

REGULATORY IMPACT ASSESSMENT

EXTENDING SCHEDULE 5 OF THE ANTI-TERRORISM, CRIME AND SECURITY ACT, 2001

1. ISSUES AND OBJECTIVES

1.1 The central objective in extending the list of controlled pathogens and toxins in Schedule 5 of the Anti-Terrorism, Crime and Security (ATCS) Act, 2001 is, in light of new scientific findings, to secure those substances that potentially pose the greatest risk to human life if misused by terrorists.

1.2 Schedule 5 of the ATCS Act lists the pathogens and toxins brought under control by Part 7 of the Act. Since the ATCS Act was drafted there has been considerable debate within government and the UK scientific community about the pathogens caught within the scope of the legislation. Terrorist scenarios could involve more pathogens than those currently listed in Schedule 5 – a ‘classical’ list of agents from state biological warfare programmes produced by the ‘Australia Group’.

1.3 This list has been revisited, by a cross-government group, with the aim of placing it more squarely within the current UK context. In identifying which pathogens were of concern from the terrorist perspective a number of criteria were used:

- The extent to which the UK population is vulnerable to infection by the pathogen;
- How infectious the pathogen is when spread by the airborne route or through contamination of food or water supplies;
- The extent to which the disease caused by the pathogen is transmitted from person-to-person;
- Availability of measures, such as vaccines, to deal with potential incidents;
- The severity and duration of illness caused by the pathogen, including the availability of treatment;
- How long the pathogen is able to survive in the environment
- How easy it is to grow, and store, the pathogen.

1.4 A new list of biological agents has consequently been drawn up extending beyond the existing schedule 5. This list offers more comprehensive and meaningful coverage of substances that could be used in acts of terrorism. This revised list has been independently validated.

2. RISK ASSESSMENT

2.1 A number of terrorist groups have sought to acquire and use chemical or biological materials as terrorist weapons. Of greatest concern to the UK is Al Qaida – whose interest in unconventional weapons is at least a decade old - and some associated terrorist networks. Al Qaida’s interest in developing anthrax, for instance, was noted by the US 9 /11 Commission.

2.2 There have been a number of attacks using pathogens and toxins. For example:

- Several envelopes containing anthrax powder were sent to addresses in the US in autumn 2001. Some 22 people were affected with cutaneous or pulmonary anthrax, of whom 5 died. Actual or suspected anthrax contamination also caused significant disruption and decontamination costs;
- In February 2004 ricin powder was discovered in the office of the US Senate majority leader;
- In 1984 members of a religious cult in Oregon produced salmonella in their own (state-licensed) laboratory and used it to contaminate salad bars in local restaurants. At least 751 people became ill, although none died.

The threat posed by the possible terrorist use of pathogens and toxins therefore remains real.

2.3 The intended measures will extend the legal framework to a full range of agents of concern from a terrorist perspective.

OPTIONS

2.4 Section 58 of the ATCS Act refers to the pathogens and toxins in relation to which requirements under part 7 apply. It provides the Secretary of State with the power, by order, to modify the Schedule 5 list. Section 75 of the Act also provides for the power to extend the legislation to cover animal pathogens that could be used in an act of terrorism to cause widespread damage to property, significant disruption or alarm to the public. In the current climate, Ministers have decided that 'doing nothing' is not an option and have therefore given agreement to extending the list of controlled pathogens and toxins included in Schedule 5 of the ATCS Act, and to extend the Act to cover animal pathogens.

2.5 Updating the list was a recommendation of both the Science and Technology Committee and the Privy Counsellor Review of the Anti-Terrorism, Crime and Security Act.

3. BENEFITS

3.1 It is imperative to ensure that terrorists do not have access to dangerous substances. The benefits of increasing the scope of substances subject to control is difficult to quantify as it is impossible to assess to what extent greater national safety is secured and the potential dangers avoided by such preventative measures. However, denying terrorist access to such substances is an important part of the preventative

measures taken by Government as it is evident that terrorist organisations are prepared to use any methods available to them, including use of chemical and biological tools.

4. COSTS

4.1 During the summer of 2006 an audit was completed regarding all those laboratories that had registered with the Home Office (under their duty to notify the Secretary of State prior to keeping or using any dangerous substance) and those that had been identified under the Vulnerable Sites and Sectors (VSS) Programme. This Programme, managed by the National Counter Terrorism Security Office (NaCTSO), involves identification of sites, site visits by police Counter Terrorism Security Advisers (CTSA) and the provision of generic and site specific protective security advice. Laboratories are required to ensure that they have adequate safeguards and security measures in place and are monitored to ensure that necessary improvements are made. The emphasis is on personnel security and the insider threat.

4.2 There are a total of 395 laboratories listed. Not all of these are liable under the legislation. There are approximately 100 sites which have been made exempt by Statutory Instrument 1281 of 2002 (diagnostic laboratories). Although exempt, they are still visited by the CTSA and encouraged to comply with security regulations if they are isolating dangerous pathogens on a regular basis.

4.3 The decision to extend the legislation to include animal pathogens will affect less than 10 additional sites as most are already included under the current legislation due to their work on pathogens that are hazardous to both animals and humans.

4.4 Costs will vary from one establishment to another. Many companies who work on such organisms have extensive security arrangements in place already, to protect commercial secrets. Hospitals and universities may need to upgrade security but will already have some competent system in place. A one-off cost of £5,000 per laboratory is considered a reasonable average estimate of the security costs that will be involved. Based on the maximum number of laboratories that will be affected (40 in total) the total overall cost to the sector is estimated to be in the region of £200,000. Approximately 30 sites will be affected by the revised Schedule 5 list and 10 sites affected by extending the legislation to cover animal pathogens.

4.5 Most of the laboratories which will be affected by the revision of Schedule 5 have already been visited and given preliminary security advice by their local Counter-Terrorist Security Adviser (CTSA), under the VSS Programme. It is stressed that when being provided with security advice, laboratories are provided with generous time scales to allow for financial planning.

5. PUBLIC SERVICES THRESHOLD TEST

5.1 No additional costs for the public services will be incurred (e.g. in policing) by amending the legislation.

6. EQUITY AND FAIRNESS

6.1 The proposals will affect all registered labs equally although the measures they will individually need to take may vary (as described above under Costs).

7. SMALL FIRMS IMPACT TEST

7.1 By the very nature of microbiology, there are very few small companies involved in such work. Larger companies already have state of the art security systems to protect commercial secrets. All those laboratories that will be affected by the amendment to the legislation have already been visited and advised of security requirements.

8. COMPETITION TEST

8.1 Given the relatively low one-off cost involved for each laboratory it is very unlikely that the proposals will have any effect on competition.

9. ENFORCEMENT AND SANCTIONS

9.1 Part 7 of the ATCS Act sets out measures to ensure compliance with security requirements. These measures are applicable to all laboratories holding substances in schedule 5 and will apply equally in respect of the new list. No additional enforcement costs will be incurred as a result of extending the schedule.

9.2 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 this part of the Act.

9.3 There has been no requirement, to date, to invoke the legislative powers to require disposal of, or to deny access to, dangerous substances.

10. CONSULTATION

10.1 The original Schedule 5 has been revisited, by a cross-government group, with the aim of placing it more squarely within the current UK context. Representatives from the Health and Safety Executive, the Health Protection Agency, the Defence Science and Technology Laboratory at Porton Down, the National Counter Terrorism Security Office and the Security Service met to consider which pathogens handled in UK facilities could have the potential to cause serious harm if used by a terrorist. This group has become known as the ‘Salisbury Group’.

10.2 The ‘Salisbury Group’ has produced a new list of biological agents ranked according to the criteria identified above (paragraph 1.3). In drawing up this new list information was drawn from US, Canadian and British sources, including directly from leading scientists working with particular agents. This list extends beyond the existing list in schedule 5 but is UK-focused. The Security Service earlier brought together a small group of clinicians to independently review the list of pathogens handled in UK facilities from a clinical perspective. The results of this validation exercise broadly agree with the conclusions of the Salisbury Group.

10.3 All those laboratories affected by the new Schedule 5 have had initial contact with the Counter-Terrorism Security Advisers and been provided with security advice. Labs have been aware for 18 months of the likelihood of amendments to the list of controlled substances as they were identified with the assistance of the Health and Safety Executive in December 2002.

11. MONITORING AND REVIEW

11.1 The approach that generated the ‘Salisbury List’ is a robust one and will withstand wider challenge; the process is proven, and auditable. Producing a list of biological agents ranked in this way is not a precise science, because of the limited or contradictory information on some pathogens. Experience with ‘lists’ of pathogens produced for other purposes, such as for health and safety at work, is that there is always debate about the precise position of individual agents in such lists and that they need to be reviewed from time-to-time as more information on the agents becomes available. The key action is to make pragmatic decisions based on the available knowledge of the experts involved.

12. SUMMARY AND RECOMMENDATION

12.1 The requirement to address terrorist activity is paramount. The proposed steps described above are therefore recommended as reasonable measures to be taken to increase security and to provide reassurance to the UK public. The costs involved are one-off and relatively low for those affected.

13. MINISTERIAL DECLARATION

“I have read the Regulatory Impact Assessment and am satisfied that the benefits justify the costs.”

Signed:

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