年報 科学・技術・社会
第17巻(2008), 95-116頁
apan Journal for Science, Technology & Society
VOL. 17 (2008), pp.95-116

Defining the Emerging Concern with Biosecurity: For Who? From What? What Now?*

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Abstract

- 1. Introduction
- 2. Biosecurity Multiple Precautions
- 3, 'Dual Use' as an Aspect of Biosecurity
- 4. Questions about 'Dual Use'
 - 4.1. Defining the problem of 'dual use'?
 - 4.2. Who defines the problem of dualuse?
- 4.3. What is doable in science?
- Formalizing Dual Use: The National Science Advisory Board for Biosecurity Oversight Framework for Dual Use Research
- Communication
 - A Threat to Science?
- 7. Closing Remarks

Abstract

Developments in science are often linked-to_fundamental ethical, social, and political concerns that raise questions about the appropriateness of existing forms of societal regulation. In recent years, with the increasing international attention to matters of national security, the term 'biosecurity' has gained prominence within the agendas of many governments and organizations. While diverse in its formulations, the attention to it typically signals a questioning of previous research preoccupations and practices in the life sciences. Potentially wide-ranging concerns are being posed about the responsibilities of scientists and the proper oversight of their work vis-à-vis concerns about the destructive potential of equipment, agents, techniques, skills and knowledge. This article outlines the broad contours of this emerging attention to biosecurity with a view to considering it as a case for how problems with science are defined and responses are formulated. Emphasis is given to the so-called 'dual use' potential of knowledge and techniques as part of wider biosecurity concerns. Through drawing on previous work in the social studies of science and elsewhere, the article reviews international developments with a view to identifying their emerging themes, tensions, disjoints, and contradictions. Particular attention is given to the activities of the US National Science Advisory Board for Biosecurity (NSABB) as a leading example of national responses.

^{*} Keywords: Biological weapons, Security, STS, Regulation, Dual use

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1. Introduction

Throughout its history, Science and Technology Studies (STS) has posed questions about the ethical, social, and political dimensions of research. Central to such efforts have been attempts to understand the commitments and limitations of the contingent ways that problems become defined, policies get tabled, and practices become established.

In that vein, this article outlines the broad contours of emerging international attention to 'biosecurity' with a view to asking how certain claimed problems with science are being defined and how responses are being formulated. In recent years, renewed attention has been given to 'security matters' across a range of public affairs (see Rappert et al. 2007). Of particular note in this regard, the term 'biosecurity' has emerged as a shorthand for varied measures designed to prevent and mitigate the deliberate and inadvertent spread of disease. While biosecurity in the past was a widely used term for measures designed to keep livestock and crops free from disease, today it has taken on an additional dimension aligned within national security agendas. This revised notion is now a commonplace label and goal in the policies and discourses of governments, inter-governmental agencies, non-government agencies, and others. As part of this, life science research has received perhaps unprecedented attention in terms of its security dimensions; especially how it might facilitate the development of so-called 'weapons-of mass destruction'. New streams of funding, national and international conferences, and policy initiatives are being launched to enhance the state of biosecurity.

By way of exploring the commitments and limitations of present discussions, in this article emphasis is given to the so-called 'dual use' potential of knowledge and techniques as part of wider biosecurity efforts. Through drawing on previous work in the social studies of science and elsewhere, the article reviews international efforts in order to identifying the emerging themes, tensions, disjoints, and contradictions associated with biosecurity and dual use initiatives. Particular attention is given to the activities of the US National Science Advisory Board for Biosecurity (NSABB) as a leading example of national responses.

2. Biosecurity — Multiple Precautions

Security is often a contested concept: security for whom and from what are only two of the many points on which individuals can sharply disagree. Therefore, when the attempt is made to understand the commitments and limitations of how security problems are addressed, the mix of alternative definitions is worthy of attention.

Among the range of definitions given to biosecurity today, the more narrow ones relate to concerns about the physical security of pathogens, toxins and other biological agents. In 2006, the World Health Organization (WHO) released a report titled *Laboratory Biosecurity-Guidance* that provided some recommendations for the safeguarding of valuable biological

materials (with an emphasis on pathogens) from those who would use them for ill. Biosecurity was said to pertain to 'reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of [valuable biological materials] to tolerable, acceptable levels' (WHO, 2006, 11). The notion of biosecurity was related to and contrasted with more long standing preoccupations about biosafety; the latter defined as 'reducing the risk of unintentional exposure to pathogens and toxins or their accidental release' (ibid.). The range of measures noted for enhancing biosecurity included: limiting access to certain materials, keeping records (e.g., about inventories), enacting approval procedures for those working with materials, undertaking biorisk assessments, disposing of materials, reporting security breaches, and fostering a positive culture of responsibility.

In framing biosecurity in terms of laboratory management practices, WHO shares an approach with others (e.g., Salerno and Gaudioso 2007). Within international diplomatic processes, such a fairly bounded way of thinking has also been evident. In 2003 under the Biological and Toxin Weapons Convention, States Parties and their experts meant to promote common understanding and effective action on 'national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins'. Although not phrased as meetings about 'biosecurity' as such, a number of states adopted the term as a way of referring to the issues at hand. This included Japan (2003), whom prepared a Working Paper titled *Possible Measures for Strengthening Biosecurity*. Herein it was stated that:

Preventing unauthorized access to disease-causing microorganisms and other infectious materials and toxins that could be used in the development and manufacture of biological weapons is called 'biosecurity,' and it is only quite recently that people have become aware of the importance of taking additional measures in this regard (ibid: 1).

Japan itself was included among those states identified as only recently having become aware. It was said to be 'not most advanced in the area of biosecurity' (ibid: 1). By way of substantiating the claim of the overall limited international attention to the topic at the time and also outlining what might be done, a brief summary description was given of the findings of a survey of policies in ten (unnamed) countries. These included: keeping lists of dangerous pathogens and toxins; monitoring of facilities and individuals that handle controlled pathogens and toxins; controlling the transfer of controlled pathogens, and ensuring the physical security measures applied to facilities with controlled agents. The Working Paper argued state practices varied widely. While 'most' countries were said to have undertaken conventional 'biosafety' measures that were also relevant for 'biosecurity', the number that had taken biosecurity-specific measures remained 'small'. The adequacy of biosafety for biosecurity has been a theme of commentary elsewhere. For many countries of Africa with emerging biotech capabilities but limited resources, it has been argued that the implementation of biosafety measures will sufficiently address security concerns.² In any case, in 2006 the Japanese Law

Concerning the Prevention of Infections and Medical Care for Patients of Infections was revised for the third time to include legally-binding standards for the physical security of certain pathogens and the registration of facilities.

Biosecurity has taken on a rather more expansive conceptualization elsewhere. In its activities to promote greater attention to this general topic, the Organization for Economic Cooperation and Development (OECD) defines biosecurity as measures to 'protect against the malicious use of pathogens, parts of them, or their toxins in direct or indirect acts against humans, livestock or crops.' The use of expansive definitions is most apparent in the US where much of the focus is with bioterrorism. In the prominent report of the US Institute of Medicine and the US National Research Council's titled Globalization, Biosecurity and the Future of the Life Sciences, biosecurity was defined as:

security against the inadvertent, inappropriate or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling or use of biological weapons as well as natural outbreaks of newly emergent and epidemic disease. Although it is not used as it is often in other settings, to refer to a situation where adequate food and basic health is assured, there may be significant overlap in measures that guarantee "biosecurity" in either sense (2006: 25).

With regard to the latter point, for instance, much of the use of the term biosecurity in India has related to this broader sense of human security (Roul 2007). In referring to 'biological agents or biotechnology', Globalization, Biosecurity and the Future of the Life Sciences opened up a space for moving beyond a concern with physical access to agents. So the report highlighted the destructive potential of non-traditional means (e.g., through the use of bioregulator compounds). The report also was not only concerned with the access to laboratory agents, but how the knowledge and techniques generated through advanced life science research were enabling new destructive capabilities. The latter required scrutinizing access to information available in the open scientific literature. It is this sense of the 'dual use' potential of knowledge and techniques that has underlined many of the biosecurity initiatives in the US (e.g., the establishment of the National Science Advisory Board for Biosecurity, see below).

Still elsewhere, though still in the US, biosecurity has also taken on a relatively expansive definition. The journal *Biosecurity and Bioterrorism* (started in 2003) — with an editorial staff now at the Center for Biosecurity of the University of Pittsburgh Medical Center — publishes on a wide range of issues including: threat assessments, preventative policies, detection and surveillance technologies, and medical response to the deliberate and inadvertent spread of disease. Others have used the term biosecurity to promote particular agendas within such a wide range of possible ones. The Alliance for Biosecurity, for instance, is collaboration

among more than a dozen pharmaceutical and biotechnology companies who promote medical responses to deliberately initiated disease outbreaks.⁵

Indicating both the diversity of existing definitions and an uneasiness with this situation, in 2006 the US National Academies held a workshop titled 'Advancing the International Biosecurity Dialogue: Clarifying Definitions' to promote more common understanding about the meaning of biosecurity among identified stakeholders.

In brief then, while a shared international discourse about the recognized importance of biosecurity is now evident, just what that translates into for local practice is far from straightforward to determine. Stated concern about 'biosecurity' as such signals little about what sorts of problems are being identified or how they should be addressed. Tucker (2007) illustrated these points in a comparative review of biosecurity policies in Germany and the US. While these countries share much by the way of policy language, political systems, and advanced biotech capabilities, they are different significantly with regard to their policies. Tucker summarized some of those differences in writing that:

...Germany relies on broad biosafety regulations rather than narrowly targeted biosecurity measures. The German biosafety regulations predated the US anthrax letter attacks of autumn 2001 and have changed little since then. The only area that has been expanded since 9/11 involves personal reliability checks of scientists who work with dangerous pathogens, and this vetting process draws on existing legislative authority. Unlike the United States, Germany does not deny access to dangerous pathogens strictly on the basis of nationality...The United States has largely ignored how other countries view its laboratory threat-characterisation programme, which includes experiments that appear to skirt if not cross the red lines laid down by the BWC. Germany, in contrast, has sought to reassure other countries about the strictly protective nature of its biodefence programme by avoiding provocative experiments and striving for maximum transparency (ibid.).

Such differences led him to voice certain doubts about the prospects for a harmonized international approach between these two countries.⁶

Additional comparative studies of activities elsewhere would no doubt identify further national differences. Take the wider issue of national medical, police, fire, and intelligence bio-preparedness measures in the case of natural, accidental or deliberate outbreaks of disease. Lentzos and Rose (2007) argued that the bio-preparedness policies of major European countries about this 'biosecurity' area differ significantly from the US; where in the latter concerns about bioterrorism are often identified as requiring a distinct (and financially substantial) response from other disease threats. Countries such as France, German, and the UK though differ between themselves in alternatively stressing contingency planning, protecting populations, and enhancing resilience.

As is evident from this section, the range of definitions given to and responses undertaken with regard to biosecurity are inseparable from basic policy and (geo-) political questions about the relative threats from the spread of disease, the priority such threats against other health and security concerns, the acceptability of regulations on communication and movement, the appropriateness of international standardization, and other such issues. The particulars of concepts of biosecurity on offer matter because they are not just put forward as abstract descriptions, but inexorably tied to determinations about what concerns require attention and resources.

3. 'Dual Use' as an Aspect of Biosecurity

Within the contested range of what counts as biosecurity, the remainder of this paper concentrates on what has become known as the 'dual use' problem. The term 'dual use' is itself an umbrella phrase with a long history. For instance, it has been widely employed in the past to refer to technologies with civilian and military applications or, more generally, those technologies that can serve alterative purposes beyond those routinely accorded to them. The specific sense in which I wish to consider it here is the possibility that 'the generation and dissemination of scientific knowledge [...] could be misapplied for biological weapons development and production' (Atlas and Dando 2006: 276).

Arguably the most influential statement of this conceptualization was the US National Academies report *Biotechnology Research in an Age of Terrorism* first released in late 2003. As stated in the report, the problem that needed addressing was 'the intentional use of biotechnology for destructive purposes' (NRC 2003: 14-15). Attention to the security implications of the life sciences was justified by recent developments including, 'the discovery of nations with clandestine research programs dedicated to the creation of biological weapons, the anthrax attacks of 2001, the rapid pace of progress in biotechnology, and the accessibility of these new technologies by the Internet' (Fink 2003: vii-viii).

Professor Gerald Fink of the Whitehead Institute for Biomedical Research chaired the Committee and offered this depiction of the issued at stake: (ibid. vii).

...[A]Imost all biotechnology in the service of human health can be subverted for misuse by hostile individuals or nations. The major vehicles of bioterrorism, at least in the near term, are likely to be based on materials and techniques that are available throughout the world and are easily acquired. Most importantly, a critical element of our-defense against bioterrorism is the accelerated development of biotechnology to advance our ability to detect and cure disease. Since the development of biotechnology is facilitated by the sharing of ideas and materials, open communication offers the best security against bioterrorism. The tension between the spread of technologies that protect us and the spread of technologies that threaten us is the crux of the dilemma.

Thus, even at first glance, concerns about destructive applications of biology pose a vexing dilemma, since the promising aspects go hand in hand with its threatening sides.

Yet, once the basic issues associated with dual use are examined in further detail, the situation become ever thornier. Take the uncertainty and disagreement over the severity of the threats associated with biological weapons. Much of the emphasis today in international security discussions relates to their use by terrorist groups. But the likelihood of the successful weaponization of bioagents has been hotly disputed. Interpol President Jackie Selebi (2005) spoke to one end the spectrum of appraisals in stating:

The bio-terror threat has increased over the past few years. As bio-technology advances and as information becomes more accessible, particularly through the Internet, the risk of biologic agents or toxins being misused as an evil tool for terrorism, increases... Today, there are indications that terrorist organizations have a heightened interest in the use of biological weapons, establishing terrorist support cells in different regions around the world with the ability and willingness to carry out bio-terrorist attacks. Using bio-weapons could potentially result in thousands of casualties in addition to other disastrous long-term consequences. Since pathogens (biological agents or germs) reproduce easily, even a small amount of agents smuggled out from secured premises could be used as the basis of a large arsenal. These biological agents or germs are virtually undetectable and can be brought relatively easily and safely into a country by an individual...The issue of bio-terrorist attacks is not 'if' but 'when'.

Elsewhere such assessments have been strongly criticized (Leitenberg 2001; 2005, see as well Tucker 2007). The limited number of bioterrorist attacks in the past (see Turnbull and Abhayaratne 2003) and the difficulties experienced by even well funded groups and states in weaponizing pathogens are key factors cited to indicate a low likelihood of attacks of any significance. This has been argued to be the situation by doubters even if sub-state groups act in concert with likely "states of concern". Following from this overall evaluation, the possibility that sub-state groups could make use of advanced life science research — as in the concern today associated with dual use research — is even more remote.

Of course, at issue in such disagreement is just what counts as a 'successful' or 'highly consequential' attack. As Collins and Pinch (1998) demonstrated in the case of the Patriot missile system, making determinations of effectiveness is a social activity wherein much scope can exist for disagreement about whether, and by what criteria, technological systems get judged as 'successful', 'effective', etc. In relation to bioterrorism, much of current disagreement turns on often unstated assumptions about whether bioattacks need to cause mass casualties to be taken as 'significant'. As a counter to this suggestion it can be said that the 2001 US anthrax letter mailings might not have caused mass casualties but they were highly disruptive and economically costly. In other words, a split is whether biological weapons

are treated as worrying because they are 'weapons of mass destruction' or 'weapons of mass disruption'.

The issues of the previous paragraphs play out in Japan in relation to how the Aum Shinrikyo activities in the 1990s should be interpreted. Although much of detailed information about the cult's bioweapon program remains within police files (thus increasing the scope for speculation), some basic information is known. Starting in 1990, Aum Shinrikyo members experimented with the use of bioagents — this including the release of what senior figures believed (perhaps erroneously) to be bacteria botulinum and (erroneously) virulent anthrax. In both cases, no known casualties resulted. On the one hand, this history might be taken to indicate little scope for concern with bioterrorism due to the problems experienced in weaponization; especially since the Aum was well funded and had access to (at least certain) scientific expertise. On the other hand, its interest in the bioweapons and the willingness of highly educated people to work towards their production could be taken to indicate the possibility for bioterrorists attacks, even if in this particular case it did not prove possible for a group to undertake highly lethal attacks.

Perceptions of threats do no just exist as universally understood understandings. Rather they must be communicated and individuals persuaded. The extent and nature of such communication raises important issues that relate to basic concerns about the negotiation of threats. While the popular communication of and debate about perceived threats associated with the dual use potential of advanced research is prudent in terms of promoting public dialogue, it itself threatens to foster fears about potential attacks. That preoccupation may well have implications far beyond the democratic countries in which they take place. For instance, the case has been made that interest in biological weapons by the top echelon of those in Al Qaeda pre-9/11 was spurred on in substantial measure because of the preoccupation with bioweapons in the US (Givner-Forbes 2007; Leitenberg 2001). In a somewhat parallel manner, it might well be argued that the way in which biological weapons have been defined as distinctively horrific weapons (e.g., because they affect civilian and military sectors, their working is unseen, etc. -- see Sims 1991) may also contribute to their ultimate 'disruptive' implications. If biosecurity is about enhancing the sense of being protected from danger, then the extent and nature to which bioweapon threats are promulgated and flagged is an important and problematic issue vis-à-vis perceptions of vulnerability.

4. Questions about 'Dual Use'

The preceding paragraphs suggest the importance of the particulars of how capabilities, threats, and risks get defined. While in theory any knowledge might be said to be of 'dual use', just what research, in just what respect, and with what likelihood are important concerns in affecting determinations about what should be done. Consider then a few further points along the lines of just what and who; points that can be informed by lessons from STS.

4.1. Defining the problem of 'dual use'?

Stemming from reports such as Biotechnology Research in an Age of Terrorism much of way the problem of dual use knowledge and techniques has been defined is through a language of risks and benefits. For instance, in recent years, a number of science journals and funders have established procedures for the reviewing individual publications or projects for their biosecurity risks and benefits (see Rappert 2008). What is curious is that while, it is widely said that almost any knowledge and techniques can be used for destructive purposes, in practice it has been extremely rare that such procedures have identified any research as 'of concern', let alone determined that the risks of research outweigh its benefits.

For instance, at the beginning of 2003, more than thirty science journals agreed general progress guidelines for reviewing, modifying, and perhaps rejecting manuscripts where 'the potential harm of publication outweighs the potential societal benefits' (Journal Editors and Authors Group, 2003: 1464). This included the journals of the American Society for Microbiology. One figure that has gained some prominence (see below) is that of a sample of 16,000 manuscripts submitted to the journals of the American Society for Microbiology, only three were given additional biosecurity peer review and of those only one was required to be modified in any way prior to publication.

The lessons that one draws from such an experience is key to defining 'the problem' of dual use. For instance, it might be taken to indicate the system is working and there is little potentially problematic research to find. Yet, the experience to date might lead to different conclusions. Even working within a conventional understanding of risk-benefit analysis it may be taken as proving the need for a more sophisticated methods of calculating risks and benefits than are currently in place, as suggesting the need for greater awareness about threats to sensitivity to risks, or as requiring a moment away from the focus with individual instances of research (see Rappert 2008).

Alternatively, influenced by work in STS and the sociology of science, one might wish to question the basic ways of thinking informing how risks and benefits get treated. Lentzos (2006) has called for a questioning of the basic conceptual framings provided by political rationalities, styles of thought, forms of risk and frameworks of knowledge associated with biosecurity.

4.2. Who defines the problem of dual-use?

Conceptualizing risks in terms of their construction bring to the fore the question of just who is involved in the definitional process. A recurring theme in much of the policy analysis of dual use issues is the importance of 'the scientific community' developing self-governance measures. This general option in contrast to controls being devised by government and imposed through legislative measures (see Rappert 2007a: Chapter 1). It has been argued that governments such as US and Japan have chosen to impose legal regulations on research because of perceived inadequacies of responses by the science community. One example is

the development of legally binding standards for the physical security of pathogens in Japan through the 2006 revised Law Concerning the Prevention of Infections and Medical Care for Patients of Infections (Furukawa 2008). The danger expressed is that a similar dynamic in relation to the knowledge products of research might lead to a debilitating censorship of science.

One matter of note in international dual use discussion is that those voices warning of the dangers of government meddling routinely come from government as well (see Rappert and Balmer 2007). There seems little appetite overall or even by security-related ministries in governments to halt particular research from being done or communicated outright because of dual use concerns (see below).

Also, of note for those in STS, underlining discussions about the importance of self-governance are often highly idealized notions of science — so it operates according to the free and open exchange of information in an unfettered 'marketplace of ideas', where peer reviewed publications and the replication of experiments ensure the production of valid knowledge (Rappert and Balmer 2007). Working with such assumptions, nearly any government intervention threatens to destroy the delicate fabric of science.

4.3. What is doable in science?

Such presumptions of science are linked to questions about what is 'doable' and 'not doable' from research — that is, how readily the knowledge and techniques of science translate into destructive capabilities. Calling for a clarification of how 'dual use' is conceived, McLeish (2007) has drawn on lessons from STS and elsewhere to consider the sorts of (often implicit and contrasting) assumptions underlining claims about the potential for the destructive application of research. As she argues, much of the analysis of the dual use potential of research relies on now outdated linear models of innovation wherein applied science brings forth new technologies. Moreover, this literature and related regulation shift in an uneasy fashion between treating the locus of concern with 'dual use' between the act of technology transfer, the intention of users of knowledge and hardware, or the physical technology itself.

Also drawing on lessons from STS, about the importance of tacit knowledge (as in Polanyi (1958) Collins (1974); MacKenzie and Spinardi (1996)), Vogel has questioned how easy it is too move from the science to bioweapons. For instance, she argued that experiences in the former Soviet BW programme in the mass weaponizing of anthrax illustrate the importance of tacit and what might be called engineering-based knowledge (Vogel 2006). Despite extensive research on the design of weapons and the causative properties of anthrax, for instance, the Soviets experienced severe practical difficulties in making highly lethal weapons. More relevant to contemporary dual use discussions, Vogel (2008) has called into doubt the ease of reproducing certain work in synthetic biology. Such analyses pose major doubts for the likelihood that scientific developments could readily lead to 'weapons of mass destruction'.

Following in the STS discursive tradition, one might go somewhat further and take any

claims about of the 'utility' of research for destructive or non-destructive as discursive, interpretative accomplishments. Gilbert and Mulkay's (1984) study of the claims making process in biology elaborated how notions about the utility (or not), novelty (or not), and replication (or not) of research are subject to situational negotiation. Examining the manner in which warrant is given to claims might well bring to the fore many implicit assumptions and ways of reasoning employed by those making determinations of risks and benefits.

While the previous section outlined some of the basis issues associated with the dual use dilemma of research, this one has considered some more specific questions associated with how it becomes defined as a problem. In part this has been done through drawing on the STS literature. And yet, despite the more specific focus of this section, the argument has remained at a fairly abstract and general level. Developing a sense of how the general issues associated with biosecurity and dual use research are negotiated to particular practices necessitates a closer examination of specific cases. The next section changes tack from considering dual use in general to considering one particular attempt to define and respond to dual use concerns.

5. Formalizing Dual Use: The National Science Advisory Board for Biosecurity

That attempt is the effort ongoing at the time of writing by the US National Science Advisory Board to provide advice to the US federal government about how to respond to dual use concerns. The mandate of the Board was in large part derived from the recommendations of the US National Academies report Biotechnology Research in an Age of Terrorism. NSABB set up a number of Working Groups to deliberate options and provide recommendations; ones dealing with dual use criteria/oversight, communication, codes, synthetic biology, and international outreach. By way of giving a detailed treatment to practical efforts to define and respond to dual use issues, this section examines the first two.8

Considering the example of NSABB in some detail will provide an illustration of attempts to address, for practical purposes, the types of questions posed and the tensions identified in previous sections of this paper. As will be evident, through its deliberations, members of the Board have contended with thorny issues such as the likelihood of the destructive use of advanced life science knowledge as well as who and how should define the scale of the dual use potential. In doing so, whether explicitly or implicitly, NSABB has addressed geopolitical questions about how security can be secured.

Oversight Framework for Dual Use Research

A central task of NSABB-is the development of "guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results." Initially a 'Criteria for Identifying Dual Use Research and Results' was conveyed and the results of this feed into an overarching 'Oversight Framework Development' Working Group. The guidelines for risk/benefit analysis and oversight represent attempts

to define, evaluate, and handle concerns about the dual use potential of research through the creation of bureaucratic procedures. With such efforts, concerns about the scale of threats and the burdens of any response come to the fore.

By way of outlining how NSABB has gone about its task of devising guidelines, it can initially be noted that central to the responses has been the split between research that might have some sort of dual use potential and that which is "of concern". So for the Board, the term "dual use research" is used 'to refer in general to legitimate life sciences research that has the potential to yield information that could be misused to threaten public health and safety and other aspects of national security such as agriculture, plants, animals, the environment, and materiel' (NSABB 2007: 4). In contrast, "dual use research of concern" refers to 'subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security' (NSABB 2007: 16). So, as in following the remarks above by Professor Gerald Fink in *Biotechnology Research in an Age of Terrorism*, while in theory almost all biotechnology could be used for destructive ends, NSABB has sought to distinguish different potentials.

By way of preliminary remarks it is also important to note that, in general, the overwhelming tendency has been for Board members to argue that they do not expect oversight mechanisms will identify many experiments or publications as 'of concern' (let alone then subject to some form of restriction). ¹⁰ In a March 2006 meeting of NSABB, for instance, the above mentioned figures that 3 of 16,000 manuscripts submitted to the journals of the American Society for Microbiology were determined to need further review was cited to downplay the concern about the scale of "dual use research of concern".

That the NSABB appears to expect a low identification rate for research 'of concern' has justified a particular type of evaluation procedure — one that starts with a 'tick box' form that research investigators can quickly complete. Because it is thought little will need to be given significant dual-use review, the emphasis has been with devising a non-demanding first stage that should exclude the vast majority of research from further consideration. In this regard, it has suggested that the initial review of whether or not research is 'of concern' be undertaken by the Principal Investigator (i.e. the senior project leader). Herein, this person would ask of their work whether it fit the criterion of being:

Research that, based on current understanding, can be reasonably anticipated to-provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel (NSABB 2007: 17).

That assessors must be able to reasonably anticipate a direct threat based on current understanding sets a rather high threshold for when concern should be identified. To make this assessment, NSABB has identified seven broad categories to flag those instances of research

that *might* be 'of concern'. At this initial stage of the review process, the determination of the status of research is not intended to impose significant demands on Principal Investigators. Should research be found to match the criterion, then it would be subjected to institutional risk review for which NSABB has identified possible points for consideration (ibid.: Appendix 4).

Such an approach can be contrasted with alternative oversight model suggested by those at the Center for International and Security Studies at Maryland (CISSM) called the Biological Research Security System. This is envisioned as a legally binding system, requiring the licensing of personnel and research facilities, that would be applied to all such institutions, and have international coverage. While in broad terms subscribing to the likely limited number of experiments and publications that are likely to be 'of concern', the Maryland system requires independent peer review. Herein, an oversight body would need to approve work going ahead, rather than the investigators making the initial determination. This was justified on the basis that '[i]n addition to having a self-interest in seeing their research proceed, such individuals are also unlikely to have the security and other expertise necessary to recognize the possible dual use risks of their work' (Harris 2007: 120).

A case for the relative unfamiliarity of practicing scientists with dual use issues and thus the need for enhanced education about these issues has been made elsewhere (Dando and Rappert 2005; Rappert 2007a; Rappert and Davidson 2008). As a result, just how and what education should be required is a matter of some concern. According to the advice developed at the time of writing, it is envisioned by NSABB that the process of education in the US will be divided between different types of organizations. The NSABB has released draft recommendations that:

the federal government should develop training and guidance materials on federal requirements that can be used as educational resources at the local level. Furthermore, scientific societies, professional associations, and others in the private sector have an important contribution to make in promoting a culture of awareness and responsibility by educating broadly about dual-use research, the associated tenets of responsible research, and the best practices in identifying and overseeing dual-use research (NSABB 2007: 10).

This suggests that the federal government will have the task of instructing about the narrow matters of compliance requirements while non-governmental organizations have dual-use educational tasks related to wider issues. Yet if such an approach means that the training and guidance materials on federal requirements is as non-demanding as the procedures envisioned, then there may well be grounds for concern. A basic worry is that education limited to proper form filling will simply mean that PIs varying initial presumptions will become codified through the review process. In contrast, the Biological Research Security System mandates training in biosafety and biosecurity as part of licensing arrangements.

Defining the Emerging Concern with Biosecurity: For Who? From What? What Now? (Rappert)

certain aspects of this. If we don't do this carefully, we, in fact, run the risk of losing

what's really the greatest scientific engine the world has ever seen, and in what really

should be viewed as a race as opposed to an all or nothing type situation where we are

racing against bioterrorists and against people who are against our society and country.

The criteria proposed as part of the risk/benefit analysis in the Biological Research Security System also extend beyond the NSABB proposal. These both place further demands on assessors and pose basic questions about the need for research. As part of assessing research, for instance, individuals are supposed to consider whether the same experimental outcome could be pursued through alternative means, whether the research is being done is in response to a validated (credible) threat, and whether it will yield results definitive enough to inform policy decisions. Such questions place additional demands on those taking part in the assessment process than those as part of NSABB recommendations and require forms of knowledge that the average Principal Investigator is likely to posses. As another contrast to the NSABB proposals, the Maryland one provides a basic metric for evaluating research based on the responses given to the questions.

In tracking the developments of the Communications Working Group, it is possible to see how this concern informed the manner this Group as well as NSABB as a whole defined the problems at stake with dual use as well as what responsive measures. In short, the Communications Working Group — and through it the Board as a whole — shifted from focusing on the security threats deriving *from* research to the threats to research from security concerns.

At the heart of such alternative policy options is the matter of expertise: how this should be defined in practice and its relation to society at large. While NSABB devolves much of the decision making down to senior individual scientists who are aided (in a way still to be settled) by others, the CISSM proposal placed much more emphasis on diverse expertise itself informed by mandatory requirements. Expertise and how it should be exercised also figured in the deliberations of the NSABB Communications Working Group.

To elaborate; the 2004 Charter of NSABB said it was to 'Advise on national policies governing publication, public communication, and dissemination of dual-use research methodologies and results.' By the first public meeting of NSABB in November 2005, the Communication Working Group had articulated a vision for its activities. Paul Keim, the chair of the group, developed its-main charges deriving from the Charter as:

6. Communication

* Identify concerns and examine options and strategies for addressing issues related to the communication of dual use research information

As noted in a previous section, a recurring concern in recent policy deliberations has been that any controls placed on science vis-à-vis its destructive application could jeopardize the advancement of knowledge and the development of non-destructive applications of research. So too has this been a concern of those in NSABB. During the introductory statements at the inaugural meeting, for instance, both voting and ex officio government members repeatedly spoke about the imperative to not undermine the basis for scientific advancement. As the first member to make such an introductory statement, Dr. Paul Keim (later to become chair of the Communications Working Group) made a number of remarks that would be echoed in other introductory statements and NSABB meetings when he said:

* Develop draft recommendations for the NSABB that will facilitate the consistent application of well-considered principles to decisions about communication of information with biosecurity implications (Keim 2005).

I guess I'd just like to remind everybody what we have to lose in this process. You know, the United States scientific community and the European world community has really generated an enormous amount of progress in the last several decades, and this has really been based upon a competitive and interactive process where information was free to flow not only to your collaborators, but also to your competitors so that any result or any progress that you might make would be instantly peer reviewed and critiqued and vetted in a scientific dog fight, if you will.

To achieve these aims, a number of concrete deliverables were proposed, including the production of overarching principles for communication, advice on the oversight of communication, a framework for assessing risks and benefits with different types of dissemination, and case studies of good communication strategies. The audiences identified for these included those undertaking research, those administering it within institutions, journal

editors, and funders.

At this early stage, however, 'the public' only marginally figured into the deliberations. It was noted by Keim in November 2005 that public (mis-) understanding and trust were important and as a result researchers had to consider providing further 'contextual/explanatory information to minimize concerns and misunderstanding' (as had happened as a result of NSABB intervention regarding the publication of the reconstruction of the 1918 Spanish Flu virus in *Science* — see Rappert 2007a). In the open discussion, one member of the Board noted the public was an important audience for the deliverables given the need to allay certain of its fears and wider concerns about the lack of science literacy.

By the July 2006 meeting, however, 'the public' had assumed a much more central place. Keim now specified the Communication Working Group's main charges as deriving from the

In the process of increasing our security, it's going to be necessary to begin restricting

Charter as the development of guidance and tools to:

- * Facilitate consistent and well-considered decisions about communication of information with biosecurity implications;
- * Demonstrate to the public that scientists recognize, and are being responsive to, concerns about the security implications of their work (Keim 2006).

In addition, an overarching principle for communication was added that explicitly addressed questions of public trust in stipulating:

Public trust is essential to the vitality of the life science research enterprise.

It has always been important for life scientists to participate in activities that enhance public understanding of their research. Because of the potential for public misunderstanding of, and concerns about dual use research, it is especially important that life scientists engage in outreach on a regular basis to raise awareness of the importance of the research and to reassure the public that the research is being conducted and communicated responsibly (ibid).

In the Board discussions that followed Keim presentation, numerous references were made to the need to ensure a proper public understanding of dual use research.

The justification for and character of the movement from thinking about dual_use communication within NSABB — as centered on direct security threats in late 2005 towards something much more centered on the protection of science by mid 2006 — can be gleamed by considering Board interactions between these dates. Consider the March 2006 meeting of NSABB and the discussion had within regarding the scale of dual-use concerns identified by the Working Group.

The aforementioned 3 in 16,000 submissions identified as needing additional review figured repeatedly featured in the Board deliberations in defining the nature of the problem. For instance, in relation to the risk/benefit framework and what it might advise researchers to in terms of the content, timing and distribution of information, Keim outlined possible options as:

Communicate as is, communicate immediately, and there should be no limitation to distribution. So that is going to be something on the order of, something slight less than 16,000 out of 16,000 papers we believe will fall under than first category. However, again, even though this number is close to zero, it is not zero and those small number of paper that fall under those other categories are important to consider...(Keim 2006)

However, it was later reiterated that any action other than communicating 'as-is' would be

extremely rare.

But then if it was so extremely rare that the communication of any information would be identified as posing significant concerns (let alone worthy of some type of restriction) and suggestions had been forwarded that the actual scale of the any problem with communication was negligible, what would the deliverables of the Working Group achieve? This was addressed by Keim subsequently in considering the risk/benefit framework:

So continuing with the risk analysis, if the information is broadly communicated as-is, is there potential for public misunderstanding and is there potential for sensationalism? Again this comes back to the probability that the information could, in fact, elicit a misunderstanding from the public or from the government, Congress, or the President. And as our committee has concluded, we will see situations like this in the future, the probability of this is very high and so this needs to be part of the risk analysis in addition to just what the scientific impact would be for a real bioterrorism event. This is a very real consideration and in our interaction with the scientific community up till now, this is the thing that actually has been the most compelling for motivating the scientists we talked to actually get on board with dual use guidelines and evaluations (Keim 2006 - emphasis in original).

Echoing these sentiments, suggestions were forwarded that a 'hammer' (Casadevall 2006) could land on research because of the actions of those outside of it.

The framing of needing to balance the concerns of the science community against those of the public was reiterated again when the two groups were said to have the following principal concerns:

Scientific Community

- * Red tape and restraints on communication slow progress
- * Restricting communication -- starting down a slippery slope to censorship?

The Public

- * Need for more effective oversight of dual use research
- * Laws and regulations may be necessary (Keim 2006).

To mitigate the possibility of said misunderstanding or sensationalism, the communication plan presented at this meeting included calls for researchers (in those extremely rare cases of concern) to proactively speak to:

- * The public health significance of the research findings
- * How the new information or technology will be useful to the scientific community

Japan Journal for Science, Technology & Society Vol. 17

- * The biosafety measures in place as the research was carried out
- * The dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to communicate (Keim 2006)

Such statements sign posted the ways the education of the public and government so as to avoid hampering science became a prominent matter for NSABB.

A Threat to Science?

But while there was talk from Keim and others about the need to be seen responding before others outside of civilian science acted, evidence for the willingness of 'government' or 'the public' to do so was limited.

To expand, it is difficult to point to security initiatives from the Executive or Legislative branches in the US aimed at restricting the communication of research. The interjection of the assistant secretary of the Department of Health and Human Services for Public Health Emergency Preparedness that slightly delayed the publication of an article regarding the distribution of botulism toxin within the US milk supply system, the (additional) limitations imposed on the handling of the Variola major and minor viruses introduced in the 2004 Intelligence Bill (S. 2845), and the ever *possibility* of interpreting the Homeland Security Act of 2002 requirement to 'identify and safeguard homeland security information that is sensitive but unclassified'13 to include basic civilian life science research would be some examples. However, it would be difficult to argue that any of these or other initiatives had led to significant restrictions on what research was done or how it was communicated. When the range of actions is set along side the multi-billion dollar expansion of biodefense research in the US post-9/11 (Schuler 2005), the suggestion that the US government was bent on 'hammering' down on science seems untenable.

Perhaps the most prominent instance cited of the potential for legislative action was a US House of Representatives resolution that was proposed by eight members in reaction to the 2002 publication in *Science* of the artificial chemical synthesis of poliovirus. This Congressional move has been portrayed as an indication of the willingness by at least some politicians to act (Couzin 2002). Yet even this 'extreme' (and inconsequential) resolution though itself recognized both value in the free exchange of information and the need for the scientific community itself to act (see Weldon et al. 2002).

In contrast to the argument in this section regarding the lack of desire to control research findings, in relation to other areas of biosecurity, politicians within the US have undertaken consequential legislative steps. Mainly these have related to the control of materials and training. The 2001 US PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 brought in a variety of enhanced controls on the registration, transfer, storage and use of recognized dangerous agents. In 2005, the Department of Agriculture and Health and Human Services published final rules for the possession,

use and transfer of certain agents and toxins. As well, in areas of science and engineering, consequential approval procedures were introduced for foreign students and scholars (see Epstein 2001). With this mixed picture regarding the eagerness of government to take action, alternative portrayals of the threats from those 'outside' of science could be readily justified.

7. Closing Remarks

In outlining the broad contours of the emerging attention to 'biosecurity', this article has sought to ask how the term has been varyingly defined and responded to. Through drawing on previous work in the social studies of science and elsewhere, it has sought to highlight some of the emerging themes, tensions, disjoints, and contradictions associated with this area.

As argued, the debate over the meaning of biosecurity derives, in part, from contrasting ways of thinking about what is possible and likely through life science research. As one aspect sometimes identified as part of biosecurity, the so-called 'dual use' potential of knowledge is one topic in which questions of what and who play out. In theory, the prominent identification of the 'dilemma' or 'problem' of the dual use implications of advanced science knowledge and techniques raises wide ranging-and-profound issues for the conduct of science and the responsibility of researchers. The responses undertaken by organizations such as the US National Science Advisory Board for Biosecurity are attempts to reduce the risks associated with the hostile use of advanced research and thus increase that state of biosecurity. Just how they frame the problem and responses needed may well have significant implications for whether the destructive application of science can be prevented in years to come.

Notes

- ¹ For a sense of the variety of definitions of biosecurity see WHO (2006: 11-12).
- ² For a discussion of this and related points see the special issue of African Security Review (ISS 2005).
- http://www.biosecuritycodes.org/gloss.htm#biosec
- ⁴ For a statement of the problems the journal was to initially address, see Kwik et al (2003).
- 5 http://www.upmc-biosecurity.org/website/special_topics/alliance_for_biosecurity/
- 6 For a statement by Tucker about the need for this in relation to physical access to laboratory pathogens, see Tucker (2003).
- 7 Unlike the chemical weapon activities; those were matters of legal prosecution and thus became publicly known
- ⁸ For a discussion about the Codes of Conduct Working Group see Rappert (2007b).
- 9 Charter National Science Advisory Board for Biosecurity. 16 March 2006: 1. See http://www.biosecurityboard.gov/revised%20NSABB%20charter%20signed%20031606.pdf
- ¹⁰ As in comments made by Paul Kiem as Chair of Communications Work of the National Science Advisory Board for Biosecurity 30 March 2006. See http://www.biosecurityboard.gov/meetings_archive_033006.asp, at times 4:17:5, 4:20:20, and 4:27-4:28, 4:57.
- ¹¹ As in comments made during National Science Advisory Board for Biosecurity 20 March 2006.

- Transcript of Department of Health and Human Services National Science Advisory Board For Biosecurity Inaugural Meeting June 30, 2005: 70-110 and 120-164. See http://www.biosecurityboard.gov/meetings/ 200506/063005 nsabb transcript final%20revisions.pdf
- 13 Homeland Security Act of 2002 Sec. 892(a)(1)(B).

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Japan Journal for Science, Technology & Society Vol. 17

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