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21ST CENTURY BIODEFENCE:

RISKS, TRADE-OFFS & RESPONSIBLE SCIENCE

The dramatic increase in the number of laboratories and scientists working on dangerous pathogens and toxins has exacerbated safety and security risks

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- There has been a dramatic increase in biodefence activities and in the number of facilities and researchers working with dangerous pathogens around the world.
- This has generated a number of trade-off risks related to safety, security, responsible science and transparency.
- The 2016 BWC Review Conference must encourage states to implement stringent national biosafety, biosecurity and dual-use research regulations; task the science advisory group to develop clear, internationally-recognised guidelines governing dual-use research of concern (DURC); establish a working group to revise the CBMs; and encourage states to participate in the CBM mechanism as well as more interactive information exchanges such as peer review and compliance assessment.

The biodefence boom

Over the last two decades, there has been a dramatic increase in biodefence activities and in the number of facilities and researchers working with dangerous pathogens around the world. The biodefence activities of greatest relevance to the Biological Weapons Convention (BWC) are those that involve scientific research on dangerous pathogens that could be used as weapons, activities to assess the threats posed by such pathogens, and capabilities for testing the efficacy of medical countermeasures. Most of these activities occur in laboratories equipped with special biological safety features to prevent accidental infections of researchers or the environmental release of a pathogen. These laboratories might be run by the military or public health agencies or be privately-owned facilities working on government contracts.

Declarations about biodefence programmes were first introduced on the BWC Confidence Building Measures in 1992. That year, 13 states declared programmes. In 2004, 22 states declared programmes. In the most recent submissions, 29 countries declared biodefence programmes.

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Concerns about bioterrorism and emerging infectious disease have also triggered a construction boom in high biocontainment laboratories, called biosafety level 4 (BSL4) labs, around the world. There are thirteen BSL4 laboratories in operation or under construction in the United States and at least twenty-four such laboratories in operation in the rest of the world.[2] In addition, there are more than 1400 BSL3 laboratories registered to work with dangerous human, plant, or animal pathogens in the United States.[3] Such laboratories are increasingly common around the world as countries upgrade their public health infrastructure, but exact numbers are unknown.

> The antiviral drugs and vaccine candidates deployed to Western Africa in response to the recent Ebola outbreak originated in the US biodefence programme.[4]

Risks associated with biodefence

The biodefence research boom has increased risks in four domains: biosafety, biosecurity, dual-use research and BWC compliance. Sound biodefense policy must continually evaluate these trade-off risks in decisions on how best to prevent, prepare for and respond to existing and emerging biological threats.[5]

BIOSAFETY RISKS

One of the key risks from increased biodefence activities and increased numbers of facilities and researchers working with dangerous pathogens is that pathogens are accidentally released from a laboratory. Accidental releases include accidental infections of laboratory workers who then transmit the disease to members of the community, a breach of containment that allows a pathogen into the environment, and the escape of an infected animal from a lab.

There has been a series of high-profile breaches in recent years where dangerous pathogens have been improperly handled by or inadvertently released from labs run by the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Dugway Proving Ground. Lesser breaches don't usually make it into newspapers, but their sheer volume led one newspaper to publish a series of reports documenting hundreds of accidents, safety violations and near misses at public and private research facilities in the United States.[8]

> A thorough investigation in the UK revealed more than 100 accidents or near-misses at the high security labs that handle the most dangerous viruses and bacteria in Britain.[9]

A major biosafety concern with implications for public health is that a labora-

BOX 1

WHAT IS BIODEFENCE?

'Biodefence' has traditionally been defined narrowly to describe military bioweapon programmes. But in recent years a broader definition tends to be adopted, encompassing activities to prevent, prepare for and respond to large-scale biological threats to both civilian and military populations from natural disease outbreaks, bioterrorism and biological warfare. The broader definition incorporates research and development related to prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection and decontamination. At present, roughly one-third of the States Parties declaring national biodefence research programmes in their CBM submissions also report civilian research. For the remaining two-thirds of States Parties, it is not clear whether they have construed the request for information to apply only to military programmes, or whether they do not have biodefense research programmes conducted by civilians aimed at protecting the civilian population.[1]

tory accident could introduce a novel disease or reintroduce a contagious disease that has already been eradicated or otherwise contained. The last known cases of smallpox and SARS, for example, were both caused by laboratory exposures, and both viruses were able to spread from infected researchers to a small number of individuals outside of the laboratory.[10]

BIOSECURITY RISKS

Another key risk is that pathogens or other related material are stolen from a laboratory, and that insiders use their special knowledge and skills for malevolent purposes.

The dramatic increase in the number of laboratories and scientists working on dangerous pathogens and toxins has created more opportunities for these agents to be stolen. Historically, laboratories and culture collections have been the preferred source of pathogens and toxins for terrorists and criminals; there is no evidence that any terrorist or criminal group has successfully acquired a pathogenic microorganism from nature.[11]

The increased number of individuals with expertise that could be misused also poses a risk. According to the Federal Bureau of Investigation (FBI), Bruce Ivins, a scientist at the US Army Military Research Institute of Infectious Diseases (USAMRIID), the US military's premier biodefence facility, was the sole perpetrator of the 2001 anthrax letter attacks in the United States that sickened 17 and killed five.[12]

DUAL-USE RESEARCH RISKS

A different type of security risk is that the knowledge and methods used to understand and manipulate the biological and epidemiological properties of pathogens for peaceful purposes is misused.[13] Advances in science have the potential to provide new knowledge and tools to national militaries, international terrorist networks, criminal groups, religious extremists, disgruntled or mentally ill scientists, or even 'biohackers'—do-it-yourself biologists who aren't necessarily motivated by politics or religion, but by curiosity, revenge, greed or boredom.[14] Biodefence research on dangerous pathogens is especially susceptible to this 'dual-use dilemma' since it is frequently focused on studying characteristics such as infectivity (ability of a microorganism to infect a host), pathogenicity (ability of a microorganism to cause disease), virulence (severity of the disease caused by the organism), and transmissibility (ability of the pathogen to spread from person to person).

Early high-profile experiments that raised dual-use concerns aimed to make mousepox—a skin disease of mice, similar to smallpox—more deadly, synthesize poliovirus from scratch and reconstruct the extinct 1918 flu virus that may have killed as many as 100 million people. More recently, entire fields of biological research have raised concern. These include potentially pandemic pathogen research, synthetic biology, genome editing, and neurobiology.[15]

BOX 2

BIOSAFETY V. BIOSECURITY

The terms 'biosafety' and 'biosecurity' have multiple meanings. In the context of biodefense, biosafety refers to measures taken by a laboratory to prevent the transmission of biological agents to researchers, the community and the environment. In the context of the BWC, biosecurity refers to "the protection, control and accountability measures implemented to prevent the unauthorized access, retention, loss, theft, misuse, transfer, diversion or intentional release of biological agents and toxins."[6] A simple formulation that helps to distinguish between biosafety and biosecurity in the laboratory context is that biosafety protects people from germs, whereas biosecurity protects germs from people.

In addition, the agricultural and environmental communities have their own definitions of these terms. Under the Cartagena Protocol to the Convention on Biodiversity, biosafety is associated with "the transboundary movements, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[7] In the agricultural context, biosecurity refers to measures to prevent or decrease the transmission of naturally occurring infectious diseases and pests in crops and livestock.

COMPLIANCE RISKS

A final, major risk from increased biodefence activities and increased numbers of facilities and researchers working with dangerous pathogens is that they could be used as a cover for an offensive programme, or, more likely, be perceived as doing so. The perception that another country is using its biodefence programme to disguise an offensive programme may provide justification for initiating or continuing an offensive biological warfare programme.

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Synthetic biology is often identified as an area of research particularly prone to these concerns. For example, two thirds of US investment in the field of synthetic biology is estimated to come from the Department of Defense or its research agency DARPA.[16] The majority of these funds are allocated to basic science and do not come with security classification or publication restrictions.

Indeed, many scientists view their defence-sourced funding on par with their other funding from, for instance, the National Institutes of Health or the National Science Foundation. But from an international security perspective, the extensive influx of military funding in civilian research can be perceived as threats by analysts in other countries. After all, part of the concern for security analysts looking at the rapidly developing field of synthetic biology is the possibility of a military agenda lurking behind the copious funding, and the purpose, or alternate purposes, to which the technology and its applications might be put, including the development of sophisticated biological weapons.

BOX 3

BIODEFENCE AND THE BIOLOGICAL WEAPONS CONVENTION

Whilst the term biodefence is not mentioned in the text of the BWC, activities in this area are nonetheless directly relevant to a number of articles of the BWC:

- Article I of the BWC prohibits the development, production, stockpiling and acquisition of biological weapons, but it permits work with biological agents of appropriate types and quantities for "prophylactic, protective or other peaceful purposes." Biodefence research for protective purposes is thereby permissible under the BWC, but must be conducted in such a way that it does not cross the line, intentionally or not, into prohibited activities.
- Article III prohibits States Parties from transferring biological weapons and from assisting or encouraging any recipient to develop biological weapons. This includes taking proactive measures to prevent the theft of dangerous pathogens and ensuring that biodefence insiders do not misuse their access, knowledge and skills.
- Article IV requires States Parties to take measures to ensure national implementation of the treaty. Ensuring that biodefence programmes are subject to strict biosafety, biosecurity and dual-use research oversight is integral to fulfilling this provision.
- Article V calls on States Parties to consult and cooperate with one another in solving any compliance concerns. Biodefence programme declarations under the Confidence Building Measures (CBMs) promote transparency and build confidence between States Parties that no one is crossing the line into prohibited activities, and peer review and compliance assessment exercises demonstrate, and provide reassurance on, implementation.
- Article VII calls on States Parties to provide assistance to states victim of a biological attack, and Article X calls on States Parties to provide international cooperation and assistance more generally. National biodefence programmes provide capabilities, such as trained personnel, mobile and deployable laboratories, diagnostic tests, medical countermeasures and biosurveillance systems that can be drawn upon to support other countries and to provide assistance in the aftermath of a biological attack.

Recommendations

Developing defences against biological threats must be done safely, securely, responsibly and transparently. To this end, states parties at the Eighth Review Conference should:

- Encourage responsible science. States parties must ensure that all 'dual use research of concern' (DURC) within their jurisdiction, including that carried out for biodefence purposes, is subject to comprehensive risk assessment and only allowed under rigorous justification—and then always under stringent control. DURC measures should be annually declared in national CBM submissions. Experiments deemed to carry excessive risks, broadly understood, should not be permitted. There should be transparency in the review processes and outcomes of DURC experiments. Accountability must be ensured and exercised in the oversight regimes.[17]

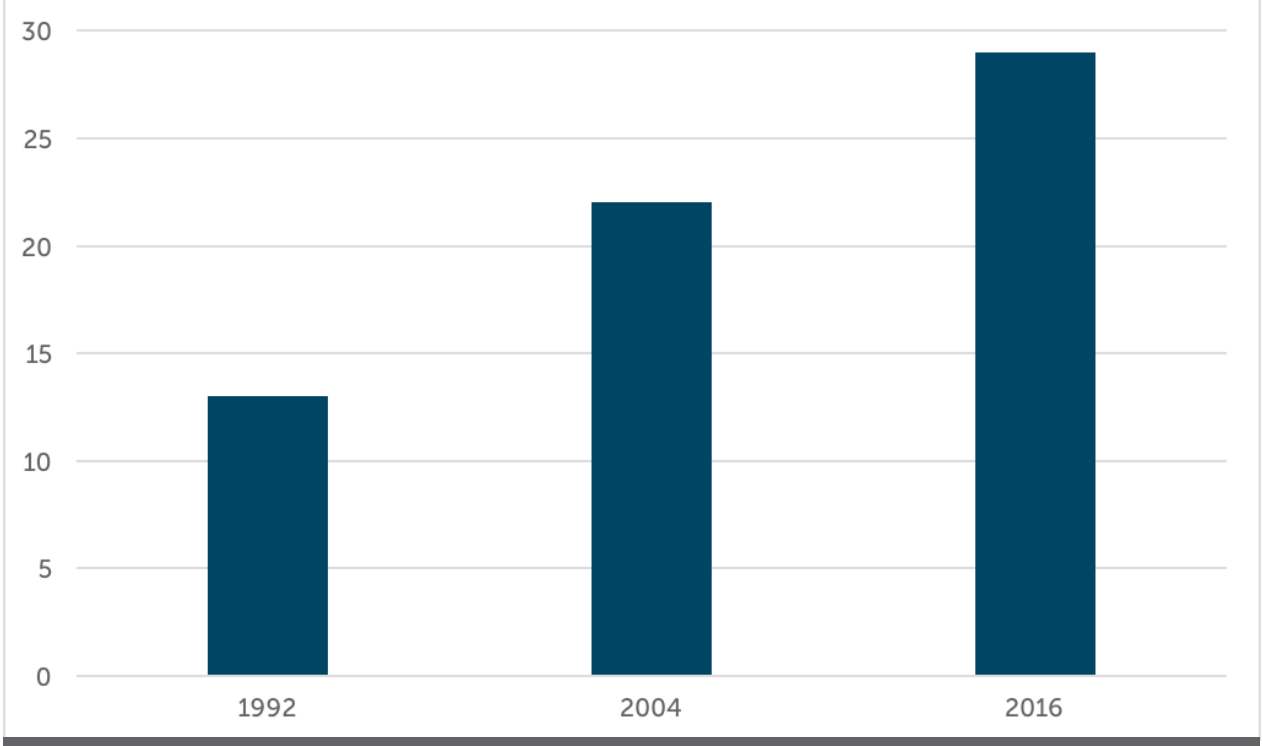
- Task a BWC science advisory group to work towards clear, internationally-recognised guidelines governing dual-use research of concern (DURC).

- Establish a dedicated working group on CBMs to revise the forms as deemed necessary to maximise confidence-building for the 21st century, and encourage states to make their CBM submissions publicly available to maximise transparency.

- Ensure their biodefence activities are subject to stringent biosafety and biosecurity regulations enshrined in national law. These should be annually declared in national CBM submissions. Biosafety regulations should cover the construction and operation of biosafety laboratories, training and certification of personnel working in these labs, and mechanisms for reporting biosafety incidents and protecting 'whistleblowers'. Laboratory biosecurity measures should include a list of dangerous pathogens that require special security measures, standards for physical and cyber security measures, a system for screening and monitoring personnel with access to these pathogens, and a mechanism for reporting biosecurity incidents to the appropriate authorities that includes protection of whistleblowers.

FIGURE 1

NUMBER OF DECLARED BIODEFENCE PROGRAMMES



- Encourage states with biodefence programmes to: (1) ensure they have in place national legislation implementing the BWC; (2) regularly review that their biodefence activities are in compliance with the BWC; (3) annually declare their biodefence programmes in national CBM submissions; and (4) participate in interactive information exchanges like on-site peer review exercises with other states and civil society to increase transparency and allay any suspicions that biodefence activities, particularly those that are classified and engaged in threat assessment, do not cross the line into prohibited activities.

ENDNOTES

1 BWC/CONF.VIII/PC/WP.6 'Strengthening confidence building and consultative mechanisms under the BWC' submitted by the United States of America.

2 National Research Council (2011) Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories. Washington, DC: National Academies Press.

3 J. Kaiser (2011) 'Taking stock of the biodefence boom', Science, vol. 333, no. 6047: 1214.

4 C. Boddie C (2015) 'Federal Funding in Support of Ebola Medical Countermeasures R&D', Health Security, vol. 13, no. 1: 3–8.

5 G. Koblentz (2016) 'Quandaries in contemporary biodefense research', in F. Lentzos (ed.) Biological Threats in the 21st Century, London: Imperial College Press.

6 G. Avramchev (2008) 'Synthesis of Considerations, Lessons, Perspectives, Recommendations, Conclusions, and Proposals Drawn from the Presentations, Statements, Working Papers, and Interventions on the Topics under Discussion at the Meeting of Experts', October 10.

7 'Cartagena Protocol on Biosafety to the Convention on Biological Diversity', 29 January 2000. See http://www.cbd.int/biosafety/protocol.shtml.

8 A. Young and N. Penzenstadler (2015) 'Inside America's secretive biolabs', USA Today, May 28. See http://www.usatoday.com/story/news/2015/05/28/biolabs-pathogens-location-incidents/26587505/ (accessed 14 Sept 2016).

9 I. Sample (2014) 'Revealed: 100 safety breaches at UK labs handling potentially deadly diseases', The Guardian, December 4. See https://www.theguardian.com/science/2014/dec/04/-sp-100-safety-breaches-uk-labs-potentially-deadly-diseases (accessed 14 Sept 2016).

10 D.L. Heymann, R.B. Aylward and C. Wolff (2004) 'Dangerous Pathogens in the Laboratory', Lancet, vol. 363, no. 9421: 1566–8.

11 W.S. Carus (2001) Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century. Washington, DC: National Defense University, 8.

12 Department of Justice (2010) Amerithrax Investigate Summary. Washington, DC: Department of Justice.

13 G. Koblentz (2014) 'Dual-Use Research as a Wicked Problem,' Frontiers in Public Health, vol. 2: 1–4.

14 G. Koblentz (2010) 'Biosecurity Reconsidered: Calibrating Biological Threats and Responses,' International Security, vol. 34, no. 4: 96–132.

15 F. Lentzos (2016) 'Biology's misuse potential,' Connections – The Quarterly Journal, vol.15, no. 2: 48–64.

16 F. Lentzos (2015) 'Synthetic Biology's Defence Dollars: Signals and Perceptions' PLOS Blog, December 24. See http://blogs.plos.org/synbio/2015/12/24/synthetic-biologys-defence-dollars-signals-and-perceptions/ (accessed 14 September 2016).

17 F. Lentzos and N. Evans (2016) 'Four steps to rebuild trust in biology', The Guardian, May 23. See https://www.theguardian.com/science/political-science/2016/may/23/four-steps-to-rebuild-trust-in-biology (accessed 14 September 2016); F. Lentzos, K. van der Bruggen and L. Nixdorff (2015) 'Can we trust scientists' self-control?', The Guardian, April 26. See https://www.theguardian.com/science/political-science/2015/apr/26/can-we-trust-scientists-self-control (accessed 14 September 2016); F. Lentzos (2014) 'Preventing a man-made pandemic', The Bulletin of Atomic Scientists, December 18. See http://thebulletin.org/preventing-man-made-pandemic7856 (accessed 14 September 2016).

TITLES IN THIS SERIES

The International Law and Policy Institute (ILPI) produced this series of briefing papers to coincide with the Eighth Review Conference of the Biological Weapons Convention:

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3. GREGORY D. KOBLENTZ and FILIPPA LENTZOS, 21st Century biodefence—Risks, trade-offs and responsible science: The dramatic increase in the number of laboratories and scientists working on dangerous pathogens and toxins has exacerbated safety and security risks.

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