Title:
Amendments to Schedule 5 of the Anti Terrorism, Crime and Security Act (2001)
IA No: HO
Lead department or agency:
Home Office
Other departments or agencies:

Impact Assessment (IA)

Date: 29/10/2011
Stage: Final
Source of intervention: Domestic
Type of measure: Other
Contact for enquiries:

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£1.4m	£0.4m	£0m	Yes	OUT

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

ATCSA (2001) lists the pathogens and toxins that require suitable security measures to be put in place. The list was reviewed by an experts' panel and a number of proposals were suggested, amongst them the removal and addition of certain substances to ensure the installation of proportionate security measures. The Government regulates the storing of these high risk substances to ensure adequate and proportionate security measures are put in place to protect biological agents from criminal misuse whilst maintaining an environment conducive to legitimate research and progress in the biological research field.

What are the policy objectives and the intended effects?

The Government must take into account public health needs and the risk to the public if biological agents are misused by criminals while still allowing scientific progress in the area. The objectives of the policy are to a) reduce the availability of pathogens to terrorists, and b) reduce the non-proportionate physical and personnel security burdens on laboratories.

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

Option 1: Do nothing.
Option 2.i) Add SARS Coronavirus to Schedule 5.
Option 2.ii) Remove Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana from Schedule 5.
The preferred option is Option 2. This provides for the installation of proportionate security measures by laboratories in the case of part (i) and removal of unnecessary burdens in the case of part (ii).

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2013

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Date: 30/01/2012

Summary: Analysis & Evidence

Policy Option 2

Description: (i) Add SARS Coronavirus from Schedule 5 and (ii) Remove Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana from Schedule 5

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** £1.4m

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

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

None.

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

None from part (ii). From part (i), no additional costs are expected since only one laboratory in the UK holds SARS Coronavirus. This laboratory also holds other Schedule 5 substances in the same category and already has the necessary security arrangements in place. Additionally, the consultation asked interested parties whether they would need to acquire the substance in the foreseeable future and none thought they would.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		£170,000	**£1.4m**

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

From part (ii), savings by the public and private sectors on inspections (premises holding Schedule 5 substances are inspected once a year by a CTSA and a civilian to ensure the appropriate security measures are in place and to offer advice regarding their implementation) of approximately £110,000 p.a. and £50,000 p.a. respectively

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

The benefits of part (i) are for the general public and would be ongoing: the aim of putting a substance on the Schedule is to reduce the likelihood of terrorists acquiring the substance and thereby reducing the likelihood of its misuse. The benefits of part (ii) are: Private sector – the laboratories which choose to discontinue certain security arrangements will benefit from this proposal in terms of savings on maintenance costs of security arrangements; Wider – Consultees mentioned that research involving these substances may become easier to progress as a result of the removal from Schedule 5.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

For part (i): There may be additional costs if other laboratories decided to acquire SARS Coronavirus in the future. However, no consultees thought this likely to be the case. For part (ii): Assuming this leads to a reduction in security arrangements, this may increase the probability that terrorists acquire these substances. However, we have assessed there is little potential for malicious and effective use. Key additional sensitivities are: (i) The benefits could be less if CTSAs spend less than one day at the site, or more if they spend longer; (ii) Savings for law enforcement could be greater than expected if the number of laboratories that would have been inspected had no changes taken place increases over time.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** N/A	**Net:** N/A	Yes	OUT

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

Use of biological agents: the threat

Terrorist organisations aspire to use biological weapons. There have been a number of attacks using biological agents. In 1984 a religious cult called the Rajneeshees contaminated salad bars in restaurants in Oregon, USA with salmonella: 750 people became sick. Between 1993 and 1995, the Japanese cult organisation Aum Shinrikyo tried to manufacture biological agents including anthrax and Botulinum toxin. Five people died when envelopes containing anthrax powder were sent to addresses in the US in 2001. Suspected anthrax contamination during this time also caused considerable social disruption and decontamination costs. In January 2003, attempts by an Algerian cell in London to make the toxin ricin were disrupted.

Al Qa'ida supports the use of CBRN (chemical, biological, radiological and nuclear) weapons against civilian targets and to try to acquire them. They established facilities in Afghanistan during the rule of the Taliban to research chemical and biological weapons and training in the use of contact poisons was provided to large numbers of Al Qa'ida members.

Furthermore, the internet has made information widely available on the technology of CBRN devices and the materials which might be used to develop them. This significantly increases the risk of malicious use of hazardous biological agents.

Legislation

The objective of the Anti-Terrorism, Crime and Security Act 2001 (ATCSA) is to ensure that the Government has the necessary powers to counter the terrorist threat to the UK.

Within the Act, Part 7 sets out measures to ensure compliance with security requirements; Section 58 refers to the pathogens and toxins to which requirements apply; and the list of dangerous pathogens and toxins (collectively referred to as biological agents) that fall under the scope of the Act are contained in Schedule 5.

In order for a substance to be included in Schedule 5, The Secretary of State must be satisfied that the pathogen or toxin could be used in an act of terrorism to endanger life or cause serious harm to human health.

Security requirements

ATCSA gives the police powers to inspect premises that hold substances listed in Schedule 5 on an annual basis; requires that suitable security measures be put in place; and sets out the measures needed to ensure compliance.

Within Schedule 5, substances are divided into three categories; different levels of protection are attached to each category. Because of the classification level of this document, we cannot go into details but this does not affect materially the readers' understanding.
However, all laboratories regardless of the "level" of the Schedule 5 substance(s) they hold have to maintain a full inventory of stocks, comply with personnel security measures and have in place site and information security plans. Depending on what type of substances are held, to ensure that substances are dealt with in a commensurate way, physical security measures vary. Where multiple substances are stored or used at a particular site, security requirements must be achieved in line with the higher risk substance.

Inspections are carried out by Counter-Terrorism Security Advisors (CTSAs) who are located within police forces and are responsible for providing specialist protective security advice to local organisations. Their work is coordinated by the National Security Counter-Terrorism Office (NaCTSO). It is the

responsibility of the CTSAs to undertake security assessments of laboratories holding Schedule 5 substances and, as stated above, they have the power to require improvements to the security arrangements operating.

Review of the substances included in Schedule 5

In 2007 the Prime Minister asked Lord West (then the Home Office Parliamentary Under-Secretary of State for Security and Counter-Terrorism) to review what more needed to be done to protect against terrorist use of chemical, biological, radiological and explosive materials. The review found *inter alia* that Schedule 5 should be reviewed to ensure that measures to protect the listed substances were proportionate to the risks they posed. In 2008 the Home Office commissioned a group of experts from across Government and academia to review, in light of recent scientific and healthcare developments, the list of pathogens and toxins contained within Schedule 5 of ATCSA. The group was led by Professor Lightfoot of the Health Protection Agency (thereafter referred to as the Lightfoot Review) and included representatives from the National Counter- Terrorism Security Office, Department of Health, Department for Environment, Food and Rural Affairs, Defence Science and Technology Laboratory, National Institute for Biological Standards and Control, Association of British Pharmaceutical Industry, Imperial College, Health and Safety Executive, Centre for the Protection of National Infrastructure and the Home Office.

To help identify which biological agent should be included or excluded, the Lightfoot review considered the following criteria:

- Availability
- Ease of production/proliferation
- Ease of dispersion
- Amount required to create a big impact
- Persistence in the environment
- Susceptibility of the population
- Availability of treatment
- Time needed to cause an impact

The Lightfoot review recommended that SARS Coronavirus be added to Schedule 5 and that Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana be removed.

A.2 Groups Affected

The groups likely to be affected by the proposals are:

- Biological science laboratories;
- Law enforcement officers; and
- The general public as the ultimate beneficiary of security measures and progress in the biomedical field.

A.3 Consultation

Within Government

The Lightfoot review included representatives from the National Counter-Terrorism Security Office, Department of Health, Department for Environment, Department of Food and Rural Affairs, Defence Science and Technology Laboratory, National Institute for Biological Standards and Control, Health and Safety Executive, Centre for the Protection of National Infrastructure and the Home Office.

Public Consultation

The public consultation was published twice: once in April 2010 and again in March 2011. The consultation document was made available through the Home Office website. The first 12 week consultation was not promoted due to pre-election period rules. The second 12 week consultation period was promoted through emails to interested parties. The Home Office received 20 responses during the two consultation periods from the following organisations:

- National Counter-Terrorism Security Office

- Health Protection Agency (HPA)
- Belfast Department of Justice
- University of Edinburgh
- Imperial College London
- Oxford University
- University of Southampton
- University College London (UCL)
- The University of Manchester and University Hospital South Manchester
- University of Cambridge
- Greater Manchester Police
- Pfizer Ltd
- Westward Laboratories
- ILS - International Laboratory Services
- Scottish Water
- Cancer Research UK London Research Institute
- Sheffield Teaching Hospitals NHS Foundation Trust

The outcomes of the consultation were that six of the consultees supported adding SARS Coronavirus to the list and none of the consultees suggested we should do nothing; fifteen of the consultees supported the removal of the four organisms (Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana) from the Schedule and none of the consultees supported doing nothing; six consultees agreed that the recommendations would result in proportionate measures but two disagreed because the evidence behind the proposals was not given in the public document. Additionally and inter alia, consultees suggested several other substances should be removed from the Schedule but in order not to delay the implementation of the Lightfoot Review recommendations, these suggestions will be examined at the next review to be held in 2013.

B. Rationale

Although biological agents are of interest to terrorists, they are predominantly used for legitimate purposes and contribute substantially to advances in research in the fields of medical science, biotechnology, the pharmaceutical industry, agriculture, etc. Research outputs are directly and indirectly exploited to the benefit of the UK economy, through the development of innovative products and processes, including new medical treatments and diagnostics, novel approaches to industrial processes, and practical applications for agriculture and food production. As such, the security of these substances must be proportionate to the risks and the right balance must be struck so as not to restrict developments in research.

Furthermore, leaving substances in Schedule 5 that pose no or low risk of misuse by terrorists on the list can undermine the credibility of the legislation, possibly lead to non-compliance, and place unnecessary burdens on businesses.

However, Schedule 5 lists the substances that are deemed to pose a substantial threat if it falls in the wrong hands. The Government must ensure that minimum security standards are installed at locations where Schedule 5 substances are held. The list was reviewed recently and to ensure requirements are commensurate to the risks, it will be reviewed every two years.

C. Objectives

The policy objectives of amending Schedule 5 in line with the Lightfoot Review recommendations are:
- To reduce the accessibility of pathogens to terrorist use; and
- To reduce unnecessary security burdens on those laboratories that hold only low risk substances.

If the recommendations are implemented, reassurance will be provided that holders of SARS Coronavirus samples are beholden to the Law and that laboratories which plan on holding only Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and/or Cladophialophora bantiana do not have to install unecessary measures.

D. Options

Option 1: Do nothing.

Option 2.i) Add SARS Coronavirus to Schedule 5.
Option 2.ii) Remove Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana from Schedule 5.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

- We use a discount rate of 3.5% over 10 years as per HMT Green Book guidance.
- The number of laboratories holding schedule 5 substances was obtained from Home Office records.
- Costs of security measures to be put in place were obtained from the consultees.
- The estimate of the number of laboratories who may be affected by the proposed changes was obtained from the consultees.
- SARS figures from the Asia Business Council can be found at: http://www.asiabusinesscouncil.org/docs/DiseaseBriefing.pdf
- Estimates of the salaries for the CTSA (£50,000 p.a.) and the civilian (£25,000 p.a.) who accompanies him/her for the annual inspection were obtained from the National Counter Terrorism Security Office (NaCTSO).
- A typical site survey (inspection plus a report) lasts one day (source: NaCTSO)
- To obtain a salary per hour, we assume 42 working weeks per year, 7 hours per day. Therefore in total (for a CTSA and a civilian) the salary cost per hour is: £51/hour
- Travel expenses: 40 pence/mile (source: Home Office). We assume a typical trip involves travelling 50 miles
- Salaries of bio-safety officers were obtained from two job adverts on the Science and Technology Recruitment (http://www.sci-techrecruitment.co.uk/job_section/jobs/job135.html) and University of London (http://www.ucl.ac.uk/hr/vacancies/adverts/LC43.html) websites.

OPTION 2(i) – Add SARS Coronavirus to Schedule 5

COSTS

None. Only one laboratory in the UK holds SARS Coronavirus. This laboratory also holds other Schedule 5 substances in the same category and already has the necessary security arrangements in place. Additionally, the consultation asked interested parties whether they would need to acquire the substance in the foreseeable future and none thought they would. Also, whether a laboratory holds one or more same-category Schedule 5 substances does not make a difference in terms of time spent inspecting the premises for law enforcement. No wider (environmental, social, etc) costs associated with this option have been identified.

BENEFITS

The benefits are for the general public and would be ongoing: the aim of putting a substance on the Schedule is to reduce the likelihood of terrorists acquiring the substance and thereby reducing the likelihood of its misuse. According to the Asia Business Council, about 8,000 SARS cases were reported in 2003, resulting in approximately 800 deaths, mainly in Asia.

ONE-IN-ONE-OUT (OIOO)

COSTS (INs)
None (see above)
BENEFITS (OUTs)
Not quantified (see above).
NET
Zero.

OPTION 2(ii) – Remove Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana from Schedule 5

COSTS

There would be no costs associated with this option (the security costs incurred are sunk and therefore not taken into account).

BENEFITS

No one-off benefits have been identified but there would be ongoing benefits for both the public sector and the private sector.

Public sector: Premises holding Schedule 5 substances are inspected once a year by a CTSA and a civilian to ensure the appropriate security measures are in place and to offer advice regarding their implementation. These visits take typically one day and the travelling incurred is typically 50 miles (this is our working assumption and we include a sensitivity analysis). Approximately 300 laboratories hold only one of the above-mentioned substances and no other Schedule 5 substance.
Savings calculations:

Salary costs: £51/hour x 7 hours = £357
Travel costs: £0.4/hour x 50 miles = £20

Total inspection costs are: (£357 + £20) x 300 laboratories = £113,100 p.a., which we will round to £110,000 p.a. to avoid spurious accuracy. Assuming the number of laboratories remains the same over time, this equates to a saving of approximately £940,000 in NPV terms.

Sensitivity: If the travelling incurred is + or – 30 miles, i.e. 20 miles and 80 miles, it would affect costs as follows:

- 20 miles: travel costs would be £8 (£0.4/hour x 20 miles) and total inspection costs would be £109,500 p.a. or £910,000 in NPV terms.
- 80 miles: travel costs would be £32 (£0.4/hour x 80 miles) and total inspection costs would be £116,700 p.a. or £970,000 in NPV terms

To increase/decrease the distance travelled by +/-60% entails an increase/decrease in total inspection costs of +/-3%.

Private sector:
During inspections of premises holding Schedule 5 substances, a bio-safety officer from the laboratory accompanies the CTSA and civilian. This will no longer be required, therefore we estimate a saving:
Savings calculations:

Salary costs: £26/hour x 7 hours = £179

Total inspection costs are: £179 x 300 laboratories = £53,600 p.a., which we will round to £55,000 p.a. to avoid spurious accuracy. Assuming the number of laboratories remains the same over time, this equates to a saving of approximately £450,000 in NPV terms.

Additionally, the laboratories which choose to discontinue certain security arrangements will benefit from this proposal in terms of savings on maintenance costs of security arrangements, however, we surveyed some laboratories and they said they would carry on maintaining their security arrangements.

Wider: Consultees mentioned that research involving these substances may become easier to progress as a result of the removal from Schedule 5.

ONE-IN-ONE-OUT (OIOO)
Costs (INs)
None identified.
Benefits (OUTs)
£55,000 p.a. (see above)
NET
£55,000 p.a.

F. Risks

OPTION 2(i) – Add SARS Coronavirus to Schedule 5

Although only one laboratory holds SARS Coronavirus and no consultees thought that another laboratory would acquire it in the near future, it is a risk one or more laboratories decide to acquire SARS Coronavirus (out of 54 notifications the Home Office received (laboratories have to notify the HO when acquiring a Schedule 5 substance) over the past 9 years, 7 concerned substances in the same category as SARS Coronavirus). Acquiring SARS Coronavirus will only have a financial impact if the laboratory does not already hold same-category substances, and in the case of law enforcement, if the laboratory does not hold any other Schedule 5 substances.
An inspection costs approximately £377, security measures (capital cost) costs between £9,000 and £50,000 and the maintenance costs of these measures are also very variable and will depend on the nature of the security measures (maintenance costs can include monitoring costs, repair/servicing costs, energy consumption costs, etc).

OPTION 2(ii) – Remove Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana from Schedule 5

Assuming this leads to a reduction in security arrangements, this may increase the risk that these substances are acquired for malicious use. However, some laboratories indicated that they would carry on maintaining their security arrangements regardless.

Sensitivities

The benefits are sensitive to:
- The duration of an inspection, and
- The number of laboratories.

G. Enforcement

Enforcement of the policy is compliant with the principles of the Hampton Code as follows:
- By removing substances from Schedule 5 we are reducing unnecessary burdens on businesses and law enforcement agencies;
- The policy places substances into security categories based on an assessment of the risk posed by their use by terrorists and proportionate security measures are assigned to each category;
- The policy does not create a new regulator;
- There is no clear need to protect the four substances to be removed from Schedule 5;
- By removing security requirements for substances no longer considered to pose a terrorist risk, the policy recognises the need for economic progress; and
- Site security is assessed against national standards to ensure a consistent approach. The results of the site specific assessment are shared with the site managers for openness.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2(i)	0	Not quantified
2(ii)	0	£0.9 million (PV; to the public sector)
		£0.5 million (PV; to the private sector)

Source:

The preferred option, supported by the consultees, is to take up the recommendations of the Lightfoot Review:

- To add SARS Coronavirus to Schedule 5; and
- To remove *Mycobacterium tuberculosis*, *Clostridium perfringens*, *Cryptococcus neoformans* and *Cladophialophora bantiana* from Schedule 5.

I. Implementation

The Government plans to implement these changes on 1 October 2012 subject to agreement from the relevant cabinet committees and debate in both Houses of Parliament.

The following tasks will be allocated:
Seek clearance from the Regulatory Policy Committee – CBRNE unit, CT social science – Oct 2011
Seek cabinet committee clearance – CBRNE unit –Oct 2011
Draft the Statutory Instrument and Explanatory Memorandum – HO LAB, CBRNE unit – Feb 2012
Lay before both Houses of Parliament – HO LAB, CBRNE Unit, Parly unit – April 2012

J. Monitoring and Evaluation

The list of substances in Schedule 5 will be reviewed every 2 years, as recommended by the Lightfoot review. Modern science can be fast moving and new and emerging diseases will need to be considered.

Basis of the review: To keep up to date with emerging diseases and scientific advances.
Review objective: To check that high risk substances are properly secured and to ensure there are no unneccessary burdens on laboratories holding only low risk substances.
Review approach and rationale: A cross-Government and Academic Expert group will be asked to review the list of substances in Schedule 5. They will be asked to consider the appropriateness of the security category for the substance (and, therefore, the appropriate security controls) and whether any substances should be added or removed from Schedule 5. Good evidence will be required for each recommendation. CTSAs will be surveyed for concerns from sites about disproportionate measures. Public and Ministerial correspondence will also be taken into account.
Baseline: Number of notifications per year up to 2011 and number of complaints received about disproportionate measures.
Success criteria: Success would mean that the risk of acquisition of substances on Schedule 5 from a site is reduced and there are no complaints from laboratories saying that measures are disproportionate.
Monitoring information arrangements and data collected: Ongoing scientific research will assist in identifying new substances and advances that might make inclusion of a substance unsuitable.
CTSAs return data on the number of sites included in their inspection regime every 6 months. This data can be used to see how many sites are removed from the requirement for an annual inspection. This data also includes an assessment of compliance with security advice at each site.
The Home Office will collect number of notifications (as and when they arrive) and number of complaints (as and when they arrive) about the proposed regime. Someone within the Office for Security and Counter Terrorism (OSCT) will be in charge of data collection.
The effectiveness of the policy will be assessed in 2013 for the next review of the substances in the Schedule.
Projected outcome and counterfactual: It is expected that the number of complaints will diminish when surveyed. If the proposals are not implemented, particularly option 2(ii), we would expect the number of complaints to remain the same or even to increase.

K. Feedback

We will ask interested parties to complete a survey on the effects of the policy one year after implementation. The results of this survey will be considered as part of the expert review in 2013.

Annex 1. Specific Impact Tests

Statutory Equality Duties

Equality Impact Assessment
On the advice of the Strategic Diversity Action Team, this impact assessment and the consultation form part of the equality impact assessment.
No consultees thought any community or group would be unfairly affected by this policy.

Economic Impacts

Competition Assessment
The amendments to the Act are unlikely to affect competition. The recommendations do not impose additional costs and there is no expected entry onto the market in the foreseeable future therefore we do not anticipate an adverse impact on competition.

Small Firms Impact Test
There are very few small companies involved in microbiology work and information from consultees suggests none would be concerned with the addition of SARS Coronavirus.

Social Impacts

Justice
The Ministry of Justice carefully considered the proposal and decided that it did not need to be subject to clearance through the Criminal Offences Gateway. The amendments to the Act will not have an impact on justice.