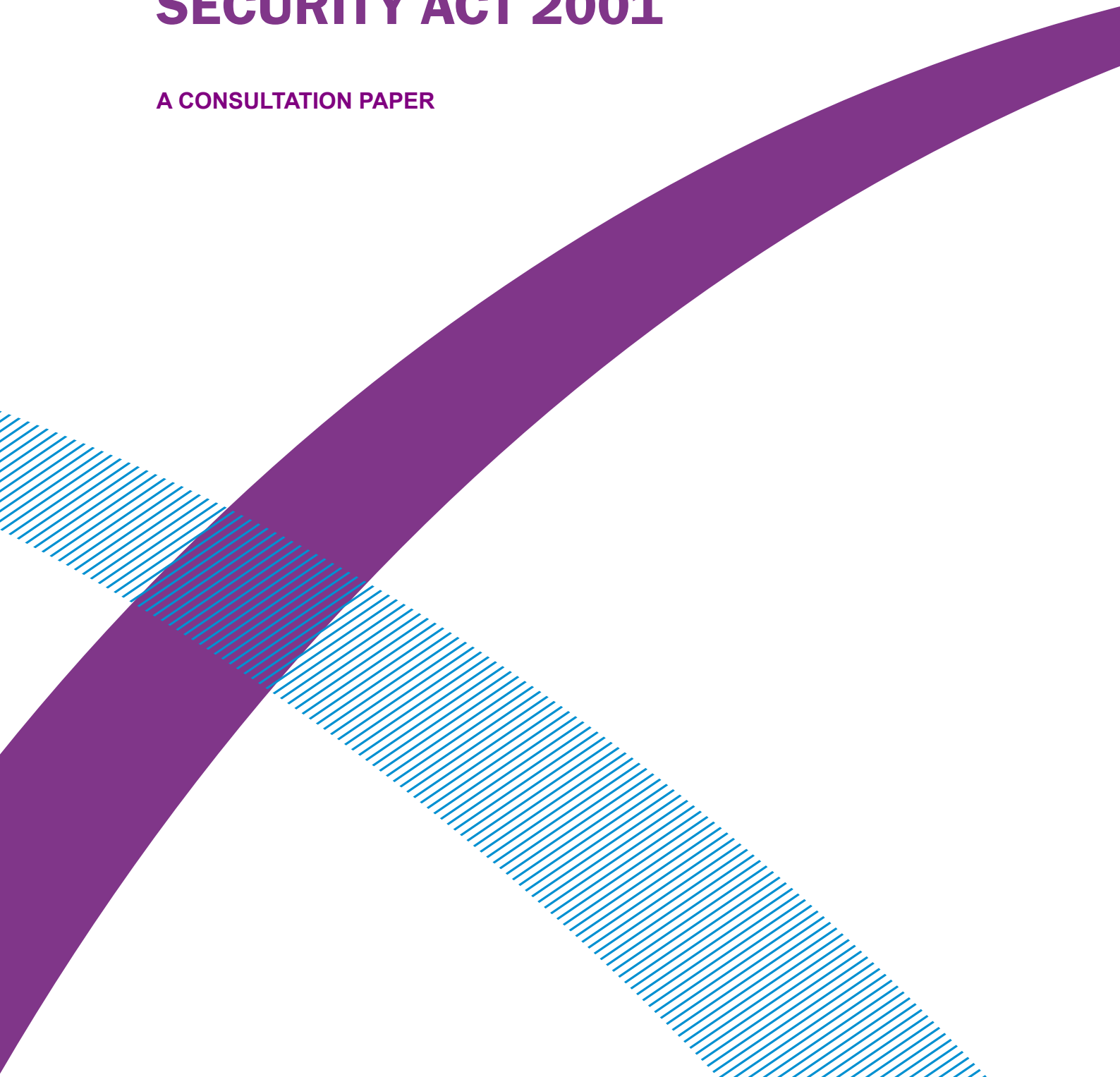
Home Office

AMENDMENTS TO THE ANTI-TERRORISM CRIME AND SECURITY ACT 2001

A CONSULTATION PAPER



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SUMMARY

SCOPE OF THE CONSULTATION

Topic of this consultation	How to amend the list of Schedule 5 Pathogens within the Anti-Terrorism Crime and Security Act 2001.
Scope of this consultation	To seek views on the costs and benefits of the options identified for amending the list.
Geographical scope	England, Scotland and Wales
Impact assessment	An impact assessment is attached.

BASIC INFORMATION

To	This consultation is open to everyone, but we would particularly like to hear from laboratories that handle/ store pathogens, local CTSAs, police forces and health trusts.
Duration	Until 17 June 2011
Enquiries	CBRNE Unit Home Office Office for Security and Counter Terrorism 5th Floor, Peel Building 2 Marsham Street London SW1P 4DF Tel: 020 7035 0896 Email: public.enquiries@homeoffice.gsi.gov.uk
How to respond	Postal address as above. Email: ATCSAconsultation@homeoffice.x.gsi.gov.uk
Additional ways to become involved	This will be a written consultation exercise. Please contact the CBRNE Unit (as above) if you require a copy of this paper in any other format, such as Braille, large font or audio.
After the consultation	A summary of responses will be published before or alongside any further action.

BACKGROUND

Getting to this stage	A group of experts from across Government and academia reviewed the current legislation. Recommendations were made to amend the list of scheduled substances.
Previous engagement	Ministers and officials have been discussing with stakeholders the extent of the problem and the available options.

INTRODUCTION

The purpose of this consultation paper is to seek views on amending the list of Schedule 5 pathogens that fall under Part 7 of the Anti-Terrorism Crime and Security Act 2001 (ATCSA) (which can be found at http://www.opsi.gov.uk/Acts/acts2001/ukpga_20010024_en_1). It sets out the existing list and controls and what is known about the threat of terrorist use of pathogens and toxins within the UK. The main paper discusses options for amendments to the list and seeks views on the best way forward.

This paper can be downloaded from www.homeoffice.gov.uk.

This consultation is being conducted in line with the Government's Code of Practice on Consultation, the criteria for which are set out in annex A of the paper.

An impact assessment is included at **annex B.**

The Government welcomes informed views from any quarter and therefore invites responses from any interested parties.

The consultation period will end on 17 June 2011. We expect to publish a summary of responses before or alongside any further action, and this will be made available on the Home Office website.

HOW TO RESPOND

The closing date for responses to this consultation is 17 June 2011.

You can email your views to us at: ATCSAconsultation@homeoffice.x.gsi.gov.uk

Or you can write to us at:

CBRNE Unit
Home Office
Office for Security and Counter Terrorism
5th Floor, Peel Building
2 Marsham Street
London SW1P 4DF

Additional copies of this paper can be downloaded from our website at www.homeoffice.gov.uk.

ALTERNATIVE FORMATS

You should also contact the Chemical, Biological, Radiological, Nuclear and Explosive (CBRNE) Unit if you require a copy of this consultation paper in any other format, such as Braille, large font or audio.

RESPONSES: CONFIDENTIALITY & DISCLAIMER

The information you send us may be passed to colleagues within the Home Office, the Government or related agencies.

Furthermore, information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation but we cannot give assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Home Office.

Please ensure that your response is marked clearly if you wish your response and name to be kept confidential.

Confidential responses will be included in any statistical summary of numbers of comments received and views expressed.

The Home Office will process your personal data in accordance with the DPA; in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Individual responses will not be acknowledged unless specifically requested.

Representative bodies are asked to give a summary of the people and organisations they represent when they respond.

PART 1: EXISTING CONTROLS

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. Part 7 of the Act is intended to improve the security of dangerous substances that may be targeted or used by terrorists. The Act gives the police powers to inspect premises that hold listed substances and require suitable security measures to be put in place.

Part 7 of the Act sets out measures to ensure compliance with security requirements. The list of dangerous pathogens and toxins (biological agents) that fall under the scope of the Act are contained within Schedule 5. Under the legislation:

- Police have powers of entry to relevant premises to assess security measures.
- Police can require occupiers to provide information about the security of any dangerous substances kept or used on their premises, and about persons with access to these substances.
- Police have the power to require the occupier of the premises to make improvements to the security arrangements operating there.
- The Secretary of State has the power to require the disposal of any dangerous substances kept or used on premises where security arrangements are unsatisfactory.
- The Secretary of State has the power to require that any specified person be denied access to dangerous substances or the premises in which they are held, where this is necessary in the interest of national security.
- It is an offence for occupiers of premises to fail, without reasonable excuse, to comply with any duty or directions imposed by or under part 7 of the Act.

Counter-Terrorism Security Advisors (CTSAs) are located within police forces and are responsible for providing specialist advice about protective security measures to local organisations. Their work is coordinated by the National Security Counter-Terrorism Office (NaCTSO). It is the responsibility of the CTSAs to undertake risk assessments of ATCSA laboratories and, as stated above, they have the power to require improvements to the security arrangements operating.

The list of pathogens and toxins that fall under Schedule 5 currently are below.

VIRUSES (AFFECTING HUMANS)

- Chikungunya virus
- Congo-crimean haemorrhagic fever virus
- Dengue fever virus
- Dobrava/Belgrade virus
- Eastern equine encephalitis virus
- Ebola virus
- Everglades virus
- Getah virus
- Guanarito virus
- Hantaan virus
- Herpes simiae (B virus)
- Influenza viruses (pandemic strains)
- Japanese encephalitis virus

- Junin virus
- Kyasanur Forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Mayaro virus
- Middleburg virus
- Mobala virus
- Monkey pox virus
- Mucambo virus
- Murray Valley encephalitis virus
- Ndumu virus
- Nipah virus
- Omsk haemorrhagic fever virus
- Polio virus
- Powassan virus
- Rabies and rabies-related Lyssaviruses
- Rift Valley fever virus
- Rocio virus
- Sabia virus
- Sagiyama virus
- Sin Nombre virus
- St Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus
- Western equine encephalitis virus
- West Nile fever virus
- Yellow fever virus

VIRUSES (AFFECTING ANIMALS OTHER THAN MAN)

- African horse sickness virus
- African swine fever virus
- Bluetongue virus
- Classical swine fever virus
- Contagious bovine pleuropneumonia
- Foot and mouth disease virus
- Goat pox virus
- Hendra virus (Equine morbilivirus)
- Highly pathogenic avian influenza (HPAI) as defined in Annex I(2) of Council Directive 2005/94/EC
- Lumpy skin disease virus
- Newcastle disease virus
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus

RICKETTSIAE

- Coxiella burnetii
- Rickettsia prowazeki
- Rickettsia rickettsii
- Rickettsia typhi (mooseri)

BACTERIA

- Bacillus anthracis
- Brucella abortus
- Brucella canis
- Brucella melitensis
- Brucella suis
- Burkholderia mallei (Pseudomonas mallei)
- Burkholderia pseudomallei (Pseudomonas pseudomallei)
- Chlamydophila psittaci
- Clostridium botulinum
- Clostridium perfringens
- Enterohaemorrhagic Escherichia coli, serotype 0157 and verotoxin producing strains
- Francisella tularensis
- Mulitple-drug resistant Salmonella paratyphi
- Mycobacterium tuberculosis
- Salmonella paratyphi A, B, C
- Salmonella typhi
- Shigella boydii
- Shigella dysenteriae
- Shigella flexneri
- Vibrio cholerae
- Yersinia pestis

FUNGI

- Cladohialophora bantiana
- Cryptococcus neoformans

TOXINS

- Abrin
- Botulinum toxins
- Clostridium perfringens epsilon toxins
- Clostridium perfringens enterotoxin
- Conotoxin
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga and shiga-like toxins
- Staphylococcus enterotoxins
- Tetrodotoxin
- Viscum Album Lectin 1 (Viscumin)
- Volkensin toxin

PART 2: THE THREAT TO THE UK FROM TERRORISM

Contemporary terrorist organisations aspire to use chemical or biological weapons. There have been a number of attacks using pathogens and toxins. For example, in 1984 a religious cult called the Rajneeshees contaminated salad bars in restaurants in Oregon, USA with salmonella. At least 750 people became sick.

Between 1993 and 1995, the Japanese cult organisation Aum Shinrikyo tried to manufacture biological agents including anthrax and botulinum toxin. Aum Shinrikyo members released sarin on the Tokyo metro in 1995 killing 12 people.

Five people died when envelopes containing anthrax powder were sent to addresses in the US in 2001. Suspected anthrax contamination at this time also caused considerable social disruption and decontamination costs.

In January 2003 Police and Security Service action disrupted attempts by an Algerian cell in London to make the toxin ricin.

Al Qa'ida is the first transnational organisation to support the use of Chemical, Biological, Radiological and Nuclear (CBRN) weapons against civilian targets and to try to acquire them. They established chemical and biological weapons research facilities in Afghanistan during the rule of the Taliban and provided training in the use of contact poisons to large numbers of Al Qa'ida members.

The internet has made information on the technology of CBRN devices and the materials which might be used to develop them widely available. CBRN materials can be used for legitimate purposes, for example medical science and biotechnology. These factors significantly increase the risk that biological agents may be used by terrorist organisations. The threat from terrorist use of pathogens and toxins remains real.

PART 3: THE REVIEW

In 2007 the Home Office reviewed what more needed to be done to protect against terrorist use of chemical, biological, radiological and explosive materials. The review found that good work was already being done but that more was needed to be done to address vulnerabilities in certain areas.

Individuals and businesses must be free to carry on normal social, economic and democratic activities and as a result of this there will always be some vulnerability to terrorist attack. Counter-terrorism protective security measures must be **proportionate to the risk** and one of the main purposes of the review was to ensure that effort is directed to those areas where the counter-terrorism benefits will be the greatest. In other words the Government wants to **reduce the accessibility** of substances that pose the **highest terrorist risk**.

As recommended within that review, 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 the Health Protection Agency 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.

The Lightfoot review made a number of recommendations (see below). These included the addition of one substance to the list in Schedule 5 and the removal of four other substances.

i. Substances listed in Schedule 5 should be placed into one of three categories, depending on the security standards appropriate for that substance.

ii. Schedule 5 should be reviewed every 2 years.

iii. SARS coronavirus should be added to Schedule 5.

iv. Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana should be removed from Schedule 5.

v. "Pandemic flu strains" should be redefined across the three categories.

vi. Plant pathogens should continue to be excluded from Schedule 5.

The Government believes its primary responsibility is to ensure national security. But it does not wish to interfere with the genuine and important need for healthcare and research laboratories to handle pathogens and toxins and wants to protect and support business. Therefore, it is important to seek an effective but proportionate response to the problem.

PART 4: OPTIONS

Section 58 of ATCSA refers to the pathogens and toxins to which requirements under Part 7 apply. It provides the Secretary of State with the power by order to modify the Schedule 5 list.

Two possible options have been identified for each of the recommendations relating to changes to the list of Schedule 5 substances: adopt the recommendation or do not adopt the recommendation.

Recommendation 1 – SARS Coronavirus should be added to the list. Options: do nothing or add SARS Coronavirus to the list.

SARS coronavirus fulfils the requirements of Section 58 of the ATCSA. Not adding SARS coronavirus to the list could potentially lead to it being held in unsecured premises and vulnerable to theft and terrorist misuse.

Only one laboratory holds this substance in the UK. This laboratory also holds other Schedule 5 listed substances and complies with the required measures. There will be no additional costs to them. This laboratory also falls under the inspection regime so there will be no additional enforcement costs. We are not aware of any other laboratories that have a need to hold this substance in the near future.

Increased security around this pathogen would mean a reduction in the accessibility for terrorist purposes, helping to protect the public.

- Are there any additional substances that should be added to the list?
- Are consultees able to confirm that the addition of SARS coronavirus will in fact not add any additional security burdens? Do consultees foresee the need for any other laboratories to hold SARS Coronavirus in the near future?

Recommendation 2 – Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana should be removed from the list. Options: do nothing or remove the substances from the list.

These substances are not considered to have the potential to cause serious harm if used by a terrorist and they are widely distributed in nature.

Leaving substances that pose no or low risk of misuse by terrorists on the list can undermine the credibility of the legislation and lead to non compliance. It would unnecessarily place burdens on small businesses to increase or maintain security measures that are not proportionate to the risk posed by those substances. Removing substances that pose little or no risk of terrorist misuse from Schedule 5 would reduce unnecessary security burdens to laboratories.

There are no benefits to be gained from leaving substances that do not pose a terrorist risk within the scope of ATCSA. There would be no additional costs from removing any of the above substances from the list.

- 200 clinical laboratories hold Mycobacterium tuberculosis. These laboratories will hold other Schedule 5 substances from time to time and so would remain subject to the requirements of ATCSA.

- 300 laboratories hold Clostridium perfringens (pathogen). None of these laboratories hold any other Schedule 5 substances. Removing Clostridium perfringens from Schedule 5 would remove some security requirements from the laboratories, saving approximately £10,000 per year per laboratory.

- 200 clinical laboratories hold Cryptococcus neoformans. These laboratories will hold other Schedule 5 substances from time to time and so would remain subject to the requirements of ATCSA.

- Two laboratories hold Cladophialophora bantiana. These laboratories hold no other Schedule 5 substances. Removing Cladophialophora bantiana from Schedule 5 would remove various security requirements from the laboratories, saving approximately £10,000 per year per laboratory.

- Are there any other substances which consultees think should be removed from the Schedule 5? Do laboratories agree with the estimated savings? If not, are consultees able to give an estimate of the likely savings from not needing physical and personnel security measures per year?

Recommendation 3 – Pandemic flu strains should be redefined to allow for categorisation of individual strains according to threat to human health. Options: do nothing or re-categorise the different influenza strains.

The categorisation of influenza viruses considers the actual threat to human health posed by each strain. Different levels of physical and personnel security would be required based on the category. Only three laboratories hold pandemic flu strains and these already fall under the scope of ATCSA. Therefore, no additional costs are expected to be incurred by the laboratories or by enforcement. We are not aware of any laboratories that plan to hold these substances in the near future.

- Can consultees confirm that the re-categorisation of pandemic flu viruses based on the threat posed by them will not incur additional costs to laboratories or enforcement?

In general the recommendations of the Lightfoot Review clarify the existing arrangements and propose the removal of certain substances from Schedule 5. As such the proposals are considered to be a simplification and will reduce the associated security costs.

CONSULTATION QUESTIONS

We are interested to receive feedback on all aspects of this consultation. To help guide your consideration, you might want to consider a number of questions that are set out in this section. These cover this publication and the accompanying Impact Assessment. The Impact Assessment (Annex B) is based on two options for each recommendation: adopt the recommendation or do not adopt the recommendation.

- The Government states that protective security responses must be proportionate to the risk. Will the amendments described in the document result in proportionate action on the ground?

- Are there additional options to be considered?

- Are consultees able to share estimated costs for counter-terrorism protective security measures for laboratories where such measures have been introduced?

- In addition to the costs and benefits identified in the documents, do consultees identify other costs or benefits being realised on implementation of the recommendations? If yes, please state what they are.

IMPACT ASSESSMENT QUESTIONS

- Are there any additional substances that should be added to the list?

- Are consultees able to confirm that the addition of SARS coronavirus will in fact not add any additional security burdens? Do consultees foresee the need for any other laboratories to hold SARS Coronavirus in the near future?

- Are there any other substances which consultees think should be removed from Schedule 5? Do laboratories agree with the estimated savings? If not, are consultees able to give an estimate of the likely savings from not needing physical and personnel security measures per year?

- Can consultees confirm that the recategorisation of pandemic flu viruses based on the threat posed by them will not incur additional costs to laboratories or enforcement?

- Do you think that there are any communities or groups (for example, race, disability, gender, gender identity, religion and belief, sexual orientation, age) that the measures will have a greater impact upon compared to the public at large? If so, please state which communities or groups and describe the particular measures and related impacts.

ANNEX A – THE SEVEN CONSULTATION CRITERIA

The Consultation follows the Government's Code of Practice on Consultation – the criteria for which are set out below:

1 – WHEN TO CONSULT

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

2 – DURATION OF CONSULTATION EXERCISES

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

3 – CLARITY OF SCOPE AND IMPACT

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

4 – ACCESSIBILITY OF CONSULTATION EXERCISES

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

5 – THE BURDEN OF CONSULTATION

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

6 – RESPONSIVENESS OF CONSULTATION EXERCISES

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

7 – CAPACITY TO CONSULT

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

The full Code of Practice on Consultation is available at: http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

CONSULTATION COORDINATOR

If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Nigel Lawrence. Please DO NOT send your response to this consultation to Nigel Lawrence. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

The Coordinator can be emailed at: Nigel.Lawrence@homeoffice.gsi.gov.uk or alternatively write to him at:

Nigel Lawrence, Consultation Coordinator
Home Office
Performance and Delivery Unit
Better Regulation Team
3rd Floor Seacole
2 Marsham Street
London
SW1P 4DF

ANNEX B – IMPACT ASSESSMENT

Title: **Amendments to Schedule 5 of Anti-Terrorism, Crime and Security Act 2001** **Lead department or agency:** Home Office/ OSCT **Other departments or agencies:**	Impact Assessment (IA) **IA No:** **Date:** 23/09/2010 **Stage:** Consultation **Source intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** J. Fanshaw 020 7035 0896

Summary: Intervention and Options

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

Schedule 5 of the Anti-Terrorism, Crime and Security Act 2001 (ATCSA) lists the pathogens and toxins brought under control by Part 7 of ATCSA. ATCSA gives the police powers to inspect premises that hold listed substances and require suitable security measures to be put in place. The list was reviewed by a cross-Government and academic group and a number of amendments to the scheduled substances and classifications were recommended. The Government regulates these high risk substances because there is no commercial incentive for the private sector to do so. The Government also realises the need to protect legitimate research and not to prevent important progress in biological sciences.

What are the policy objectives and the intended effects?

Government policy must take into account public health needs and the risk to the public if pathogens and toxins are misused by criminals while still allowing scientific progress in the area. The objectives of the policy are thus to a) reduce the availability of pathogens to terrorists, whilst b) to reduce the unnecessary physical and personnel security burdens on laboratories who hold only low-risk substances.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Recommendation 1 – SARS Coronavirus should be added to the list. Options: do nothing or add SARS Coronavirus to the list. SARS Coronavirus fulfils the requirements of Section 58 of ATCSA.

Recommendation 2 – Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana should be removed from the list. Options: do nothing or remove all substances from the list. These substances are no longer considered to fulfil the requirements of Section 58 of ATCSA.

Recommendation 3 – Pandemic flu strains should be redefined. Options: do nothing or place into three categories dependent upon the threat posed. Categorising these substances according to the threat posed means that security measures can be targeted in a way that is proportionate to the threat.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 04/2013
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Ministerial Sign-off For consultation 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:.....  ..... Date:2 March 2011

Summary: Analysis and Evidence — Policy Option 1

Description:

Recommendation 1: SARS Coronavirus should be added to Schedule 5.

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

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

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

The only laboratory that holds SARS Coronavirus also holds Schedule 5 substance and complies with the Act, therefore, no additional costs will be incurred by the laboratory or police forces if this amendment is made as the cost does not increase with more substances.

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

Unknown

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	Unknown		Unknown	Unknown

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

Unknown

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

A reduction in the accessibility of the substance for terrorist use, resulting in increased public protection and reduction in the risk of it being used for terrorism.

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

Assumption that no other laboratories are planning to use/hold SARS Coronavirus in the near future.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			06/10/2011		
Which organisation(s) will enforce the policy?			CTSAs/NaCTSO		
What is the total annual cost (£m) of enforcement for these			no extra costs		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** neglig.	**Non-traded:** neglilg.	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.
Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[2]? Equality and Human Rights Commission: General guidance	No	30
Economic impacts		
Competition? Competition Impact Assessment	No	30
Small firms? Small Firms Impact Test	No	30
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence — Policy Option 2

Description:

Recommendation 2: Remove Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans, Cladophialophora bantiana from Sch. 5

Price Base Year	PV Base Year	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** £25.1M

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

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

Removes need for physical security measures at approximately 302 laboratories that only hold one Schedule 5 substance across UK.

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

By removing physical and personnel security burdens on substances considered to be of low or no risk of terrorist use, the legislation is more credible with the community and, therefore, more likely to be followed.

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			£3020000	£25.1M

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

Removes need for physical security measures at approximately 302 laboratories that only hold one Schedule 5 substance across UK.

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

By removing physical and personnel security burdens on substances considered to be of low or no risk of terrorist use, the legislation is more credible with the community and, therefore, more likely to be followed.

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

Annual costs include security measures such as CCTV, access control, vetting of personnel.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			06/10/2011		
Which organisation(s) will enforce the policy?			CTSAs/NaCTSO		
What is the total annual cost (£m) of enforcement for these			no extra costs		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** neglig.	**Non-traded:** neglilg.	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.
Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[2]? Equality and Human Rights Commission: General guidance	No	30
Economic impacts		
Competition? Competition Impact Assessment	No	30
Small firms? Small Firms Impact Test	No	30
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence — Policy Option 3

Description:

Recommendation 3: Redefine pandemic flu strains

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

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

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

Only three labs within the UK hold these substances and already comply with the measures under ATCSA. No additional costs are expected.

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

Unknown

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

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

Unknown

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

Measures are proportionate to the risk posed by each strain meaning the legislation is more credible and, therefore, more likely to be followed.

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

Assumption that no other laboratories are likely to use/hold these substances in the near future and that the change in classification will not add more onerous security standards than those in place already.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			06/10/2011		
Which organisation(s) will enforce the policy?			CTSAs/NaCTSO		
What is the total annual cost (£m) of enforcement for these			no extra cost		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.
Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[3]? Equality and Human Rights Commission: General guidance	No	30
Economic impacts		
Competition? Competition Impact Assessment	No	30
Small firms? Small Firms Impact Test	No	30
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[3] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Implementation).

No.	Legislation or publication
1	http://www.opsi.gov.uk/Acts/acts2001/ukpga_20010024_en_1
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs	0	0	0	0	0	0	0	0	0	0
Transition benefits										
Annual recurring benefits		3	3	3	3	3	3	3	3	3
Total annual benefits	3	3	3	3	3	3	3	3	3	3

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office
Excel Worksheet

EVIDENCE BASE (FOR SUMMARY SHEETS)

A. STRATEGIC OVERVIEW

A.1 BACKGROUND

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 threat to the UK. Part 7 of ATCSA is intended to improve the security of dangerous substances that may be targeted or used by terrorists. ATCSA gives the Police powers to inspect premises that hold listed substances and to require suitable security measures to be put in place.

Contemporary terrorist organisations aspire to use chemical or biological weapons. There have been a number of attacks using pathogens and toxins. 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. Aum members released sarin on the Tokyo metro in 1995 killing 12 people. 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 Police and Security Service action disrupted attempts by an Algerian cell in London to make the toxin ricin.

Al Qa'ida is the first transnational organisation to support the use of CBRN 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.

The internet has made information widely available on the technology of CBRN devices and the materials which might be used to develop them. These factors significantly increase the risk that biological agents may be used by terrorist organisations. The threat from terrorist use of pathogens and toxins remains real. However, CBRN materials are used for legitimate purposes, and contribute to advances in the fields of medical science and biotechnology.

A.2 GROUPS AFFECTED

Those likely to be affected by the proposals are biological science laboratories and law enforcement.

B. RATIONALE

In 2007 the Government reviewed how best to strengthen security to protect against the use of hazardous substances for terrorist purposes. The results of this review were announced in Parliament on 22 July 2008.

The review identified areas where further improvements could be made but recognised that we must ensure that protective security measures are proportionate to the risk. One of the recommendations of the review was to consider whether any changes were necessary to the list of pathogens currently within the scope of ATCSA.

Professor Nigel Lightfoot then of the Health Protection Agency was commissioned by the Home Office to lead a review of the pathogens and toxins listed under Schedule 5 of ATCSA. The review was conducted by a group of cross government and academic representatives.

In order to identify which pathogens were high risk a number of characteristics were looked at:

- 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

This review recommended a number of amendments to the list of substances that fall under the regulations. The costs and benefits of each recommendation which would result in a change to the legislation are considered separately below. In summary, the recommendations seek to ensure that ATCSA continues to strike the right balance between maintaining biosecurity standards whilst not imposing disproportionate physical and personnel security burdens on those engaged in legitimate research. Laboratories holding and those wishing to hold a listed substance with a legitimate need to do so are visited by a local Police Counter-Terrorism Security Adviser (CTSA). The CTSA will assess the security measures in place and can order the laboratory to make improvements in order to comply with ATCSA. The review made a number of recommendations, including the addition of one substance to the list in Schedule 5 and the removal of four other substances, as follows:

i. Substances listed in Schedule 5 should be placed into one of three categories, depending upon the security standards appropriate for that substance. This classification system will enable CTSAs to give more targeted advice, but will not require changes to be made to legislation.

ii. Schedule 5 should be reviewed every 2 years. Modern science can be fast moving and new and emerging diseases will need to be considered.

iii. SARS coronavirus should be added to Schedule 5. The review considers SARS Coronavirus to fulfil the requirements of Section 58 of ATCSA.

iv. Certain pathogens (Mycobacterium tuberculosis, Clostridium perfringens, Cryptococcus neoformans and Cladophialophora bantiana) should be removed from Schedule 5. These organisms are not considered to fulfil the requirements of Section 58 of ATCSA.

v. "Pandemic flu strains" should be redefined across the three categories. The classification of influenza viruses as recommended considers the actual threat posed by each strain and applies security measures that are proportionate to the risk.

vi. Plant pathogens should continue to be excluded from Schedule 5. Plant pathogens are already strictly controlled by plant health legislation.

C. OBJECTIVES

The objectives of the amendments to the ACTSA are:

- To reduce the accessibility of pathogens to terrorist use;
- To reduce unnecessary security burdens on those laboratories that hold only low risk substances.

To achieve this we plan to:

- Ensure a proportionate approach such that low risk substances do not incur unnecessary costs;
- Consider the recommendations of the review of ATCSA led by Professor Lightfoot;
- Review guidance for laboratories and CTSAs regarding following the measures within the Act.

D. OPTIONS AND APPRAISAL

Recommendation 1 – SARS Coronavirus should be added to the list

Because SARS Coronavirus fulfils the requirements of Section 58 of ATCSA, one of the recommendations of the Lightfoot review is to add it to Schedule 5.

OPTION 1 – DO NOTHING

COSTS

Not adding SARS Coronavirus to the list could potentially lead to it being held in unsecured premises, leaving it vulnerable to theft and terrorist misuse. Not adding this substance to the list of scheduled substances therefore means there is a **potential increase in the risk of it being misused**. As an illustration, according to "the economic and social costs of crime against individuals and households 2003/04" published by the Home Office (updated to 2008 prices), the average cost of death of an adult is £1.8 million; the cost of severe wounding is £25,092 and the cost of slight wounding is £9,866. In addition, terrorist attacks have an effect on GDP, both as a result of impacts on tourism and as a result of impacts on inward investment; and there would be non-monetisable costs produced by fear and opportunity costs of additional security measures. If SARS Coronavirus was successfully misused, the likely costs to society would be high.

Benefits

None.

OPTION 2 – ADD TO LIST

COSTS

Only one laboratory holds this substance in the UK. This laboratory also holds other Schedule 5 listed substances and already complies with the required measures. There will be **no additional costs** to them as in effect the cost of holding a schedule 5 substance is incompressible, i.e. holding 1 or 10 substances cost the same. This laboratory also falls under the local CTSA inspection regime so there will be no additional enforcement costs (assuming the inspection is not lengthened by this addition). We are not aware of any other laboratories that have a need to hold this substance in the near future.

BENEFITS

Increased security around this pathogen would **reduce its accessibility to terrorists**, helping to protect the public **and potentially reduce the risk of it being used.**

Consultation question: are there any additional substances that should be added to the list? Are consultees able to confirm that the addition of SARS coronavirus will in fact not add any additional burden? Do consultees foresee the need for any other laboratories to hold SARS coronavirus in the near future?

Recommendation 2 – Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans and Cladophialophora bantiana should be removed from the list

These substances are not considered to have the potential to cause serious harm if used by terrorists and they are widely distributed in nature; therefore the Lightfoot review recommends their removal from Schedule 5.

OPTION 1 – DO NOTHING

COSTS

None.

Leaving substances on the list that pose no or low risk of misuse by terrorists can undermine the credibility of the legislation and lead to non compliance. It would unnecessarily place burdens on small businesses to increase or maintain physical and personnel security measures that are **not proportionate to the risk** posed by those substances.

BENEFITS

There are no benefits to be gained from leaving substances that do not pose a terrorist risk within the scope of the ATCSA.

OPTION 2 – REMOVE SUBSTANCES FROM LIST

COSTS

There would be no additional costs involved with removal of any of the substances from the list.

BENEFITS

Removing substances that pose little or no risk of terrorist use from the scope of the ATCSA would reduce unnecessary physical and personnel security burdens to laboratories.

- 200 clinical laboratories hold Mycobacterium tuberculosis. These laboratories hold other Schedule 5 substances from time to time and so would remain subject to ATCSA.
- 300 laboratories hold Clostridium perfringens (pathogen). None of these laboratories hold any other Schedule 5 substances. Removing Clostridium perfringens (pathogen) from Schedule 5 would remove various security requirements from the laboratories, saving approximately £10,000 per year per laboratory.
- 200 clinical laboratories hold Cryptococcus neoformans. These laboratories hold other Schedule 5 substances from time to time and so would remain subject to ATCSA.
- Two laboratories hold Cladophialophora bantiana. Neither of these laboratories holds any other Schedule 5 substances. Removing Cladophialophora bantiana from Schedule 5 would remove various security requirements from the laboratories, saving approximately £10,000 per year per laboratory.

Removal of burden = £3,020,000 per year (see above). This gives a Net Present Value of £25.1 M over 10 years.

No inspection for 302 laboratories.

Consultation question: are there any other substances that consultees think should be removed from Schedule 5? Do laboratories agree with the estimated savings? If not, are consultees able to give an estimate of the likely savings from not needing physical and personnel security measures per year?

Recommendation 3 – Pandemic flu strains should be redefined to allow for categorisation of individual strains according to threat to human health. Options: do nothing or re-categorise the different influenza strains.

The categorisation of influenza viruses considers the actual threat to human health posed by each strain and recommends different levels of physical and personnel security based on that threat. Only three laboratories hold pandemic flu strains and these already fall under the scope of ATCSA, therefore, no additional costs are expected to be incurred by the laboratories or by enforcement. We are not aware of any laboratories that plan to hold these substances in the near future.

Consultation question: Can consultees confirm that the re-categorisation of pandemic flu viruses based on the threat posed by them will not incur additional costs to laboratories or enforcement?

In general the recommendations of the review led by Professor Lightfoot clarify the existing arrangements and propose the removal of certain substances. As such they are considered to be a simplification and will reduce unnecessary security costs.

F. RISKS

Recommendation 1 – SARS Coronavirus should be added to Schedule 5

Assumption that no other laboratories are planning to use/hold SARS Coronavirus in the near future.

Recommendation 2 – Remove Mycobacterium tuberculosis, Clostridium perfringens (pathogen), Cryptococcus neoformans, Cladophialophora bantiana from Schedule 5

Annual costs include security measures such as CCTV, access control, vetting of personnel.

Recommendation 3 - Redefine pandemic flu strains

Assumption that no other laboratories are likely to use/hold these substances in the near future and that the change in classification will not add more onerous security standards than those in place already.

Information received from six laboratories supports our assessment of the costs and benefits and our preferred option to take up the recommendations.

G. ENFORCEMENT

The pathogens and toxins within Schedule 5 are based on risk assessments and only substances considered of high risk are listed so as not to limit scientific progress.

CTSAs provide advice to sites at no cost to the site.

H. SUMMARY AND RECOMMENDATIONS

The preferred option is to take up the recommendations. Recommendations 1 and 3 are assessed as not adding any costs to laboratories or enforcement. Annual savings of approximately £3million have been estimated for Recommendation 2.

I. IMPLEMENTATION

The Government plans to implement these changes on 6 October 2011 subject to agreement from the relevant cabinet committees.

J. MONITORING AND EVALUATION

The effectiveness of the new regime will be monitored through review processes, potentially every two years in order to keep up with scientific advances.

K. FEEDBACK

We welcome any feedback to the consultation email address: ATCSAconsultation@homeoffice.x.gsi.gov.uk.

ANNEX 1: POST IMPLEMENTATION REVIEW (PIR) PLAN

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their actual costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];
To keep up to date with emerging diseases and scientific advances.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
See above.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Cross-Government and Academic Expert Group.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

ANNEX 2. SPECIFIC IMPACT TESTS

STATUTORY EQUALITY DUTIES

EQUALITY IMPACT ASSESSMENT

On the advice of the Strategic Diversity Action Team, this impact assessment and consultation will form part of the equality impact assessment.

ECONOMIC IMPACTS

COMPETITION ASSESSMENT

The amendments to the Act are unlikely to affect competition.

SMALL FIRMS IMPACT TEST

The Government will consider carefully in the light of responses to this consultation whether any new burden placed on small businesses is proportionate to the risk of terrorism. There are very few small companies involved in microbiology work.

JUSTICE IMPACT

We will consider how the changes to Schedule 5 will impact on the current offences and civil penalties in this area. This is to prevent the proliferation of unnecessary new offences.

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