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Strengthening the Biological Weapons Convention

Briefing Paper No 17 (Second Series)

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EFFECTIVE ACTION TO STRENGTHEN THE BTWC REGIME: THE IMPACT OF DUAL USE CONTROLS ON UK SCIENCE

by Caitríona McLeish[†] & Paul Nightingale[*]

Introduction

1. Concerns about the proliferation of biological weapons and the threat posed by bioterrorism have assumed greater political prominence in recent years.[1] In response, governments are actively attempting to frustrate the diffusion of technologies, relevant to the production of biological weapons, to regimes and non-state actors which might develop and use such weapons. Their most recent efforts have involved the introduction of a range of new national measures to control access to materials, knowledge and technologies. The States Parties to the Biological and Toxin Weapons Convention (BTWC) have at their annual meetings during the intersessional period between the Fifth Review Conference and the Sixth Review Conference been seeking to *'discuss, and promote common understanding and effective action'* on some such national measures[2].

2. The topics being addressed by the States Parties are:

> *i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
>
> *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
>
> *iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*
>
> *iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
>
> *v. The content, promulgation, and adoption of codes of conduct for scientists.*

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[1] United Nations Secretary-General, *A More Secure World: Our Shared Responsibility. Report of the Secretary-General's High Level Panel on Threat, Challenges and Change*, A/59/565, 2 December 2004 (see also Graham S. Pearson, *The UN Secretary-General's High Level Panel: Biological Weapons Related Issues*, University of Bradford, Department of Peace Studies, Review Conference Paper No. 14, May 2005. Available at http://www.brad.ac.uk/acad/sbtwc), G8 (2004), *Action Plan on Nonproliferation*, Sea Island Summit, 9 June 2004, G8 (2003), *Non Proliferation of Weapons of Mass Destruction: A G8 Declaration*, Evian Summit, 3 June 2003

[2] United Nations, Fifth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Geneva, 19 November - 7 December 2001 and 11 - 22 November 2002, *Final Document*, BWC/CONF.V/17, 2002. Available at http://www.opbw.org

Topics i and ii were addressed in 2003, topics iii and iv in 2004 and topic v will be addressed in 2005 at the Meeting of States Parties on 5 to 9 December 2005 which will be preceded by the Meeting of Experts on 13 to 24 June 2005.

3. The topics addressed in 2003 in regard to the *adoption of necessary, national measures to implement the prohibitions* and to *national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins* together with the topic for 2005 regarding *codes of conduct for scientists* are directly related to measures to control access to materials, knowledge and technologies.

4. Preventing the diffusion of the necessary knowledge and technologies used to develop biological weapons is complicated because the underlying technologies often have legitimate and socially beneficial applications. Any controls to prevent their hostile application can also potentially disrupt legitimate activity, thereby generating social costs. For example, anecdotal evidence suggests that the introduction of biosecurity controls in the US and Germany are adversely affecting scientific research in those countries.[3] Governments therefore need to balance these costs against the security benefits that such controls generate.

5. To do this policy makers need information on the impact of these new 'biosecurity' measures. However, this is a new area of policy and few impact assessments have been performed. This pilot project, funded by the UK Economic and Social Research Council[4], has developed and validated new methods for assessing the impact that UK government biosecurity policies, introduced to prevent legitimate scientific research from being misused, are having on the practice of science. This Briefing Paper outlines the project and provides some initial results in order to assist the States Parties to the BTWC in their consideration in 2005 of *codes of conduct for scientists* and in 2006 at the BTWC Sixth Review Conference when States Parties will be considering further action to be taken on the five topics considered during the intersessional period.

What is dual use?

6. This project was concerned with 'dual use' technologies. Dual use is a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications.[5] Most peaceful applications are civilian in context, but there are also peaceful military applications, such as developing and producing vaccines against biological weapon agents. Hostile contexts have traditionally been thought of as military and state-based, but increasingly attention has been directed towards the possibility that non-state actors, such as terrorists, might use biological weapons.[6]

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[3] See for example, "An open letter to Elias Zerhouni" *Science*, Vol 307, Issue 5714, March 4th 2005; Cohen et al, "The pitfalls of bioterrorism preparedness: the anthrax and smallpox experiences", *American Journal of Public Health*, vol 10, 2004; Brumfiel G, "US universities up in arms over licence plans for foreign staff", *Nature*, vol 431, 2004; van Aken et al, "Biosecurity requires international supervision", *Nature*, vol 431, 2004; May T. "Isolation is not the answer", *Nature*, vol 429, 2004.

[4] The ESRC is an independent research council in the UK charged with promoting and supporting research into key issues of concern to social science.

[5] Molas-Gallart J and JP Robinson (1997), Assessment of Dual-use Technologies in the Context of European Security and Defence, Report for the Scientific and Technological Options Assessment (STOA), European Parliament.

[6] See for example, Interpol "Final Communiqué", 1st Interpol Global Conference, Lyon, France, 1-2 March 2005 as downloaded from http://www.interpol.int/Public/BioTerrorism/Conferences/FinalCommunique.asp

The dual use nature of some of the relevant technologies and scientific knowledge raises the possibility that scientists engaged in legitimate research for peaceful purposes might have their work misused and applied to biological warfare purposes. This includes the possibility of inadvertent assistance through seemingly harmless activities, such as postgraduate teaching.

7. The 'dual use dilemma' faced by the many countries who are determined to take measures to reduce opportunities for biological weapons development is that, compared to hostile applications, there is a vast range of peaceful purposes. Moreover, these applications are spreading across the world and in many cases their diffusion should be encouraged rather than slowed down. Governing dual use technologies therefore poses a serious policy design dilemma: the regulatory regime needs to balance the suppression of negative applications (in order to reduce the risk of biological weapons) without hindering the development of technology for peaceful and permitted purposes.

8. The governance regime to achieve this has at its heart the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC). This Convention came into force in 1975 and currently has 153 state parties and 16 signatory states[7]. The BWC obliges its States Parties *never in any circumstance to develop, produce, stockpile or otherwise acquire or retain:*

> *Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
> *Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*[8]

Furthermore, the Convention requires its States Parties to implement it nationally by taking *any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.*[9]

9. When implementing the BTWC nationally, the United Kingdom, through the adoption of the *Biological Weapons Act* 1974, placed the obligation on all of its citizens *"never in any circumstance to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful*

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[7] United Nations, Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, *List of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction as at December 2004*, Second Meeting, 6 - 10 December 2004, BWC/MSP/2004/INF.2 dated 3 December 2004. Available at http://www.opbw

[8] Article 1, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, 1972. Available at http://www.opbw

[9] Article 1V, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, 1972. Available at http://www.opbw

purposes".[10] The 1974 Act additionally obliges citizens not to transfer, enter into an agreement to transfer, or make arrangements under which another person transfers any biological agent or toxin *"if the biological agent or toxin is likely to be kept or used (whether by the transferee or any other person) otherwise than for prophylactic, protective or other peaceful purposes and he knows or has reason to believe that this is the case"*.[11]

10. As well as implementing the BTWC at the national level, governments use a range of other national policies to control the proliferation of dual use technologies. Most of these regulatory efforts aim to provide sufficient oversight of the possession and transfers of technology so that roadblocks can be put in place in time to stop the application of technology for illicit purposes. The most recent pieces of biosecurity legislation that entered into UK law are the *Anti-Terrorism Crime and Security Act*, 2001[12] which amended the *Biological Weapons Act*, 1974 and placed new legal obligations on the scientific community to ensure their technologies are not misused and misappropriated, and the secondary legislation[13] to the *Export Control Act*, 2002 made in 2003 and implemented in 2004 which regulates the transfer of intangible technologies.

11. The *Anti-Terrorism Crime and Security Act*, 2001[14] amends the *Biological Weapons Act*, 1974 (e.g. the legislation now covers the transfer and making of arrangements to transfer or agree to transfer any biological agent or toxin) and places new security obligations on the certain pathogens and toxins listed in Schedule 5 of the Act. The new legal obligations include the duty to notify Secretary of State before keeping or using dangerous substances; information about security of dangerous substances and information about persons with access to dangerous substances. The list of pathogens and toxins in Schedule 5 of the Act contains 19 viruses, 5 rickettsiae, 13 bacteria, and 11 toxins; these are reproduced in the Annex to this Briefing Paper. The Act also includes any genetic material containing any nucleic acid sequence associated those listed pathogens and toxins and any genetically modified organism containing any such sequence.

12. The further piece of new legislation is the secondary legislation[15] to the *Export Control Act*, 2002 introduced in 2004. By the introduction of this secondary legislation, export controls in the UK have been extended to include transfers related to a WMD end-use (i) made by any means; (including face-to-face discussions and demonstration); (ii) made within the UK or by UK persons outside the EC (where the end-use is outside the EC); and (iii) technical assistance to a WMD programme outside the EC.

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[10] Article 1, *The Biological Weapons Act*, United Kingdom, 1974. Available at http://www.opbw

[11] Article 1A, *The Biological Weapons Act*, United Kingdom, 1974 (as amended by the *Anti Terrorism Crime and Security Act*, 2001).

[12] *Anti-Terrorism Crime and Security Act*, 2001. Available at http://www.hmso.gov.uk/acts/acts2001/20010024.htm Part VI amends the *Biological Weapons Act 1974*.

[13] Statutory Instrument 2003 No. 2764, *Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003*, made 30 October 2003, coming into force 1 May 2004. Available at; http://www.opsi.gov.uk/si/si2003/20032764.htm

[14] *Anti-Terrorism Crime and Security Act*, 2001. Available at http://www.hmso.gov.uk/acts/acts2001/20010024.htm

[15] Statutory Instrument 2003 No. 2764, *Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003*, made 30 October 2003, coming into force 1 May 2004. Available at; http://www.opsi.gov.uk/si/si2003/20032764.htm

Project objectives and methods

13. The aim of this pilot project was to assist the successful design and implementation of policy by developing and validating new methods for gathering qualitative and quantitative data on the impact of biosecurity controls on UK science.

14. The project gathered data using questionnaires and interviews from a small sample of the UK scientific community. The sample was constructed using standard bibliometric methods based on a network of UK scientists who had worked with and published peer-reviewed articles between 1989 and 2004 relating to dangerous pathogens, as defined in Schedule 5 of the *Anti Terrorism Crime and Security Act,* 2001. This dataset was then reduced to provide a sample of 100 scientists engaged in work with Schedule 5 agents who had published more than one article on such agents between 1989 and 2004. A control group of 28 members of the scientific community who had not worked with Schedule 5 agents although they were working on other agents in BL2 or BL3 laboratories was also selected to take part in this project. This control group enabled the results of the research to be placed in a wider context and allowed the research team to evaluate how representative the views of our sample were.

15. The development, piloting and validation of the questionnaire was undertaken in collaboration with both the security and scientific communities in the UK over a six month period. This involved an iterative process of finding unambiguous terminology and becoming aware of the specific issues facing different communities. The questionnaire sought information under four main headings:

a. The type of institution, its size and the nature of its work;
b. The impact of the current regime of biosafety and biosecurity regulations;
c. Institutional costs and benefits of these regulations.
d. Perceptions within the scientific community about a range of biological weapons issues.

Once the questionnaire was piloted, it was sent to all 128 – the dataset of 100 and the control group of 28 – members of the UK scientific community, which included scientists, funders of science, biosafety officials and security officials.

16. The project achieved a 53% response rate (68 usable responses). Interviews were also conducted with 27 of the responders to explore at a deeper level the individual answers received and to test the general trends emerging. The following is based on the 68 usable questionnaire responses and additional data collected during the 27 interviews

Who participated?

17. The scientists in the dataset of 100 who responded to the questionnaire had all worked with agents listed in Schedule 5 of the 2001 *Anti Terrorism Crime and Security Act* (71% with the pathogens, 76% with Schedule 5 toxins and 91% with the genetic material associated with the action of either the pathogens or toxins). The majority were located within universities or other teaching institutions (68%), although government laboratories (9%) and commercial R&D (6%) were also represented. Institution size was typically between 11 and 100 active researchers, although a number of smaller institutions with less than ten active researchers were also represented. The institutions contained the necessary equipment and infrastructure to perform work at hazard group 2 (91%) and hazard group 3 (74%), as detailed

in the 2002 *Control of Substances Hazardous to Health Regulations*.[16] Seventy-nine per cent of the institutions were able to work with toxins or with genetic material associated with the action of pathogens or toxins under conditions of containment.

18. The respondents tended to be more senior, better networked and more experienced than a typical member of the UK scientific community would be. For example, 71% of the scientists held positions of overall responsibility for research projects using Schedule 5 agents, 68% were day-to-day managers of laboratories, and just over half of the scientists (53%) were actively engaged in research with Schedule 5 agents. Several of the participants indicated having experience as biosafety (44%) and/or biosecurity advisors (24%).

19. Over half of the total sample, 56%, described themselves as having been previously involved with biosecurity issues including interactions with relevant government officials.

What did the project find?

20. The project produced three key findings of policy interest:

• The first finding is that thus far the implementation of new biosecurity measures in the UK do not seem to have had the same negative impact as has been reported in the US and Germany. This unexpected finding is important because it suggests that biosecurity policy options do not have to involve a trade-off between advances in scientific research and security. While clearly it is possible that advances in scientific understanding can increase the risks of misuse, and, similarly, that draconian security measures could disrupt science, this finding suggests that, at present, this is not **necessarily** the case.

• The second finding is that the success of the implementation of these new biosecurity measures was related to three factors (1) pre-existing security and biosafety measures; (2) a responsive approach to regulation by the implementing body; and (3) a flexible and socially responsible reaction by this sample of the scientific community. Had any one of these conditions not been in place, the costs could have been substantially higher. However, together they have contributed towards a successful implementation thus far.

• The third finding is that, while there has been successful implementation thus far of the requirements of the 2001 *Anti Terrorism Crime and Security Act*, if there is a requirement to further strengthen the biosecurity norm such implementation may be more difficult. If such further security measures are required then a greater degree of interaction between the scientific and the security communities is likely to be necessary to minimise implementation costs.

[16] Schedule 3, Additional Provisions Relating to Work with Biological Agents, Part 1, Provisions of General Application to Biological Agents, *The Control of Substances Hazardous to Health Regulations*, United Kingdom, 2002.

Specific findings

21. This section examines some of the specific findings of the pilot project as they relate to operational procedures, impact of the new requirements and perceptions held by our sample of the UK scientific community about biological weapons issues.

Channels of communication

22. Our sample of the UK scientific community received most of their information about changes in biosafety or biosecurity regulations through channels of communication which have been designed primarily for the distribution of health and safety information. Our sample indicated that their main sources of information were targeted distributions of information from the Health and Safety Executive (85%), whilst 59% of the sample performed proactive scanning of health and safety websites. However, over half the sample (53%) also received information from targeted distribution by governmental departments such as the Department of Trade and Industry. Only 15% actively scanned other sources for information, which included those sources primarily handling biosecurity issues.

23. The finding that our sample used for health and safety channels to gain their information reflects the long-established, close links between the scientific communities and those involved in ensuring that health and safety requirements are met, which is especially true in the life sciences area in regard to biosafety. This established relationship has been used to successfully implement a range of regulations on scientific practice in the UK since the 1970s. This is important because it highlights how the UK scientific community in the life sciences was already subject to regulations before the introduction of new biosecurity controls, and that this earlier implementation of these biosafety regulations created a link between government and science.

Procedures in place before 2001

24. One of the main factors which has influenced the level of costs associated with introducing new biosecurity controls in the UK seems to have been the existence of a range of procedures at institutions before the introduction of the *Anti Terrorism Crime and Security Act* in 2001. Many organisations in the sample of the UK scientific community had pre-existing procedures for the purposes of either biosafety obligations or concerns about animal rights terrorism. These procedures also functioned as biosecurity controls and thus helped reduce the costs of implementing the specific security requirements attached to Schedule 5 pathogens and toxins. For example, the majority of our respondents reported their institutions as having procedures to monitor the acquisition of dangerous material (71%) and disposal of equipment (71%) which pre-dated the obligations found in the *Anti Terrorism Crime and Security Act*, 2001. Similarly, 71% and 74% of the sample reported that access to laboratories and data by occasional visitors and short-term workers was controlled in their institutions prior to 2001. There were similar pre-existing controls in place in over half the institutions to govern the transfer of dangerous materials on-site (56%) and off-site (65%).

Changes in operational procedures since 2001

25. Notwithstanding these existing procedures, our sample of the UK scientific community indicated that substantial changes have occurred in the operational procedures of their institutions since 2001. When asked about those changes, the sample reported that more

attention is now being given to: biosafety obligations (79%), risk assessments (68%), material safety (53%), material transfer (56%), and ethical reviews (47%). Whilst a substantial number of the sample (41%) reported their institutions as having had in place procedures to review personnel with current access to controlled pathogens prior to 2001, only 26% reported an increase in that activity since the introduction of the *Anti Terrorism Crime and Security Act*, 2001.

26. When asked what the sample believed had caused these procedural changes, the majority of our sample (74%) believed they were the result of the new legal requirements but almost half (41%) believed that other pressures, such as the increased activities in the UK of animal rights protestors, might have been responsible.

Benefits: new funding contracts and partners

27. Only a small subset of the sample (15%) reported having received any direct benefit from the increased attention to biosecurity since 2001. Of those that did record a benefit, it typically took the form of winning new contracts or collaborative partners. The small number of participants that had moved into new areas of R&D (15%) did so mainly for financial reasons. Only one institution listed as a benefit the increased opportunities for discussion with government officials on the validity of these measures. Whilst these numbers seem low, it is important to note that 26% of our sample thought that it might be too soon to judge whether they could experience any benefits. In the USA, concerns about bioterrorism have opened up new funding sources for research, and it is conceivable that our sample of the UK scientific community may benefit from this in the future.

Costs: experiences of major complications or setbacks in the last three years

28. Although some of the sample has experienced benefits, the project also gathered data on a range of costs that have been experienced since 2001. Forty one percent of the sample indicated having experienced no major complications or setbacks in the last three years. However, our sample did indicate that four research projects have had to be abandoned as a direct result of the recent increase in national and international attention to the need to prevent science and technology from being diverted into biological warfare or bioterrorism purposes.

29. Despite this low number, a large proportion of the sample reported experiencing other ‘major complications or setbacks’ over the last three years. The issue causing the most complications or setbacks was the difficulty in obtaining pathogens and toxins, but other issues have also caused major complications such as increased mandatory biosafety requirements (15%), increased mandatory biosecurity requirements, and changes to waste disposal requirements (both experienced by 12% of the sample).

30. Further investigation of these results found that those who had experienced these ‘major complications and setbacks’ believed they were as much a result of changes in US biosecurity controls as changes in UK requirements. The influence of US regulations on UK science reaffirms the global nature of science and consequently indicates the global impact of any form of biosecurity control.

Which policies are worth considering?

31. Our sample of the UK scientific community was presented with a list of policy options that might be considered to enhance biosecurity and asked which they would consider as a means to strengthen the biosecurity norm. The figures presented in Table 1 indicate respondents who thought the measures were worth considering, rather than respondents who supported such measures.

Table 1: Views on biosecurity policy options

Policy Options to Enhance Biosecurity	**Percentage who would consider the option**
Increased security checks on all personnel currently working with dangerous pathogens, toxins or genetic material	62%
Increased screening of all new personnel with future access to dangerous pathogens, etc.	62%
Requiring procedures to authorise and control off-site transfers of dangerous pathogens, etc.	56%
Increased requirements for material control in institutions	53%
Scrutiny by funding bodies considering R&D proposals	47%
Scrutiny by scientific journals when papers are submitted	47%
More rigorous (safety) risk assessment of proposed work	41%
More rigorous ethical review of proposed work	41%
Codes of conduct	32%
Denying access to nationals from countries of concern to dangerous pathogens, etc.	21%

These results indicate that the sample of the UK scientific community are willing to consider a wide range of possible policy options, but prefer options that do not unduly hinder research or teaching.

32. Further investigation of the reasons for lack of support for more rigorous safety or ethical assessment found a widespread belief that current levels of risk assessment and ethical review were adequate and that further rigour would impede research. It was also discovered that the limited support for the last two options was due to a lack of understanding of their underlying logic. For example, the sample of the UK scientific community failed to see how implementing a code of conduct would strengthen biosecurity or help to ensure an effective biosecurity norm across the UK science base.

33. In the case of the last option, only 21% of the sample believed that denying access to nationals from countries of concern was an option worth considering. This result seems to conflict with the high scoring options of increased security checks on all personnel with current or future access to dangerous pathogens. This suggests the presence of other factors in the samples' decision-making processes. The project found that one such factor is the support for the cultural norm of universality of participation in research irrespective of an individual's nationality.

Who ought to have responsibility for protecting against misuse?

34. When asked who ought to be responsible for protecting against the possible misuse of the life sciences, our sample of the UK scientific community favoured self-governance by the institutions themselves (76%) and the scientific community at large (71%). There was also a preference for funding bodies to take responsibility for assessing risk before research takes place rather than for scientific journals to address the risks after the research is completed (a 59% to 29% preference). Reasons given for the high preference toward some form of self-governance were based on a response to frustration caused by "overly complex and bureaucratic regulations".

35. However, the sample generally recognised that some form of government participation was necessary. Fifty-eight per cent of the sample believed that of the options they would consider to strengthen the biosecurity norm, the best practice for implementation would be through formal regulation by government following consultation with members of the scientific community. Participants explained the need for formal regulation as ensuring "consistency", "uniformly high standards of design and implementation" and application "across the board". Mention was also given to the need for "outside auditing and regulation with sanctions that pose a real threat to those that do not comply" indicating some scepticism about self-regulation.

36. Of the options given, a marked preference was given for a focal role in the development and implementation of formal regulations to be given to government departments with which the sample have pre-existing relationships, such as the Health and Safety Executive (68%) or the Department of Trade and Industry (32%). Of those government departments primarily involved with non-health and safety issues, 47% of the sample preferred the involvement of the Home Office or the Security Services.

Analysis

37. When interpreting the results from this work it is important to recognise that this was only a pilot project. Care therefore needs to be taken in drawing conclusions or policy implications, as results are indicative rather than conclusive. However, having noted these caveats these the results do suggest that the implementation of new biosecurity controls in the UK has been conducted very successfully. The project found that 79% of our sample regarded the current balance in the UK between scientific freedom and security as satisfactory.

38. It is, of course, possible that the research was undertaken too early – however, the requirements of the *Anti Terrorism Crime and Security Act*, 2001 came into force in December 2001 hence our sample had had more than three years experience of its implementation. Although new legislation or improperly handled implementation has the

potential to generate substantial costs, the lack of substantial disruption is an important finding as it suggests that science and security do not necessarily have to be in conflict with one another.

39. As already noted, the research suggests three factors that have contributed to the successful implementation (thus far) of UK biosecurity controls:

1. Pre-existing biosafety measures which provided a degree of biosecurity;
2. A responsive approach to regulation by the implementing body; and
3. A flexible and socially responsible reaction to the new controls by the UK scientific community.

Factors influencing successful implementation 1: biosafety and biosecurity

40. One of the main contributing factors for the successful implementation thus far of the obligations in the *Anti Terrorism Crime and Security Act*, 2001 has been the high level of pre-existing biosafety procedures that can also function as biosecurity measures. The links between biosafety and biosecurity have been a recurring theme in this project.

41. Scientific activity in the UK has been heavily regulated since the 1970s through successive health and safety measures. The *Health and Safety at Work Act*, 1974 for example:

> *[I]ntroduced a broad goal setting, non-prescriptive model, based on the view that 'those that create risk are best placed to manage it'.*

Instead of existing detailed and prescriptive industry regulations, it created a flexible system whereby regulations express goals and principles, and are supported by codes of practice and guidance. Based on consultation and engagement, the new regime was designed to deliver a proportionate, targeted and risk-based approach.[17]

42. That 'flexible system' has since created procedures to deal with the acquisition of dangerous material, access to laboratories and data by visitors and short-term workers, and the transfer of dangerous materials.

43. Although biosafety and biosecurity are fundamentally different – biosafety being concerned with protecting the health and safety of workers and the environment whilst the central concern of biosecurity is unauthorised acquisition – the norms are compatible and it can be argued that the implementation of UK biosecurity measures has drawn heavily on the biosafety model. The new biosecurity legislation, for instance, has concentrated on tightening existing practices rather than introducing radically new requirements. Indeed some of the procedural changes introduced into UK laboratories since 2001, such as more rigorous risk assessment procedures, increased material safety requirements, and improved recording and regulation of the possession and transfer of dangerous materials, may have occurred as a result of the periodic reviews of biosafety that have become the practice in UK workplaces, rather than specifically in response to biosecurity legislation and government inspections.

[17] Health and Safety Executive *Thirty Years on and Looking Forward: The Development and Future of the Health and Safety System in Great Britain*, 2004.

44. This suggests that the variation in the implementation costs, nationally and internationally, of biosecurity policies (e.g. disruption to research, additional spending) can be explained, at least in part, by the extent of pre-existing national biosafety regulations. Furthermore, this suggests that the costs of implementation might be substantially higher in institutions with lower levels of health and safety procedures. Given that the sample was biased towards scientists working with dangerous human pathogens, extending the implementation process beyond Schedule 5 of the *Anti Terrorism Crime and Security Act*, 2001 might generate more substantial costs.

Factors influencing successful implementation 2: the implementation process

45. Effective implementation of any biosecurity control on dual use technologies is challenging because it has the potential to impose substantial costs upon legitimate actors. Further, effective implementation requires the co-operation of the scientific community, many of whom will not have had previous contact with the security community. Given the cultural differences between the 'open' scientific community and the 'closed' security community, care is needed to avoid a clash of cultures. [18]

46. Given these difficulties, the second factor which has influenced successful implementation has been the actions of the implementing body – the UK National Counter Terrorism Security Office.[19] This body has come close to producing a textbook example of successful change management. The implementation of new regulations has exploited pre-existing links and channels of communication between the biosafety and scientific communities and used them as avenues into the scientific research community. The implementation process has thus far been non-confrontational and, because of the role given to biosafety officials, has to some extent been responsive to the organisational culture and work practices of the scientific community.

47. However, only 21% of the sample believed that the police ought to have responsibility for protecting against the misuse of the life sciences. Given the bias in the sample, this result suggests that practising scientists favour the use of other mechanisms to protect the life sciences against misuse.

48. One participant explained that there were good interactions between officials and university biosafety staff "but a great deal needs to be done to get leaders of research projects involved. They will be at the front line when implementation is required". It is possible therefore that the current low level of support may increase once direct communication occurs between the police and practising scientists.

Factors influencing successful implementation 3: the response of the scientific community

49. The third factor influencing successful implementation has been the proactive response of the sample of the UK scientific community. The scientists interviewed repeatedly expressed a recognition that scientific research does not exist within a moral or social vacuum and that they, as scientists, have to be responsive to changes in society. As a result, they were

[18] Atlas R, "National security and the biological research community", *Science*, vol 298, no 5594, 2002.

[19] The National Counter Terrorism Security Office (NaCTSO) is a specialist police organisation co-located with the Security Service in the National Security Advice Centre. For more information see http://www.mi5.gov.uk/output/Page163.html#police

inclined to take a flexible and proactive approach to risk management. Even in situations where the sample thought that the risk assessments were unrealistic, they recognised the need to be responsive to public concerns and to take into consideration not just risks, but also the public's concerns and perceptions about those risks.

50. Although general awareness within the sample of the UK scientific community about current issues related to preventing legitimate science and technology being misused was quite low, there was a much higher level of awareness about how a scientist engaged on legitimate work might unknowingly contribute to the development of biological weapons or to bioterrorism. For example, participants believed that a scientist could unknowingly contribute by manipulating an organism to "overcome natural and therapeutic controls", by "inappropriate release of information", or "by making loans or gifts of equipment". Many in the sample believed that their awareness of the issues could improve if there was an opportunity for increased interaction with the government officials who design biosecurity policies.

51. The respondents also regularly reflected on the unintended consequences of different policies because of what the sample of the UK scientific community regarded as a lack of appreciation of the subtleties of scientific research. For example, policies based on the constraint of dissemination of information at the publication stage were considered inappropriate because the research methodology and findings would already have been publicised at conferences. Similarly, controls restricting the number of foreign nationals with access to dangerous pathogens were considered problematic in an environment where universities are actively encouraged to increase their foreign student numbers.

52. Many in the sample repeatedly expressed their desire to be better guardians of their science and wished to be more actively involved in the process of developing effective UK biosecurity policies by offering their scientific expertise and cultural knowledge. These participants felt they could be better guardians if they had better understanding of the types and risks of misuse, and of the logic underpinning regulatory measures such as control lists and export licences.

53. Their desire to have more active engagement with biosecurity officials is unlikely to be a result of any perceived direct benefit, as only 15% of the sample had received any. Their desire is more likely to stem from revulsion at the possibility of their legitimate research being misused and concerns about the impact of inappropriate regulations.

Risk management and the scientific community

54. Although this pilot project only explored a very specific part of security policy with a very small sample of the UK scientific community, it does suggest that there has been a major change in how the scientific community conceives of risk and attempts to manage it. On several occasions our interviewees stated that the BSE disaster had fundamentally changed the way that British society was prepared to accept risk assessments from scientists. Similarly, the House of Lords Select Committee on Science and Technology report on *Science and Society*[20] drew attention to how the British public was increasingly unwilling to accept scientific statements in an unquestioning manner. Partly in response to these changes, interviewees noted that the social legitimacy of scientific knowledge is increasingly

[20] House of Lords Select Committee on Science and Technology, *Science and Soci*ety, HMSO, March 2002.

dependent on scientists engaging with wider society, suggesting that the proposals of the Royal Society report on the management of scientific risk have been adopted.[21]

55. Clearly the project was drawing on a self-selecting sample of interviewees who, by agreeing to be interviewed, were already more likely to be inclined to engage outside their disciplines. However, the consistency of their responses suggests that there is at least a subpopulation of the scientific community that not only recognises the risks of misuse of scientific knowledge, but also recognises the importance of public perceptions of that risk, and their role in responding to those perceptions. This reflexive nature can be seen by the fact that while 47% would consider editorial scrutiny of papers at publication, only 39% believed the process would reduce the risks of misuse. This indicates that at least some thought that such policies should be considered either because they might be effective for unintended reasons, or because they considered them effective ways of dealing with other concerns and perceptions.

56. Interviews suggested that the scientific community was prepared to expend considerable effort engaging with the wider community to generate and maintain what Gibbons and colleagues call 'socially robust knowledge'.[22] In the context of biological weapons non-proliferation this involved recognising the uncertainties surrounding risk assessments and a focus on processes that manage and reduce unknown and possibly unknowable risks. This focus on improving risk management processes is reflected in the support for the Health and Safety Executive as the preferred medium through which government should enact regulations. The Health and Safety Executive has a long established working relationship with the scientific community and focuses on allowing scientists to exploit their expert knowledge of local situations to create more effective policy. While the academic social science literature has called for the scientific community to be more reflexive in its approach to risk management, our results, though only indicative, suggest that at the micro-level this has already happened. The policy issue is therefore not about changing scientists' understanding of risk, but of providing them with the time and resources they need to effectively engage with the policy making process.

Reflections

57. The results from this pilot project indicate that thus far, the implementation of UK biosecurity controls has been carried out with limited negative impact on the scientific community. It thus appears that post 9/11 changes in attitudes and procedures within the scientific community working with controlled pathogens have been less disruptive in the UK than in the US and German scientific communities.

58. As already mentioned, it is possible that this research was undertaken too early, and that future legislation or improperly handled implementation has the potential to generate substantial costs to UK science. As such it will be necessary to regularly review the impact of dual use controls on UK science. This project has developed and validated a methodology to identify relevant members of the scientific community and obtain such information.

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[21] Royal Society *Risk: Analysis, Perception and Management*, Second edition, London: UK, The Royal Society, 1992.

[22] Gibbons M, C Limoges, H Nowotny, S Schwartman, P Scott and P Trow, *The New Production of Knowledge*, London Sage, 1994.

59. One participant highlighted the need for a two-stage implementation process of national biosecurity measures – the first stage involving securing adherence with minimal costs, the second stage involving a long-term culture change in the scientific community. With the first stage being conducted successfully, implementers can now turn their attention to the longer-term objective of a cultural change within the scientific community. This project has shown that this may require a change to the type of engagement currently conducted between the scientific and security communities, to take into consideration the norms and practices of the scientific community. An appreciation of these norms will reduce potential resistance to new or extended biosecurity legislation and may encourage full and effective participation by the scientific community in UK efforts to reduce the threat from biological weapons.

Conclusions

60. This Briefing Paper has described a project which developed and validated new methods for assessing the impact that UK government biosecurity policies, which were introduced to prevent legitimate scientific research from being misused, are having on the practice of science. As already noted, the project has produced three key findings relevant to the implementation thus far of biosecurity policy:

- The **first** is that implementation of these new national biosecurity measures do not seem to have had the same negative impact as has been reported in the US and Germany. This is an unexpected finding and is important because it suggests that biosecurity policy options do not have to involve a trade-off between advances in scientific research and security objectives. While clearly it is possible that advances in scientific understanding can increase the risks of misuse, and, similarly, that draconian security measures can disrupt science, this finding suggests that, at present, this does not **necessarily have to be** the case.

- The **second** is that the successful implementation of these new national biosecurity measures was related to three factors

  (1) pre-existing biosafety measures which provided some security benefits;
  (2) a responsive approach to regulation by the implementing body; and
  (3) a flexible and socially responsible reaction by this sample of the scientific community.

  Had any one of these conditions not been in place, the costs could have been substantially higher. However, together they have contributed towards successful implementation.

- The **third** finding is that, while the initial stage of implementing the 2001 *Anti Terrorism Crime and Security Act* has been successful, future efforts to further strengthen the biosecurity norm might be more difficult. If further security measures are required then a greater degree of interaction between the scientific and the security communities will be necessary. Changes to current forms of interaction, so that norms and practices of the scientific community are fully considered, may reduce potential resistance to new measures and encourage full and active participation in efforts to reduce the threat.

61. These results provide valuable insight for consideration by the States Parties to the BTWC in regard to identifying effective action in relation to the topics addressed in 2003 in regard to the *adoption of necessary, national measures to implement the prohibitions* and to *national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins* and to the topic for 2005 regarding *codes of conduct for scientists.* Effective action through measures to control access to materials, knowledge and technologies will strengthen the regime totally prohibiting biological weapons and benefit **all** States Parties to the BTWC.

62. This project has highlighted the fact that although biosafety and biosecurity are fundamentally different – biosafety being concerned with protecting the health and safety of workers and the environment whilst the central concern of biosecurity is unauthorised acquisition – the norms are **compatible** and it can be argued that the implementation of UK biosecurity measures has drawn heavily on the biosafety model. The new biosecurity legislation, for instance, has concentrated on tightening existing practices rather than introducing radically new requirements. Indeed some of the procedural changes introduced into UK laboratories since 2001, such as more rigorous risk assessment procedures, increased material safety requirements, and improved recording and regulation of the possession and transfer of dangerous materials, might also have occurred as a result of the periodic reviews of biosafety that have become the practice in UK workplaces, rather than specifically in response to biosecurity legislation and government inspections.

63. It is noted that the Royal Society in its policy document 04/05[23] addressing the issues to be considered by the States Parties to the BTWC in 2005 has noted that:

> *In the UK, scientists must comply with local and national safety legislation that is related to some of the BTWC provisions. Consequently, by complying with the safety regulations scientists will also be complying with some of the obligations of BTWC or the UK 1974 Biological Weapons Act, which implements the terms of the BTWC in UK national law. It has been suggested that the requirements of the risk assessment process already required by the health and safety regulations could be widened slightly to ensure that the proposed activity does not present a risk to the prohibitions enshrined in the BTWC (Pearson 2005[24]). However, not all BTWC States Parties have national legislation implementing the BTWC or the same level of health and safety regulations as the UK.*
>
> *Introducing extended codes of conduct or practice based on existing health and safety regulations provides an opportunity for education and training to reinforce these regulations. Such a code would need to be consulted before any new work was conducted and at key stages during the project, and have greater value than a code that is a reference document. This would also reinforce the responsibility of scientists to take into consideration the reasonably foreseeable consequences of their activities.*

[23] The Royal Society, *Issues for discussion at the 2005 Meeting of Experts of the Biological and Toxin Weapons Convention*, RS policy document, June 2005. Available at: http://www.royalsoc.ac.uk/document.asp?id=1170

[24] Graham S. Pearson, *A Code of Conduct for the Life Sciences: A Practical Approach, University of Bradford, Department of Peace Studies, Briefing Paper No. 15, November 2004. Available at http://www.brad.ac.uk/acad/sbtwc*

This project found evidence of a desire, by scientists, to be better guardians of their work, and to be more actively involved in the process of strengthening the biosecurity norm. As such, this project supports the view expressed above by the Royal Society that introducing codes of conduct or practice provides educational and training opportunities – a by-product of which will be better guardianship of their science.

64. Although this project focuses on the UK's national biosecurity regulations, introduced since 2001, it should be noted that the various health and safety regulations in the UK are consistent with the comparable EU regulations. For example, the European Directive (98/24/EC)[25] *Protection of the health and safety of workers from the risks related to chemical agents at work* and Directive (2000/54/EC)[26] *Protection of workers from risks related to exposure to biological agents at work* set out the requirements for the determination and assessment of risks in a comparable way to that elaborated in the UK national regulations and codes of practice. In a similar way, the European Directive (98/81/EC)[27] sets out the requirements for the contained use of genetically modified microorganisms and for the provision of risk assessments in a comparable way to that elaborated in the UK national regulations and code of practice.

65. In looking to the wider international scene, it is also noted that adherence to the United Nations Environmental Programme's International Technical Guidelines for Safety in Biotechnology[28] and The Cartagena Protocol on Biosafety[29] means that two of the three findings from this pilot project (that, in the UK, pre-existing biosafety measures which already provided a degree of security, and a responsive approach taken by the implementing authority seems to have contributed to initial successful implementation of national biosecurity measures), have potential global applicability.

66. The States Parties to the BTWC are recommended to take the findings from this project into consideration in considering effective action in regard to the topic for 2005 of *codes of conduct for scientists* and again at the Sixth Review Conference in 2006 when States Parties will be giving consideration to further action in regard to the topics addressed in 2003 in regard to the *adoption of necessary, national measures to implement the prohibitions* and to *national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins* as well as of the topic for 2005 regarding *codes of conduct for scientists.*

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[25] European Council, *COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work,* Official Journal of the European Communities, L131/11, 5 May 1998. Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_131/l_13119980505en00110023.pdf

[26] European Council, *DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND COUNCIL of18 September 2000 on the protection of the health and safety of workers from the risks related to exposure to biological agents at work,* Official Journal of the European Communities, L262/21, 17 October 2000.

[27] European Council, *COUNCIL DIRECTIVE 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms,* Official Journal of the European Communities, L330/13, 5 December 1998. Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf

[28] United Nations Environment Programme, *UNEP International Technical Guidelines for Safety in Biotechnology*, December 1995. Available at: http://www.biosafetyprotocol.be/UNEPGuid/Contents.html

[29] United Nations Environment Programme, *Cartagena Protocol on Biosafety.* Available at: http://www.biodiv.org/biosafety/protocol.asp

ANNEX: Schedule 5 Pathogens and Toxins, *Anti-Terrorism Crime and Security Act,* 2001[30]

Viruses	Chikungunya virus
	Congo-crimean haemorrhagic fever virus
	Dengue fever virus
	Eastern equine encephalitis virus
	Ebola virus
	Hantaan virus
	Japanese encephalitis virus
	Junin virus
	Lassa fever virus
	Lymphocytic choriomeningitis virus
	Machupo virus
	Marburg virus
	Monkey pox virus
	Rift Valley fever virus
	Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
	Variola virus
	Venezuelan equine encephalitis virus
	Western equine encephalitis virus
	Yellow fever virus
Rickettsiae	Bartonella
	quintana (Rochalimea quintana, Rickettsia quintana)
	Coxiella burnetii
	Rickettsia prowazeki
	Rickettsia rickettsii
Bacteria	Bacillus anthracis
	Brucella abortus
	Brucella melitensis
	Brucella suis
	Burkholderia mallei (Pseudomonas mallei)
	Burkholderia pseudomallei (Pseudomonas pseudomallei)
	Chlamydophila psittaci
	Clostridium botulinum
	Francisella tularensis
	Salmonella typhi
	Shigella dysenteriae
	Vibrio cholerae
	Yersinia pestis
Toxins	Aflatoxins
	Botulinum toxins
	Clostridium perfringens toxins
	Conotoxin

[30] The Act is available at http://www.hmso.gov.uk/acts/acts2001/20010024.htm

	Microcystin (Cyanginosin)
	Ricin
	Saxitoxin
	Shiga toxin
	Staphylococcus aureus toxins
	Tetrodotoxin
	Verotoxin