in any event. It is also hard to envisage a scenario where a JP would wish to impose a restriction lasting over 28 days but will be prevented from so doing under this regulation. There is a notional possibility that a local authority would need to apply for an extension to an order that would not have been necessary if the order were still running. However, this is likely to happen so infrequently that we do not think that any extra costs can be identified from this requirement.

4.6 Summary of costs

In summary, we estimate the total extra costs falling to the local authority from the Part 2A orders regulations as follows.

		Lower estimate	Mid estimate	Upper estimate
I	Evidence for JP orders	£375	£1,500	£3,375
II	Affected persons	£0	£0	£0
III	Notifications to individuals of order	£120	£480	£1,080
IV	Reporting of applications for orders to HPA	£240	£720	£1,440
V	Duty to provide information	£0	£0	£0
VI	Duty of care	£0	£0	£0
VII	Local authority power to charge	£0	£0	£0
VIII	Time limit for JP orders	£0	£0	£0
Total cost of these regulations		£735	£2,700	£5,895

4.7 Risks

There are some risks associated with our proposed measures:

- the evidential requirements will delay or hinder applications in an emergency;
- JPs will find the evidential requirements unhelpful and will be deterred from making an order.

Adequate preparation before the regulations come into play should mitigate these risks. In the case of the second, we will liaise with the Ministry of Justice and the Justices' Clerks' Society to try to ensure that clerks advising JPs are apprised of the requirements, along with, of course, the new provisions in Part 2A itself. We are working with the Health Protection Agency to produce guidance to support implementation. (We have not assigned costs to JPs' clerks from the new requirements, because cases arise only rarely and clerks are unlikely to engage substantially with the changes until presented with a case requiring knowledge.)

We do not foresee any other significant risks.

5. Health Protection (Local Authority Powers) Regulations

5.1 Background

Local authorities currently have a range of powers under the Public Health (Control of Disease) Act 1984 to protect public health. Many of these powers are out-of-date. The new Part 2A provides a framework to modernise these powers.

5.2 Reason for intervention

Part 2 of the 1984 Act will be repealed when the new Part 2A is brought into force. Part 2 gives a number of standing powers to local authorities to exercise a public health protection function. The new Part 2A gives powers to JPs so that they may make an order specifying actions to be taken to protect human health, on application by a local authority. However, we think it is necessary for local authorities to retain, in an updated form, some of the powers and duties from Part 2, for use when judicial oversight is not necessary. The Health Protection (Local Authority Powers) Regulations provide these powers and duties.

5.3 Policy objective

We want local authorities to have sufficient powers to enable them to continue to play their front-line role in health protection, while protecting the rights of people who might be affected. To this end, we have retained certain powers from the current Part 2, with some necessary modernisation to these powers in order to meet modern human rights expectations.

5.4 Options

Option 1 - Do nothing, i.e. rely on informal action backed by JP powers.
Option 2 - Use all the Act's relevant powers to make regulations.
Option 3 - Regulate to provide powers and require functions only where a need to do so to protect public health can clearly be seen.

We proposed, and consulted on, **Option 3**. Engagement with stakeholders indicated that there is a need for a local authority to have some powers available to enable formal action to protect public health, without resorting to applying for a JP order. On the other hand, we have not used, at this stage, all the regulation-making powers available - for example, we have not taken an explicit power for a local authority to prohibit or restrict an event or gathering, as we do not think it currently necessary. This can be reviewed as necessary in the future. In the meantime, the local authority could use their request power to deter a gathering or apply for a JP order as necessary.

5.5 Summary of proposed regulations

We are retaining and/or updating the existing legislation to provide powers to:

- keep a child away from school;
- require a list of contact details of pupils at a school;
- disinfect or decontaminate;
- request cooperation for health protection purposes;
- restrict contact with dead bodies.

5.6 Benefits and costs

We believe that these regulations will have a negligible impact on business and no impact on the voluntary sector.

5.6.1 Keeping a child away from school

Under current legislation, a local authority can issue a notice to keep a child away from school. Notices made under this power are made very infrequently (from our discussions with health protection consultants we estimate about 3 a year). Voluntary cooperation, where the parent clearly understands the reason for their child being asked to stay away from school, is always the objective. Such voluntary

cooperation is more likely to be successful in protecting public health (and the interests of the child in question) than a strict legislative restriction on attendance.

Some small changes to this power have been made in order to modernise it, including:

- the notice of the requirement to stay off school is time-limited to 28 days;
- the headteacher or person in charge must be informed of the notice;
- the parent can request a review of the notice - the local authority must then carry out a review, but only one review has to take place in any one notice period.

At consultation, we asked whether the requirement for a local authority to review a notice would work fairly in practice. The majority agreed that it would. Those who did not agree felt that the review would not be undertaken with the appropriate degree of independence. Some respondents suggested setting out a detailed and independent mechanism for these reviews, but we do not think this would be proportionate to the numbers likely to be affected. We considered a requirement that the review must be conducted by someone who was not involved in the original decision to issue the notice but we do not believe this would be practicable, because in effect the notice is served by the council as a body, while small size of some environmental health teams and the way in which they work could make it difficult to identify a person who was genuinely independent of the original decision. In practice, liaison with the other health protection professionals in the Health Protection Agency and PCT creates an element of independence in both the original decision to serve the notice and in the review.

a) Benefits

The chosen policy option of modernisation with the small modifications outlined above ensures that this power protects human health but also safeguards the rights of those that may be affected by its use. There are no cost benefits compared to the current legislative power to keep a child off school.

b) Costs

Notices to keep a child away from school are currently made very infrequently. Because the numbers involved are so small, we believe the minor modernisations proposed should incur no significant cost burden beyond that currently incurred. They require actions that a local authority might take as a matter of course under the existing arrangements, even though they are not set down in law. For example, it would be reasonable to expect that a local authority would keep a headteacher appraised of a situation affecting a pupil at their school; it would reasonable for the local authority to regularly review the requirement and the child's health while a notice is in force and on a request by the parent. Frontline professionals have explained that, as standard practice, they would keep the health of the child under review over the period of the notice, even though this requirement is not currently set down in legislation.

It is not predicted that this power will create any burden on business.

5.6.2 Local authority power to request a list of names of pupils at a school

Under current legislation, a local authority can require the headteacher of a school to provide the authority with a list of the names and contact details of pupils at the school. This power has been modernised so it can be used if any adult or child that attends the school is, or is suspected of being, infected or contaminated with an infection or contamination that presents, or could present, significant harm to human health.

As in section 5.6.1, we believe that the power to request a list of names of pupils at a school if necessary should remain a local authority power, since without this power the authority would then have to apply for a JP order to require these contact details. We do not believe judicial oversight should be required to be able to exercise this power.

At consultation stage, it was proposed that the power would apply only if a child or member of staff at the school was, or was suspected of being, infected or contaminated. Following the consultation, we have extended this to include possible exposure to visitors to the school who are, or are suspected of being, infected or contaminated. This slight amendment will have a negligible impact on resources.

Several respondents suggested that this power should be widened to allow local authorities to request the contact details of adults as well as children, for example staff and visitors. However, we have not

revised the regulations in this way on the basis that a local authority may apply for a JP order if the contact details of adults were necessary.

a) Benefits

The existing power contains a compensation requirement, whereby the local authority is obliged to pay the headteacher 2p per 25 names provided. We have not continued this compensation requirement because we do not consider it has any merit in encouraging compliance. Rather, it just increases costs and the administrative burden of the overall procedure. Dropping the requirement to pay compensation reduces the overall potential burden of the power on local authorities. We therefore assume that the cost to the school of no longer receiving this compensation payment is counteracted by the cost saving to the local authority (and, possibly, the school itself) of reduced administrative burden, so that the net benefit of the change in policy is assumed to be approximately zero.

b) Costs

We estimate that the incremental cost of policy changes under this section is zero, compared to the current situation. It is not predicted that this power will create any burden on business.

5.6.3 Local authority power to disinfect/decontaminate

Under current legislation, a local authority may provide a disinfection station to have any article brought there disinfected free of charge. We therefore included in the consultation draft regulations a discretionary power for the local authority to disinfect or decontaminate an article (including a conveyance) or a premises, or have this done (perhaps by using contractors) at the request of the owner of the article or the premises, or the tenant of a premises. In the consultation, we asked whether there was a need for this power to be retained and updated. The vast majority of respondents to this question agreed that there was such a need.

Two respondents preferred ‘things’ to ‘articles’, in order to achieve consistency with the parent legislation. We have redrafted the wording accordingly.

a) Benefits

The benefit is that a clear, swift means for a local authority to deal with infection or contamination is in place, so helping to avoid risks to public health.

b) Costs

The regulations enable the local authority to provide this service only when they consider it necessary, and to pass on their costs for the provision of this service to the service user. Any such services must currently be provided free of charge (although the rarity of their current use makes comparisons invalid). We do not therefore expect any financial impact on the authority because of the modernisation of this power.

There will be a cost impact on individuals or businesses who request this service. This is unquantifiable and will arise only on the occasion where the service is used. It is likely that if the local authority did not provide the service, the individual or business would need to contract for it privately, or incur greater costs at a later stage to deal with an infection or contamination which takes hold or spreads.

In addition, the local authority can only disinfect/decontaminate premises at the request of the tenant if they are reasonably satisfied that the premises will not be devalued because of disinfection/decontamination.

5.6.4 Local authority power to request cooperation for health protection purposes

Local authorities currently have a number of powers to require people to do certain things to protect public health (for example, to stay off work). We have replaced these provisions with a single, general power for a local authority to request cooperation to prevent, protect against, or control an incidence or spread of infection or contamination presenting significant harm to human health.

In the consultation, we asked whether this power would be helpful. The vast majority of respondents to this question felt that it would. In the consultation, we proposed a discretionary power to pay an incentive payment, compensation or expenses to comply with the request. Several respondents suggested that paying people money as an incentive not to put people at risk was an unsound principle. We agree, and have therefore redrafted the regulation so that the power relates only to compensation payment.

In addition, some respondents argued that compensation for compliance should be a mandatory requirement of the local authority rather than a discretionary power. However, this would be to impose a non-discretionary financial burden on local authorities, which do not believe would be appropriate. Acting promptly to secure voluntary compliance using this power could prevent the local authority incurring a greater financial burden in the long run if a health protection incident were to develop further.

Currently, local authorities have the power to require a person to discontinue working with food. Some respondents argued for the retention of this power. However, we believe that the combination of a local authority request power backed up by JP order-making powers will be effective in protecting public health in these circumstances. A degree of judicial oversight is necessary to meet human rights concerns, and the threat of formal action is typically enough to ensure compliance.

a) Benefits

The benefits are:

- the availability of a broad and flexible power to protect public health, which could be backed by an application to a JP for an order if the requested action is not taken, or complied with;
- it helps to future-proof the health protection framework by allowing a local authority to deal with unforeseen threats to public health.

b) Costs

There might be a very small administrative cost associated with making the requests and following up on them. However, this is no different from the current powers whereby local authorities have the power to request that someone refrain from working. The administrative costs may also be higher if the JP power were to be relied upon in all circumstances.

Under the existing power, the local authority is obliged to pay compensation to a person that they request stay off work. Under the modernised version of the power, the local authority will have discretion to pay compensation for compliance. There may therefore be a small cost to the local authority of providing the discretionary compensation payment to comply with the request, but this, again, is no different from the current situation when a request is made for someone to stay off work.

The modernisation of this power allows the local authority to make other sorts of requests to protect public health. However, we do not believe it is necessary to quantify any new use of the power since we still believe that it will be used rarely, and the compensation payment is discretionary rather than mandatory. It is not predicted that this power will create any burden on business over what currently exists if someone is requested to stay off work.

5.6.5 Local authority power to restrict contact with dead bodies

We are modernising local authority powers to limit contact with a body that could present significant harm to human health through infection or contamination. This brings forward and modernises the aspects of current powers in this area that it appears desirable to retain, without replicating those provisions that are out of date.

The regulations will empower the local authority to take action, such as having the body moved to a place where contact can be restricted and issue a notice stating that unauthorised contact with the body is prohibited. At the moment, local authorities do have some powers to restrict contact with a body of a person who has died whilst suffering from certain infections, and local authorities do have standing powers to bury or cremate dead bodies where ‘no suitable arrangements’ have been made. However, the interaction of the powers is slightly updated under these modernised regulations so local authorities can specifically take action to move or restrict access to a body whose condition because of infection or contamination might represent a risk of significant harm to human health.

a) Benefits

The benefits are:

- any risk to human health from infection or contamination from a body is minimised;
- it provides a flexible way for a local authority to protect public health at minimum cost.

b) Costs

Making the notice would involve some cost to the local authority in terms of administrative time. There will also be some cost associated with the moving of the body, where necessary. However, we predict that such enforced movement of the body under these regulations will only be used very rarely. The action required might be as straightforward as moving the body to a lockable room before it is later taken for burial or to a mortuary. More unusual cases may require more costly movement or isolation procedures, but by their nature such cases would be rare. We therefore suggest that this movement power is more for use on a contingent basis, should a health protection professional come across a risk to human health that could be avoided by recourse to it. We therefore consider it inappropriate to try to estimate the costs associated with this power. It is not predicted that this power will create any burden on business.

5.7 Summary of costs

These regulations involve, for the most part, the modernisation of existing powers, so we do not believe that any new, significant costs will be incurred because of implementation of these regulations.

5.8 Risks

It is possible that the use of these powers might increase as awareness of the new or revised provisions increases. This brings a notional risk that increased use of legal powers rather than seeking voluntary cooperation could damage relationships between public health officials and those they deal with - members of the general public, headteachers, parents and employers. Should this happen, the likelihood of the power fulfilling the policy objective of protecting against a public health risk would be reduced. We think that public health officials will always prefer to aim for voluntary cooperation as a first step, and that this risk is therefore unlikely to be realised, but we propose that guidance will reinforce the point in order to mitigate this risk.

6. Costs of training

We do not believe there are significant extra costs associated with training for the new measures. No recurring costs arise, although a limited amount of one-off costs will be entailed.

The method of delivering the training is to be determined by the relevant organisations. This might be delivered in some cases by cascading information at training/education events, for example in local Health Protection Units (of the Health Protection Agency).

The Department of Health and the Health Protection Agency are developing policy and operational guidance on the new measures to assist the familiarisation process. The costs (as indicated in the table below) of producing the guidance will be borne by the Department and the HPA as part of their ongoing work.

The costs to those receiving training arise from the time required for completion of the appropriate training package at the relevant time. Below we set out our estimate of the time required for basic training in the new measures for the various groups affected. The maximum time envisaged for any one person is 2 hours.

Most people requiring training will be in professional positions, where they are required, as a matter of usual practice, to undertake “continuing professional development” (CPD) of their skills and competencies. The relatively short amount of time required to complete the necessary training, or to attend a meeting to discuss the changes, could be included in the individual’s CPD, and indeed should be, as it will cover essential information to enable them to carry out their roles effectively. This work will

supplant the training activity they would otherwise have undertaken and is therefore shown as a one-off opportunity cost.

We assume that solicitors working for local authorities on health protection cases will only be required - or wish - to become accustomed with the changes to the regulations when presented with a case requiring such knowledge. Since they would similarly have had to become accustomed to previous legislation prior to the change in regulations, we assume a zero incremental cost. In addition, we have assumed in this Impact Assessment that the number of cases arising under these changes in regulations is fairly small.

The relatively short amount of time required to complete the necessary on-line training to become aware of the changes to the regulations for the notification of diseases, means that the cost of training in this area is also fairly low.

Person requiring training	**Type of training required**	**Time needed for the training**	**Additional cost**
Scientific & administrative staff in laboratories (2 each per laboratory)	New notification requirements	1 hour average per person	Scientific staff: 2 x hourly cost of £26 = £52 per laboratory Admin staff: 2 x hourly cost of £12 = £24 per laboratory 252 (no. of labs) x £(52+24=76) = £19,152 total
Registered medical practitioners	New notification requirements Summary of other Part 2A provisions - JP orders and local authority powers	Marginal - information would be conveyed by "Dear Doctor" letter from the Chief Medical Officer or similar Registered medical practitioners may wish to acquaint themselves with the new Part 2A provisions - likely only if presented with a case requiring knowledge	None quantifiable ~ 0, due to the rare nature of cases
Solicitors employed by local authorities	Summary of all new provisions	Only required if presented with a case requiring knowledge	~ 0, due to the rare nature of cases
Health Protection Agency employees + individuals appointed by local authorities as proper officers for health protection work – Consultants in Communicable Disease Control, Consultants in Health Protection, Environmental Health Officers	New notification requirements, and other Part 2A provisions - JP orders and local authority powers	2 hours per person on average	c. 130 people across the country - 130 x 2 x £26 =£6,760

7. Summary of costs and benefits for final proposed regulations

	Lower estimate	Mid estimate	Upper estimate
Costs			
Notification Regulations (p.a.)	£80,529	£218,974	£489,105
Part 2A Orders Regulations* (p.a.)	£240	£720	£1,440
Local Authority Powers Regulations (p.a.)	None	None	None
TOTAL (p.a.)	**£80,769**	**£219,694**	**£490,545**
Training (one-off)	£25,900	£25,900	£25,900
Benefits			
Notification Regulations (p.a.)	-£120,000	-£240,000	-£360,000

* Note that costs here refer to the incremental costs of the preferred option as compared to Option 1

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	No
Small Firms Impact Test	No	No
Legal Aid	No	Yes
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	Yes
Race Equality	No	Yes*
Disability Equality	No	Yes*
Gender Equality	No	Yes*
Human Rights	No	Yes*
Rural Proofing	No	No

*The impact on race, disability, gender and human rights are considered as part of the Equality Impact Assessment, which is published alongside this document.

Annexes

Annex 1

Health Impact Assessment: Health Protection Regulations

These regulations will take a significant step towards the completion of a new, modern framework for the protection of public health from significant harm arising from infectious disease or contamination by chemical or radiological agents.

We do not believe that changes made to the regulations as a result of the consultation will have any impact on our assessment of their health impact.

Three specific questions need to be considered as part of this health impact assessment:

1- Are the potential positive and/or negative health and well-being impacts likely to affect specific sub groups disproportionately compared with the whole population?

As we have said in the Equality Impact Assessment, the policies are aimed at addressing risk to public health wherever a risk arises, and a person's membership or identification with a particular population sub-section is not a factor that would have a bearing on the requirements or the use of the powers. However, as pointed out in the Equality Impact Assessment, it is true to say that some diseases tend to affect specific sub-groups disproportionately compared to the whole population. The evidence base indicates that some infectious diseases can disproportionately affect lower socioeconomic groups - for example, the rate of tuberculosis in London is higher among homeless people. People in lower socioeconomic groups may also be more vulnerable to infectious diseases because of their relatively poorer living conditions (overcrowding, for example, is more prevalent in lower socioeconomic groups and can be associated with infectious disease transmission). Thus, individuals from lower socioeconomic status groups may more frequently be the subject of the powers. Compared to the existing legislation, the updated legislation goes further to protect the individual rights and freedoms of the individual. As explained in the main Impact Assessment, we are making regulations to protect the interests of vulnerable people (including those from lower socioeconomic groups) and ensure that these individuals are supported by an obligation on local authorities to provide information and have particular regard to their welfare as necessary.

Ultimately, these regulations allow actions to be taken to protect groups that might be particularly vulnerable to these infectious diseases, by allowing appropriate action to be taken to protect against an outbreak of these diseases.

2- Are the potential positive and/or negative health and well-being effects likely to cause changes in contacts with health and/or care services, quality of life, disability or death rates?

As these regulations replace existing legislation designed to protect public health, we do not believe that the updated regulations will result in a significant change in frequency of contact with health or care services (as compared to the effect of the current regulations). The modernisation of the legislation is designed to make a legislative solution to a public health threat easier to implement (compared to the existing situation). This may prevent morbidity and mortality associated with a specific public health threat such as a disease outbreak. The legislative safeguards put in place by the regulations also better preserve the human rights of those who are affected by the powers, potentially improving their quality of life compared to if they had been subject to the older legislative powers.

3- Are there likely to be public or community concerns about potential health impacts of this policy change?

The position of people with HIV has come under scrutiny during our work to prepare the regulations. Compared to the population of England as a whole, the prevalence of HIV is higher in men who have sex with men. (See http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1227515299695.) Some stakeholders have expressed the view that people with HIV could fear being made the subject of a JP order and that this would deter engagement with health services. This issue is discussed further in the Equality Impact Assessment.

Annex 2

Legal/Justice Impact Test: Health Protection Regulations

1. Broad outline

The power to make regulations to create offences in public health legislation is found within the new Part 2A of the Public Health (Control of Disease) Act 1984 (the 1984 Act), which was inserted by the Health and Social Care Act (2008) (the 2008 Act). The new Part 2A also specifies that those offences may not be punishable with imprisonment, a fine exceeding £20,000 or a further daily fine exceeding 2% of a level 5 standard scale fine (this is a high ceiling for offences because it potentially includes corporate offences/fines).

Following a formal consultation exercise, we are introducing three sets of regulations.

The 'Local Authority Powers Regulations' roll forward and modernise powers and duties originally given to Local Authorities (LAs) in relation to their health protection role by the 1984 Act. They include regulations to ensure that LAs can:

- keep a child off school if a child's attendance could present a significant risk to human health (because that child has a condition that could be passed to other children);
- obtain a list of contact details of pupils attending a school (where there is a threat to public health and a contact tracing exercise might have to be performed);
- restrict unnecessary contact with a dead body where such contact might represent a risk to human health.

The powers these regulations confer have their origin in the original 1984 Act. They were associated with offences. We are modernising these powers and the associated offences, so that when someone breaches the regulations outlined in paragraph 2, they commit an offence. Two new fines are also required. We want the fines associated with the offences to be substantial enough to be a credible reason to comply, so the legislation is not a 'paper tiger'.

Another set of regulations will make provision for the statutory notification of specified infectious diseases in humans by registered medical practitioners and laboratories for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England.

These new regulations will replace the current provisions in the 1984 Act and the Public Health (Infectious Diseases) Regulations 1988, and will:

- update the current list of diseases to be notified by registered medical practitioners, including provision for diseases that may be caused by emerging infectious diseases or chemical or radiological contamination;
- introduce a new requirement for diagnostic laboratories testing human samples to notify specified infectious diseases to the Health Protection Agency;
- provide timescales for notification by registered medical practitioners and laboratories.

We have dropped the existing offence in the 1984 Act for failure by a registered medical practitioner to report a notifiable disease to the proper officer of the local authority. This is because the current offence provision only appears to have been used extremely rarely and there are other ways in which compliance with this requirement can be encouraged or enforced (e.g. disciplinary procedures by the General Medical Council,

the professional regulatory body for registered medical practitioners).

We have created a new offence for failure to report a notifiable infectious disease by a diagnostic laboratory as a deterrent against not reporting and as a sanction when required.

The third set of regulations concerns the requirements to be met before a Justice of the Peace can exercise the power to make certain orders to prevent significant harm to human health from infection or contamination. These regulations do not include offences.

2. What we intend to achieve

The detail of the updated offences, and what they are intended to achieve, is outlined below:

The Local Authority Powers Regulations

- *When a parent fails to keep a child off school after being issued a notice to take such action: offence*: a fine not exceeding level 2 on the standard scale, and a fine not exceeding 50% of level 1 on the standard scale for every day subsequent that the parent fails to keep the child away. We want the fine to be substantial enough so the parent is compelled to comply with the order; also, we believe that an ongoing fine for non-compliance is necessary; although should this situation of ongoing non-compliance arise, other action would of course be taken to mitigate any ongoing public health risk.
- *A headteacher's responsibility to provide contact details of attendees at school to the local authority when asked to do so: offence*: a fine for the head not exceeding level 1 on the standard scale. This low fine relies on a headteacher's professional sense of responsibility and their general duty to comply with the law.
- *For unauthorised contact with a dead body (where contact with that body has been restricted) and for unauthorised entry into a room where a dead body is held: offences:* fines not exceeding level 3 on the standard scale. These fines have to be reasonably high to encourage compliance with the order. Certain individuals might have very strong feelings regarding their contact with a deceased next of kin being restricted, even if such a restriction is in place to protect their health. The regulations also require that any person in charge of premises where a dead body is lying must cooperate with the LA if it wishes to relocate the body, and that non-cooperation will be an offence, again with a fine not exceeding level 3 on the standard scale. The new offence is necessary, we feel, to give teeth to the requirement. In addition, following the consultation in which an influential stakeholder organisation argued in favour of the following approach, it is a requirement for the LA to serve the notice stating the terms of the restriction on any person having charge or control of the premises where the dead body is located. Failure of the person to put up the notice, or for any person to remove or deface the notice, is also an offence with a fine not exceeding level 3 on the standard scale.

The Notification Regulations

- *For failure by a diagnostic laboratory to report a notifiable infectious disease to the Health Protection Agency: offence:* a fine not exceeding level 5 on the standard scale, which we consider appropriate for the nature of the offence. The offence would apply to the corporate body for the laboratory, or if there is not one, to the director of the laboratory.

The fines associated with the offences are intended to be substantial enough to be a credible reason to comply, while not being excessive or unrealistic. Of course, we want to fulfil the policy objective of protecting public health, and while the offence is necessary to ensure that the legislation is enforceable, if an offence is actually committed, it implies someone has been exposed to a public health risk probably unnecessarily. Therefore, we have taken other broad powers to request people to take action to protect public health; and the new Part 2A gives LAs very flexible powers to go to a Justice of the Peace (JP) to obtain orders to get people to do things to protect public health, should the situation warrant it. The new Part 2A of the 1984 Act also outlines the offence incurred should the JP's order be breached.

One of the regulations regarding requirements to be met before a JP can exercise powers to make certain orders concerns the next of kin's right to apply for variation or revocation of a notice requiring the burial or cremation of a body. The next of kin might exercise their right to apply for variation or revocation of an order, and therefore impact on the work of JPs; the next of kin may also apply for legal aid for help in making such a variation or revocations. However, as the main IA explains, we expect a JP order for disposal of a body would be a rare occurrence, possibly once a year. It could not be assumed that the deceased person would have a next of kin or that the next of kin would always apply for variation or revocation. Therefore, the impact would be significantly less than one extra application a year nationally and can be regarded as having no significant impact on the work of JPs or legal aid.

3. Changes to what happens now

The table below outlines the changes to what happens now as regards the existing powers and associated offences we are modernising.

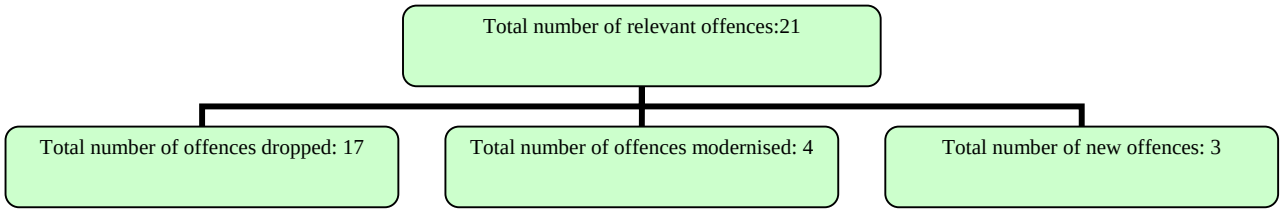
Existing related power (under the unamended 1984 Act)	**Estimated frequency of use of power (*not* associated offence), as indicated in main IA**	**Associated offence**	**To be carried over?**
S21 Exclusion from school of child liable to convey notifiable disease	3 times a year nationally	Punishable by a level 1 fine.	Yes, but at level 2
S22 List of day pupils at school having case of notifiable disease (requiring principal to supply a list)	Once a year nationally	Punishable by a level 1 fine.	Yes, still at level 1
S43, S44, and S45, concerning restricting contact with a dead body	Once a year nationally	All three Sections enforced by three separate level 1 fines.	2 (not 3) similar offences at level 3; 2 new offences at level 3
S11 Cases of notifiable disease and food	This is a standing duty	Punishable by a level 1 fine	No – this offence will be removed, but there will be a new offence to

poisoning to be reported			enforce a new requirement on diagnostic laboratory testing human samples to report notifiable infectious diseases to the Health Protection Agency. The penalty will be a level 5 fine.

The table above shows that the current powers that these regulations update are not used frequently (except of course for the standing notification requirements), and we see no reason to expect any significant increase in the use of the powers upon 'modernisation'. An offence occurs in relation to the notification requirements about once every twenty years nationally. We are not aware of any offences being committed in relation to the current "contingent" powers.

These powers need to be on the statute book to provide the tools health protection professionals may need to do their job. Their contingent nature means we do not anticipate them being used frequently. In most cases, we anticipate that they would give professionals the authority to take action and encourage cooperation, rather than having to resort to the powers themselves. As such, we think the offences associated with these powers would be used considerably less frequently than the powers themselves. We have not therefore attempted to cost up the legal impact of these regulations as we believe it would be so low so as to be negligible.

We are dropping a large number of offences from public health legislation without any form of modernisation. We are only rolling forward or introducing offences as outlined in the table above. A 'balanced account' of the number of offences to be dropped, modernised and introduced when these regulations come into force is shown below.



There is no next of kin right to apply for variation or revocation of an order concerning burial or cremation of a dead body under the unamended 1984 Act. This is a new (but as explained above, extremely limited in scope and effect) feature of the legislation.

4. What commitments have been given, and to whom

As explained in para 1, the Public Health Act (1984), was amended by the insertion of a new Part 2A by the Part 3 of the Health and Social Care Act (2008). Provisions for JP

orders and the proposed accompanying regulations (the “Part 2A orders” regulations, which the Department is obliged to consult upon before commencing Part 3 of the 2008 Act), replace most of the requirements and prohibitions in the existing Part 2 in the 1984 Act. However, there are certain standing responsibilities and requirements that Local Authorities need to fulfil in regard to health protection without resort to a JP, not covered by the new Part 2A itself, but about which the new Part 2A does confer powers to make regulations. We need to make such regulations so Local Authorities and Healthcare Professionals have the requisite tools available to fulfil their function to protect human health from risks of infection or contamination.

A commitment was made in the House of Lords during the passage of the 2008 Act that next of kin would be told if an application for an order was made in relation to burial or cremation of a dead body of a relative.

5. Concluding remarks

As explained in the Impact Assessment itself, we went out to consultation on draft regulations from July to September 2009. The consultation led to one new offence in relation to restricting contact with and access to a dead body (see above).

We believe these regulations would not have a significant legal impact either in terms of an increase in the frequency of offences; or in terms of legal aid. We do not propose further consideration of the legal impacts in our suite of impact assessments.

Annex 3

Additional diseases to be notified by registered medical practitioners	Estimated annual incidence	Comments
Any infection which presents or could present significant harm to human health; or contamination in a manner which presents or could present significant harm to human health.	~3,600/y	Based on experience of a large London Health Protection Agency Health Protection Unit, approximately 3% of total notifications and reports are in this category. The reporting is currently happening by the clinicians and others (including emergency services) on a voluntary basis.
Botulism	~20/y	* see source of data
Brucellosis	Very rare	* see source of data
Invasive group A streptococcal disease (including necrotising fasciitis)	~1500/y (including ~50 necrotising fasciitis)	This is based on the report of a European enhanced surveillance programme[14].
Legionnaires' disease	~400/y	* see source of data
SARS	Very rare	In the event of an outbreak numbers would rise. This would not happen on annual basis.
Total	**5,520**	

* The above estimates are based on epidemiological data available on the Health Protection Agency's website. These data are from multiple sources including laboratory reports, hospital records, clinical diagnosis, death certificate, etc. They provide the best estimates available.

Estimated total annual incidence of additional diseases	**5,520**
Numbers voluntarily reported at present (50-75%)	**2,760 – 4,140**
Estimated increase in the number of additional diseases notified	**1,380 – 2,760**
Current notifications	**121,813**
Percentage increase	**1.1% - 2.2%**

[14] Lamagni TL, et al. Epidemiology of Severe Streptococcus pyogenes Disease in Europe. J CLIN MICRO, Vol. 46, No. 7, p. 2359–2367.

EQUALITY IMPACT ASSESSMENT: REGULATIONS UNDER PART 2A OF THE PUBLIC HEALTH (CONTROL OF DISEASE) ACT 1984

Regulations under powers in Part 2A of the Public Health (Control of Disease) Act 1984 (inserted by the Health and Social Care Act 2008).

The regulations will complete the new, modern framework for the protection of public health from significant harm arising from infectious disease or contamination by chemical or radiological agents. This process began with the Health and Social Care Act 2008 (the "2008 Act"), which replaces out-of-date provisions in the Public Health (Control of Disease) Act 1984 (the "1984 Act") with a modern and flexible regime that is fully compatible with human rights requirements.

The regulations will provide the detail of the new provisions. A 12-week consultation on their content was held from 8 July - 30 September 2009.

The regulations will cover:

Notification of disease or contamination: provision for the statutory notification of specified infectious diseases and disease caused by non-infectious health hazards, i.e. chemicals and radiation, in humans. Notification will be made by registered medical practitioners and diagnostic laboratories for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of notifiable disease in England.

Currently there are provisions for statutory notification of specified infectious diseases in the 1984 Act and the Public Health (Infectious Diseases) Regulations 1988. These new regulations will replace the current provisions by:

- updating the current list of diseases that are notifiable by registered medical practitioners, including provision for notification of other infectious diseases or diseases caused by chemical or radiological contamination that present or could present significant harm to human health;
- introducing statutory notification of specified infectious diseases by diagnostic laboratories testing human samples.

Part 2A (JP) orders: some requirements on local authorities in connection with applications to a Justice of the Peace (JP) for an order under the new Part 2A of the 1984 Act, to protect the public from infection or contamination. The regulations will provide safeguards for people who might be the subject of an order. They will cover:

- the evidence to be produced;
- who must be notified and who can appeal;
- the person's rights to information and help to access support if needed;
- reporting of applications for JP orders to the Health Protection Agency.

Local Authority standing powers relating to their health protection role: replace or update existing powers in the 1984 Act. They will cover powers to:

- keep children off school;
- require a list of contact details of pupils attending a school;
- disinfect or decontaminate articles or premises if requested to do so;
- request action to be taken, or not taken, in order to protect public health;
- prohibit contact with dead bodies which pose a risk.

The regulations will set out the range and scope of powers local authorities will have without needing recourse to a JP.

Negative impact

We do not consider that the policies to be implemented in these regulations will have a negative impact on equality. The policies are aimed at addressing risk to public health wherever it arises, and a person's disability, ethnicity, gender, sexual orientation, age, or religion or belief, are not factors which have a bearing on the requirements or the use of the powers.

The **Notification regulations** will impose an ongoing duty on registered medical practitioners and laboratories. However, the powers in the **Part 2A orders regulations** and **Local Authority powers regulations** are expected to be used only rarely and might be described as "contingency" powers. This assessment is based on evidence of the use of the powers that they replace (currently in the 1984 Act). For example, there are now only about 10 JP orders a year. We have no reason to expect the numbers will increase when the new provisions are available.

Although there are generally no biological reasons for notifiable infectious diseases to affect individuals differently because of their race, disability, gender, sexual orientation, age, or religion or belief, some diseases are more common in certain groups of the population compared to the general population. For example, some notifiable diseases may affect age groups differently (e.g. Legionnaires' disease is more common in older people). Certain diseases may be more common in people who originate from or travel to countries where certain infectious diseases may be common (e.g. typhoid fever). See http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1231419801008?p=1158945066450

The effect of this would be a greater likelihood that the local authority powers would be required in relation to a particular group, to protect public health against certain diseases. However the effect on individuals in the group would be countered by the positive impact of the measures in helping to protect the health of the group. The overall effect is likely to be minimal (because the powers will be used infrequently).

Individuals' exposure to chemical or radiological health hazards may be due to the nature of their occupation, leisure activities, lifestyle, area of residence or neighbourhood or similar social factors. These parameters may have a correlation with race, disability, gender, sexual orientation, age, or religion or belief (e.g. area with a high proportion of an ethnic group, or some occupations being disproportionately represented by one gender or an age group).

It is therefore possible that some population groups will be at higher risk of exposure to chemicals or radiation depending on their circumstances. As above, the effect of this would be a greater likelihood that the local authority powers would be required in relation to a particular group, to protect public health against certain hazards. However the effect on individuals in the group would be countered by the positive impact of the measures in helping to protect the health of the group. The overall effect is likely to be minimal (because the powers will be used infrequently).

The particular relevance of the regulations to the six equality 'strands' is considered below. Note that the equality impact of the measures contained in the 2008 Act has already been considered as part of the Impact Assessment for the Health and Social Care Bill (available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433). We have not duplicated this work here.

Disability: We are unable to identify any reason why any of the measures proposed for these regulations will have a negative impact on people with a disability. In the local authority powers regulations, the local authority power to request anyone to do anything to protect public health might be seen as potentially posing difficulties for a disabled person - but the local authority would be expected to take account of any practical difficulties caused to someone with a disability, and to make provision to address them. If they did not, the request would not fulfil

the public health objective that it sets out to achieve.

In response to the consultation on the regulations, some respondents, on behalf of various organisations in the field of HIV and sexual health or as practitioners in that field, expressed the view that people with HIV could fear being made the subject of a JP order and that this would deter engagement with health services. It was also argued that we had failed adequately to address the significance of applying the powers to a lifelong disability as opposed to a time-limited infection, nor the application of powers to often stigmatised sexual behaviour. The point was made that the use of JP orders in relation to sexually transmitted infections (STIs) would have a disproportionate effect on BME groups, men who have sex with men and people with HIV.

These concerns have come about as a result of the new "all-hazards" approach to health protection, which has led to fears that people with HIV or other sexually transmitted infections could fall within the remit of the powers. However, the criteria for a JP order do not allow an order to be made unless there is no other way to deal with a risk of significant harm to human health. An order could not be made solely on the basis that an individual had HIV (or any other sexually transmitted infection) if the relevant criteria for making an order were not met. The regulations will increase the safeguards, because they impose very strict evidential requirements relating to the criteria which must be met before an order can be made.

We do not therefore believe that there is potential for any negative effect on this group. Nor do we think there could be any disproportionate effect, because the numbers of people subject to an order will be very low, and within that already very small group, the number with an STI will be very low indeed. We envisage that it will be rare for an order to be made in relation to a person with a sexually transmitted infection.

We recognise that despite these assurances some concerns may remain. We propose to address these through inviting participation in the preparation of guidance, and through monitoring the outcome of the new health protection powers. We have invited relevant organisations in the field of HIV and sexual health to participate in the preparation of guidance for local authorities and health protection professionals who will be responsible for implementing the new powers. We will also ensure that information from the reports to the Health Protection Agency of applications for orders (required under the regulations) will be published annually. This will allow the use of applications for orders to be monitored and provide transparency about the reasons for them.

Ethnicity: There are higher levels of incidence of some infectious diseases among some ethnic groups than others (for example, as above, typhoid fever). This could mean that the use of the powers to be provided in the regulations to mitigate the effects of the disease on public health will result in a higher proportion of people from a minority ethnic group than would be expected from their representation in the population coming into the ambit of the powers. The impact of these powers, taken together with those in the Act relating to JP orders (already considered in the context of the Impact Assessment for the 2008 Bill) will however be beneficial, because they safeguard the wider health and welfare of populations that might be exposed to a particular risk to health because of a characteristic of that population. The overall effect will be minimal due to the low frequency of use of the powers (see below).

Gender: The regulations apply to both genders equally (and to transgendered people) on the basis of risk to public health. We can see no potential for differential impact.

Sexual orientation: The position of people with HIV has come under scrutiny during our work to prepare the regulations. Compared to the population of England as a whole, the prevalence of HIV is higher in men who have sex with men. See http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1227515299695. Some stakeholders have expressed concerns that the powers could be used disproportionately against this group.

We do not see this as a valid concern because the powers are exercisable only on the basis of risk to public health. Sexual orientation, or HIV infection per se, are not relevant factors in this risk assessment.

Religion or belief: The local authority powers regulations propose to allow the local authority to restrict unnecessary contact with a body where such contact presents a significant risk to human health. Some religions believe in washing of the body, or burial of the body within a specified time frame, so that there is a potentially negative impact on these groups. It seems implausible that we could regulate to specify what sort of contact could be allowed under specific circumstances. Therefore, we have made the power flexible enough so that the local authority can be sensitive in its application, so that if a particular type of contact which might be considered by next of kin to be necessary on religious or belief grounds does not present a significant risk to human health, restrictions need not be imposed. According to the risk of infection and nature of transmission some forms of contact may be possible for some cases, but not for others. More details can be found at:

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947412580
or
Commun Dis Public Health 2001; **4**: 283-7

We estimate that this power would be used very rarely because the conditions that require such restrictions are themselves very rare (e.g. anthrax, viral haemorrhagic fever). It will be extremely rare for a local authority to restrict contact contrary to the tenets of religious belief of those who might wish to have contact with a body. Overall, the negative impact would be minimal due to the very low use of the power.

Age: Some notifiable diseases occur more frequently in certain age groups, such as Legionnaires' disease which mainly affects people over 50 years of age. Therefore, there are likely to be proportionately more notifications of certain infections in respect of this age group. However, this does not readily translate into a negative or positive impact for that group, as the purpose of notification is to allow effective intervention to protect others in the community from infection. There could be a positive impact for specific age groups if they were more likely to be the subject of interventions than other age groups. Overall the effect would be minimal.

We can see only one area in the regulations where a differential impact could apply. The local authority power to keep children off school obviously applies only to children (although their parents may be affected if time off work is needed as a result). While not being able to attend school for a limited period could be said to have a minor negative impact on the child in question, there is compensatory benefit to other children (and staff members) who are not infected as a result of the measure. The policy objective of this regulation is to provide the local authority with a power to help prevent communicable conditions being passed from child to child in an environment where children are in very close contact with a large number of their peers for much of the time. This is particularly relevant to younger children who may not have as strong an immune response or may not maintain as good standards of hygiene as older children or adults. It is worth noting that this is not a new power, but a modernisation of existing powers so that they better protect the rights of the individual.

We are aware that local authorities have a duty to ensure that educational provision for the ill child (or a child excluded from school for any reason) during their recuperation (or other form of exclusion) is appropriate. Section 19 of the Education Act 1996 states that: "Each local education authority shall make arrangements for the provision of suitable education at school or otherwise than at school for those children of compulsory school age who, by reason of illness, exclusion from school or otherwise, may not for any period receive suitable education unless such arrangements are made for them." We intend to remind local authorities of this duty in guidance to ensure that no child's education is adversely affected because of the exclusion.

Human rights: The regulations will be consistent with human rights legislation, in line with their enabling powers.

Deprivation of liberty / imposition of restrictions and requirements:

The primary legislation safeguards human rights by ensuring that a person cannot be subject to an order imposing restrictions or requirements under the Part 2A Order regime - including an order depriving the person of their liberty - without prior judicial oversight. The Part 2A orders regulations further enhance this safeguard by making a JP's power to grant an order conditional on certain evidential thresholds being met. As well as ensuring in general that orders are not made without a high standard of evidence being put forward, it also ensures that the principle of ECHR case law that the justification for depriving a person of their liberty must be 'reliably shown' is satisfied.

Furthermore, the Part 2A order regulations introduce additional safeguards which come into play after an order is made. The regulations provide for a person subject to an order to be given support, if required, in understanding the terms of an order, the reasons it was made, and their right to apply for it to be varied or revoked.

Keeping a child away from school:

We do not consider that keeping a child away from school interferes with that child's right to education by reason of section 19 of the Education Act and the obligation to provide continuing educational provision for those unable to attend school by virtue of their health.

But even if keeping a child away from school were to be an interference with a human right (a proposition we do not accept), we consider that judicial review suffices as a mechanism by which the decision can be reviewed. This is on the basis that the decision is one taken on the basis of specialist expertise and knowledge (following the House of Lords' decision in *Runa Begum*).

In any event, the draft regulations do provide for a right of review in respect of the decision with the review to take place within 5 working days of the request for a review
We do not therefore believe that we need to set up a formal mechanism of appeal against the use of this power, as human rights will be adequately protected by other safeguards within the regulations.

Therefore the answers to the key questions are:

Will the policy present any **problems or barriers** to any community or group? ~~Yes~~/No

Will any group of people be **excluded** as a result of your policy? ~~Yes~~/No

Does the policy have the potential to **worsen** existing discrimination and inequality? ~~Yes~~/No

Will the policy have a negative effect on **community relations**? ~~Yes~~/No

Positive impact

The regulations safeguard the interests of the small number of individuals who could fall within their ambit, and make provision for the welfare of vulnerable groups (more information on this is below). They may have an indirect positive impact, by helping to control the spread of diseases that particularly affect certain minority ethnic groups. However they do not, and could not, have a significant positive impact on equality by reducing existing inequalities.

The notification regulations might also bring a secondary benefit by allowing public health surveillance, providing information on infectious disease trends over time. In turn this allows services to be tailored to particular groups where the need arises. However it is not possible to quantify the positive effect of the notifications system as against other factors.

With regard to how our policy will meet our duty to:
1. Promote **equality of opportunity**?
2. Eliminate **discrimination**?
3. Eliminate **harassment**?
4. Promote **good community relations**?

establishing clear objective requirements which must be met in every case before an order can be made, thereby safeguarding against inappropriate use of these powers. We do not accept that such inappropriate use is a real possibility, but the existence of the evidential requirements might reassure those with concerns.

Evidence

Notification regulations

There is limited evidence published in peer-reviewed literature available on how existing notification requirements for infectious diseases might impact on equality issues and how the proposed changes may do so. We have considered:

- Current systems of statutory notification of infectious diseases and voluntary reporting of identified organisms by the laboratories
- Evidence published in scientific and medical journals
- Views of a number of Health Protection Agency consultants in communicable disease control or health protection who are proper officers for their relevant local authorities for the purpose of notification of infectious diseases.

The existing notification and voluntary reporting systems are designed to collect minimum data required for surveillance and public health action. They are not designed to collect information on equality issues. Although age and gender are usually reported by the notifying medical practitioners and reporting laboratories, ethnicity or race is not routinely reported. Information on sexual orientation, disability and religion or belief is not included in the notification systems and is almost never reported.

The notification system does not include follow-up information on patients and it is not possible to identify the impact on patients.

We conducted a database search for published national and international literature about equality impact of notification of infectious disease, including issues relating to race, age, gender, sexual orientation, religion or belief and disability. The search strategy is described in Annex 1.

We did not find any relevant published evidence of positive or negative impact of the notification of infectious diseases on equality despite the fact that many countries worldwide have established systems for notification of specified diseases.

Part 2A orders regulations and Local Authority powers regulations

The evidence for the answers above is drawn from actual experience of the existing public health protection powers. We have asked people working in health protection around the country about the impact of the regulations from an equality perspective. We also raised the issue at our stakeholder meeting on 26 January 2009. (See the Impact Assessment for more information about our information-gathering process.)

We have not been able to identify any relevant statistical collections or research evidence to draw on.

Screening assessment

Adverse impact is very unlikely. Moreover, the legislation and policy has been developed to mitigate the risks and consequences of any adverse impacts, should they occur. Positive impact in relation to equalities, beyond the protection of an individual's human rights, is also unlikely.

The regulations are concerned primarily with the protection of public health against risks which apply to all groups in society. They do not seek to achieve social change, which is outside the remit of this policy. They do seek to ensure that human rights are protected and support is given to those groups who might need it.

Next steps

We do not consider, on the basis of the above, that a full EqIA is required for these regulations.

Name of person completing the EqIA: Janet Whybrow

Date EqIA completed: 14 December 2009

Name of Deputy Director / Director General endorsing EqIA: J.C. Stopes-Roe

Signed: ***Jonathan Stopes-Roe***

Date EqIA endorsed: ***17 December 2009***

Annex 1

Search strategy for notification regulations

We searched the last 20 years of these resources:

- PubMed
- Web of Knowledge e.g. combined search of
  - Web of Science
  - Medline
- National Library for Health databases, including
  - British Nursing Index (BNI)
  - Cumulative Index of Nursing & Allied Health (CINAHL)
  - Health Business Elite
  - Health Management Information Consortium (HMIC)
  - PsycINFO
- Cambridge Scientific Abstracts (CSA) databases
  - Applied Social Sciences Index and Abstracts (ASSIA)
  - Social Services Abstracts
  - Sociological Abstracts

We used the following terms:

disease notification
notifiable disease
reporting disease
surveillance
epidemiology

[For Sociological Abstracts and ASSIA we used - (disease and surveillance) and (infectious or communicable)]

In combination with

1- ‘race’ or ‘ethnicity’ or ‘ethnic minority’ or ‘BME’

2- ‘gender’ or ‘sex’ or ‘trans-sex’ or male or female

3- ‘sexual orientation’ or ‘homosexual’ or ‘heterosexual’

4- ‘aged’ or ‘elderly’

5- ‘disabled persons’ or ‘handicapped’ or ‘people with disabilities’ or ’persons with disabilities’ or ‘physically challenged’ or ‘physically disabled’ or ‘physically handicapped’ or ‘learning disabilities’ or ‘learning disorders’ or ‘ developmental academic disorder’ or ‘adult learning disorders’ or ‘developmental disorders of scholastic skills’

6- ‘religion’ or ‘religious beliefs’