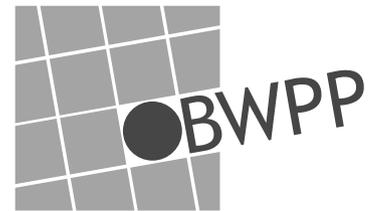


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# BioWeapons Monitor ● 2012

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BioWeapons Prevention Project

BioWeapons Monitor 2012



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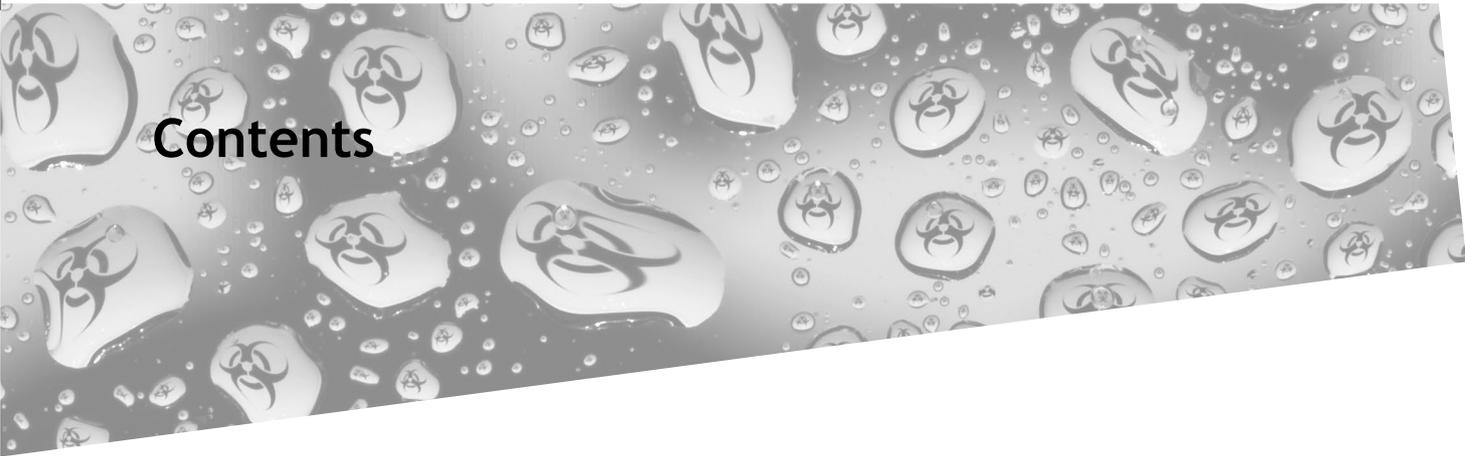
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## About Bioweapons Monitor

The *BioWeapons Monitor* is an initiative of the BioWeapons Prevention Project (BWPP)—a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence—to help monitor compliance with the international norm prohibiting biological weapons, laid down chiefly in the 1972 Biological Weapons Convention (BWC). Particularly, it aims to increase the transparency of activities relevant to the BWC, and thereby complement the current treaty regime. Preventing states and non-state actors from acquiring and using biological weapons is an urgent need. The *BioWeapons Monitor* seeks to provide factual information that will enhance discussions on strengthening the effectiveness and improving implementation of the BWC and other national and international measures relating to the prohibition of biological weapons. Its objective is to benefit the international community as a whole.

The *BioWeapons Monitor* seeks to complement and work with governments in their activities to effectively implement the BWC and to fulfill their obligations to permanently eliminate biological weapons and prevent their re-emergence. Following the Seventh Review Conference in 2011 and its

agreement of Standing Agenda items on international cooperation and assistance, developments in science and technology and strengthening national implementation, the *BioWeapons Monitor* will seek to provide relevant national information that will assist the States Parties in developing approaches that will enhance the effectiveness and improve the implementation of the BWC. A key starting point is the information submitted by the BWC States Parties annually under the BWC confidence-building measures (CBMs). The proposals submitted by Canada and Switzerland to the Seventh Review Conference<sup>1</sup> to explore a broader concept of compliance assessment based on examining and assessing the national regulatory programme that has been implemented to ensure compliance with a regulatory/legislated requirement provide an interesting approach.

The *BioWeapons Monitor 2012* contains country reports on BWC-relevant activities in eight states: Brazil, Germany, India, Japan, Kenya, Switzerland, the United Kingdom, and the United

<sup>1</sup> Canada and Switzerland, *National Implementation of the BTWC: Compliance Assessment*, submitted to the Seventh Review Conference and issued as MSP/2012/MX/WP. 17,

States. In-country authors collected and analysed relevant information that is distributed through this publication. The authors used open sources and actively sought information from government departments, research institutions, industry, scientific societies and other entities. This wide range of sources helps to ensure that the project is as comprehensive as possible and draws on as many reliable sources as possible. The *BioWeapons Monitor 2012* is based on the model for 2011: For future years the intention is to extend the coverage to include all three of the Standing Agenda items of the Intersessional Process.

The *BioWeapons Monitor* takes the Landmine Monitor - a product of the International Campaign to Ban Landmines, which is a global network of civil society organisations - as its role model. Although a civil society initiative, the Landmine Monitor is regarded as the de facto monitoring regime for the 1997 Mine Ban Treaty, reporting on States Parties' implementation of, and compliance with, that accord. The country reports in the *BioWeapons Monitor 2012* provide factual information and are constructive in their analysis. As a rule, any potentially controversial piece of information is backed by two different sources. More importantly, States Parties are invited to advise on and comment on the information prior to publication. This third edition of the *BioWeapons Monitor* builds on experience obtained during work on the second issue in 2011. The Third edition was, and future editions will be, able to build on relationships established by the in-country authors with relevant experts on the ground and experience of finding and using data sources, allowing, over time, reports to be more comprehensive and presenting a more complete picture of BWC-relevant activities. The *BioWeapons Monitor* is a work in progress, being constantly updated, corrected and improved. We welcome

comments from governmental and non-governmental actors.

## Origins of the *BioWeapons Monitor*

The *BioWeapons Monitor* idea grew in response to the wish to find a way forward to strengthen the effectiveness and improve the implementation of the Convention in the early twenty-first century. Over time, its aims have become more concrete. In 2008, a group of four civil society organisations - the Institute for Security Studies in South Africa, the Research Group for Biological Arms Control in Germany, the Society for the Study of Peace and Conflict in India, the Verification Research Training and Information Centre in the UK - took up the challenge of increasing transparency in areas related to the BWC by monitoring the activities of states. With the input of the BWPP Board of Directors, the *BioWeapons Monitor* was further developed and initial funding secured in early 2010. The first edition of the *BioWeapons Monitor* was released on 10 December 2010.

## Acknowledgements

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# Introduction

## State of the biological weapons disarmament regime

The centrepiece of the multilateral biological weapons disarmament regime is the Biological Weapons Convention (BWC) of 1972, which entered into force 1975. In total, there are 166 members and 12 signatories to the BWC. Nineteen countries remain outside of the Convention. Compared to other multilateral treaties on weapons of mass destruction, the BWC has a long way to go towards achieving universality.

### States that signed the BWC but have yet to ratify

1. Central African Republic
2. Cote d'Ivoire
3. Egypt
4. Guyana
5. Haiti
6. Liberia
7. Malawi
8. Myanmar
9. Nepal
10. Somalia
11. Syrian Arab Republic
12. United Republic of Tanzania

### States not members of the BWC

1. Andorra
2. Angola
3. Cameroon
4. Chad
5. Comoros
6. Djibouti
7. Eritrea
8. Guinea
9. Israel
10. Kiribati
11. Mauritania
12. Micronesia (Federated States of)
13. Namibia
14. Nauru
15. Niue
16. Samoa
17. South Sudan
18. Tuvalu

Efforts to strengthen the effectiveness and improve implementation of the Convention by adding compliance / verification measures ended unsuccessfully in summer 2001 after 6.5 years of negotiations. States Parties were unable to reach a consensus on the drafting of a Final Declaration.

Instead, subsequent to the Fifth Review Conference States Parties agreed to hold meetings on an annual basis to discuss a range of issues, including national implementation, disease surveillance, and the role of the scientific community.

The intersessional meetings took place twice a year and continued up to and after the Sixth BWC Review Conference in 2006. They have led to the opening of proceedings in Geneva, Switzerland, that include contributions from both international and non-governmental organisations (NGOs), and bring into the process of strengthening the Convention a broad range of expertise, especially from the public health sector. The intersessional process has increased common understanding on a range of issues, but thus far discussions have produced little in the way of effective action, such as multilaterally agreed decisions or guidelines.

At the Seventh Review Conference in December 2011, State Parties recognized the need for the Intersessional Process to go ahead with sustained and continuing considerations of three Standing Agenda items: a review of developments in the field of science and technology, to strengthen national implementation, and cooperation and assistance, specifically under Article X. Furthermore, a biennial topic to be considered in the Intersessional Process in 2012 - 2013 is how to enable fuller participation in the CBMs.

Article I on the BWC defines the scope of the Convention which states that: 'Each State Party to this Convention undertakes never in any circumstance to develop, produce, stockpile or otherwise acquire or retain:

- (1) 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;
- (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflicts'

Whilst a number of State Parties voiced general concerns at the 2006 Review Conference about the use of biological weapons by non-state actors such as terrorist groups or individuals, currently there are no states that admit to having or developing biological weapons, nor are there allegations of non-compliance with the BWC under investigation in international fora.

## Why transparency is important

All States Parties are expected to be in compliance with the Convention as they are legally bound to implement the Convention fully and comprehensively. It is important to demonstrate such compliance with the Convention by providing transparency about the activities in the life sciences being carried out within the State Party whether by government, industry or academia. The importance of such transparency is underlined because of the inherent "dual-use" nature of activities in the life sciences.

In regard to the Convention, it is important to provide transparency about the programmes within a State Party to counter outbreaks of disease - whether natural, accidental or deliberate - in humans, animals or plants. States Parties are committed under Article IV of the Convention "to take any necessary measures to prohibit and prevent" biological weapons. It has become apparent over the past decade that more attention needs to be given to effective biosecurity and biosafety as well as to education and outreach of all those engaged in the life sciences. Transparency about such steps taken

nationally to ensure the effective implementation of all Articles of the Convention is vital to build confidence that States Parties are in compliance with the Convention.

## Existing transparency-building efforts under the BWC

One example of States Parties promoting transparency in issues of BWC compliance can be found in the working paper submitted to the Meeting of Expert in July 2012, Geneva, by Canada and Switzerland.<sup>1</sup> The working paper is part of an earlier effort by Canada to show how States Parties could show compliance by providing information about their national legislation as well as evidence of implementation of the Convention. In addition, year-specific information is also given, for example, the number of announced and unannounced inspection visits to facilities. Annex I and II of the working paper provide exemplars based on Canada and Switzerland, respectively.

Besides this concerted individual effort to show how BWC compliance could be assessed, the biological weapons control regime includes a number of multilateral mechanisms to foster transparency. The consultative mechanism under Article V of the BWC allows for multilateral meetings to consider problems and to clarify ambiguities regarding BWC compliance. The current annual BWC meetings are a forum for face-to-face information exchanges. States Parties are invited to report on their own compliance every five years to the BWC Review Conferences. Most importantly, there are annual data exchange measures, the so-called confidence-building measures (CBMs).

1 Canada and Switzerland 'National Implementation of the BTWC Compliance Assessment', BWC/MSP/2012/MX/WP.17

## Confidence-building measures

The existing transparency enhancement measures have, however, limited utility. Only one state has taken advantage of the consultative process under Article V in a multilateral setting;<sup>2</sup> many states do not submit the politically-binding CBMs; and there appears to be little follow-up after the initial data-gathering step. However, as agreed at the Seventh Review Conference, the issue of how to enable fuller participation in the CBMs is being addressed by States Parties during the Intersessional Process in 2012 - 2013.

CBMs are the only permanent transparency mechanism and every State Party to the BWC is under a politically-binding obligation to submit a CBM declaration by 15 April of each year, providing information on a range of activities and facilities. As of 22 November 2012, 66 states had submitted their CBM for the year, a few less than in 2011, and still less than half of the 165 BWC State Parties. The BWC Implementation Support Unit collects the CBM returns and makes them available to State Parties.<sup>3</sup> CBMs were agreed in 1986 'to prevent or reduce the occurrence of ambiguities, doubts and suspicions'<sup>4</sup>

2 Cuba requested a consultative meeting in 1997 to receive clarification about an outbreak of *Thrips palmi*, an insect pest, on its territory, which it suspected was connected to the overflight of a US agricultural airplane. The US presented information on why there was no connection between the two events. For more information, see, for example, Report of the Formal Consultative Meeting to the BWC, 29 August 1997, BWC/CONS/1, [http://unog.ch/1997-08-FCP/BWC\\_CONS\\_01.pdf](http://unog.ch/1997-08-FCP/BWC_CONS_01.pdf); and Zilinskis, R.A. (1999) 'Cuban Allegations of Biological Warfare by the United States: Assessing the Evidence', Critical reviews in Microbiology, Vol. 25, No. 3, pp. 173 - 227.

3 Detailed guidelines on how to collect information, complete the forms and submit the CBM declaration to the United Nations are available at <http://www.unog.ch/bwc/cbms>

4 See [http://bwc.unog.ch/1986-09-2RC/BWC\\_CONF.II.13.pdf](http://bwc.unog.ch/1986-09-2RC/BWC_CONF.II.13.pdf), Part II, p. 6.

and were extended in 1991. In later years, states made a number of proposals to improve them and to cover more topics, but, by and large, these did not result in changes to the CBM mechanism. At the Seventh Review Conference in 2011, State Parties agreed to increase the scope of the CBMs in order to promote cooperation and exchange of information between life scientists.<sup>5</sup> The following topics are to be covered within a CBM submission:

- A. Part 1: Exchange of data on research centres and laboratories;  
Part 2: Exchange of information on national biological defence research and development programmes.
- B. Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
- C. Encouragement of the publications of results and promotion of use of knowledge.
- E. Declaration of legislation, regulations and other measures.
- F. Declaration of past activities in the offensive and/or defensive biological research and development programmes.
- G. Declaration of vaccine production facilities.

CBM declarations are largely made available to BWC States Parties only. A limited but increasing number of states - 22 out of the 66 that have submitted them as of 22 November 2012 - have made them publicly available.<sup>6</sup>

5 See the Annex I of the Final Document of the Seventh Review Conference, <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/600/60/PDF/G1260060.pdf?OpenElement>

6 See [http://www.unog.ch/\\_\\_80256ee600585943.nsf/%28http-Pages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=26#\\_Section26](http://www.unog.ch/__80256ee600585943.nsf/%28http-Pages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=26#_Section26)

## States and topics covered in the country reports

The eight country reports in this publication contain information from open sources that is relevant to the compliance with the BWC. The objective is to demonstrate that confidence in compliance can be increased through transparency of relevant activities available from open-source information.

We selected countries (Brazil, Germany, India, Japan, Kenya, Switzerland, the UK, and the US) that are biotechnology leaders in their geographical sub-regions. An advanced biotechnological capability is a necessary, even if by no means a sufficient, precondition for a large-scale biological weapons programme. No widely accepted global ranking of the biotechnological capabilities of states exists, however. While abundant data are available on biotechnology research, development and production capabilities in individual countries, global comparative overviews based on common methodology are extremely rare. One effort to develop such a ranking system was published in 2005.<sup>7</sup> The *BioWeapons Monitor* has used the methodology suggested in that publication and updated the listing.

We selected one country each from Africa, South America and North America as well as two countries and three from Europe to sustain the *BioWeapons Monitor*'s principle of global distribution.

7 See [http://www.biological-arms-control.org/publications/hunger\\_CBM.pdf](http://www.biological-arms-control.org/publications/hunger_CBM.pdf), pp. 46 - 51.

## Selection of topics

Transparency is fostered by collecting, processing, analysing and distributing relevant information. The challenge is to define what information is relevant in the context of biological weapons disarmament. The country reports focus on capabilities that would be important to any biological weapons effort, particularly if the intended product is a weapon with massive destructive or disruptive force.

Each country report opens with information on the status of the BWC and the Geneva Protocol in the country in question, as well as on the national contact point for biological weapons issues and general national policy towards biological arms control. Because information can only be properly assessed if it is put in context, each country report has some basic information on the national life-science and biotechnology industry landscape.

A country's capacity for working with agents of particular biological weapons concern or conducting activities with high misuse potential is covered by providing information on:

- Biodefence activities and facilities;
- Maximum and high biological safety level (BSL-3 and BSL-4) facilities and their activities;
- Any work on smallpox, and other dual-use research of immediate misuse potential; and

A country's capacity for producing biological agents in large quantities is covered by supplying information on vaccine production facilities.

Biological weapons-related accidents or cases of use will manifest themselves in unusual disease outbreaks. The following disease outbreaks are covered:

- Outbreaks of particularly dangerous and rare diseases (anthrax, botulism, plague, smallpox, tularaemia, and viral haemorrhagic fevers such as Ebola, Lassa, and Marburg); and
- Suspicious disease outbreaks.

States are under the obligation to implement the international norm prohibiting biological weapons into national laws and regulations. This is also an important aspect of countering the threat of terrorist use of biological weapons. The country reports provide information on:

- Relevant national laws, regulations and guidelines; and
- Codes of conduct, education and awareness-raising efforts.

To indicate how committed a state is towards the well-being of the BWC, the *BioWeapons Monitor 2011* covers:

- CBM participation; and
- Participation in BWC meetings in Geneva.

Finally, the country reports examine past biological weapons activities and accusations thereof, from both governmental and non-state actors, with a focus on the post-1972 period. Bioterrorism hoaxes also are covered.

# COUNTRY REPORT: BRAZIL

Status of ratification, signature, etc. in regard to 1972 Bioweapons Convention and 1925 Geneva Protocol; other relevant international agreements

## 1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 28 August 1970

Brazil does not have any reservations to the Geneva Protocol.

## 1972 Biological Weapons Convention

Signed: 10 April 1972

Deposit of ratification: 27 February 1973

## 1991 Declaration of Mendoza

Signed: 5 September 1991

National focal point (name and contact detail) for bioweapons control issues.

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## General policy statements on bioweapons and bioweapons/ bioterrorism threat perception

On 5 September 1991, Brazil, together with Argentina and Chile, signed the Mendoza Agreement in which it expressed its 'total commitment not to develop, produce or acquire in any way, stockpile or retain, transfer directly or indirectly, and not to use chemical or biological arms'.<sup>1</sup>

At the 7<sup>th</sup> Review Conference Brazil has stated that it is concerned about possible misuse of biological research, especially considering rapid advances in the life sciences. Brazil supports the review, simplification and updating of the CBMs to enhance participation. For Brazil the "full, effective and non-discriminatory" exchange of equipment, materials and scientific and technical information for peaceful uses of biological agents under Article X of the convention is "essential for the realization of the objectives and purpose of [the] Convention".<sup>2</sup> Brazil has also voiced concern about the BWC's lack of means for assuring that States parties were in compliance with the convention, stating that

1 [cns.miis.edu/inventory/pdfs/aptmendoza.pdf](http://cns.miis.edu/inventory/pdfs/aptmendoza.pdf)

2 BWC/CONF.VII. Statement by Brazil (December 2011)

it “is critically important for States parties to be collectively reassured that the provisions of the Convention are being realized”.<sup>3</sup>

## Status of the life science and biotechnology industry

Brazil’s biotechnology industry shows considerable breadth and Brazil has identified biotechnology as a priority sector for growth for the government although that trend appears to be in the decline.<sup>4</sup> A recent report indicated that Brazil has more than 820 biotechnology companies employing almost 100,000 people working to serve the world’s tenth largest biopharmaceutical market.<sup>5</sup> All major biotechnology and pharmaceutical companies now have a foothold in this emerging market.<sup>6</sup>

Brazil has a strong focus on plant biotechnology and is the second biggest producer of genetically modified (GM) crops in the world.<sup>7</sup>

A break-down of the biotechnology industry shows

- 3 States News Service, Statement by Luiz Filipe De Macedo Soares to the First Committee. 22 October, 2010. & BWC/CONF. VII. Statement by Brazil (December 2011)
- 4 Luisa Massarani. “Innovation is ‘imperative,’ says Brazil science minister.” *Nature* (online) 25 January 2012. doi:10.1038/nature.2012.9903; and Luís Amorim. “Scientists protest against fresh S&T budget cuts” 6 March 2012. *SciDev.net*
- 5 Global Health Progress (2010) Report: Biopharmaceutical sector Brazil. See press release on: <http://www.globalhealth-progress.org/brazil%E2%80%99s-biopharmaceutical-sector-contributes-economic-growth-expands-access-healthcare>, accessed June 2012.
- 6 Mike May. (2011) “Brazilian drug companies hope to benefit from foreign investment”. *Nature Medicine* 17, 1171 doi:10.1038/nm1011-1171a. Published online 11 October 2011
- 7 Brazil, number two on the list behind the US, was planting just over 30 million hectares with GM crops in 2011. See: *Nature* (2012) Seven Days. Vol 482, Iss 7385. 15 February 2012. Based on 2011 data from the International Service for the Acquisition of Agribiotech Applications (ISAAA).

that the leading segment is human health, which accounts for 32 percent of its firms. Reagents and animal health account for another 16 and 15 percent, respectively. Brazil’s strong focus on agrobiotechnology, and agriculture-related companies only make up 11 percent of the country’s biotechnology industry. Environmental and bioenergy sectors comprise 7 and 3 percent of the Brazil’s biotechnology firms, respectively. Other sectors (bioinformatics, molecular diagnostics and contract research organizations) account for 16 percent of the firms.<sup>8</sup> Bibliometric research on life science activities shows Brazil to be linked strongly in international co-authorship of scientific publications.<sup>9</sup>

Brazil, amongst other BRIC countries, is supporting innovation in biotechnology through approaches including increasing investment, building infrastructure, strengthening intellectual property protection and improving education. Brazil has become the third largest source of venture capital for inventions involving medical technology behind China and the US.<sup>10</sup> New legislation - including the 2004 Innovation Law, and policies, such as the 2008 Productive Development Policy - aim to foster interaction and collaboration between academia and the industrial sector, which have traditionally been isolated from one another.<sup>11</sup> Other legislative changes have opened up some research avenues,

- 8 BrBiotec Brasil and Centro Brasileiro de Análise e Planejamento - CEBRAP (2011) “Brazilian Biotech Mapping 2011”. Available at: [www.cebrap.org.br](http://www.cebrap.org.br), accessed July 2012
- 9 See for example various papers by: Ilchmann, Reville, McLeish & Nightingale (2011) on the United Nations Disarmament Think-Zone, on “Synthetic Biology & the BWC”, “Vaccine Development & the BWC”, “Nanotechnology & the BWC”
- 10 PricewaterhouseCoopers (PwC)—“Medical Technology Innovation Scorecard: The race for global leadership”, January 2011. Available at: <http://pwchealth.com/cgi-local/hregister.cgi?link=reg/innovation-scorecard.pdf>, accessed July 2012.
- 11 Scientific American (2011) Worldview - Deconstructing the BRICs. Available at: <http://www.saworldview.com>, accessed July 2012

for example the 2005 Biosafety Act, which allows human embryonic stem cells to be obtained for research purposes.<sup>12</sup> Brazil has invested into the development of science and biotechnology, although recently this trend has been reversed - despite growing GDP and political assurances for continued investment.<sup>13</sup> Bureaucracy and red tape is still a hurdle, considerably hampering research.<sup>14</sup>

## Biodefence activities and facilities

Three branches are involved in biodefence activities. The Brazilian Army Chemical, Biological and Nuclear Defence Company (Companhia de Defesa Química, Biológica e Nuclear (Cia DQBN)), under the Directorate of Specialized Extension (Diretoria de Especialização Extensão), reports to the Land Forces Command. Cia DQBN is charged with the assessment and support in CBRN-related matters, as well as to offer support to the Land Forces, the other Special Forces and/or Auxiliaries and civil defence. The Brazilian Special Forces maintain a platoon charged with CBRN defence (1º Pelotão de Defesa Química, Biológica e Nuclear). The platoon trains to perform support operations in operational risk assessment and decontamination activities; as well as guiding the use of non-lethal weapons for crisis management. The platoon has participated in emergency exercises of nuclear power plants and provided security detail for VIP events.

The Brazilian Army Biology Institute (Instituto de

Biologia do Exército (IBEx)) is the primary provider of laboratory support for the health system of the Army. However, agent identification and analysis is carried out by the civilian public health laboratory FIOCRUZ.<sup>15</sup> IBEx develops and carries out research projects in partnership with various civil institutions in several areas, such as: medical bacteriology, medical mycology, medical virology, immunology, tropical medicine, human physiology, snakes venoms, entomology and human genetics.<sup>16</sup>

The third branch involved in biodefence activities is a section of the Army's science and technology centre (Centro Tecnológico do Exército - CTEEx). CTEEx carries out basic and applied research and development for defence against chemical, biological and nuclear attacks. In particular in the following areas: analytical methods for the identification of chemical and biological warfare agents; methodologies and procedures for care of emergencies involving CBRN; environmental impacts of CBR agents.<sup>17</sup>

## Maximum and high biological safety level (BSL-3 and 4) facilities and their activities

There are a total of 12 BSL-3 laboratories under the responsibility of the Ministry of Health and 8 BSL-3 laboratories under the responsibility of the Ministry of Agriculture (see Table 1).<sup>18</sup> Brazil currently has no

15 Personal communications with FIOCRUZ & CTEEx.

16 Instituto de Biologia do Exército (IBEx) website: [www.ibex.eb.mil.br](http://www.ibex.eb.mil.br)

17 Research group profile: Grupo de Defesa Química, Biológica, Nuclear e Radiológica. Information available at: <http://dgp.cnpq.br/buscaoperacional/detalhegrupo.jsp?grupo=0992106U2BNX4D>, accessed May 2012

18 National Academy of Sciences and National Research Council. (2012) Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories. E1: Brazil. National

BSL-4 laboratories, although there has been ongoing discussion for several years about building one. The *BioWeapons Monitor* has found that the absence of BSL-4 laboratories does not preclude research with pathogens that produce serious and transmissible disease normally handled in BSL-4 laboratories.

This research is carried out in University research laboratories where little regulation, or reporting requirements exist, according to information provided to the *BioWeapons Monitor*.

**Table 1 BSL-3 Laboratories under the responsibility of the Ministry of Agriculture and Ministry of Health**

Name	Location	Agents
UNESP - Faculdade de Ciências Farmacêuticas Araraquara, Depto Análises Clínicas	Araraquara, São Paulo	HIV; <i>M. tuberculosis</i> MDR; Hepatitis virus
LANAGRO/SP Setor de Sanidade Aviária	Campinas, São Paulo	Avian Influenza virus; Newcastle virus
Merial Saúde Animal LTDA - SP Departamento Qualidade - Segurança Biológica	Campinas, São Paulo	<i>Brucella abortus</i> ; FMDV
Embrapa Gado de Corte - MS Lab. Sanidade Animal e Virologia	Campo Grande, Mato Grosso do Sul	FMDV; <i>Brucella</i> spp.; <i>Mycobacterium bovis</i>
Embrapa Suínos e Aves - SC Lab. Virologia/ Laboratório de Sanidade	Concórdia, Santa Catarina	Avian Flu virus; Newcastle virus; virus of respiratory and reproductive syndrome in swine (PRRS); <i>Mycobacteria</i>
Ouro Fino Saúde Animal	Cravinhos, São Paulo	FMDV
LACEN - CE Laboratório de Microbiologia	Fortaleza, Ceará	<i>Mycobacterium tuberculosis</i> MDR; <i>Yersinia pestis</i> ; <i>Burkholderia pseudomallei</i>
Fundação de Medicina Tropical do Amazonas - Divisão de Virologia	Manaus, Amazonas	<i>M. tuberculosis</i> MDR; Hepatitis virus; Dengue virus; Oropouche- and Mayaro virus
Universidade Federal do Amazonas - Laboratório de Genética Animal	Manaus, Amazonas	<i>Aspergillus</i> ; <i>M. tuberculosis</i> MDR
Fiocruz - Centro de Pesquisas Aggeu Magalhães (CPqAM) Biotério Central	Recife, Pernambuco	<i>Yersinia pestis</i> ; Hantavirus

Fiocruz - Centro de Pesquisas Aggeu Magalhães (CPqAM) Lab. Imunologia	Recife, Pernambuco	Hantavirus
Fiocruz - Centro de Pesquisas Aggeu Magalhães (CPqAM) Lab. Serviço de referencia em peste	Recife, Pernambuco	<i>Yersinia pestis</i>
Universidade Federal de Pernambuco Departamento de Antibióticos/Laboratórios de Fármacos e Processos microbianos e laboratório de Processos Fermentativos	Recife, Pernambuco	<i>Escherichia coli</i> ; <i>Clostridium botulinum</i> ; <i>Coccidioides immitis</i> ; <i>Penicillium</i> spp.; <i>Aspergillus</i> spp.; <i>Candida</i> spp; <i>Salmonella</i> spp.
Universidade Federal de Pernambuco Lab. Microbiologia	Recife, Pernambuco	<i>E. coli</i> ; <i>Salmonella</i> ; <i>Listeria monocytogenes</i> ; <i>Vibrio parahaemolyticus</i> ; <i>Vibrio cholerae</i>
Universidade Federal de Pernambuco - Lab. Virologia	Recife, Pernambuco	HIV; HTLV; <i>Chlamydia trachomatis</i>
FIOCRUZ - IOC Laboratório de Biologia e Parasitologia de Mamíferos Silvestres Laboratórios	Rio de Janeiro, Rio de Janeiro	<i>T. cruzi</i> ; <i>Leishmanias</i>
Fiocruz - IOC Laboratorio de AIDS e Imunologia Molecular	Rio de Janeiro, Rio de Janeiro	HIV
Universidade Federal do Rio de Janeiro Departamento de Diagnóstico Oral e Patologia	Rio de Janeiro, Rio de Janeiro	HIV
Universidade de São Paulo Núcleo de Pesquisas em Raiva do Lab. Virologia Clínica e Molecular do Depto Microbiologia	São Paulo, São Paulo	Arbovirus; Hantavirus; rabies virus

## Research on smallpox, allegations of smallpox outbreaks, policy on smallpox destruction

Research on smallpox (variola major) could not be detected in Brazil during the report time frame.

## Other dual use research of immediate misuse potential

No research of immediate misuse potential could be detected in Brazil during the report time frame.

## Vaccine production

Four vaccine production facilities have been identified for the present report (see Table 2 below).<sup>19</sup> The Brazilian government states that domestic production delivered 128.7 million doses of viral and bacterial vaccines to the public health system in 2009, with supply rising by 11% in 2010. Excess production is transferred to institutions including the World Health Organization (WHO), the Pan-American Health Organization (PAHO), and UNICEF.<sup>20</sup>

The Butantan Institute is the largest domestic producer of vaccines and serums and the leading developer of scientific research into venomous animals responsible for over 93% of serums and vaccines produced in Brazil.<sup>21</sup> The Research, Innovation and Dissemination Centers (RIDC) of the São Paulo Research Foundation, FAPESP includes the Center of Applied Toxinology (CAT). CAT focusses on the synthesis of molecules that can be used for new drugs— obtained from snake poison, from the bristles of the caterpillar *Lonomia obliqua* and from the saliva of the tick *Amblyomma cajennense*.<sup>22</sup> Natural extracts are also investigated by scientists linked to BIOprospecTA, a network of researchers, institutions and labs working on the identification of molecules or processes of economic interest in microorganisms,

19 Previously, according to CBMs up to 2004 Brazil declared ten vaccine production facilities, seven of which were active in 2003. Iris Hunger (2005) “Confidence Building Needs Transparency - A summary of data submitted under the Bioweapons Convention’s confidence building measures 1987 - 2003” The Sunshine Project.

20 [http://www.brasil.gov.br/sobre/science-and-technology/health-technology/vaccines/br\\_model1?set\\_language=en](http://www.brasil.gov.br/sobre/science-and-technology/health-technology/vaccines/br_model1?set_language=en)

21 <http://www.butantan.gov.br>

22 Scientific American (2012) Worldview - Searching for the next wave. Available at: <http://www.saworldview.com>, accessed July 2012

macroscopic fungi, plants, invertebrates (including marine) and vertebrates.<sup>23</sup> Outbreaks of particularly dangerous diseases

In June 2012 a suspected outbreak of tick-borne Spotted fever killed one woman and infected three of her family members.<sup>24</sup> In 2011 the state of Minas Gerais reported 8 cases, 3 of them lethal; in 2010 the number of confirmed cases was 15 with 6 fatalities.<sup>25</sup> Other states also report Spotted Fever occurrences. Between 6 and 27 fatal cases per year were registered nationally during 2007 to 2010.<sup>26</sup> National figures for confirmed cases and fatalities could not be ascertained.

In April 2012 two cases of hantavirus infections were confirmed in Uberaba, Minas Gerais. 2 people, one 22 and the other 18, were infected and died.<sup>27</sup> In 2010 Regional Directorate of Health of Minas Gerais confirmed 14 cases of the disease half of these were lethal.<sup>28</sup>

In February 2012 Secretariat of Health (SESA) of the State of Parana confiscated all lots of a manufactured

23 [www.bioprosecta.org.br](http://www.bioprosecta.org.br)

24 Jornal do Cruzeiro do Sul. 29 June 2012. <http://www.cruzeiro-dosul.inf.br/acessarmateria.jsf?id=398752>, via ProMED-mail: 20120630.1185436

25 Estado de Minas. 9 Nov 2011. [http://www.em.com.br/app/noticia/gerais/2011/11/09/interna\\_gerais.261017/divinopolis-reg-istra-primeiro-caso-de-febre-maculosa.shtml](http://www.em.com.br/app/noticia/gerais/2011/11/09/interna_gerais.261017/divinopolis-reg-istra-primeiro-caso-de-febre-maculosa.shtml), via ProMED-mail: 20111125.235743

26 Spotted fever , fatal - Brazil (02): background. ProMED-mail post: 20110404.1045

27 Correio. 28 Apr 2012. <http://www.jornalcco.com.br/noticia/1680/Secretaria-da-Saude-confirma-dois-casos-de-hantavir-rose-em-Uberaba--MG>, via ProMED-mail: 20120501.1119924

28 Jornal da Manhã. 13 Jan 2011. <http://www.imonline.com.br/novo/?noticias,7,SA%DADE,40022>, via ProMED-mail: 20110115.0170

Table 2 Vaccine production institutes in Brazil.

Name	Location	Vaccines
Paraná Technology Institute	Curitiba, Paraná	Rabies Tetanus Haemophilus influenza type B
Ataulpho de Paiva Foundation	Rio de Janeiro, Rio de Janeiro	BCG (tuberculosis)
Immunobiological Technology Institute of the Oswaldo Cruz Foundation - Fiocruz (also known as Bio-Manguinhos)	Rio de Janeiro, Rio de Janeiro	Poliomyelitis Triple (measles, rubella, mumps) Yellow Fever Meningitis A & C Haemophilus influenza type B DTP (Diphtheria, Tetanus, Pertussis)
Butantan Institute	São Paulo, São Paulo	Tetanus Double (Diphtheria - Tetanus) DTP (Diphtheria, Tetanus, Pertussis) Hepatitis B

sausage, about 400 kg, distributed in the Alto Piquiri area, due to the suspicion of the presence of the bacterium that causes botulism (*Clostridium botulinum*). 2 people died, 2 were symptomatic, and 10 others are suspected cases of the disease.<sup>29</sup> This episode followed an outbreak of botulism in Santa Catarina in the 1<sup>st</sup> half of March 2011. Six people received medical attention and recovered, a seventh died.<sup>30</sup>

A number of outbreaks of glanders (*Burkholderia*

29 Gazeta do Povo. 23 Feb 2012. <http://www.gazetadopovo.com.br/vidaecidadania/conteudo.phtml?id=1226353>, via ProMED-mail: 20120305.1060430

30 Radio Criciúma. 6 Apr 2011. <http://www.radiocriciúma.com.br/portal/vernoticia.php?id=17414>, via ProMED-mail: 20110407.1090

*mallei*) have been reported in horses in several Brazilian states in early 2012.<sup>31</sup> In 2011, there were 9 outbreaks of glanders reported from 3 states in the Northeast Region - Pernambuco, Paraíba, and Rio Grande do Norte. The disease is fairly common, 209 outbreaks have been reported between 2005-2011 across a number of Brazilian states.<sup>32</sup>

A disease control initiative worth noting here is the release of genetically modified *Aedes aegypti* which carry a gene that causes their offspring to die before reaching adulthood. The mosquito, *A. aegypti*, is the carrier of dengue, yellow fever, which are prevalent

31 World Animal Health Information Database(WAHID), weekly disease information 2012; 25(21)

32 ProMED-mail, additional information on WAHID report. ProMED-mail archive number: 20120528.1147807

in Brazil. The Brazilian National Biosafety Technical Committee has approved the control method and its roll out in several cities.<sup>33</sup>

## Suspicious outbreaks of disease

The BioWeapons Monitor has not detected any outbreaks of disease to raise suspicion of biological terrorism or warfare in Brazil during the reporting period.

## Allegations and hoaxes

The BioWeapons Monitor has not detected any allegations of biological weapons use or hoaxes perpetrated in or by Brazil during the reporting period.

## National legislation and regulations

Brazilian national legislation and regulations pertaining to *aspects* of BW is extensive. The national implementation database counts 57 different instruments.<sup>34</sup> These 57 instruments include, besides the instruments for the Geneva Protocol and the BWC<sup>35</sup>, penal legislation criminalising intentional spread of disease<sup>36</sup>, manufacturing and/or selling

counterfeit or adulterated products<sup>37</sup>; notification regulations for disease; regulation of export of goods and services with possible military applications or dual use<sup>38</sup>; regulation of transport of dangerous products<sup>39</sup>; financial detection and hindering of illicit activities connected to the development of weapons of mass destruction and their means of delivery<sup>40</sup>; definitions of the National Sanitary Surveillance System<sup>41</sup>; regulations for agrotoxins<sup>42</sup>; financing of terrorism; establishes best practice for production of medical goods; and a whole host of regulations, decrees and laws concerned with GMOs.

Relevant sections of the Federal Constitution<sup>43</sup> have been extended with interpretations to include prohibitions to the access to any element of the Brazilian genetic patrimony or its use in connection with chemical or biological weapons.<sup>44</sup>

Biosecurity is covered by the 1995 National Biosecurity Law (Lei Nacional de Biossegurança (n° 8974/95)), which was updated in 2005 (Lei de Biossegurança (Lei n° 11.105 de 24/03/2005)). However, this Biosecurity law ostensibly covers safety standards and enforcement mechanisms of the construction, cultivation, production, handling, transportation, transfer, import, export, storage,

33 Helen Mendes. "Brazil tests GM mosquitoes to fight dengue". 10 April 2012. SciDev.net

34 National Implementation Database. [http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/\\$file/BWC\\_NID\\_Report.htm#br](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/$file/BWC_NID_Report.htm#br)

35 These include, for example, decree No. 5459, 7 June 2005 which establishes sanctions for the development of biological weapons.

36 Penal Code of Brazil, 1940 Article 131 (intentional disease transmission); 1940, Article 267 (cause a disease outbreak); 1940, Article 270 (poison drinking water); 1940, Article 129 (jeopardize the physical integrity or the health of another person); 1940, Article 259 (disseminate an illness or plague that may cause damage to forests, plantations or animals of economic relevance)

37 E.g. Law No. 9.677, 2 July 1998

38 E.g. Law No. 9.112, 10 October 1995

39 E.g. Resolution No. 420/2004, 12 February 2004 updating Regulation No. 204, 20 May 1997

40 E.g. Law No. 9613, 3 March 1998

41 Law No. 9.782, of January 26, 1999 & Provisional Remedy No. 2.039-20, 25 August 2000

42 E.g. Decree No. 4.074, 4 January 2002

43 Constituição de 1988 da República Federativa do Brasil, Capítulo VI, Artigo 225

44 Provisional Decree 2186-16, 2001

research, marketing, consumption, release into the environment and disposal of genetically modified organisms (GMOs) and their derivatives for the protection of life and health of humans, animals and plants; and observance of the precautionary principle to protect the environment. The Biosecurity Law thus implements the provisions of the Cartagena Protocol on Biosafety. Under the provision of the Biosecurity Law (1995) authorised creation of the National Technical Commission on Biosafety (CTNBio) and outlines its responsibilities, structure, staffing, functioning and standards. The Law requires any organization using genetic engineering techniques and methods to create an Internal Biosafety Commission (CIBio) and outlines their responsibilities.

The General Coordination Office for Sensitive Materials, within the Ministry of Science and Technology (CGBE/MCT) is the organ responsible for controlling imports, exports and re-exports of sensitive goods.<sup>45</sup> The CGBE implements controls and authorizes transfers of items contained in the National Lists of Control of Sensitive Goods and Technologies, after necessary consultations with other governmental organs involved. This activity is undertaken through the Foreign Trade Integrated System (SISCOMEX). This system aims to automatically detect non-authorized imports, exports and re-exports, by centralizing all information on transfers.

Brazil's legislation for the control of export of sensitive goods and technology and services related to WMD, as well as items of dual use, is implemented and maintained by the Interministerial Committee for the Control of Sensitive Goods (CIBES)<sup>46</sup> and the

Interministerial Committee for the Implementation of the Directives of the Chemical Weapons Convention (CIAD-CWC). The Brazilian Intelligence Agency (Abin) works together with CIBES as an advisory agency to the General-Coordination of Sensitive Goods of the Ministry of Science and Technology (CGBE/MCT) Executive Secretariat. CIBES maintains a list of controlled agents and equipment linked to WMD or dual-use. The list is divided into 5 sections:

- (i) Agents of relevance for animals (26 bacteria, 13 rickettsia, 5 fungi, 79 viruses or prions, 1 protozoan group and related agents)
- (ii) Agents of relevance for plant (23 bacteria, 7 phytoplasma, 50 fungi, 10 viruses or prions, 6 nematodes)
- (iii) Toxins (19 entries)
- (iv) Genetic elements (associated with pathogenicity and encoding toxins contained in the list in section (iii))
- (v) Equipment
  - a. Containment and protection equipment.
  - b. Aerosol inhalation chambers
  - c. Cross (tangential) flow filtration equipment
  - d. Fermenters, bioreactors (>20 litres) as well as chemostats and continuous-flow systems
  - e. Steam sterilisable freeze-drying equipment
  - f. Spray drying equipment with droplet dispersal <50microns and flow above 2l/min

<sup>45</sup> As established under Regulation No. 49, 16 February 2004

<sup>46</sup> Established in Law No. 9.112, 10 October 1995, Decree No. 4.214, 30 April 2002 defined the composition and responsibili-

## Codes of conduct, education and awareness raising

In 2004 the National State-Private Industry Integration Programme for Sensitive Goods (PRONABENS)<sup>47</sup> was created by the Brazilian Intelligence Agency (ABIN) in response to address the provisions of UN Security Council Resolution 1540. The focus of PRONABENS is on the implementation of outreach activities for industry and public bodies involved in the development of sensitive equipment or dual-use equipment, offering guidance on government controls regarding the transfer of sensitive goods and services. PRONABENS activities led to the development and approval of the “List of Sensitive Goods and Controlled Equipment in the Biological Area” in Resolution no. 10 of March 13, 2008. The *BioWeapons Monitor* has learned that this initiative has been suspended recently. The reasons

47 PRONABENS - Programa Nacional de Integração Estado-Empresa na Área de Bens Sensíveis [http://www.abin.gov.br/modules/mastop\\_publish/?tac=PRONABENS](http://www.abin.gov.br/modules/mastop_publish/?tac=PRONABENS)

for this suspension could not be identified. Efforts are underway to instigate educational programmes and outreach activities by NGOs; foremost amongst these is the National Association for Biosecurity (ANBio).<sup>48</sup>

## CBM participation

Brazil has submitted 17 out of 26 CBMs since 1987, although on an irregular basis. Brazil first submitted in 1991, then from 1993-99, 2001 and 2002, 2004-07, and 2010-2012.

Brazil has repeatedly called for reviewing, updating and simplifying CBMs to increase participation and transparency; most recently these calls were made at the 7<sup>th</sup> Review Conference.<sup>49</sup> Despite calls for greater transparency in various Brazilian statements over the past few years, Brazil has yet to make its CBM submission publically available.

48 ANBio - Associação Nacional de Biossegurança, <http://www.anbio.org.br/>

49 BWC/CONF.VII. Statement by Brazil. See also: BWC/CONF.VI/WP.12

**Table 3 Summary of CBM submissions by Brazil**

Year	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
CBM					x		x	x	x	x	x	x	x		x	x		x	x	x	x			x	x	x

## Participation in BWC meetings

Brazil has participated in all relevant meetings since the Sixth Review Conference of the BWC in 2006, the period under investigation here (see Table 4 below). In addition to formal meetings Brazil was also represented at the meetings preparing for the 7<sup>th</sup> Review conference in Montreux, Switzerland

organized and co-hosted by Norway, Indonesia and the BWC Implementation Support Unit (ISU); and two meetings in Beijing, China: one organised by the Chinese Academy of Sciences (CAS), the US National Academy of Sciences (NAS) and the InterAcademy Panel (IAP) Biosecurity Panel together with the International Union of Microbiological Sciences (IUMS) and the International Union of Biochemistry and

Molecular Biology (IUBMB) and entitled Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention, and the second workshop was organised by the Government of China and the Government of Canada together with the Implementation Support Unit (ISU) of the

Biological Weapons Convention (BWC) and entitled Strengthening International Efforts to Prevent the Proliferation of Biological Weapons: The Role of the Biological and Toxin Weapons Convention. Brazil attended both workshops.

**Table 4 Size of Brazilian delegation at BWC-related meetings in Geneva**

<b>Meeting</b>	<b>Number of delegates from Brazil</b>
BWC RevCon Preparatory Committee 2006	6 (4 from Geneva)
BWC Review Conference 2006	11 (5 from Geneva)
Expert Meeting 2007	9 (4 from Geneva)
States Parties Meeting 2007	11 (4 from Geneva)
Expert Meeting 2008	10 (5 from Geneva)
States Parties Meeting 2008	9 (5 from Geneva)
Expert Meeting 2009	8 (5 from Geneva)
States Parties Meeting 2009	8 (4 from Geneva)
Expert Meeting 2010	14 (7 from Geneva)
BWC RevCon Preparatory Committee 2011	9 (4 from Geneva)
BWC Review Conference 2011	10 (4 from Geneva)
Expert Meeting 2012	8 (4 from Geneva)

## **Past bioweapons development and use, and accusations of bioweapons development and use**

Brazil has neither conducted nor been accused of conducting a biological weapons programme and has made no submission under CBM Form F.

# Country report: Germany

## 1972 Biological Weapons Convention

Signed: 10 April 1972

Deposit of ratification: 7 April 1983

The former German Democratic Republic ratified the BWC on 28 November 1972. With effect from 3 October 1990, the German Democratic Republic acceded to the Federal Republic of Germany.

## 1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 25 April 1929

Germany does not have any reservations to the Geneva Protocol.

## National point of contact

Head of BW Division, Federal Foreign Office,

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E-mail: 243-rl@diplo.de

Germany is a long-standing supporter of the international prohibition on biological weapons. It is associated with the common position adopted by the European Union on 18 July 2011.<sup>1</sup> According to this Council Decision relating to the EU's position on the Seventh BWC Review Conference in December 2011, the EU aims inter alia to strengthen the BWC by building confidence in compliance, supporting national implementation, and promoting universality; the EU supports strengthening the role of the Implementation Support Unit (ISU), continuing the Intersessional Process with an expanded list of topics and a new 'decisional character', is willing to work towards identifying options that could achieve similar goals as verification, which remains a central element of a complete and effective disarmament and non-proliferation regime (namely declarations, consultations and on-site activities) and reviewing the implementation of Article X. In this regard the EU submitted a document on assistance and cooperation on the 2012 Meeting of Experts.<sup>2</sup>

On the Seventh BWC Review Conference, Germany submitted in line with its activities in the preparation

1 COUNCIL DECISION 2011/429/CFSP of 18 July 2011

2 BWC/MSP/2102/MX/INF.7

of the Conference (see BW-Monitor 2011), three working papers WP. 15 “The intersessional bureau: a new element to solidify BWC work in Geneva”,<sup>3</sup> WP. 14 “Confidence building and compliance: two different approaches”,<sup>4</sup> and together with Norway and Switzerland WP.9 “Review and update of the Confidence-Building Measures”.<sup>5</sup> In addition Germany submitted information on developments in the fields of bioinformatics, drug delivery systems, synthetic biology, and response to risks of the latter. to the ISU INF.3 paper on “New scientific and technological developments relevant to the Convention”, In the INF.3 document Portugal reports on cooperation in anthrax research conducted in German facilities.<sup>6</sup>

## Status of the life sciences and biotechnology industry

According to BWPP’s 2011 global survey, Germany is one of the world’s leading countries in the field of the life sciences and biotechnology. Globally, Germany ranks fifth; in its geographical sub-region, Western Europe, it ranks first. More specifically, globally, Germany ranks seventh in terms of publications and third in terms of patents.<sup>7</sup>

The auditing company Ernst & Young cites 397 German biotechnology companies.<sup>8</sup> The German Biotech Database, a directory and information platform comprising data on life-science

3 BWC/CONF.VII/WP.15

4 BWC/CONF.VII/WP.14

5 BWC/CONF.VII/WP.9

6 BWC/CONF.VII/INF.3/Corr.2

7 See Annex.

8 Ernst & Young (2011) *Deutscher Biotechnologie-Report 2011*, [http://www.ey.com/Publication/vwLUAssets/Deutscher\\_Biotechnologie-Report\\_2011/\\$FILE/German\\_Biotechreport\\_2011\\_SEO.pdf](http://www.ey.com/Publication/vwLUAssets/Deutscher_Biotechnologie-Report_2011/$FILE/German_Biotechreport_2011_SEO.pdf)

and biotechnology companies and institutes in Germany, lists 2.199 such companies and institutes.<sup>9</sup> Biotechnology-Europe - which is part of Biotechnology-World, a web-based, privately-owned service whose mission is to organise the world’s biotechnology and pharmaceutical information and market - lists 763 companies and 94 universities and research institutes in Germany.<sup>10</sup>

The Association of German Biotechnology Companies (Vereinigung Deutscher Biotechnologie-Unternehmen), a federation of companies and institutions active in the biotechnology field and related sectors, such as pharmaceutical technology, diagnostics, and medical and laboratory technology, has 223 members.<sup>11</sup> Bio Deutschland, the sector association of the German biotechnology industry, has 302 members.<sup>12</sup>

## Biodefence activities and facilities

Germany’s military biodefence programme dates from the 1950s.<sup>13</sup> Germany started to declare information on its biodefence programme in 1992, when this information was first required under the CBMs of the BWC. Funding for this programme, roughly speaking, tripled between the early 1990s and 2005. However, since the all-time high in 2005 a decline of funding can be observed. In 2011, EUR 9.13 million was spent on Germany’s military biodefence programme. Figure 1 shows the trend in funding for this programme between 1991 and 2011.

9 See <http://www.germanbiotech.com/de/info/info.php>

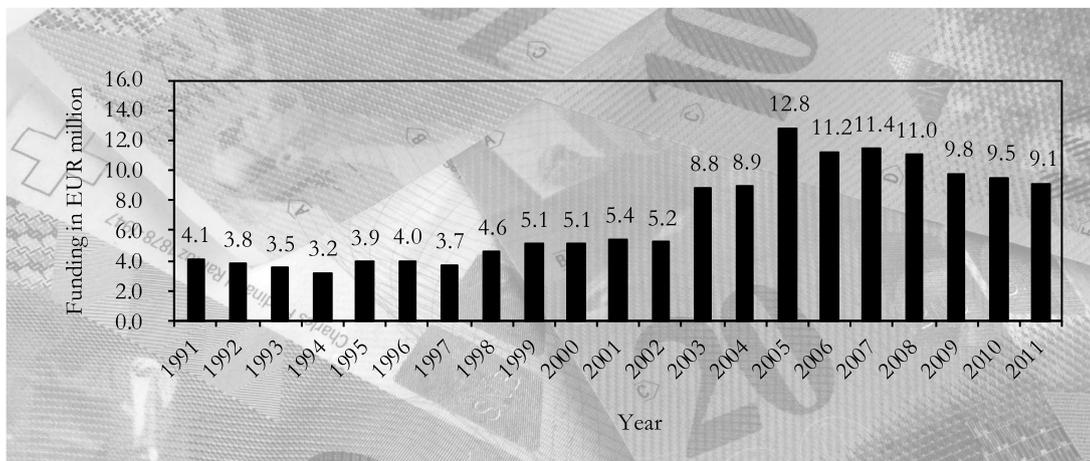
10 See <http://www.biotechnology-europe.com/Germany.html>

11 See <http://www.v-b-u.org/Mitglieder/Unsere+Mitglieder.html>

12 See <http://www.biodeutschland.org/a---e.92.html>

13 Germany 1992 CBM.

**Figure 1.** Declared funding for the German Ministry of Defence biodefence programme, 1991-2011



**Note:** until 2001, amounts were given in DEM; these have been converted to EUR at the official rate of EUR 1 = DEM 1.95583.

**Source:** Germany 1992-2012 CBMs.

According to Germany's 2012 CBM declaration, the same four facilities as since 2009 were involved in the military biodefence programme in 2011 (see Table 1).

The Institute of Microbiology in Munich is Germany's central military biodefence facility. It has grown considerably since it was first declared in 1992. The number of staff employed there has tripled subsequently. Only one of Germany's biodefence facilities, the Scientific Institute for Protection Technologies and NBC-Protection of the Federal Armed Forces in Munster, conducted outdoor studies during 2011 using *Bacillus atrophaeus*, *subtilis*, and *thuringiensis* for aerosol studies and disinfection tests, and *Escherichia coli* (R I), *Micrococcus luteus*, and *Pseudomonas fluorescens* for water purification

tests.<sup>14</sup>

In 2011, approximately 13 per cent of the Ministry of Defence (MoD)'s funding went to contracted facilities.<sup>15</sup> The names of these contractors are not made public, but a number of universities, governmental agencies, and private companies appear to be involved in biodefence work - a conclusion based on the fact that they have presented their research at medical biodefence conferences in Munich. Every two years, the Institute of Microbiology organises the Medical Biodefence Conference, an international gathering at which military and civilian research institutions from Germany and around the world present their biodefence work. Close to 500 participants from 36 nations attended the 2011 conference in Munich on 25-28 October.

<sup>14</sup> Germany 2012 CBM.

<sup>15</sup> Germany 2012 CBM.

**Table 1.** German facilities involved in the military biodefence programme

Name	Location	Number of staff	Highest containment level	Agents employed
NBC Defence and Self-Protection School of the Federal Armed Forces	Sonthofen	8 (4 military, civilian)	BL2 (270 square metres (sqm.) of 270 sqm. overall laboratory space)	R I and R II organisms, inactivated material of R III and R IV pathogens, insects and ticks, high- and low-molecular weight toxins
Institute of Microbiology of the Federal Armed Forces	Munich	65 (41 military, 24 civilian)	BL3 (67 sqm. of 1,325 sqm. overall laboratory space)	Alpha-, bunya-, filo- and flaviviruses, Orthopox viruses, Bacillus spp., Brucella spp., Burkholderia spp., Coxiella spp., Francisella spp., Yersinia spp.
Scientific Institute for Protection Technologies and NBC-Protection of the Federal Armed Forces	Munster	34 (all civilian)	BL3 (360 sqm. of 880 sqm. overall laboratory space)	R I, R II and R III organisms, low-molecular weight toxins, outdoor aerosol research with simuli
Central Institute of the Federal Armed Forces Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis	Kronshagen	5 (3 military, 2 civilian)	BL3 (47 sqm. of 321 sqm. overall laboratory space)	Pathogen R I, R II and R III organisms, avian influenza and other influenza viruses, norovirus, rabies virus, Bacillus anthracis, Coxiella burnetii, Leishmania spp., Vibrio cholerae, infectious animal diseases (especially swine fever and babesiosis), Clostridium botulinum toxins

Germany describes the aims and activities of its military biodefence programme as follows: ‘The research and development activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection’.<sup>16</sup> Short descriptions of all research-and-development

projects on medical biodefence are available online.<sup>17</sup> A similar list could not be located for non-medical biodefence work, in particular research projects conducted at the Scientific Institute for Protection Technologies and NBC-Protection in

<sup>16</sup> Germany 2011 CBM.

<sup>17</sup> See [http://www.sanitaetsdienst-bundeswehr.de/portal/a/sanitaetsdienst/!ut/p/c4/04\\_SB8K8xLLM9MSSzPy8xBz9CP3I5Eyr-pHK9quLEPL3c1JTMqsw8vbT8ouLkjNK8dL3EpGQQq6RKvyDbURE-AGlhxFw!!/](http://www.sanitaetsdienst-bundeswehr.de/portal/a/sanitaetsdienst/!ut/p/c4/04_SB8K8xLLM9MSSzPy8xBz9CP3I5Eyr-pHK9quLEPL3c1JTMqsw8vbT8ouLkjNK8dL3EpGQQq6RKvyDbURE-AGlhxFw!!/)

Munster. The latter presented its work at the 2011 Medical Biodefence Conference in Munich. More details on the projects presented can be found in the BW-Monitor 2011.

Since 1989, the German MoD has informed the Bundestag (national parliament) annually about MoD-funded projects involving genetic engineering work. According to the 2011 report, 23 such projects were conducted in 2010 (see BW Monitor 2011 for detailed information).<sup>18</sup> The 2012 report was, according to the MoD, submitted. However, offices of concerned MPs of two different fractions in the Bundestag could not yet confirm this information.

Besides its long-standing military biodefence programme, Germany has already since 2005 declared a civilian biodefence programme aimed at improving preparedness and response to biological threats in order to enhance protection of first-responders and the population. This programme is funded by the Federal Office of Civil Protection and Disaster Assistance of the Ministry of the Interior. While in the previous years funding was well above EUR 100,000/year (see earlier issues of the BW-Monitor), in 2011 funding declined to EUR 5,179.<sup>19</sup>

Responsibility for civil protection activities in Germany rests with the state governments, not with the federal government. At the request of the states, the Robert Koch Institute (RKI) was tasked in 2002 by the German Ministry of Health with coordinating the development of a preparedness plan describing the preparatory and countermeasures necessary to control an epidemic due to a bioterrorist attack

18 Ministry of Defence written communication with the Defence Committee of the German Parliament, VA 1780002-V09, 22 March 2011.

19 Germany 2012 CBM.

involving smallpox. The smallpox preparedness plan also constitutes the basis for dealing with other epidemics resulting from a bioterrorist attack.<sup>20</sup>

The Centre for Biological Security (ZBS) at the RKI is the central federal institution dealing with public health related biodefence issues. The Centre was established in 2002 and is composed of six units. It focuses on epidemiology, risk assessment, diagnostics, prevention, therapy, pathogenesis, and risk and crisis management in relation to highly pathogenic and bioterrorism-related agents.<sup>21</sup> In 2010-11, the ZBS conducted 60 projects. Three of these have German military institutions as cooperation partners. Nine of the 60 projects address basic research, diagnosis or therapy issues associated with orthopox viruses.<sup>22</sup> Germany declares the existence of the ZBS in his 2012 CBM for the first time. According to the CBM the total ZBS funding was approx. EUR 5,9 mio for personnel, consumable items and equipment in 2011.

Since 2007, Germany also has engaged in biodefence research activities funded by the Ministry of Education and Research under its Research for Civil Security programme, which aims to increase civil security without limiting the freedom of citizens. Seven biodefence projects - all listed in the *BioWeapons Monitor 2010* - were initiated in 2007 and 2008 under the programme line 'Detection of hazardous substances'.<sup>23</sup> Further additional projects

20 See [http://www.rki.de/cln\\_178/nn\\_216446/EN/Content/Prevention/Bioterrism/bioterrism\\_\\_node\\_\\_en.html?\\_\\_nnn=true](http://www.rki.de/cln_178/nn_216446/EN/Content/Prevention/Bioterrism/bioterrism__node__en.html?__nnn=true)

21 See [http://www.rki.de/DE/Content/Institut/OrgEinheiten/ZBS/zbs\\_\\_node.html](http://www.rki.de/DE/Content/Institut/OrgEinheiten/ZBS/zbs__node.html)

22 See [http://www.rki.de/cln\\_160/nn\\_199408/DE/Content/Institut/OrgEinheiten/ZBS/Projekte,templated=raw,property=publicationFile.pdf/Projekte.pdf](http://www.rki.de/cln_160/nn_199408/DE/Content/Institut/OrgEinheiten/ZBS/Projekte,templated=raw,property=publicationFile.pdf/Projekte.pdf)

23 See [http://www.bmbf.de/pub/Zivile\\_Sicherheit\\_Gefahrstoffe.pdf](http://www.bmbf.de/pub/Zivile_Sicherheit_Gefahrstoffe.pdf)

**Table 2. Projects that are completely or partly biodefence projects conducted under the Research for Civil Security programme of the Ministry of Education and Research<sup>1</sup>**

Name	Content	Number of sub-projects	Funding (EUR million)	Duration
BEPE	Internet-based tool for the evaluation of hospitals' level of preparedness for biological emergencies	6	1.06	April 2010-March 2013
SILEBAT	Securing feed and food supply chains in bioterrorism and agroterrorism events	9	6.08	October 2010-September 2014
STATUS	Protecting the drinking water supply in CBRN (chemical, biological, radiological, nuclear) scenarios	6	4.2	October 2009-February 2013
VOTEKK	Preparation for terrorist attacks, crises and disasters	6	3.04	June 2009-May 2012

<sup>1</sup> See <http://www.bmbf.de/en/12874.php>

that are completely or partly biodefence projects were identified under different programme lines; four of them are in execution during the reporting period of this issue (see Table 2).

In addition, German institutions are involved in a number of European projects that are completely or partly biodefence projects that are funded by the European Commission's 2007 - 2013 Seventh Framework Programme FP7 - Security (see Table 3 for programmes conducted during the reporting period).

Moreover the EU Directorate General for Health

and Consumers (DG SANCO) and the EU Directorate General for Home Affairs (DG HOME) are funding relevant projects. Among these projects QUANDHIP (DG SANCO) is being conducted during the reporting period with the RKI as main organisation. It aims to stabilise an existing European Laboratory network in support of an European response strategy to highly pathogen infections plus generating a biodiverse repository of reference materials. The project is funded with approx. EUR 3.3 million.

**Table 3. Projects that are completely or partly biodefence projects funded by the European Commission's Seventh Framework Programme FP7-Security<sup>1</sup>**

Name	Content	Number of project partners	Funding (EUR million)	Duration
ANTIBOTABE	Neutralising antibodies against botulinum toxins A, B and E	9	3.0	September 2010-August 2014
BIO-PROTECT	Ionisation-based detector of airborne bio-agents, viruses and toxins for fast alert and identification	8	3.1	June 2010-May 2013
CATO	CBRN crisis management architecture, technologies and operational procedures	26	10.3	January 2012-December 2014
EQUATOX	Harmonise and standardise detection capabilities	9	1.3	January 2012-December 2014
IF REACT	develop protective clothing for first responders and/or for the public in case of a CBRN crisis	11	3.4	January 2012-December 2014
MULTISENSE CHIP	The laboratory-free CBRN detection device for the identification of biological pathogens on nucleic acid and immunological level as lab-on-a-chip system applying multi-sensor technologies	8	6.6	June 2011-May 2015
PLANTFOODSEC	Plant and food biosecurity	13	4.6	February 2011-January 2016
SECUREAU	Security and decontamination of drinking water distribution systems following a deliberate contamination	14	5.3	February 2009-January 2013
SLAM	Reviewing the needs for standardisation of CBRN analysis and suggesting a road map for its implementation	7	1.1	April 2012-March 2014

<sup>1</sup> See [http://cordis.europa.eu/fp7/home\\_en.html](http://cordis.europa.eu/fp7/home_en.html)

**Table 4. BSL-4 facilities in Germany**

Name	Location	Size of BSL-4 facility	Agents worked with	Comments
Bernhard Nocht Institute for Tropical Medicine	Hamburg	One unit, 70 square metres (sqm.)	Arena viruses, Crimean-Congo fever virus, dengue virus, haemorrhagic fever viruses (Ebola, Hanta, Lassa, Marburg), monkeypoxvirus	BSL-4 since 1982; extension building with a new BSL-4 facility inaugurated in July 2009  Special contract with the MoD
Institute of Virology, Philipps University Marburg	Marburg	Two units, 110 sqm. each	Crimean-Congo haemorrhagic fever virus, Ebola virus, Junin virus, Lassa virus, Marburg virus, Nipah virus, SARS Corona virus and other class 4 viruses, smallpox virus (diagnosis only)	The new BSL-4 laboratory opened in December 2007; the old BSL-4 laboratory has been converted to office space.  Some MoD funding
Friedrich Loeffler Institute, Federal Research Institute for Animal Health	Greifswald-Insel Riems	Three units, 190 sqm.	African swine fever, bovine spongiform encephalopathy, classical swine fever, foot-and-mouth disease, and other animal diseases caused by viruses	For animal disease work only, no protection of staff; BSL-4 laboratory building officially opened in October 2010; start of routine operations planned for 2013 <sup>1</sup>
Robert Koch Institute	Berlin	Planned	n/a	Building permit issued in 2007; construction started in autumn 2010; start of operations planned for 2014 <sup>2</sup>
Institute of Microbiology of the Federal Armed Forces	Munich	Planned	n/a	-

1 See [http://www.fli.bund.de/no\\_cache/de/startseite/presse/presse-informationsseite/Pressemitteilung/fli-gibt-startschuss-fuer-den-umzug-in-den-neubau.html](http://www.fli.bund.de/no_cache/de/startseite/presse/presse-informationsseite/Pressemitteilung/fli-gibt-startschuss-fuer-den-umzug-in-den-neubau.html)

2 [http://www.rki.de/nn\\_753518/SharedDocs/FAQ/Hochsicherheitslabor/FAQ\\_\\_12.html](http://www.rki.de/nn_753518/SharedDocs/FAQ/Hochsicherheitslabor/FAQ__12.html)

To support the states in preparing for disaster management, the federal government aims to store supplies for general medical emergencies at 100 different locations.<sup>24</sup> It is planned to complement them by specific supplies for protection in the event of an NBC (nuclear, biological, chemical) scenario. In particular, the antibiotic Ciprofloxazin shall be stored to protect people from or to treat people after an outbreak of anthrax or plague.<sup>25</sup> Since late 2003, Germany has amassed a national stockpile of around 100 million doses of smallpox vaccine. In an international emergency, Germany would provide two million doses to the World Health Organization (WHO).<sup>26</sup>

## Maximum and high biological containment laboratories

Germany has two working BSL-4 facilities for human pathogens. One BSL-4 facility for animal pathogen work opened in October 2010; preparatory work still needs to occur before the facility begins routine work. Two more BSL-4 facilities are in the planning or early construction phase. Table 4 contains information on them.<sup>27</sup>

Besides the BSL-4 facilities there are many facilities of lower safety levels, which are managed at the state level. Table 5 provides an overview of such

24 In contrast to information in earlier editions of the BW Monitor, these stockpiles are not yet in place.

25 See [http://www.bbk.bund.de/DE/AufgabenundAusstattung/GesundhBevschutz/Allgemeines/Sanitaetsmaterialbevorrratung/sanitaetsmaterialbevorrratung\\_node.html](http://www.bbk.bund.de/DE/AufgabenundAusstattung/GesundhBevschutz/Allgemeines/Sanitaetsmaterialbevorrratung/sanitaetsmaterialbevorrratung_node.html)

26 Pockenimpfstoff für die gesamte Bevölkerung in Deutschland gesichert, 10 November 2003, <http://www.denis.bund.de/aktuelles/04332/index.html>

27 Germany 2011 CBM; reply by the Ministry of Education and Research to a question from Social Democratic Party (SPD) parliamentarian René Röspele, July 2010.

facilities that are engaged in genetic engineering work.<sup>28</sup>

**Table 5.** Number of BSL-1, 2 and 3 facilities engaged in genetic engineering work (as of February 2011)

Biosafety level	Public	Private	Total (2011)
1	3,583	906	4,489
2	1,266	191	1,457
3	87	10	97

## Vaccine production facilities

Six licensed vaccine production plants were active in Germany in 2011 (see Table 6).<sup>29</sup>

The *BioWeapons Monitor* found the following information on production capacity:

- the GlaxoSmithKline facility in Dresden has an annual production capacity of 70 million vaccine doses;<sup>30</sup>
- the IDT Biologika GmbH facility in Dessau-Rosslau has two production buildings with 6,000 square metres of floor space; its fermenters for bacterial vaccine production range in capacity from 5-800 litres;<sup>31</sup> and
- Vibalogsics GmbH in Cuxhaven runs a '2,500 m<sup>2</sup> facility with 1,100 m<sup>2</sup> classified rooms' and has '3 bioreactors up to 30 l working volume (1 single-use)'.<sup>32</sup>

28 See [http://www.bvl.bund.de/DE/06\\_Gentechnik/02\\_Verbraucher/03\\_Genehmigungen/03\\_GentArbeitenAnlagen/genetechnik\\_GenehmigungGentArbeitenAnlagen\\_node.html](http://www.bvl.bund.de/DE/06_Gentechnik/02_Verbraucher/03_Genehmigungen/03_GentArbeitenAnlagen/genetechnik_GenehmigungGentArbeitenAnlagen_node.html)

29 CBM Germany 2012.

30 See [http://www.glaxosmithkline.de/docs-pdf/unternehmen/Folder\\_dt\\_eng.pdf](http://www.glaxosmithkline.de/docs-pdf/unternehmen/Folder_dt_eng.pdf)

31 See <http://www.idt-biologika.de>

32 See <http://www.vibalogsics.com>

**Table 6. Vaccine production facilities**

Name	Location	Diseases covered/additional information
Novartis Vaccines and Diagnostics GmbH <sup>1</sup>	Marburg	Botulism (antitoxin), diphtheria, influenza, meningococcal meningitis, pertussis, rabies, tetanus, tick-borne encephalitis
GlaxoSmithKline Biologicals <sup>2</sup>	Dresden	Influenza
IDT Biologika GmbH <sup>3</sup>	Dessau-Rosslau	Production of bacterial and viral vaccines for clinical trial: filoviruses, human immunodeficiency virus (HIV), malaria, Salmonella typhi, smallpox
Rhein Biotech GmbH. Dynvax Europe <sup>4</sup>	Düsseldorf	Hepatitis B (commissioned production)
Bavaria Nordic GmbH <sup>5</sup>	Berlin	smallpox, fowlpox, other infectious diseases, cancer
Vibalogics GmbH <sup>6</sup>	Cuxhaven	Tuberculosis (commissioned production for clinical trials), other bacterial and viral vaccines

1 See [http://www.novartis-vaccines.de/about/uebernovartisvacines\\_marburg.php](http://www.novartis-vaccines.de/about/uebernovartisvacines_marburg.php)

2 See [http://www.glaxosmithkline.de/html/unternehmen/dresden\\_standort.html](http://www.glaxosmithkline.de/html/unternehmen/dresden_standort.html)

3 See <http://www.idt-biologika.de>

4 See <http://www.rheinbiotech.de/products.0.html>

5 See <http://www.bavarian-nordic.com>

6 See <http://www.vibalogics.com>

### Disease outbreak data

With regard to particularly dangerous diseases, the following outbreaks were recorded in Germany in 2010<sup>33</sup>, 2011<sup>34</sup>, and 2012<sup>35</sup>:

- Anthrax: two cases of cutaneous anthrax in 2010 and four in 2012 due to contaminated heroin; four recovered, one of the 2012 patients died.
- Botulism: four cases in 2010, nine cases in 2011, none in 2012.
- Lassa/Ebola/Marburg: none.
- Plague: none.
- Smallpox: none.
- Tularaemia: 31 cases in 2010; 17 cases in 2011, 14 cases in 2012.

### Relevant national laws, regulations and guidelines

Germany has extensive legislation and regulations on the safety and security of life-science activities. Many of the relevant legal instruments date from before the twenty-first century and were implemented in response to concerns about genetic engineering work. Only a limited number of changes have been made to existing legal instruments in response to bioterrorism concerns.

Germany's legislation and regulations vis-à-vis its obligations under the BWC are set out in detail in its national report on the implementation of Security Council Resolution 1540 (2004).<sup>36</sup> The central legal

33 See [http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch\\_2010.pdf?\\_\\_blob=publicationFile](http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2010.pdf?__blob=publicationFile)

34 See [http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch\\_2011.pdf?\\_\\_blob=publicationFile](http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2011.pdf?__blob=publicationFile)

35 See Robert Koch-Institut: SurvStat, <http://www3.rki.de/SurvStat>, as of 19 November 2012

36 See <http://www.un.org/sc/1540/nationalreports.shtml>

instruments are: 1) the War Weapons Control Act of 1961, which prohibits any activity relating to biological weapons, including development, trade, transfer, actual control, and inducement to such activities; and 2) the German Act on the BWC of 1983, which establishes penal sanctions for violations of treaty prohibitions.

Various legal provisions are in place to monitor the handling of biological agents. These include the Animal Disease Act of 2004 (which dates back to 1880), the Protection against Infections Act of 2000 (which replaced the Disease Act of 1961 and a number of other laws), the Health and Safety at Work Protection Act of 1996, the Genetic Engineering Act of 1990, and the Plant Protection Act of 1986, all containing detailed reporting, control and licensing requirements.

Besides national legal measures, obligations also stem directly from EU legislation. An example is Council Regulation (EC) No. 428/2009 of 5 May 2009, which sets out the European Community's regime for the control of exports of dual-use items and technology.

All relevant legal instruments are available in the ISU national implementation database.<sup>37</sup>

### Codes of conduct, education and awareness-raising

Specific codes of conduct to address the dual-use problem in the life-science field are rare in Germany. The German Research Foundation (DFG) published its 'Code of Conduct for Work with Highly Pathogenic Micro-organisms and Toxins' in April 2008.<sup>38</sup> The DFG

37 See [http://www.unog.ch/80256EE600585943/\(httpPages\)/4AD-F8E868AAE82B3C1257578005563E1?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/4AD-F8E868AAE82B3C1257578005563E1?OpenDocument)

38 See [http://www.dfg.de/download/pdf/dfg\\_im\\_profil/reden\\_stellungnahmen/2008/codex\\_dualuse\\_0804.pdf](http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2008/codex_dualuse_0804.pdf)

**Table 7. Number of German delegates at BWC meetings since 2006**

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	MX 2012
Number of delegates	18	7	8	8	10	11	6	9	8	6	8

Notes: RC stands for Review Conference MX stands for Meeting of Experts  
MSP stands for Meeting of States Parties PC stands for Preparatory Commission (PrepCom)

is the central public funding organisation responsible for promoting research in Germany. In its Code of Conduct, it endorses the list of experiments that the National Research Council of the National Academies of the United States considers to be particularly relevant to the dual-use dilemma (the ‘Fink report criteria’).

A large part of the DFG Code comprises language that makes clear that: research on highly pathogenic microorganisms and toxins needs to be conducted; as few restrictions as possible should be imposed on such activities; DFG funding for such research will continue; it needs to be possible to publish the results of such research; and international cooperation and exchange should continue to be promoted. The Code recommends that project leaders and reviewers should be made more aware of the dual-use problem in the life-science field and should tackle dual-use aspects in their proposals and reviews, and that relevant seminars and other events should be organised regularly at universities and other pertinent institutions. The DFG Code of Conduct is supported by the industry organisation Bio Deutschland.<sup>39</sup>

39 See <http://www.biodeutschland.org/position-papers-and-statements.html>

Germany also is the home of the initiators of the International Association Synthetic Biology (IASB). An important project of the IASB is its ‘Code of Conduct for Best Practices in Gene Synthesis’, which was finalised in November 2009.<sup>40</sup> This is a self-regulation initiative of synthetic biology companies that provides a comprehensive set of best practices for DNA sequence screening, customer screening and ethical, safe and secure conduct of gene synthesis.

The Max Planck Society - a large independent, non-profit research organisation - addresses the problem of dual use in a general way in its ‘Guidelines and Rules of the Max Planck Society on a Responsible Approach to Freedom of Research and Research Risks’, which were approved by its Senate in March 2010.<sup>41</sup> The Union of the German Academies of Sciences and Humanities is one of the 68 national and international academies of sciences that developed and signed the *Statement on Biosecurity* in 2005.<sup>42</sup>

40 See <http://www.ia-sb.eu/go/synthetic-biology/synthetic-biology/code-of-conduct-for-best-practices-in-gene-synthesis/>

41 See <http://www.mpg.de/pdf/procedures/researchFreedom-Risks.pdf>

42 Interacademy Panel on International Issues (2005) ‘IAP Statement on Biosecurity’, 1 December, [http://sites.nationalacademies.org/xpedio/groups/pgasite/documents/webpage/pga\\_054651.pdf](http://sites.nationalacademies.org/xpedio/groups/pgasite/documents/webpage/pga_054651.pdf)

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There is very little in the way of awareness-raising of biosecurity issues in Germany. A 2010 survey of academic life-science education in the country revealed that biosecurity issues are rarely on university curricula. Only a handful of universities address this matter as part of bioethics education.<sup>43</sup>

### **CBM participation**

Germany has submitted CBM declarations regularly - it is one of nine states that have filed CBM declarations in each of the 26 years since their establishment in 1987. Germany makes its CBM declarations publicly available on the website of the ISU.

### **Participation in BWC meetings**

Germany participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference of the BWC in 2006, Germany has taken part in all relevant meetings (see Table 7).

### **Past biological weapons activities and accusations**

Germany has neither conducted nor been accused of conducting a biological weapons programme since 1972. The last allegations of offensive activities date from the late 1960s. In 1968, Dr Ehrenfried Petras, who had worked at a West German research facility, moved to East Germany and accused West Germany of developing chemical and biological weapons. Petras, it was later revealed, worked for the East German state security services. His claim proved to be completely unfounded.<sup>44</sup>

<sup>43</sup> See <http://www.biological-arms-control.org/publications/2010BiosecurityUmfrage-Publikation-Final-English.pdf>

<sup>44</sup> Geißler, E. (2010) *Drosophila oder die Versuchung. Ein Genetiker der DDR gegen Krebs und Biowaffen*, Berliner Wissenschafts-Verlag, Berlin, pp. 119-124.

# Country report: India

## 1972 Biological Weapons Convention

Signed: 15 January 1973

Deposit of ratification: 15 July 1974

## 1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 9 April 1930

India retains a reservation to the Geneva Protocol: a right to retaliate in kind to a biological or chemical weapons attack.<sup>1</sup> This reservation is inconsistent with India's obligations as a State Party to the 1972 Biological Weapons Convention and the 1993 Chemical Weapons Convention, which prohibit States Parties from possessing these weapons.

On 2 December 2008, India voted in favour of United Nations (UN) General Assembly Resolution 63/53, 'Measures to uphold the authority of the 1925 Geneva Protocol', which, inter alia, '[c]alls upon those States that continue to maintain reservations to the 1925 Geneva Protocol to withdraw them'.<sup>2</sup>

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1 See <http://disarmament.un.org/treaties/a/1925/india/rat/paris>

2 A/63/PV.61, 2 December 2008, and A/RES/63/53, 12 January 2009.

## India and Biological Weapon Convention (BWC)

India participated in the BWC Meeting of Experts held in Geneva (July 16-20, 2012). It had earlier agreed in principle to the *Final Document* of the BWC Seventh Review Conference which includes the following declarations:

'to include in 2012 - 2015 intersessional programme a standing agenda item on developments in the field of science and technology related to the Convention.  
to take all necessary safety and security measures to protect human populations and the environment, including animals and plants, when carrying out destruction and/or diversion of agents, toxins, weapons, equipment or means of delivery as prohibited by Article I of the Convention.  
to adopt legislative, administrative, judicial and other measures, including penal legislation, to enhance domestic implementation of the Convention, ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation and to prevent unauthorized access to and removal of such agents or toxins.

to adopt positive measures to promote technology transfer and international cooperation on an equal

and non-discriminatory basis to continue supporting, directly and indirectly, capacity-building in States parties in need of assistance in the fields of disease surveillance, detection, diagnosis and combating of infectious diseases and related research to promote the development and production of vaccines and drugs to treat infectious disease through international cooperation and, as appropriate, public-private partnerships.<sup>1</sup>

India has neither the military intention nor the political will to develop and use bioweapons against an enemy target. In October 2002, then Indian President A.P.J. Abdul Kalam asserted that 'we [India] will not make biological weapons. It is cruel to human beings'.<sup>2</sup> India takes the bioweapons threat seriously, especially after the anthrax cases of 2001 in the United States. The Defence Research and Development Organisation (DRDO), under the Ministry of Defence, places a high priority on the development of biological and chemical defence systems to combat the challenges of biological/chemical terrorism. Indian intelligence agencies issue intermittent warnings to the Ministry of Home Affairs of possible biological terror attacks in different parts of the country. For example, in September 2003, the Indian security agencies issued an alert regarding terrorists making toxins after noticing instructions on how to produce ricin among al-Qaeda training materials.<sup>3</sup> In 2007, Prime Minister Manmohan Singh underscored the fact that the Government of India

is working towards mitigating bioweapon threats.<sup>4</sup> In July 2008, India devised a draft plan to counter the threat of biological disaster. According to this plan, biological disasters are scenarios involving disease, disability or death on a large scale among human beings, animals and plants due to toxins or disease caused by live organisms or their products. Such disasters may be natural in the form of epidemics or pandemics of existing, emerging or re-emerging diseases or human-made through the intentional use of disease-causing agents in biowarfare operations or bioterrorism incidents.<sup>5</sup>

## Status of the life sciences and biotechnology industry

India has an important life science and biotechnology community. In absolute terms, India ranks thirteenth globally; in its geographical sub-region, South Asia, it ranks first. More specifically, globally, India ranks sixth in terms of publications and twenty-third in terms of patents.<sup>6</sup>

The ninth annual survey conducted by the Association of Biotechnology Led Enterprises (ABLE) in collaboration with BioSpectrum notes that India's life-science and biotechnology industries experienced the fastest rate of growth in the past five years in 2010-11, achieving revenues of USD 4 billion.<sup>7</sup> Of this, the biotech industry contributed approximately USD 45 million, while the life-science education market

1 Final Document of the Seventh Review Conference, URL<<http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/600/60/PDF/G1260060.pdf?OpenElement>>

2 See <http://www.tribuneindia.com/2002/20021029/nation.htm#2>

3 See [http://articles.timesofindia.indiatimes.com/2003-09-18/india/27197960\\_1\\_ricin-castor-plant-toxin](http://articles.timesofindia.indiatimes.com/2003-09-18/india/27197960_1_ricin-castor-plant-toxin)

4 See <http://www.indiadaily.org/entry/india-taking-steps-to-counter-bioterrorism-chemical-warfare-hacking/>

5 National Disaster Management Authority, Government of India (2008) *National Disaster Management Guidelines—Management of Biological Disasters*, 2008.

6 See Annex 1.

7 The amount is converted to USD at the rate of 1 USD=54.50 INR (November 4, 2012). See <http://biospectrumindia.ciol.com/content/CoverStory/11106091.asp> .

shares USD 27 million.<sup>8</sup> In 2012 a government-industry joint report has predicted if a favourable business environment is created, the biotechnology and healthcare sectors combined will be able to grow at a rate of 25-30% and have the potential to generate revenues of US \$100 billion by 2025.<sup>9</sup>

India's biotech sector is the third largest in the Asia-Pacific region, after those of Australia and China.<sup>10</sup> The biotech industry in India is composed mainly of five distinct segments: bioagriculture, bioindustrial, bioinformatics, biopharma, and bioservices. Nearly 40 per cent of the biotech companies operate in the biopharma sector, followed by the bio services (21 per cent), bioagriculture (19 per cent), bioinformatics (14 per cent) and the bioindustrial sector (5 per cent).<sup>11</sup> While many ministries are involved in governing and promoting India's biotech industry, the Department of Biotechnology in the Ministry of Science and Technology is generally responsible for promoting research and development (R&D), catalysing human resource development at diverse levels in the biotech industry, and recommending policy measures to stimulate growth.

A 2010 estimate suggests that about 380 biotech companies are operating in India, of which 198 are in Karnataka, with 191 in Bangalore alone.<sup>12</sup>

8 *Ibid.*

9 "Indian Biotechnology The Roadmap to the Next Decade and Beyond", [http://ableindia.in/admin/attachments/reports/The\\_Report.pdf](http://ableindia.in/admin/attachments/reports/The_Report.pdf)

10 See 'India: exploring new opportunities', in Ernst & Young (2011) *Beyond Borders: Global Biotechnology Report 2011*, <http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders--global-biotechnology-report-2011>

11 See <http://www.clustercollaboration.eu/documents/10147/101938/Biotechnology+and+Pharmaceutical+Opportunities+in+India.pdf>

12 See <http://biospectrumindia.ciol.com/content/bioEv->

The BioPharma segment continues to dominate biotech industry with 61.77% share in the overall revenue. There is a speculation that India's biopharma sector may see a surge in R&D spending to about USD 25 billion in the next 15 years.<sup>13</sup> According to one assessment, during 2009-10, some USD 700 million was spent on major life-science agencies in India, almost 3.7 times higher than expenditure on life-science agencies such as the Department of Biotechnology (DBT) and the Indian Council of Medical Research (ICMR) in 2000-01.<sup>14</sup> In 2010, the Government of India announced plans to set up an INR 100 billion (USD 2.2 billion) venture fund to support drug discovery and research infrastructure development projects. Furthermore, in collaboration with private players and state governments, it is continuing to fund infrastructure investment through biotech parks.

## Biodefence activities and facilities

India is using its growing biotech infrastructure to support biodefence R&D, including the development of countermeasures—civilian and military—ranging from protective equipment to pharmaceuticals to vaccines. India's biodefence programme dates back to at least 1973.<sup>15</sup>

The DRDO is spearheading biodefence R&D for civilian and military purposes. It has been working

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[ents/11007071.asp](http://www.indianexpress.com/news/biopharma-r&d-spend-seen-at-25-bn/808157/)

13 See <http://www.indianexpress.com/news/biopharma-r&d-spend-seen-at-25-bn/808157/>

14 The ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research. It is funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare.

15 India 1997 CBM.

on detection, diagnosis and decontamination measures, such as unmanned ground vehicles and robots that could be sent into contaminated zones. Medical management during biological and chemical attacks also is being investigated. Other methods of defence currently under development include inflatable structures that can serve as shelter during a biological attack. The focus until now has been on underground facilities.<sup>16</sup>

In July 2010, India's Cabinet Committee on Security (CCS) approved a project under which the DRDO has been tasked with developing swift detection systems in case of an NBC (nuclear, biological, chemical) attack on the country's vital installations and cities or leakage in any of the installations dealing with these materials.<sup>17</sup> The DRDO, which caters primarily to the Armed Forces, unveiled plans in 2010 to upgrade its existing biotech products and to customise them for civilian use. It has budgeted more than USD 60 million for upgrading biotech products for both the Armed Forces and civilians, including intensive-care units, ready-to-eat food products, and clothing that can be worn during NBC warfare.<sup>18</sup> The Defence Acquisition Council has cleared orders for anti-NBC warfare products worth another USD 367 million in early 2011.<sup>19</sup>

In the life-science sphere, DRDO products under

manufacture are valued at USD 110 million (approx INR 600 crore). Technologies developed against NBC warfare agents include water-purification filters, nerve-agent detectors, and underground shelters.

The *BioWeapons Monitor 2012* could not find any information on funding levels for the DRDO biodefence programme.

However, it was able to identify three facilities involved in DRDO biodefence activities: the Defence Research and Development Establishment (DRDE) in Gwalior; the Defence Materials and Stores Research and Development Establishment (DMSRDE) in Kanpur; and the Defence Bioengineering and Electromedical Laboratory (DEBEL) in Bangalore. In addition, it pinpointed at least four private industrial agencies that have been working in collaboration with the DRDO on the development of biodefence mechanisms.

The DRDE in Gwalior (Madhya Pradesh), particularly its microbiology and virology divisions, is the primary military biodefence establishment. It is involved in studies of toxicology and biochemical pharmacology and in the development of antibodies for several bacterial and viral agents. It is actively engaged in research on biological agents and toxins and has developed diagnostic kits for certain biological agents.<sup>20</sup>

Scientists at the establishment also are researching new methodologies to defend the country against a range of potentially lethal agents categorised as Class A, B and C pathogens, nanotechnology-

16 For details visit the DRDO portal, especially the laboratory section, at <http://www.drdo.gov.in/drdo/English/index.jsp?pg=techclus.jsp>. Also see <http://www.frontlineonnet.com/fl2517/stories/20080829251704000.htm>

17 See <http://www.thehindu.com/news/national/article510906.ece>

18 See [http://articles.economicstimes.indiatimes.com/2010-06-07/news/27576819\\_1\\_drdo-development-organisation-defence-research](http://articles.economicstimes.indiatimes.com/2010-06-07/news/27576819_1_drdo-development-organisation-defence-research)

19 See <http://www.thehindu.com/news/national/article1076132.ece>

20 For more information see <http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp&labhits=1404>. For an inventory of available facilities/expertise at the DRDE, see [http://www.whoindia.org/LinkFiles/Public\\_Health\\_Laboratory\\_Networking\\_06-DRDE20Gwalior.pdf](http://www.whoindia.org/LinkFiles/Public_Health_Laboratory_Networking_06-DRDE20Gwalior.pdf)

based sensors, unmanned robot-operated aerial and ground vehicles fitted with NBC detection sensors, laser-based detection for chemical clouds, and self-contained NBC shelters and hospitals to handle NBC victims. The Indian Army has already inducted an NBC reconnaissance vehicle and ordered eight such vehicles to counter future threats posed by hostile state and non-state actors.<sup>21</sup> According to reports, it has introduced more than USD 140 million of NBC defence equipment and an additional USD 400 million is in the pipeline.<sup>22</sup>

Work at the facility focuses on countering bioweapons-related disease threats, such as anthrax, botulism, brucellosis, cholera, plague, smallpox and viral haemorrhage fevers.<sup>23</sup> The DRDE has advanced diagnostic facilities for bacterial, viral and rickettsial diseases. Among other activities undertaken or supported by the DRDE is outbreak investigation support.<sup>24</sup>

The DRDE's laboratory is involved in developing NBC detection and protection systems. Some of its research products have been used by the Armed Forces.

No estimated figures are available on project funding. Funding normally comes from the R&D budget allocated to the DRDE, which stood at USD 150 million in 2007-08.<sup>25</sup> How much of it is spent on

biodefence is unknown. The only number available is in India's 1997 CBM declaration: during fiscal year 1994-95, INR 2 million (approximately USD 60,000 at the time) was spent on biodefence activities at the Gwalior facility.<sup>26</sup> Exact figures are not available on the size of the laboratories and the workforce at the Gwalior facility. Again, the only numbers available are in India's 1997 CBM. At that time, biodefence activities at Gwalior involved a staff of 25 civilians and 1,080 square metres (sqm.) of laboratory space with a maximum containment level of BSL-2.<sup>27</sup> Collaborative projects receive funding from the Council for Scientific and Industrial Research, Department of Health, the All India Institute of Medical Sciences, and other life-science laboratories under the DRDO, as well as allocated funding from various life-science departments at universities. In the words of William Selvamurthy, Chief Controller, Research & Development (R&D), DRDO, the DRDE, Gwalior is one of the few laboratories in the world where world class research on Nuclear, biological and chemical safety is being carried on [...] at a cost of USD 52.294 million (approx INR 285 Crore) .<sup>28</sup>

India has recently established a state of the art Biological and Chemical sensor facility at the DRDE, Gwalior.<sup>29</sup> DRDO is also investing USD 18.349 million (approx INR 100 crore) for setting up a national center at Panipat in Haryana to train armed forces and para-military personnel as 'first responders' in Chemical, Biological, Radiological and Nuclear

21 See [http://articles.timesofindia.indiatimes.com/2009-07-04/india/28180829\\_1\\_nbc-recce-vehicle-drdo](http://articles.timesofindia.indiatimes.com/2009-07-04/india/28180829_1_nbc-recce-vehicle-drdo)

22 See <http://indiadefenceonline.com/956/nbc-reconnaissance-vehicle-inducted-into-army/>

23 'A passage to India', *CBRNE World*, Summer 2010. (Read the Interview of Dr. Rajagalopalan Vijayaraghavan, Director, DRDE.)

24 For more information see <http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp&labhits=1404>.

25 Information gathered during informal interactions with scien-

tists involved in DRDO and university-level life-science projects in mid-2008.

26 CBM India 1997.

27 CBM India 1997.

28 <http://www.dailyexcelsior.com/web1/12feb25/national.htm#1>

29 "DRDO opens Chem Bio sensor facility", 25 May 2012. <http://frontierindia.org/drdo-opens-chem-bio-sensor-facility/>

**Table 1. Contact information for government biodefence facilities in India**

<b>Biodefence facility</b>	<b>Contact information</b>
Defence Research and Development Establishment	Jhansi Road, Gwalior (Madhya Pradesh) - PIN 474 002, India Tel.: +91 751-2233490/+91 751-2340245 E-mail: director@drde.drdo.in
Defence Materials and Stores Research and Development Establishment	Grand Trunk Road, Kanpur (Uttar Pradesh) - PIN 208 013, India Tel.: +91 051-22450695 Fax: +91 051-22450404 E-mail: dmsrde@sancharnet.in
Defence Bioengineering and Electromedical Laboratory	PO Box No. 9326, CV Raman Nagar, Bangalore (Karnataka) - PIN 560 093, India Tel.: +91 802-5280692/+91 802-5058425 E-mail: dirdebel@debel.drdo.in
Defence Food Research Laboratory	Defence Food Research Laboratory, Ministry of Defence, Siddarth Nagar, Mysore (Karnataka) - PIN 570 011, India Tel.: +91 082-12473783 Fax: +91 082-12473468 E-mail:director@dfrl.drdo.in/ dfrlmysore@sancharnet.in

(CBRN) emergencies.<sup>30</sup>

The DMSRDE in Kanpur (Uttar Pradesh) specialises in the manufacture of protective suits, gloves and boots. According to its present Director, Arvind Kumar Saxena, the ongoing project on the biological suit is likely to be completed by 2013.<sup>31</sup>

The DEBEL in Bangalore (Karnataka) manufactures

such items as canisters, face masks, and NBC filter-fitted casualty evacuation bags, based on technology provided by the DRDE. The DRDE and DEBEL have together developed a Respiratory Mask that provides protection against bacteria, radioactive dust, smoke, toxic gases, and vapour. This was utilised in the civil sector during the SARS (severe acute respiratory syndrome) epidemic in 2003.<sup>32</sup> Under the auspices of DEBEL, India has initiated building bio-radars

30 <http://www.dailyexcelsior.com/web1/12feb25/national.htm#1>

31 "Indian army may soon get bio-chem suits", Rediff.com, 11 May 2011.

32 For more information on the NBC Respiratory Mask, see <http://drdo.gov.in/drdo/labs/DEBEL/English/index.jsp?pg=Products.jsp>

to mitigate any future threat of bioterrorism. It is conceived to act as an early warning system. According to DEBEL's Director V. Padaki, bio-radar's components will be able to detect the existence of dangerous chemical and biological material and then communicate that information to a central control room. This would give an indication of the quarantine material and also prepare to counter a biological or chemical attack.<sup>33</sup>

The Defence Food Research Laboratory (DFRL) located in Mysore (Karnataka) under the aegis of the DRDO provides logistical support in the area of food supplies and to help meet the varied food challenges of the Indian Army, Navy, Air Force and other paramilitary entities. In 2011, the DFRL has devised an 'Anthra-check Sand-E kit' that provides a fast, reliable, and cost-effective method of detecting anthrax, to ensure food safety due to possible bioterrorism.<sup>34</sup>

In addition, there are at least three private actors with whom the DRDO is actively involved in developing biodefence infrastructures:

Titagarh Wagons Ltd. (TWL, West Bengal) is a leading private-sector wagon manufacture in India. TWL is engaged in manufacturing specialised equipment for the defence sector, such as integrated field shelters (IFS) to combat NBC warfare, in collaboration with the DRDO.<sup>35</sup>

33 Threat of bio terrorism: India building its first bio-radar, New India Express, June 21, 2012. <http://newindianexpress.com/cities/bangalore/article547278.ece>

34 See <http://ibnlive.in.com/news/kit-to-detect-anthrax-developed/195344-60-115.html>

35 TWL as an industry partner of the DRDE manufactures certain products for the Indian defence establishment, such as special wagons, shelters and other engineering equipments. See <http://www.titagarh.biz/defence.html>

Dass Hitachi Ltd., a Gaziabad-based private company, has developed integrated NBC protection systems, IFS, NBC filtration systems, and ruggedised scooping devices for the Armed Forces. The company has invented an antigen-based diagnostic kit to aid diagnosis of anthrax, dengue, H1N1, leptospirosis, malaria, plague, typhoid, and other diseases.<sup>36</sup> Joseph Leslie Drager Mfg Pvt Ltd. has successfully developed items that provide troops with individual protection from toxic gases, radioactive dust and bacterial micro-organism. It was the first private organisation in India to obtain Defence Approvals for NBC respirators.

All three wings of the Armed Forces have their own NBC training centres: at Pune (Army), Delhi (Air Force), and Lonavla (Navy). Military exercises regularly include NBC scenarios. To maintain a high degree of preparedness and coordination by different agencies during a chemical, biological, radiological and nuclear (CBRN) emergency or disaster, Indian Army's Vajra Corps (a striking force the Indian Army) holds mock drills time to time to help civil authority during CBRN emergency. In March this year (2012) similar drill exercise, 'Vajra Sahayta' was held at a Market place (Ansal Plaza) located on the Jalandhar- Phagwara highway with an aim to synergise the efforts of all stakeholders and check their preparedness to face CBRN crisis. The exercise witnessed participations of the 8th battalion of the National Disaster Response Force (NDRF), Ghaziabad (Uttar Pradesh), a 22-member team of the Nuclear Biological & Chemical (NBC) Quick Reaction Team (QRT) platoon of the Vajra Corps and the local administration.<sup>37</sup>

36 *Ibid.*

37 "Vajra Corps holds mock drill under Vajra Sahayta, Mall evacuated, low-intensity bomb diffused", <http://www.tribuneindia.com/2012/20120308/jaltrib.htm#1>

**Table 2.** Contact information for private companies involved with the DRDO and in biodefence activities

Titagarh Wagons Ltd.	Premlata-4th Floor, 39, Shakespeare Sarani, Kolkata (West Bengal) - PIN 700 017, India Tel.: +91 332-2834467 Fax: +91 332-2891655 E-mail: corp@titagarh.biz
Dass Hitachi Ltd	8/9th Mile Stone, G T Road, Sahibabad Mohan Nagar, Mohan Nagar, Gaziabad, Uttar Pradesh 201007, India Tel.: +91 120-2638400/4755200 Fax: +91 120-4132435 E-mail: dhl@dasshitachi.com
Joseph Leslie Drager Mfg Pvt Ltd	Leslico House, Prof. Agashe Road, Dadar (W), Mumbai - 400 028, India Tel.: +91 222-4221880/1878 Fax: +91 222-4303705 E-mail: mumbai@lesliedraeger.com

The Vajra Corps holds regular military exercise also to fine tune interoperability of other armed forces (e.g. Air force) and its NBC warfare techniques as part of Integrated Theatre Battle. In Late May 2012 a four day exercise was concluded in Punjab to boost swift mobilization of units and formations and to practice offensive manoeuvres.<sup>38</sup>

Under the auspices of the National Disaster Management Authority (NDMA),<sup>39</sup> Ministry of Home

38 <http://www.punjabnewslines.com/news/Vajra-Corps-exercise-concludes-.html>

39 National Disaster Management Authority, NDMA Bhawan, A-1, Safdarjung Enclave, New Delhi - 110 029, India. Tel.: +91 11-26701700 (reception) or +91 11-26701728 (control room).

Affairs, the Government of India also is conducting civilian biodefence and disaster management activities. Most importantly, it has devised a draft plan to counter the threat of biological disaster, both natural and human-made, including bioterrorism.<sup>40</sup>

NDMA often conducts training programmes for specialised agencies and first responders including police and doctors for creating awareness and sensitization in collaboration with DRDO, ICMR

E-mail: rajeevr@ndma.gov.in or nbcdisaster@gmail.com

40 National Disaster Management Authority, Government of India (2008) *National Disaster Management Guidelines—Management of Biological Disasters*, [http://nidm.gov.in/PDF/guidelines/biological\\_disasters.pdf](http://nidm.gov.in/PDF/guidelines/biological_disasters.pdf)

(Indian Council of Medical Research) and NDRF (National Disaster Response Force). Most recently, in October 2012, the NDMA, had conducted NBCR (Nuclear, Biological Chemical and Radiological) training programmes for Indian Parliament's security personnel.<sup>41</sup> Through this eight course programme nearly 400 security personnel have been trained to handle any man made emergencies in and around the Parliament House Complex (PHC) which came under terrorist attack on December 13, 2001.

The National Industrial Security Academy (NISA) in Hyderabad (Andhra Pradesh) is a regional-level institution that conducts training for the rapid-response units, especially on NBC emergencies.<sup>42</sup> Since 2002, the National Civil Defence College (NCDC) at Nagpur (Maharashtra) has been recognised as a nodal training institute for NBC emergencies training by the Ministry of Home Affairs. Both the DRDO and the NDMA, with major funding from the Ministry of Home Affairs, will soon be building a multipurpose NBC institute in Nagpur (Maharashtra) to engage in research, development and training for the military and to support the security forces (other than formal military and state police), as well as to meet civilian needs. The institute is expected to be operational by 2016.<sup>43</sup>

### Maximum and high biological containment laboratories

India has one operational BSL-4 facility, which is located at the High Security Animal Disease

Laboratory (HSADL) in Bhopal (Madhya Pradesh). The laboratory was established in 1998; the biocontainment facility became operational in 2000. The HSADL conducts research on animal diseases such as avian influenza, Nipah virus infection, rabbit haemorrhagic fever, and swine flu.<sup>44</sup>

Another BSL-4 facility is scheduled to be operational at the National Institute of Virology (NIV) Pune. The facility will be located at the Microbial Containment Complex of NIV, situated at its Pashan campus. NIV is one of the major life-science institutes of the ICMR. According to D.T. Mourya, senior scientist and presently heading the group in charge of the new laboratory, the BSL-4 laboratory will be equipped to deal with bioterrorism in the country.<sup>45</sup> Similar concerns have been aired by NIV Director A.C. Mishra, who stated that 'viruses can be used as a bio-terrorism agent and the BSL-4 laboratory has been designed in such a way that it can detect the virus and counter any bio-terror attack'.<sup>46</sup> This USD 10 million (approx INR 55-crore) laboratory, according to Mishra, which will be commissioned later in 2012 is supposed to deal with highly infectious pathogenic agents of diseases like ebola, anthrax, lassa, haemorrhagic fever and smallpox (variola virus).<sup>47</sup>

India has a number of operational BSL-3 facilities (see Table 3).

41 "Parliament Security Staff trained by NDMA to handle any CBRN emergency," NDMA Press Release, October 11, 2012. <http://ndma.gov.in/ndma/pressrelease/pr11102012.pdf>

42 See, <http://cisf.nic.in/nisa/nisa.htm>

43 See NDMA, Home Ministry and DRDO to start first ever NBC institute', *Indian Defence.com*, 7 July 2010< <http://www.indiandefence.com/forums/f5/ndma-home-ministry-drdo-start-first-ever-nbc-institute-1070/>>

44 The HSADL is mandated to research animal diseases of exotic origin. Ranking tenth in the world (according to its portal), it is the only BSL-4 facility in Asia at present. See <http://www.hsadl.nic.in/>

45 See <http://www.thehindu.com/news/national/article2305614.ece>

46 See <http://www.indianexpress.com/news/niv-builds-hitech-virus-lab/825947/2>

47 India's first bio-safety lab at NIV to be a reality soon', *Indian Express*, 03 February 2012, <http://www.indianexpress.com/news/-india-s-first-biosafety-lab-at-niv-to-be-a-reality-soon-/907238/0>

**Table 3. BSL-3 laboratories in India**

Name	Location	Other information
Defence Research and Development Establishment	Jhansi Road, Gwalior (Madhya Pradesh) - PIN 474 002, India Tel.: +91 751-2233490/+91 751-2340245 E-mail: director@drde.drdo.in <a href="http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp">http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp</a>	The one major biocontainment laboratory in India; works on virus and bacteria isolation, identification, serotyping, molecular typing etc. Also investigates outbreaks.
National JALMA Institute for Leprosy and Other Mycobacterial Diseases	P O Box 101, M. Miyazaki Marg, Tajganj, Agra (Uttar Pradesh) - PIN 282 001, India Tel.: +91 562-2331756/+91 562-2333595 E-Mail: jalma@sancharnet.in <a href="http://www.jalma-icmr.org.in">http://www.jalma-icmr.org.in</a>	Vaccine development; research on leprosy, tuberculosis and other mycobacterial infections, HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome), and filariasis.
Microbial Containment Complex, National Institute of Virology	MCC 130/1 Sus Road, Pashan, Pune (Maharashtra) - PIN 411021, India Tel.: 91 020-26006390 Fax: 91 020-25871895 E-mail: nivicl@pn3.vsnl.net.in <a href="http://www.niv.co.in">http://www.niv.co.in</a>	Activities include outbreak response, diagnostics and kit supply, surveillance—human, mosquito, birds, and poultry-related outbreaks. Kyasanur forest disease, rotavirus, dengue, West Nile, Chandipura encephalitis, chikungunia. Dealt with H5N1 outbreak in February 2006.
National Institute of Cholera and Enteric Diseases	P-33, CIT Road, Scheme XM, Belehata, Kolkata (WB) - 700 010, India Tel.: +91 33-23633373/+91 33-23537470 Fax: +91 33-23632398 <a href="http://www.niced.org.in">http://www.niced.org.in</a>	During the avian influenza outbreak in poultry in west Bengal in January-February 2008, all suspected human samples were handled by and analysed at the BSL-3 laboratory.
National Centre for Disease Control (formerly the National Institute of Communicable Diseases)	22, Sham Nath Marg New Delhi - 110 054, India Tel.: +91 11-23913148/+91 11-23946893 E-mail: dirnicd@nic.in <a href="http://www.nicd.nic.in">http://www.nicd.nic.in</a>	Headquarters in New Delhi and eight out-station branches (although not all BSL-3 laboratories). The latter are located at Alwar (Rajasthan), Bengaluru (Karnataka), Kozikode (Kerala), Coonoor (Tamil Nadu), Jagdalpur (Chattisgarh), Patna (Bihar), Rajahmundry (Andhra Pradesh) and Varanasi (Uttar Pradesh).
Regional Medical Research Centre	P O Box No. 105, Dibrugarh - 786 001 (Assam), India Tel.: +91 373-2381494 E-mail: icmrrcdi@hub.nic.in <a href="http://www.icmr.nic.in/rmrc.htm#dibrugarh">http://www.icmr.nic.in/rmrc.htm#dibrugarh</a>	The Regional Medical Research Centre in Dibrugarh is one of six regional centres of the Indian Council of Medical Research. It focuses on mosquito-borne diseases such as Japanese encephalitis and dengue.
AIIMS (All India Institute for Medical Science)	Room 4, Cross Wing, Department of Medicine, AIIMS, Ansari Nagar, New Delhi 110029, India Tel.: 91-11-26588500, 91-11 26588700 Fax: +91 11-26588663 Email: NA <a href="http://www.aiims.edu/aiims/departments/medicine/labfacility.htm">http://www.aiims.edu/aiims/departments/medicine/labfacility.htm</a>	Commissioned in October 2009 to handle the contagious samples of tuberculosis and HIV patients. This laboratory is carrying out various diagnostic tests and research on, for example, interferon gamma release assay (IGRA), DNA isolation from sputum for line probe assay LPA, and cell culture.

**Table 4. Government vaccine production facilities in India**

<p>Central Research Institute, Kasauli, Solan (Himachal Pradesh) - PIN 173 204, India Tel.: +91 179-2272060 <a href="http://www.mohfw.nic.in">http://www.mohfw.nic.in</a></p>	<p>The Central Research Institute has been one of the Government of India's most reliable sources of vaccines and sera. Both the Government of India and the World Bank have provided aid for the renovation of infrastructure, including laboratories. The Institute also caters to military establishments.</p>
<p>National Institute of Virology, 20-A, Dr. Ambedkar Road, Post Box No. 11, Pune (Maharashtra) - PIN 411 001, India Tel.: +91 202-6127301/+91 202-6006290 E-mail: nivicl@pn3.vsnl.net.in <a href="http://www.niv.co.in">http://www.niv.co.in</a></p>	<p>Vaccines against Japanese encephalitis, Nipah virus, and influenza (H5N1).</p>
<p>Haffkine Institute for Training, Research and Testing, Acharya Donde Marg, Parel, Mumbai (Maharashtra) -PIN 400 012, India Tel.: +91 222-4160947/+91 222-4160961 <a href="http://haffkineinstitute.org">http://haffkineinstitute.org</a></p>	<p>The Institute was tasked with the development and production of plague vaccine. Subsequently, vaccinology has been an active area of research at the Institute.</p>
<p>Pasteur Institute of India, Coonoor, Nilgiris (Tamil Nadu) - PIN 643 103, India Tel.: +91 423-2231250/+91 423-2232870 <a href="http://www.pasteurinstituteindia.com">http://www.pasteurinstituteindia.com</a></p>	<p>Anti-rabies vaccine and diptheria-pertussis-tetanus group vaccines.</p>
<p>BCG Laboratory, Guindy, Chennai (Tamil Nadu) - PIN 600 032, India Tel.: +91 332-342976/+91 332-341745 <a href="http://mohfw.nic.in/dghs1.html">http://mohfw.nic.in/dghs1.html</a></p>	<p>Manufactures and supplies BCG (bacille Calmette-Guerin) vaccine.</p>

**Table 5. Private sector vaccine production facilities in India**

<p>Serum Institute of India, Hadapsar, Off Soli Poonawalla Road, Pune (Maharashtra) - PIN 411 028, India          Tel.: +91 202-6993900  <a href="http://www.seruminstitute.com">http://www.seruminstitute.com</a></p>	<p>Nasal form of the 'Fluvac' vaccine for swine flu.</p>
<p>Shantha Biotechnics, H. No.5-10-173, 3rd &amp; 4th Floors,          Vasantha Chambers, Fateh Maidan Road, Basheerbagh,          Hyderabad (Andhra Pradesh) - PIN 500 004, India          Tel.: +91 402-3234136  <a href="http://www.shanthabiotech.com">http://www.shanthabiotech.com</a></p>	<p>Focuses on childhood infectious diseases. Shantvac-B (r-DNA hepatitis B vaccine) is India's first recombinant vaccine. Shanta Biotechnics also produces influenza vaccines.</p>
<p>Biological E. Ltd., Azamabad, Hyderabad (Andhra Pradesh) - PIN 500 020, India          Tel.: +91 402-7603742  <a href="http://www.biologicale.com">http://www.biologicale.com</a></p>	<p>Japanese encephalitis, dengue, rotavirus.</p>
<p>Bharat Biotech, Vamsi Sadan, Phase II, Kamalapuri Colony, Hyderabad (Andhra Pradesh) - PIN 500 073, India  <a href="http://www.bharatbiotech.com">http://www.bharatbiotech.com</a></p>	<p>Swine flu vaccine—first indigenously developed cell-culture H1N1 swine flu vaccine under the brand name of HNVAC.</p>
<p>Sanofi Pasteur India Pvt Ltd. (the vaccines division of Sanofi-Aventis Group),<sup>1</sup> 54/A, Sir Mathuradas VasANJI Road, Andheri East, Mumbai (Maharashtra) - 400093, India  <a href="http://www.sanofipasteur.in/">http://www.sanofipasteur.in/</a></p> <p>Corporate office, D-2, Fourth Floor, Southern Park          DDA Commercial Centre, Saket          New Delhi 110017          India          Tel: +9140558000  <a href="http://www.sanofipasteur.in/">http://www.sanofipasteur.in/</a></p>	<p>Seasonal and pandemic influenza, typhoid, yellow fever, dengue fever.</p>

3 One should note that Sanofi Pasteur is behind the stores of smallpox vaccine that remain available to health authorities in different countries, including France and the United States. Sanofi Pasteur also has developed a second-generation smallpox

vaccine in case of a bioterrorism attack. In 2008, Sanofi Pasteur acquired Acambis, a company that also produces a smallpox vaccine.

## Vaccine production facilities

Vaccines and recombinant therapeutics are two leading sectors reportedly driving the growth of the biotech industry in India. Both these sectors are estimated to reach USD 20 billion in 2012.<sup>48</sup>

Mostly to tackle public health challenges, India has been conducting research on vaccines for various naturally-occurring diseases and accords high priority to vaccine manufacturing in the public and private sector (see Tables 4 and 5). The country produces a range of vaccines to counter infectious diseases. India is one of six countries in the world recognised by the World Health Organization (WHO) as a manufacturer of avian influenza vaccine and capable of manufacturing pandemic influenza vaccine. Serum Institute is the world's 5<sup>th</sup> largest vaccine producer and supplies almost 50% of all vaccines to UNICEF/WHO.

## Research and policy issues regarding smallpox

Smallpox has been eradicated in India—the last cases were reported in 1975. India has been critical of the 'deliberate' delaying of the destruction of the remaining samples of smallpox virus.<sup>49</sup> Although the WHO declared India a smallpox-free country in 1977, smallpox rumours continue to haunt Indian health agencies on occasion.

48 See <http://www.indialawoffices.com/pdf/biotechnology.pdf>

49 India's position on this is evident in 'Smallpox, the most serious threat', *Frontline*, 10-23 November 2001. (Interview with former National Institute of Virology Director Kalayan Banerjee.)

## Disease outbreak data

With regard to particular dangerous agents, the following disease outbreaks were recorded in 2012.<sup>50</sup>

**Anthrax:** the country is considered an endemic region for animal anthrax in general and south India is considered an endemic region for human anthrax.<sup>51</sup> This deadly anthrax bacteria also found in the ground water in some areas of Andhra Pradesh state. Sporadic cases were reported in livestock and wildlife in 2012. There have been at least 6 reported deaths out of 10 cases of animal anthrax in the current year.

**Botulism:** none.

**Lassa/Ebola/Marburg:** none.

**Plague:** none.

**Smallpox:** none.

**Tularaemia:** none.

## Relevant national laws, regulations and guidelines

India has created a broad-based legislative framework to prevent the misuse of micro-organisms and to regulate biomedical research:<sup>52</sup>

**The Weapons of Mass Destruction and their Delivery System (WMD) Act 2005.** This is the only piece of all-encompassing legislation in India, preventing the manufacture, export, transfer, transit and transshipment of WMD (weapons of mass destruction) material, equipment, technology and the means of delivery. The Act is a major export

50 If not indicated otherwise, the source of information is ProMED-mail (<http://www.promedmail.org>).

51 Patil, R.R. (2010) 'Anthrax: public health risk in India and socio-environmental determinants', *Indian Journal of Community Medicine*, Vol. 35, No. 1, pp. 189-190.

52 For a comprehensive overview, see [http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/\\$file/BWC\\_NID\\_Report.htm#in](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/$file/BWC_NID_Report.htm#in)

**Table 5. Size of Indian delegation at BWC-related meetings in Geneva**

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012
Number of delegates	4	6	7	8	5	7	5	5	4	6	7	4	n/a

Notes: RC stands for Review Conference MX stands for Meeting of Experts MSP stands for Meeting of States Parties PC stands for Preparatory Commission (PrepCom)

control tool under which any form of proliferation is considered a criminal offence. Penalties range from five years in jail to life imprisonment, along with fines.

**The Foreign Trade Development Regulation Act of 1992.** This regulates the import and export of micro-organisms and toxins and covers plant pathogens and genetically-modified organisms. The export of dual-use items and technologies (special chemicals, organisms, materials, equipments and technologies (SCOMET), which includes micro-organisms (bacteria, fungi, parasites, viruses, plant pathogens, and genetically-modified organisms) and toxins), is either prohibited or is permitted only with a license.

**The Disaster Management Act of 2005. Indian Environment Protection Act (1986).** This prescribes procedures and safeguards for the handling of hazardous substances. A hazardous substance is any substance or preparation that, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plants or micro-organisms.

National biosafety and biowaste disposal activities are governed by legislation issued by State Pollution Control Boards.

Codes of conduct, education and awareness-raising

While there are a number of general and specific ethical guidelines for life scientists, the *BioWeapons Monitor 2012* could not identify any codes of conduct that address specifically the misuse of life-science activities for bioweapons purposes. In addition, there is no indication of specific education on and awareness-raising of these issues in India. The *Indian Journal of Medical Research* is reported to be working on a policy and the uniform practice of publication of dual-use research results.<sup>53</sup>

### CBM participation

India submitted CBM declarations only in 1997, 2007, 2009, 2010 and 2011. It has not made any of its CBM declarations publicly available.

53 For more information see Kant, L. and D.T. Mourya (2010) 'Managing dual use technology: it takes two to tango', *Science and Engineering Ethics*, Vol. 16, No. 1, pp. 77-83.

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## Participation in BWC meetings

India participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, India has taken part in all relevant meetings (see Table 5).

### Past biological weapons activities and accusations

In its 1997 CBM, India did not say anything about the existence or non-existence of past offensive bioweapons activities. In 2003, the United States Congressional Research Service asserted that there is a danger that India may develop a bioweapons programme. It claimed that 'India is believed to have an active biological defence research program as well as the necessary infrastructure to develop a variety of biological agents'.<sup>54</sup> However, there is no evidence in the public domain of India ever having pursued an offensive bioweapons programme.

<sup>54</sup> Cited in , Andrew Feickert and K Alan Kronstadt, "Missile Proliferation and the Strategic Balance in South Asia", CRS Report (RL 32115), October 17, 2003.



## Country report: Japan

### **1972 Biological Weapons Convention**

Signed: 10 April 1972

Deposit of ratification: 8 June 1982

### **1925 Geneva Protocol**

Signed: 17 June 1925

Deposit of ratification: 21 May 1970

Japan does not have any reservations to the Geneva Protocol.

### **National point of contact**

Biological and Chemical Weapons Conventions Division, Disarmament Non-Proliferation and Science Department, Ministry of Foreign Affairs, Kasumigaseki 2-2-1, Chiyoda-ku, Tokyo 100-8919, Japan

Tel.: +81 (0) 30 3586 3311.

Japan has long supported the effort to strengthen the prohibition against biological and toxin weapons. Recently, in parallel with developments in the Inter-Sessional Process (ISP) of the BWC since 2003, Japan's proactive engagement in counter-terrorism and WMD (weapons of mass destruction) non-proliferation policies has been demonstrated in diverse international fora, such as the Australia Group, the Global Partnership (GP) programme of the Group of 8 (G8) and the Proliferation Security Initiative (PSI), as well as the UN Security Council Resolution 1540.<sup>1</sup>

Such commitment is due in part to the actual threats posed by the destructive use of science in Japan. The most prominent case of such misuse was the bioweapons development efforts of the religious group Aum Shinrikyo in the 1990s. At the Seventh Review Conference of the BWC in 2011, Japan emphasised that taking appropriate action to tackle biological threats is an urgent issue in view of potentially heightened risks associated with biotechnology and biological agents, particularly with

<sup>1</sup> See <http://www.mofa.go.jp/announce/speech/disarm2006/disarm0611.html>

regards to their illicit use or misuse.<sup>2</sup>

Therefore, Japan urged that a comprehensive approach be taken to help mitigate potential biological threats.<sup>3</sup> Details of the approach were further elaborated in the series of working papers (WP) submitted by Japan to the Seventh Review Conference. Japan with Australia and New Zealand underlined the necessity for addressing compliance issues by looking at possible role of confidence building measures (CBM), Article V and VI of the Convention and relevant science and technology (S&T).<sup>4</sup> Japan with Australia also proposed the establishment of working groups on specific agenda items at the coming Inter-Sessional Process (ISP) between 2012 and 2015, including CBM, international cooperation (Article X) and annual review of S&T.<sup>5</sup> Notably at the Seventh Review Conference, Japan declared its CBM return will be made available to the public from 2012.<sup>6</sup> S&T issue was further elaborated by WP No. 13, jointly submitted with Australia and New Zealand, proposing the establishment of “S&T Working Group Facilitator” who are appointed by the States Parties during the ISP and provide S&T report for the next Review Conference.<sup>7</sup> Finally, WP No.22 proposed the enhancement of the institutional

aspect of the BWC by making the current CBM form user friendly and setting out “Matching Needs and Resources” mechanisms to help promote international cooperation between States Parties.<sup>8</sup>

## Status of the life sciences and biotechnology industry

According to the BWPP’s 2011 global survey, Japan is one of the world’s leading countries in the field of the life sciences and biotechnology. Globally, Japan ranks second; in its geographical sub-region, East Asia, it ranks first. More specifically, globally, Japan ranks fourth in terms of publications and, together with the United States, first with regard to patents.<sup>9</sup> Japan is also home to some 5,000 companies engaged in the development, production and distribution of medical and health-care devices, equipment, instruments and materials.<sup>10</sup> There are more than 30 different types of academic life-science societies.<sup>11</sup> For example, the Molecular Biology Society of Japan has increased its membership to approximately 15,000 since 1978 and some 8,000 participants attend its annual conventions.<sup>12</sup> Around 200 universities have life-science degree courses and conduct biotechnology research projects, often in cooperation with relevant public and

2 [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/BF9E9CA69E1F3529C125795E00304467/\\$file/Japan.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/BF9E9CA69E1F3529C125795E00304467/$file/Japan.pdf)

3 *Ibid.*

4 <http://daccess-ods.un.org/TMP/262402.184307575.html>

5 <http://daccess-ods.un.org/TMP/2039310.33611298.html>

6 See [http://www.unog.ch/80256EE600585943/\(httpPages\)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument)

7 <http://daccess-ods.un.org/TMP/4891158.64038467.html>

8 <http://daccess-ods.un.org/TMP/4095795.75061798.html>

9 See Annex.

10 National Research Council (2006) *Globalization, biosecurity and the future of the life sciences*, National Academies Press, Washington, DC. See also <http://ey.com/GL/en/Industries/Life-Sciences/Beyond-borders--global-biotechnology-report-2011> and <http://www.jfmda.gr.jp/e/>

11 See <http://www.cirs.net/org-eng.php?pagemap=societes&matiere=scvie&pays=Japon#societes>

12 See <http://www.mbsj.jp/en/index.html>

**Table 1. Policy developments in NBC defence**

Type of activity	Specific activity	Year	Ministry/ agency
Research and analysis	Implementation of a commissioned investigation of NBC counter-terrorism measures in developed countries	1999	Police
	Completion of the <i>Report of the Council for Dealing with Biological Weapons</i>	2000, 2001	Defence
Structural reform	Establishment of a NBC counter-terrorism squad within the Osaka and Tokyo police agencies	1999	Police
	Placing of a 'counter-terrorism officer' in the Security Division of the Security Bureau	2000	Police
	Establishment of a 'special coordinator for special weapons' and an 'NBC counter-measure medical division' at the Ground Research and Development Command of the JGSDF	2000	Defence
Development of manuals	Creation of a response manual for medical personnel at the JGSDF	1999	Defence
	Assessment of existing examination systems for infectious diseases at inspection agencies, and the development of an examination manual on diseases	2000	Health and Labour
Training	Carrying out of NBC counter-terrorism exercises for riot police of major prefectural and city governments	2000	Police
	Development of training programmes on NBC materials and response manuals in case of NBC terrorism at the National Police Academy for chief inspectors of major prefectural and city governments	1999	Police
	Development of training programmes on NBC counter-terrorism for riot police of major prefectural and city governments	2000	Police
	Development of training programmes for medical officers on special weapons defence and information gathering in sanitary technology	2000	Defence
Medical issues	Development of training programmes for doctors, nurses and health visitors in Post-Traumatic Stress Disorder (PTSD)	1996	Health and Labour
	Creation of a list of high necessity curative drugs	2000	Health and Labour

**Table 2. Agencies, divisions and units regarding biodefence in Ministry of Defense of Japan**

Name	Location
Test and Evaluation Command, Military Medicine Research Unit, JGSDF	1-2-24, Ikejiri, Setagaya-ku Tokyo, 154-0001
NBC Countermeasure Medical Unit (NBCCBMED), CRF-GSDF	GSDF Camp Asaka, Oizumigakuen-cho, Nerima-ku, Tokyo 178-8501
Central Nuclear Biological Chemical Weapons Defense Unit (CNBC), CRF-GSDF	GSDF Camp Asaka, Oizumigakuen-cho, Nerima-ku, Tokyo 178-8501
Aero Medical Laboratory, Air SDF	1-2-10 Sakae cho, Tachikawa, Tokyo, 190-0003
NBC Special Units in prefectural police	Aichi, Chiba, Hiroshima, Hokkaido, Hukuoka, Kanagawa, Miyagi, Osaka, and Tokyo
National Defense Medical College (NDMC)	3-2 Namiki, Tokorozawa, Saitama 359-8513

private research institutions.<sup>13</sup> Since 1942, the Japan Bioindustry Association (JBA) has organised the World Business Forum, which is the longest-running international biotechnology event in Asia. In 2011, 20,606 participants attended 327 business exhibitions, leading to 1,643 business matching.<sup>14</sup>

### Biodefence activities and facilities

Japan developed training exercises for responding to nuclear, biological and chemical (NBC) weapons in the 1970s as part of the operations of the Central NBC Weapons Defense Unit (CNBC) of the Japan Ground Self-Defense Force (JGSDF) and the emergency exercises of the Japan Maritime Self-Defense Force (JMSDF). However, substantial budgeting for NBC defence capacity-building started

in 2000 following attempted biological attacks by Aum Shinrikyo in 1990-95.<sup>15</sup> Importantly, efforts to strengthen NBC counter-measures were further enhanced in light of increasing international attention to the threat of proliferation of bioweapons and their potential linkage with terrorism, including the anthrax attacks in the US in September 2001.

A number of relevant policy developments as part of NBC defence capacity-building occurred around 2000. In Fiscal Year 2000, the Government of Japan presented a budget plan for equipment for counter-chemical and biological weapons that attempted to allocate unprecedented USD 65 million to the Ministry of Health, Labour and Welfare.<sup>16</sup> For the same Fiscal Year, USD 24 million was earmarked for

13 See <http://www.cirs.net/org-eng.php?pagemap=societes&matiere=scvie&pays=Japon#societes>

14 [http://www.jba.or.jp/pc/en/top/pdf/BJ2011\\_rep\\_e\\_v2%281220%29.pdf](http://www.jba.or.jp/pc/en/top/pdf/BJ2011_rep_e_v2%281220%29.pdf)

15 See <http://www.sangiin.go.jp/japanese/joho1/kousei/syuisyo/150/syuh/s150006.htm>

16 It is not sure this budget was intended to cover the single fiscal year or multiple years from 2000.

**Table 3. Civil contractors for biodefence projects for the FY 2011-2012**

Research Programme	Funding	Plan, Admin and Execution	Design Manufacturing Contractor
Detection of biological agents	Approximately USD 1,400,000 (110 mil Japanese Yen)	TRDI-MoD	Japan Steel Works, LTD.
Protective equipment	Approximately USD 128,000 (10 mil Japanese Yen)	TRDI-MoD	Toyobo Co.LTD.

the Ministry of Defense for its counter NBC project.<sup>17</sup> These policy developments were coordinated by relevant ministries and agencies, including the coastguard, commerce, defence, fire service, health/labour, police, and science/technology. In 2010, a 15-year summary of the development of CBRN (chemical, biological, radiological, nuclear) response measures after the Aum Shinrikyo Sarin gas attack on the Tokyo subway on 20 March 1995 pointed out that, while government efforts have led to clear advancements in CBRN capacity development within relevant agencies, ‘for better CBRN preparedness in Japan, more interdepartmental and inter-organisational collaboration and co-operation should be enhanced to maximise the limited resources in this field’.<sup>18</sup> Table 1 summarises these policy developments, and Table 2 lists the relevant units and facilities.

Japan’s CBM Return of 2012 declared that Technical

<sup>17</sup> *ibid.*

<sup>18</sup> Saito, T. (2010) ‘Tokyo drift? CBRN defence capability in Japan 15 years after the subway Sarin attack in Tokyo’, *CBRNe World*, Autumn, pp. 20-26; see also [http://bio-preparedness.jp/index.php?plugin=attach&refer=MEXTP-J2007&openfile=G-SEC Biosecurity report\\_H19\\_3.pdf](http://bio-preparedness.jp/index.php?plugin=attach&refer=MEXTP-J2007&openfile=G-SEC%20Biosecurity%20report_H19_3.pdf)

Research and Development Institute (TRDI) of the Ministry of Defense has conducted research on detection of biological agents and research on protective equipment in the Fiscal Year from April 2011 to March 2012 funded by the Ministry of Defense.<sup>19</sup> The financial and organizational details of this project is summarised in Table 3.

The other declared biodefence programme for the same FY was conducted by the JGSDF. This programme was approximately USD 35,000 (2,722,000 Japanese Yen) funded by the Ministry of Defense, including:

- Research of molecularbiological diagnosis for biological agent casualties
- Research of aerobiology<sup>20</sup>

This programme did not include any private contractors. The facility, which conducted the programme, is a shared facility of the Military Medicine Research Unit, Test and Evaluation Command of the JGSDF with BSL2 laboratories

<sup>19</sup> CBM Japan (2012).

<sup>20</sup> CBM Japan (2012).

**Table 4: BSL4 facilities in Japan**

Name	Location	Size of BSL4 facility	Agents worked with	Comments
Murayama Annex of the National Institute for Infectious Diseases (NIID) <sup>1</sup>	Tokyo	One BSL4 unit (and seventeen BSL3 and its supporting laboratories) 2270.36 square metres	Laboratory diagnosis and virological studies include hemorrhagic fever viruses including Crimean-Congo, Ebola, Lassa, and Marburg	Although both institutions are technically equipped with BSL4 facilities, they are not operated as BSL4 facilities.
RIEKN Tsukuba Institute, Institute of Physical and Chemical Research (IPCR) <sup>2</sup>	Ibaraki	Two units 82 square metres each	Risk assessment of recombinant DNA material using Retrovirus	Rather, they are limited to working on BSL3 agents, due to the opposition of local residents.

1 See <http://www.nih.go.jp/niid/welcome/org-index-e.html>

2 See <http://www.riken.go.jp/engn/index.html>

(Approximately 42sqM). Scientific discipline of staff is Ph.D. of Medicine. There is no official publication policy at the facility and each programme is individually authorised for possible publication; no paper was published based on the biodefence programmes of the FY 2011-2012.<sup>21</sup>

### Maximum and high biological containment laboratories

Japan has two BSL4 facilities (see Table 4). Neither is operated at the Maximum containment level due to opposition from or an agreement with local residents; instead, they are operating as BSL 3 facilities without dealing with biological agents and research, which requires BSL 4 laboratories.<sup>22</sup> Table

21 CBM Japan (2012).

22 See <http://www.ncbi.nlm.nih.gov/pubmed/19797849> and <http://www.nature.com/nrmicro/journal/v3/n8/>

5 shows the pathogens classified as BSL4 in Japan by the National Institute for Infectious Diseases (NIID). ‘BSL4 pathogens do not exist in nature in Japan, which currently has no equivalent physical containment facilities, but the possibility exists that they may be brought into the country unintentionally by those infected in endemic areas or intentionally by bioterrorists’.<sup>23</sup> With a view to making BSL4 facilities operational in Japan, discussions have taken place between academic and governmental experts.<sup>24</sup> In addition, a 2011 study of physical and social environmental conditions pointed out that communication with the public is far more developed than it was when BSL4 facilities were introduced in

[full/nrmicro1224.html](http://full/nrmicro1224.html)

23 See <http://www.fujipress.jp/JDR/DSSTR00040005.html>, p. 352.

24 [http://www.cicorn.nagasaki-u.ac.jp/anzen/anzen\\_index.html](http://www.cicorn.nagasaki-u.ac.jp/anzen/anzen_index.html) and also <http://blog.livedoor.jp/cicorn/>

**Table 5. Pathogens classified as BSL4 by the NIID<sup>1</sup>**

Family	Genus	Genus
Arenaviridae	<i>Arenavirus</i>	<i>Guanarito virus, Junin virus, Lassa virus, Machupo virus, Sabia virus</i>
Bunyaviridae	<i>Nairovirus</i>	<i>Crimean-Congo hemorrhagic fever virus</i>
Filoviridae	<i>Ebolavirus</i>	<i>Filoviridae ebolavirus, Ivory Coast ebolavirus, Reston ebolavirus, Sudan ebolavirus, Zaire ebolavirus</i>
	<i>Marburgvirus</i>	<i>Lake Victoria marburgvirus</i>
Poxviridae	<i>Orthopoxvirus</i>	<i>Variola virus (major, minor)</i>

1 See <http://www.fujipress.jp/JDR/DSSTR00040005.html>

1981, and there is improved public understanding about the necessity.<sup>25</sup> However, financial constraints remain an issue for local governments looking to sustain such facilities.<sup>26</sup>

The NIID's research departments are engaged in the following research programmes:

The Department of Virology I is focused on the quality control of vaccines and reference activities related to hemorrhagic fever viruses: arboviruses, Chlamydia, herpesviruses, neuroviruses, and Rickettsia.

Department II is focused on biological characterisation and the pathogenesis of the following viruses: diarrhoea viruses (such as

Norwalk-like virus and rotavirus), enteroviruses, hepatitis viruses, poxviruses, tumour viruses (such as papillomaviruses and polyomaviruses).

Department III is focused on the study of the measles virus as well as quality control of measles vaccines.<sup>27</sup>

The BWPP could not identify the exact number of BSL3 facilities in Japan. According to the National Institute of Health and Sciences (NIHS), however, there are approximately 200 BSL-3 facilities, 62 of which are located in institutes of health in local municipalities. The remaining BSL-3 facilities belong to hospitals, pharmaceutical industries and universities.<sup>28</sup>

Regarding possible dual-use research of concern in relation to the Fink Report of the US National Research Council, one of the widely debated H5N1

25 See <http://scitation.aip.org/getabs/servlet/GetabsServlet?prog=normal&id=AS-MECP002010049118000189000001&idtype=cvips&gifs=yes&ref=no>

26 See <http://scitation.aip.org/getabs/servlet/GetabsServlet?prog=normal&id=AS-MECP002010049118000189000001&idtype=cvips&gifs=yes&ref=no>

27 See <http://www.nih.go.jp/niid/welcome/org-index-e.html>

28 See <http://www.nihs.go.jp/aboutnihs/itenkeika-ku/090403-2.pdf>

**Table 6. Vaccine production facilities in Japan<sup>1</sup>**

Name	Location	Disease covered (not limited/among others)/additional information
Kitasato Institute <sup>2</sup>	5-9-1, Shirokane, Minatoku, Tokyo	<ul style="list-style-type: none"> <li>• Vaccines for humans and animals</li> <li>• Inactivated vaccines for diphtheria, pertussis, and tetanus</li> <li>• Attenuated virus vaccines for measles and MMR (measles, mumps, and rubella)</li> <li>• Animal vaccines for canine madness, infectious coryza, and swine erysipelas</li> </ul>
Takeda Pharmaceutical Company, Ltd <sup>3</sup>	4-1-1, Doshomachi, Chuo ku, Osaka City, Osaka	<ul style="list-style-type: none"> <li>• Dried Live Attenuated Vaccines for MMR</li> <li>• Japanese Encephalitis Vaccine</li> <li>• Freeze-dried Live Attenuated Measles and Rubella Combined Vaccine</li> <li>• Influenza hemagglutinin (HA) Vaccine</li> </ul>
Denka Seiken Company, Ltd <sup>4</sup>	3-4-2, Nihonbashi, Kayaba cho, Chuo ku, Tokyo	<ul style="list-style-type: none"> <li>• Denka Seiken constructed a new USD 35 million state-of-the-art manufacturing facility for influenza vaccines at its Niigata facility in 2006. It has been operational since 2009</li> </ul>
Sanofi-Aventis <sup>5</sup>	3-2-20, Nishi Shinjuku, Shinjuku ku, Tokyo	<ul style="list-style-type: none"> <li>• As a Japanese section of Sanofi-Pasteur of France, Sanofi-Aventis ActHIB develops vaccine for haemophilus influenza type b (Hib)</li> </ul>
Kaketsuken (Cherno Sero Therapeutic Research Institute) <sup>6</sup>	1-6-1, Okubo, Kumamoto City, Kumamoto	<ul style="list-style-type: none"> <li>• Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine</li> <li>• Adsorbed Diphtheria-Tetanus Combined Toxoid</li> <li>• Freeze-dried, Cell Culture-Derived Japanese Encephalitis Vaccine(Inactivated)</li> <li>• Vaccines for Smallpox</li> </ul>
Research Foundation for Microbial Diseases of Osaka University <sup>7</sup>	3-1, Yamadaoka, Suita City, Osaka	<ul style="list-style-type: none"> <li>• Iridovirus (injection vaccine for fish)</li> <li>• Development of influenza vaccine</li> </ul>
Japan BCG Laboratory <sup>8</sup>	4-2-6, Kohinata, Bunkyo ku, Tokyo	<ul style="list-style-type: none"> <li>• Vaccines for Tuberculosis</li> </ul>
Japan Polimyelitis Research Institute <sup>9</sup>	5-34-4, Kumegawa cho, Higahimurayama City, Tokyo	<ul style="list-style-type: none"> <li>• Vaccines for Poliomyelitis</li> </ul>
Meiji Dairies Co. <sup>10</sup>	1-2-10, Shinsuna, Kouto ku, Tokyo	<ul style="list-style-type: none"> <li>• Vaccines for Hepatitis B</li> </ul>

1 See [http://www.bwpp.org/documents/BWM\\_2011\\_WEB.pdf](http://www.bwpp.org/documents/BWM_2011_WEB.pdf)

2 See <http://www.kitasato-u.ac.jp/research/gakubu/k117101101.html>

3 See [http://www.takeda.com/products/ethical-drugs/article\\_896.html#vaccine](http://www.takeda.com/products/ethical-drugs/article_896.html#vaccine)

4 See <http://denka-seiken.jp/english/newsroom/n20060707.html>

5 See <http://www.sanofi-aventis.co.jp/l/jp/ja/index.jsp>

6 See <http://www.kaketsuken.or.jp/eng/prod/index.html>

7 See <http://www.biken.osaka-u.ac.jp/e/>

8 See <http://www.bcg.gr.jp/english/index.html>

9 See <http://www.jpri.or.jp/>

10 See <http://www.meiji.co.jp/english/>

**Table 7. Vaccine exports by Japan<sup>1</sup>**

Vaccine	Importing countries	Amount
DPT Vaccine	Republic of Korea, Taiwan	110,000 bottles
DPT Undiluted Vaccine	Republic of Korea	460 litres
<i>Pertussis</i> Vaccine	US	2 million doses
Japanese Encephalitis Vaccine	Australia, Canada, Thailand, US	70,000 shots
<i>Varicella</i> Vaccine	33 countries from Asia, Latin America, and the Middle East	630,000 bottles
Bacille de Calmette et Guérin (BCG)	133 countries from Africa, Asia, Latin America, the Middle East, and Oceania	51 million doses
Influenza Undiluted Vaccine	Republic of Korea, Taiwan	1650 litres
Influenza Vaccine	Australia	9,500 bottles

1 The table is based on data from <http://www.mhlw.go.jp/shingi/2007/03/dl/s0322-13d-10.pdf>

influenza research from 2011 to 2012 was conducted by a Japanese national (Dr. Yoshihiro Kawaoka from the University of Tokyo) while the researcher was conducting the research at the University of Wisconsin-Madison in the United States.<sup>29</sup> The series of international debates over this research also caught experts' and media attention in Japan. A focused committee on dual-use issues under the Science Council of Japan was established on 16 November 2011, consisting of science, defence and legal experts, chaired by Dr. Hiroshi Yoshikura, an Emeritus Member, National Institute of Infectious Diseases in Japan, as well as the Adviser, Food Safety Division, Ministry of Health Labour and Welfare,

29 See <http://ojs.st-andrews.ac.uk/index.php/jtr/article/view/417>

Japan.<sup>30</sup> Currently, Dr. Kawaoka is also one of the members of the committee and the committee has been drafting a code of conduct on dual-use issues under the Council.<sup>31</sup>

### Vaccine production facilities

Japan has a comparatively large number of vaccine production facilities (see Table 6).<sup>32</sup> Little

30 Kasuga, F. (2012) 'Situation of dual-use education in Japan and effort taken by the Science Council of Japan including the outcome of recent symposium in Tokyo' presented at the Seventh Review Conference of the BWC. 12 December, Geneva: United Nations.

31 See <http://www.scj.go.jp/ja/member/iinkai/delyu/delyu.html>

32 See <http://www.mhlw.go.jp/shingi/2007/03/s0322-13.html>

information was found on production capacity; quantities of vaccine exports, listed in Table 7, though, illustrate the scale of vaccine production in Japan.<sup>33</sup>

## Disease outbreak data

With regard to particularly dangerous diseases, the following record has been reported by the Infectious Disease Surveillance Center (IDSC). While the IDSC data is available from 25 February 2012, official disease statistics in formulated tables are only available for the years up to 2010—no formulated data in the tables could be found for 2011 and 2012.<sup>34</sup> Based on the available data it is evident that Japan has a low incidence of particularly dangerous diseases:

- Anthrax: none.
- Botulism: three cases in 2007 (one food borne, two is infant botulism); two cases in 2008 (one is infant botulism and the other is unknown); one case in 2010 (infant botulism).
- Lassa: none.
- Plague: none.
- Smallpox: none.
- Tularaemia: five cases in 2008.

## Relevant national laws, regulations and guidelines

The most important piece of BWC legislation is the Law on Implementing the BWC of 1982, designed to criminalise and penalise production, possession, transfer and acquisition of biological and toxin weapons. The Law was enacted prior to Japan's

ratification of the BWC on 8 June 1982.<sup>35</sup> At the conclusion of the 'International Convention for the Suppression of Terrorist Bombings', Japan amended (in 2001) the Law to proscribe explicitly the 'use' of biological and toxin weapons.<sup>36</sup>

Various legal provisions as well as Cabinet Orders are in place to prohibit the use of biological/chemical weapons by non-state actors following the Aum Shinrikyo Sarin gas attack in March 1995 and the anthrax attacks in the US in September 2001. These include: the Law on the Prevention of Personal Injury by Sarin of 1995, which forbids the production, possession and emission of Sarin; and the Cabinet Order for the Enforcement of the BWC of 1995, which promotes the enhancement of the Law on Implementing the BWC.

In terms of measures, the Governmental Basic Directions for Addressing Bio-Chemical Terrorism of 2001 sets out more widely biosecurity initiatives, including improved public health preparedness, strengthened responses by the fire service, the JGSDF and the police, and the provision of appropriate information to the public in an emergency. The Foreign Exchange and Foreign Trade Law of 1949 was amended in 1997 to strengthen export controls, licensing legitimate financial and material transactions in the national interest. Finally, the Ministerial Notice on Laboratory Safeguards of 2001 advises research institutes to establish safeguard systems for dangerous pathogens.

33 See <http://www.mhlw.go.jp/shingi/2007/03/s0322-13.html>

34 See <http://idsc.nih.go.jp/idwr/ydata/report-E.html>

35 See <http://www.mofa.go.jp/policy/un/disarmament/policy/pamph0404.html>

36 See [http://www.opbw.org/new\\_process/mx2003/bwc\\_msp.2003\\_mx\\_wp10.pdf](http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp10.pdf)

**Table 8.** Projects on education, awareness raising and outreach in Japan<sup>1</sup>

Institution	Approaches and contentA
National Defense Medical College <sup>2</sup>	<ul style="list-style-type: none"> <li>• Compulsory biosecurity education courses: two days for undergraduate and five days for post-graduate levels (since 2008)</li> <li>• Development of an online educational resource</li> </ul>
Keio University <sup>3</sup>	<ul style="list-style-type: none"> <li>• Biosecurity educational programmes for medical students (since 2010)</li> <li>• Long series of interdisciplinary seminars on biopreparedness</li> <li>• Biosecurity watch (blog)</li> </ul>
Waseda University	<ul style="list-style-type: none"> <li>• Educational courses on social responsibility of life scientists, including biosecurity topics at the master and doctoral levels (since 2009)</li> </ul>
Jikei University <sup>4</sup>	<ul style="list-style-type: none"> <li>• Tabletop counter-bioterrorism exercises with relevant ministries (2007)</li> </ul>
Nagasaki University <sup>5</sup>	<ul style="list-style-type: none"> <li>• Japan-US symposium on biodefence,</li> <li>• CBRN News (blog)</li> </ul>
Japan Association of Bioethics	<ul style="list-style-type: none"> <li>• A panel focused on dual-use issues at the Association's conventions (2010 and 2011)</li> <li>• Publication of a newsletter in April 2010 on dual-use issues</li> </ul>
Research Institute of Science and Technology for Society (RISTEX)-JST <sup>6</sup> As well as Center for Research and Development Strategy (CRDS)-JST <sup>7</sup>	<ul style="list-style-type: none"> <li>• Establishment of a network on biosecurity issues, including officials from all relevant ministries and agencies, experts from universities and research institutions, and journalists</li> <li>• Wide range of seminars on science, dual-use and international security issues</li> </ul>

1 *Ibid.*

2 See <http://www.springerlink.com/content/j6137g35567j7731/>

3 See [http://biopreparedness.jp/index.php?MEXTPJ\\_en](http://biopreparedness.jp/index.php?MEXTPJ_en) and also <http://biosecurity.gsec.keio.ac.jp/blog/about.html>

4 See <http://www.sussex.ac.uk/Units/spru/hsp/Reports> from Geneva/HSP Reports from Geneva No. 32.pdf.

5 See [http://www.cicorn.nagasaki-u.ac.jp/anzen/anzen\\_index.html](http://www.cicorn.nagasaki-u.ac.jp/anzen/anzen_index.html) and also <http://blog.livedoor.jp/cicorn/>

6 Furukawa, K. (2009) 'Dealing with the dual-use aspects of life science activities in Japan', in B. Rappert and C. Gould (eds.), *Biosecurity: Origins, Transformations and Practices*, Palgrave Macmillan, Basingstoke, pp. 133-155.

7 <http://crds.jst.go.jp/type/workshop/>

**Table 9. Number of Japanese delegates at BWC meetings**

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	RC 2011	MX 2012
Number of delegates	9	6	7	7	6	7	8	8	5	9	5

Notes: RC stands for Review Conference MX stands for Meeting of Experts MSP stands for Meeting of States Parties

## Codes of conduct, education and awareness-raising

To help mitigate bioweapon threats, Japan has addressed—particularly in recent discussions concerning the BWC—some key aspects of awareness-raising about the BWC among scientists. According to Japan, a lack of awareness among scientists is not to be taken as a sign of ‘the immorality of scientists’. ‘[T]he misconduct and failures of scientists are not caused by a lack of ethics but rather by ignorance’.<sup>37</sup>

The government’s particular emphasis on education led to the submission of WP No.20 and No.20-Rev.1 in conjunction with (Australia, Canada, New Zealand, Republic of Korea and Switzerland (on behalf of the “JACKSNNZ”), and Kenya, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America) to the Seventh Review Conference in 2011 with detailed reports and analyses of on-going education activities as part of

37 See BWC/MSP2005/MX/WP.21, [http://www.opbw.org/new\\_process/mx2005\\_wps.htm](http://www.opbw.org/new_process/mx2005_wps.htm)

national implementation of the BWC.<sup>38, 39</sup>

Evidence from both recent official statements and academic research highlights nascent but advancing activities in the area of biosecurity education. A 2009 study surveyed 197 life-science degree courses at 62 universities in Japan by looking at different types of topics relevant to dual-use issues.<sup>40</sup> While life scientists lack education in the BWC, efforts have been made by the academic, professional and science communities to promote education in dual-use issues as part of the life-science curricula (see Table 8).

In addition, the Japan Bioindustry Association (JBA) has underscored its mandatory professional rules and guidelines, stating that such standards are important

38 <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/643/57/PDF/G1164357.pdf?OpenElement>. Also see Minehata, M. (2011) ‘Education and Biosecurity’, *The Diplomat*, 19 August, <http://the-diplomat.com/new-leaders-forum/2011/08/19/education-and-biosecurity/>

39 <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/650/58/PDF/G1165058.pdf?OpenElement>

40 See [http://epress.anu.edu.au/education\\_ethics/pdf\\_instructions.html](http://epress.anu.edu.au/education_ethics/pdf_instructions.html)

in ensuring both 'corporate compliance' and social responsibility of the industrial sector.<sup>41</sup>

Notably, at the Seventh Review Conference, the Science Council of Japan announced that it set up a committee on dual-use issues in science and technology in order to balance the discussions on tackling dual-use concerns while maintaining the freedom of scientific research.<sup>42</sup> The committee has conducted a series of meeting in 2012 and aiming to establish a code of conduct for scientists on dual-use issues by September 2012.

## CBM participation

Japan has submitted CBM declarations regularly since their establishment, except for 1987, 1989 and 1990.<sup>43</sup> It has made its CBM declarations available to the public since 2012.

## Participation in BWC meetings

Japan participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, Japan has taken part in all relevant meetings (see Table 9).

## Past biological weapons activities and accusations

Japan has neither conducted nor been accused of conducting a bioweapons programme since 1972. Japan's bioweapons programme dates from the Second World War and is comparatively well documented.<sup>44</sup> In January 2007, the US National Archives declassified some 100,000 records including *Select Documents on Japanese War Crimes and Japanese Biological Warfare*, which contained a selection of around 1,400 documents pertaining to Japan's Biowarfare Unit 731.<sup>45</sup>

With regard to the lawsuit brought against the Government of Japan by 180 Chinese citizens (survivors and families of victims), the Tokyo District Court stated on 27 August 2002 that 'although . . . the suffering caused by this case of germ warfare was truly immense and the former Japanese military's wartime actions were clearly inhumane . . . the decision whether to take certain [compensation] measures or if measures are taken what measures to take should be made in the Diet with a high level of discretion . . . the failure of the Diet to create laws for the relief of victims of this germ warfare cannot be conceived as illegal'.<sup>46</sup> The Tokyo District Court

41 See BWC/MSP2005/MX/WP.22, [http://www.opbw.org/new\\_process/mx2005\\_wps.htm](http://www.opbw.org/new_process/mx2005_wps.htm)

42 Kasuga, F. (2012) 'Situation of dual-use education in Japan and effort taken by the Science Council of Japan including the outcome of recent symposium in Tokyo' presented at the *Seventh Review Conference of the BWC*. 12 December, Geneva: United Nations.

43 See [http://www.unog.ch/unog/website/disarmament.nsf/\(httpPages\)/9b7413664d854ea0c12572dd002b-29dd?OpenDocument&ExpandSection=1%2C22#\\_Section1](http://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/9b7413664d854ea0c12572dd002b-29dd?OpenDocument&ExpandSection=1%2C22#_Section1); See also [http://www.biological-arms-control.org/projects\\_improvingtheconfid/Participation-CBMs1987-2010-1103.pdf](http://www.biological-arms-control.org/projects_improvingtheconfid/Participation-CBMs1987-2010-1103.pdf)

44 Harris, S. (1999) 'The Japanese biological warfare programme: an overview', in E. Geissler and J.E. van Courtland Moon (eds.) *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*. SIPRI Chemical & Biological Warfare Studies, No.18, Oxford University Press, Oxford, pp. 127-152.

45 See <http://www.archives.gov/iwg/japanese-war-crimes/>

46 The original text of the ruling is available on the website of the Supreme Court of Japan: <http://www.courts.go.jp/search/jhsp0030?hanreiid=5795&hanreiKbn=04>. The English translation is available at <http://www.anti-731saikinsen.net/en/bassui-en.html>.

dismissed the demand of the plaintiffs (victims) for an official apology by the Government of Japan and YEN 10 million (approximately USD 130,430) in compensation for each plaintiff, as well as five per cent annual interest from 11 August 1997, the day the lawsuit was filed, to the day of completion of the compensation payment.<sup>47</sup>

The plaintiff appealed to the Tokyo High Court which dismissed the appeal in 2005; the receipt of a further appeal to the Supreme Court was refused and dismissed in 2007. At the time of the decision in the High Court in 2005, the government of Japan during the 162<sup>nd</sup> Diet, cited an official statement of 1995 noting that it believed there is no such right to claim in the case after the Japan-China Joint Communique of 1972 and that this is the shared view between the two governments.<sup>48</sup>

A more recent and prominent case is that of Aum Shinrikyo, which was able to accumulate hundreds of millions of dollars in assets and to recruit some 10,000 members in Japan, 30,000 in Russia, and to establish a presence in Australia, Germany, Sri Lanka, Taiwan, and the United States.<sup>49</sup> Aum Shinrikyo attempted several biological attacks using botulinum

toxin and anthrax from 1990-95.<sup>50</sup> Bioterrorism by the group was unsuccessful due to a lack of technical expertise. Consequently, Aum Shinrikyo opted to use Sarin gas in its chemical attack on the Tokyo subway in March 1995, killing 13 people and injuring more than 6,000 others.

47 *Ibid.*

48 <http://www.sangiin.go.jp/japanese/joho1/kousei/youisyo/162/touh/t162014.htm>

49 See [http://www.aktualnosc.pl/images/stories/pliki/konferencje\\_inne/2007/dual\\_use/22\\_Furukawa.pdf](http://www.aktualnosc.pl/images/stories/pliki/konferencje_inne/2007/dual_use/22_Furukawa.pdf).

50 See Wheelis, M. and M. Sugishima (2006) 'Terrorist use of biological weapons', in M. Wheelis, L. Rozsa and M.R. Dando (eds.), *Deadly Cultures: Biological Weapons since 1945*, Harvard University Press, Cambridge, MA, pp. 296-297; and H. Takahashi et al. (2004) 'Historical review: Bacillus anthracis incident, Kameido, Tokyo, 1993', *Emerging Infectious Diseases*, Vol. 1, No. 1, pp. 117-120.

# Country report: Kenya 2012

## 1972 Biological Weapons Convention

Acceded on 7 January 1976

## 1925 Geneva Protocol

Acceded on 17 June 1970

Kenya does not have any reservations to the Geneva Protocol.

## National point of contact

The National Council for Science and Technology (NCST), Utalii House, Utalii Lane, P. O. Box 30623 - 00100, Nairobi, Kenya

Kenya made a statement on weapons of mass destruction (WMD) in 2007 that continues to define its position on the issue: 'Kenya does not own or possess any nuclear, chemical or biological weapons, nor does it have, and has never had, any nuclear, chemical or biological weapons production facility anywhere under its territory, nor transferred either directly or indirectly, any equipment for the production of such weapons. The country does not provide any assistance to any non-State actor to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons or their means of delivery'.<sup>1</sup>

During the Fifth Conference of the Parties to the Convention on Biological Diversity (CBD), in May 2000, Kenya spoke against the development and use of biological agents for crop eradication: 'Kenya feels that the CBD should take a stand against the development of biological agents that kill cultivated species . . . if the CBD does not take a stand, it would have set a very dangerous precedent, because today you could use an alien and invasive species to control cannabis, coca and so on, maybe tomorrow it

<sup>1</sup> See <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N10/303/20/PDF/N1030320.pdf?OpenElement>

might be coffee, maize or even sugar cane. Biological agents, if used to eradicate crops [are] infectious and aggressive [and] pose a great danger as alien and invasive species. They may, for example, spread to regions and countries that do not agree to their use'.<sup>2</sup>

In his statement to the Meeting of States Parties in December 2010, Kenya's head of delegation, Ambassador Antony Andanje, highlighted Kenya's belief that States Parties and other relevant actors must work together closely to ensure global security through effective multilateral cooperation. Andanje underscored the need for continued capacity development in relation to human resources and the mobilisation of infrastructural and financial resources. In addition, Kenya continues to make efforts at the national level. These are directed towards, inter alia, the establishment of an integrated disease surveillance and response system in line with the World Health Organization/Regional Office for Africa (WHO/AFRO)'s 1998 Integrated Disease Surveillance and Response Strategy (IDSR), which focuses on: disease surveillance, detection, reporting, analysis, interpretation and dissemination; the streamlining of biosafety capacities for major laboratories; and the establishment of an isolation facility in national hospitals for multi-drug resistance tuberculosis strains and other highly infectious agents.<sup>3</sup>

### **Status of the life sciences and biotechnology industry**

According to BWPP's 2011 global survey, Kenya has a

moderate life science and biotechnology community. Globally, Kenya ranks 51st; in its geographical sub-region, Eastern Africa, it ranks first. More specifically, globally, Kenya ranks 47th in terms of publications; no data is available on Espacenet on relevant patents.<sup>4</sup>

Monsanto International is the only biotech company in Kenya. Its activities are exclusively geared towards agricultural biotechnology. No research is conducted in Kenya, though, as products undergo only technical development.<sup>5</sup>

### **Biodefence activities and facilities**

Kenya does not engage in biodefence activities. However, the training of defence personnel is holistic—that is, it does include protection against nuclear, biological and chemical weapons.

The US Army Medical Research Unit Kenya (USAMRU-K), also referred to as the Walter Reed Project, is located within the Kenya Medical Research Institute (KEMRI) in Nairobi and Kisumu, where both institutions share laboratory space and are involved in malaria research, mainly drug sensitivity and enteric infections. USAMRU-K also has a research unit in Kericho where it runs a HIV (human immunodeficiency virus) programme that carries out vaccine and therapeutic research and supports HIV prevention, care and treatment programmes in the southern Rift Valley, supported by the US President's Emergency Plan for AIDS Relief (PEPFAR). Much of the work now is devoted to new studies aimed at assessing how and when to intervene with anti-retroviral treatment. The Unit has a tuberculosis culture laboratory to support HIV care and treatment

2 See <http://helix.iisd.org:8080/ramgen/linkages/biodiv/cop5/6a-kenya.rm>

3 See [http://www.unog.ch/80256EDD006B8954/%28httpAs-sets%29/51821B6A2457E047C12577F200353548/\\$file/BWC\\_MSP\\_2010-Kenya-101206.pdf](http://www.unog.ch/80256EDD006B8954/%28httpAs-sets%29/51821B6A2457E047C12577F200353548/$file/BWC_MSP_2010-Kenya-101206.pdf)

4 See Annex, Bioweapons Monitor 2011.

5 See <http://www.monsanto.com/whoweare/Page/kenya.aspx>

**Table 1 BSL-3 laboratories in Kenya<sup>1</sup>**

International Livestock Research Institute (ILRI), Naivasha Road, Nairobi	ILRI Laboratory <sup>1</sup>	Parasitic diseases, mainly theileriasis (East Coast fever) and trypanosomiasis; emerging zoonotic diseases such as bird flu
University of Nairobi (UoN), College of Health Sciences, Kenyatta National Hospital University Campus, Nairobi	UoN Institute of Tropical and Infectious Diseases (UNITID) Laboratory <sup>2</sup>	HIV (clinical virology and immunology); arboviruses
Kenya Medical Research Institute (KEMRI) <sup>3</sup>		
KEMRI headquarters, Mbagathi Road, Nairobi	KEMRI-Centers for Disease Control and Prevention (CDC) Laboratory <sup>4</sup>	Parasites; HIV
	KEMRI-US Army Medical Research Unit Kenya (USAMRU) Laboratory <sup>5</sup>	Parasites, HIV, influenza, haemorrhagic fevers
KEMRI Centre for Microbiology Research, Kenyatta National Hospital Complex, Nairobi	KEMRI-Nagasaki University Institute of Tropical Medicine (NUITM) Laboratory <sup>6</sup>	Sexually-transmitted infections (STIs) including HIV; mycotic infections; schistosomiasis and filariasis
KEMRI Centre for Global Health Research (CGHR), Kisian, Kisumu	KEMRI-CDC Tuberculosis Laboratory	Tuberculosis
	KEMRI-CDC Virology Laboratory	Vector-borne diseases including malaria (clinical studies, drug studies and vaccine trials), helminths, HIV and haemorrhagic fevers
KEMRI Centre for Geographic Medicine Research Coast (CGMRC), Kilifi District Hospital, Kilifi, Coast Province	KEMRI-Wellcome Trust Research Programme Laboratory <sup>7</sup>	Vector-borne diseases; malaria (clinical vaccine trials); other parasitic diseases; HIV and other STIs; paediatric pneumonia and rotavirus research

1 Personal communication with personnel from the laboratories; also see the websites connected to Table 1.

2 See <http://www.ilri.org>

3 See [http://www.uonbi.ac.ke/faculties/?fac\\_code=44](http://www.uonbi.ac.ke/faculties/?fac_code=44)

4 See <http://www.kemri.org>

4 See <http://www.cdc.gov/kenya>

5 See <http://www.usamrukenya.org>

6 See [http://www.nagasaki-u.ac.jp/index\\_en.html](http://www.nagasaki-u.ac.jp/index_en.html)

7 See <http://www.kemri-wellcome.org>

**Table 2** Animal vaccines produced at the Kenya Veterinary Vaccines Production Institute<sup>1</sup>

Vaccine name/type	Protects against
Mono-, bi-, tri- and quadrivalent (foot-and-mouth disease vaccine)	Foot-and-mouth disease
Rinderpest vax	Rinderpest
Contavax	Contagious bovine pleuropneumonia
Caprivax	Contagious caprine pleuropneumonia
Blue vax	Bluetongue
Lumpi vax	Lumpy skin disease
KS & G vax	Sheep- and goat-pox
Rift vax	Rift Valley fever
Avivax - F and Avivax - L	Newcastle disease
Fowl vax	Fowl typhoid
Pox vax	Turkeypox

1 Personal communication with Kenya Agricultural Research Institute, Veterinary Vaccines Production Institute, Nairobi.

facilities. HIV prevention, care, and treatment activities also are implemented at Kenyan military sites in partnership with senior military leaders. The USAMRU-K has approximately 20 non-Kenyan (US Army) staff.<sup>6</sup>

### Maximum and high biological containment facilities

Kenya does not have a BSL-4 facility. Eight BSL-3

facilities are fully operational in the country, of which six belong to KEMRI (see Table 1).

### Vaccine production facilities

The Government of Kenya imports all vaccines for human use. Vaccines to protect against animal infections are produced by the Kenya Veterinary Vaccines Production Institute, Kabete Veterinary Laboratories, Nairobi. This Institute is under the aegis of the Kenya Agricultural Research Institute. Another production unit also exists at the Institute's Muguga research station. Vaccine for East Coast fever

6 Personal communication with members of USAMRU-K; also see <http://www.usamrukenya.org/>

is produced at the International Livestock Research Institute, Nairobi. All of the vaccines handled by the three facilities are either in attenuated or killed form. The facilities do not handle any recombinant DNA vaccines. The bacterial and viral isolates in use were isolated in the 1920s and 1930s.

## Research and policy issues regarding smallpox

The *BioWeapons Monitor 2012* could not discover any research activity in this area.

## Disease outbreak data

The Ministry of Public Health and Sanitation monitors trends in emerging and re-emerging infections via a nationwide surveillance system. In addition, the Ministry of Livestock Development has a Veterinary Epidemiology, Surveillance and Economics Division to undertake disease surveillance. Kenya is also a signatory to the World Health organization Integrated Health Regulations (IHR, 2005) and has been implementing the integrated disease surveillance response (IDSR) since 1998. In addition, Kenya is in the process of revising its IDSR technical guidelines in order to align them to IHR.

Anthrax is endemic and widespread in Kenya. Numerous cases were reported in livestock and wildlife, as well as in human beings, in 2009 and 2010 and in previous years. ProMED-mail recorded the following anthrax disease outbreaks in humans and cattle in Kenya in 2009 and 2010 (none recorded since then as of November 2012):<sup>7</sup>

### 31 August 2010

<sup>7</sup> Personal communication with KEMRI-CDC Laboratory in 2010, Nairobi; also see <http://www.promedmail.org>

Central region, 9 human cases, 1 fatal

**31 May 2010**

Central region, 2 human cases, both fatal

**24 December 2009**

Rift Valley region, 43 human cases, 1 fatal

**October 2009**

Rift Valley region, 33 human cases, 1 fatal

**7 September 2009**

Central region, 1 human case, fatal

**3 March 2009**

Coast region, 4 human cases, 1 fatal

**10 January 2009**

Eastern region, 1 human case, fatal

Anthrax is being identified and purified in Kenyan laboratories. The existing policy approach is that such an agent on identification is to be destroyed immediately and proof of this is to be documented.

No outbreaks of botulism, Ebola, Lassa or Marburg, plague, smallpox or tularaemia were recorded in Kenya in 2009, 2010 and 2011 by ProMED-mail. Ebola was reported in July and August, 2012 in neighbouring Uganda but no cases have been confirmed in Kenya.

In August 2011, the Kenyan public health sector received an alert following the confirmation of infection of a three-year-old boy with wild polio Type 1 virus, in Migori District, South Nyanza Province. Kenya has eradicated polio from its territory and the infecting agent is suspected to have come from neighbouring Uganda. The Ministry of Public Health and Sanitation, with support from KEMRI, subsequently mounted a massive immunisation campaign that will cover 14 neighbouring districts, targeting approximately one million children aged five or under.<sup>8</sup> Daadab refugee camp is the home to

<sup>8</sup> Personal communication with a member of the Kenya National

over 300,000 refugees from the troubled north and remains extremely vulnerable to disease outbreaks. In 2011, there were several disease outbreaks and threats in both the refugee camps and the drought-affected areas of the country including cholera, measles, bloody diarrhoea and kala azar outbreaks. From week 33 to 39, there was a consistently increasing trend of malaria. A confirmed dengue fever outbreak in late September in Mandera spread very fast, with at least 7500 people infected and 7 deaths within weeks, due to limited health facilities, a shortage of medical supplies and personnel, and poor sanitation. Major outbreaks were averted as a result of the timely response from the Ministry of Public Health and Sanitation (MoPHS) and humanitarian partners<sup>18</sup>.

## Relevant national laws, regulations and guidelines

The National Council for Science and Technology (NCST) is the national focal point for all relevant information on WMD, including bioweapons. The Liaison Officer is Professor Shaukat Abdulrazak, Chief Executive Officer of NCST. Ms. Roselida Owuor acts as the alternative Liaison officer. The NCST constituted a National Biological and Toxin Weapons Convention Committee in 2009, which draws representation from relevant line ministries and state corporations, as well as an academic institution (currently the University of Nairobi), including: the Ministries of Agriculture, Foreign Affairs, Internal Security, Medical Services and Public Health; the Kenya Law Office; KEMRI; Division of Veterinary Services, Ministry of Agriculture. The Committee prepared a draft Biosecurity Policy that was finalised in April 2011 and involved wide stakeholder

input. The Biosecurity Bill was subsequently merged with two other Bills to form the Biosciences Bill which has been shared with stakeholders and Policy makers. It is awaiting next steps.<sup>9</sup>

Kenya has several pieces of legislation that have some bearing on ensuring the safety of plants, animals and humans. These include the:

- Plant Protection Act (Chapter 324), 1962, which makes provision for the prevention of the introduction and spread of diseases destructive to plants;
- Pest Control Products Act (Chapter 345), 1983, which regulates the importation, exportation, manufacture, distribution and use of products intended to control pests and the organic function of plants and animals;
- Suppression of Noxious Weed Act (Chapter 325), 1986, which states that the relevant ministry may place a notice in the gazette to declare a plant as a noxious weed in any areas of Kenya;
- Animal Diseases Act (Chapter 364), 1972, which provides for matters relating to the diseases of animals;
- Drugs and Chemical Substances Act (Chapter 254), 1970, which makes provision for the prevention of adulteration of food, drugs and chemical substances; and
- Public Health Act (Chapter 242), 1921, which makes provision for securing and maintaining health. The Public Health Act established a Central Board of Health, which is empowered to advise the Minister of Health on all matters affecting health. It

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Committee for Eradication of Poliomyelitis.

<sup>18</sup> [http://www.who.int/hac/about/donorinfo/cap\\_kenya\\_2012.pdf](http://www.who.int/hac/about/donorinfo/cap_kenya_2012.pdf)

<sup>9</sup> Statement by the representative of Kenya to the Preparatory Committee of the Seventh BWC Review Conference, 14 April 2011; and personal communication with a member of the Kenyan BWC Committee.

**Table 3.** Size of Kenyan delegation at BWC-related meetings in Geneva

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	2012
Number of delegates	5	1	2	1	4	5	6	5	5	4	Not available

**Notes:** RC stands for Review Conference MX stands for Meeting of Experts MSP stands for Meeting of States Parties PC stands for Preparatory Commission (PrepCom)

contains important provisions that ensure the protection of foodstuffs intended for human consumption. Another provision pertaining to food safety is the requirement that local authorities ensure that water supplies, food and milk are in good condition. This provision is significant as it can seal the routes through which dangerous microbes can be disseminated into the food chain of the general population.<sup>10</sup>

## Codes of conduct, education and awareness-raising

Institutions with BSL-2 and BSL-3 facilities have training programmes for staff on broad issues of biosafety and biosecurity. The content of the training modules depends on the type of facility and the complexity of the work to be done.

In May 2007, the WHO's sub-regional 'Biosafety and Laboratory Biosecurity Awareness Raising Meeting' was held in Nairobi, Kenya. WHO experts provided training in the principles of laboratory biosafety and

biosecurity for the safe handling, storage and transport of biological materials, particularly highly pathogenic avian influenza and other infectious diseases.<sup>11</sup>

Awareness-raising vis-à-vis bioweapons and biosecurity issues are minimal. This is primarily because these issues currently are not a priority for either the Government of Kenya or its citizens. The Kenyan representative at the Preparatory Committee of the Seventh BWC Review Conference in April 2011 expressed hope of improving biosecurity education in cooperation with civil society.<sup>12</sup>

## CBM participation

Kenya submitted its first CBM (confidence-building measure) declaration in June 2010. The ISU website shows that Kenya has submitted its CBM declarations for 2011 and 2012. Kenya has not publically made its CBM submission available.

<sup>10</sup> See <http://www.kenyalaw.org>; also see [http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/\\$file/BWC\\_NID\\_Report.htm#ke](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622E-C1257777004DA382/$file/BWC_NID_Report.htm#ke)

<sup>11</sup> See <http://www.bepstate.net/news.php?id=4>

<sup>12</sup> Statement by the representative of Kenya to the Preparatory Committee of the Seventh BWC Review Conference, 14 April 2011.

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## Participation in BWC meetings

Kenya participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, Kenya has taken part in all relevant meetings (see Table 3).

## Past biological weapons activities and accusations

No accusation concerning bioweapons has been levelled against Kenya. The only case of bioweapons use on Kenyan territory that the *BioWeapons Monitor 2011* could identify occurred in 1952, when a group called the Mau-Mau, a nationalist liberation movement originating within the Kikuyu tribe, used a plant toxin (African bush milk) to poison 33 steers at a Kenyan mission station, located in areas reserved for the tribe. This was believed to be part of a larger campaign of sabotage against British colonists and their livestock throughout Kenya.<sup>13</sup>

13 Carus, W.S. (2000) *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century*, Working Paper, Center for Counterproliferation Research, National Defense University, Washington, DC, pp. 75-76.

# Country report : Switzerland

## 1972 Biological Weapons Convention

Signed : 10 April 1972

Deposit of ratification: 4 May 1976

Switzerland made two formal reservations when ratifying the BWC: 1. Switzerland reserves the right to decide for itself what auxiliary means fall within the Convention's definition of prohibited weapons, equipment or means of delivery designed to use biological or toxin weapons, since such means are scarcely peculiar to such use; and 2. Switzerland's collaboration within the framework of the Convention cannot go beyond the terms prescribed by its status as a neutral state (referring explicitly, but not exclusively, to Article VII).

## 1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification 12 July 1932

Switzerland does not have any reservations to the Geneva Protocol

## National point of contact

Federal Department for Foreign Affairs, Directorate of Political Affairs, Division for Security Policy, Section for Arms Control and Disarmament, Bernastrasse 28, 3003 Bern, Switzerland.

Tel.: +41 31 32 41009

Switzerland strongly regards the proliferation and potential use of biological weapons by states as well as non-state actors as a threat to international security.<sup>1</sup>

At the national level, it has enshrined in its legislation the prohibition on anybody to commit any act related to the acquisition of weapons of mass destruction (article 7 of the 1996 Federal Act on War Material) and made provisions for penalties (article 34 of the same Act).

At the international level, Switzerland actively supports relevant non-proliferation efforts - it is in that capacity a member of the Australia Group - as well as the complete and verifiable elimination of biological weapons under international law<sup>2</sup>.

- 1 Annex to the letter dated 16 January 2008 from the Permanent Representative of Switzerland to the United Nations addressed to the Chair of the Committee. Report of Switzerland to the Security Council Committee established pursuant to resolution 1540(2004). S/AC.44/2007/22, page 2. « *Switzerland strongly affirms that the proliferation of nuclear, chemical and biological weapons, as well as their means of delivery, constitutes a threat to international peace and security* ». See [http://www.un.org/french/documents/view\\_doc.asp?symbol=S/AC.44/2007/22](http://www.un.org/french/documents/view_doc.asp?symbol=S/AC.44/2007/22)
- 2 See, 2010 Report of the Federal Council to the Federal Assembly on the Security Policy of Switzerland. <http://www.vbs.admin.ch/internet/VBS/fr/home/documentation/bases/sicherheit.parsys.5013.downloadList.36678.DownloadFile.tmp/sipolbf.pdf> (in French)

It is thus a long-standing proponent of the BWC and works towards making accession universal and strengthening the Convention.<sup>3</sup>

In this context, because Switzerland has always strongly supported the initiatives towards a stronger mechanism, to resolve concerns about the implication of and compliance with the BWC<sup>4</sup>,<sup>5</sup> and because it welcomes working towards a legally binding compliance framework improving the current situation, it has proposed various means and temporary measures to ensure compliance.

Such proposals include:  
to review, strengthen, and broaden the BWC's confidence-building measures (CBMs);

- 3 Statement by Ambassador Alexandre Fasel, Permanent Representative of Switzerland to the Conference on Disarmament, BTWC 7<sup>th</sup> Review Conference, 5 December 2011, Geneva. [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/7CACFC795B2C313AC125795E003019D6/\\$file/Swiss+English.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/7CACFC795B2C313AC125795E003019D6/$file/Swiss+English.pdf). See also, Report of Switzerland to the Security Council Committee established pursuant to resolution 1540(2004). S/AC.44/2007/22, *op.cit.*, page 2. «Universal adherence, full implementation and, where necessary, a strengthening of the existing instruments, in particular in the field of verification and monitoring, are indispensable steps towards the elimination of all weapons of mass destruction».
- 4 See, 2008 Federal Council's report on Switzerland's arms control and disarmament policy (in French) §2.2.3. <http://www.eda.admin.ch/etc/medialib/downloads/edazen/topics/peasec/peac.Par.0210.File.tmp/7253fr.pdf> and Rapport de la Suisse au Comité créé par la Résolution 1540 (2004) du Conseil de sécurité. S/AC.44/2007/22, *op.cit.*, page 9, see [http://www.un.org/french/documents/view\\_doc.asp?symbol=S/AC.44/2007/22](http://www.un.org/french/documents/view_doc.asp?symbol=S/AC.44/2007/22)
- 5 'Switzerland is of the view that this Convention is in need of stronger mechanisms for resolving concerns about implementation of, and compliance with, the BWC. In principle, Switzerland still welcomes working towards a legally binding compliance framework' Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 6 December 2010, [http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/61C232CFF9370772C12577F1005C7FBC/\\$file/BWC+M-SP+2010++Switzerland++101206.pdf](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/61C232CFF9370772C12577F1005C7FBC/$file/BWC+M-SP+2010++Switzerland++101206.pdf)

to increase efforts to ensure the implementation of effective national laws and regulations on biosecurity in all BWC States Parties to foster international cooperation in the management of biological incidents; and to improve export control measures<sup>6</sup>

At the Seventh Review Conference in December 2011, Switzerland reiterated its suggestion -made at the Conference of States Parties in December 2010<sup>7</sup>- to dedicate time at future annual meetings for sessions in which compliance with the Convention can be demonstrated, assessed and discussed<sup>8</sup>.

## Status of the life sciences and biotechnology industry

The biotechnology industry is an important pillar of the Swiss economy. According to the Swiss Biotech reports, a joint project of federal agencies and the life science clusters, SIX Swiss Exchange and the Swiss Biotech Association (SBA), Switzerland is the country with the highest density of biotechnology firms<sup>9</sup> and jobs<sup>10</sup> per

6 2008 Report on Switzerland's arms control and disarmament policy (in French), *ibid.* Annexe A.

7 Statement by Jürg Lauber, *op.cit.*

8 Document of the Seventh Review Conference, Working Paper on the Confidence Building Measures submitted by Norway, Switzerland and New Zealand, 1 November 2011. BWC/CONF.VII/WP.21. §20.

9 Von Bartenwerffer, Andrea. 'SIX Swiss Exchange: A 10- year retrospective on a strong hub for life sciences', in Ernst & Young et al., Swiss Biotech Report 2011, see, page 26, [http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/Swiss\\_Biotech\\_Report\\_2011.pdf](http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/Swiss_Biotech_Report_2011.pdf).

See also [http://www.ukti.gov.uk/fr\\_fr/uktihome/sectorbriefing/109669.html?null](http://www.ukti.gov.uk/fr_fr/uktihome/sectorbriefing/109669.html?null)

10 See, <http://www.kti.admin.ch/netzwerke/00067/index.html?lang=en>

capita in the world<sup>11</sup>.

The 2012 Swiss Biotech Report states that Switzerland hosts 249 such companies, 188 'Developers' and 61 'Suppliers' according to the auditing company Ernst & Young<sup>12</sup>. As a whole, the Swiss biotechnology industry employs more than 19,000 people<sup>13</sup>.

At the same time, other initiatives with wider filters list an even higher number of entities; the Swiss Life Sciences Database, a directory and information platform comprising data on life science and biotechnology companies and institutes in Switzerland lists 1,761 companies and institutes<sup>14</sup>, while Biotechnology-Europe, which is part of Biotechnology World, an internet-based, privately-owned service that provides biotechnology and pharmaceutical information, lists 721 companies and 22 universities and research institutes in Switzerland.<sup>15</sup>

Invention and innovation are also essential factors for the Swiss biotechnology industry. According to the Innovation Union Scoreboard survey published in early 2012, Switzerland is the most innovative nation in Europe<sup>16</sup>. This can be seen in the increasing

number of patent applications<sup>17</sup> and patent turnout<sup>18</sup>. Per capita, the number of published biotechnology patents as well as the growth of biotechnology patents more than tripled in the period from 2000-09<sup>19</sup>.

At the global level, Switzerland ranks sixth, according to the Scientific American Worldwide survey of 48 countries' capabilities to generate innovation in biotechnology<sup>20</sup>.

When looking at the fields of activities Switzerland's biotech firms specialize in, it is noted that 85% of them are dedicated to the development and production of medical biotechnologies (biopharmaceuticals, vaccines and diagnostics)<sup>21</sup>, also known as "red biotech"<sup>22</sup>. They are less active in

11 The industry grouping of enterprises and institutions active in all areas of biotechnology had 229 members as August 2012. See [http://www.swissbiotech.org/industry\\_association\\_sba/members](http://www.swissbiotech.org/industry_association_sba/members)

12 Ernst & Young et al. Swiss Biotech Report 2012. 'Facts and Figures', page 29. [http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR\\_2012\\_web.pdf](http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR_2012_web.pdf)

13 See the Swiss Biotech Report 2012, page 29, *ibid*.

14 See <http://www.biotechgate.com/gate/v3/companies.php>

15 See <http://www.biotechnology-europe.com/Switzerland.htm>

16 See Innovation Union Scoreboard 2011 (2012), Figure 9 'European Countries' innovation performance', page 17 [http://ec.europa.eu/enterprise/policies/innovation/files/ius-2011\\_en.pdf](http://ec.europa.eu/enterprise/policies/innovation/files/ius-2011_en.pdf)

17 See Innovation Union Scoreboard 2011 (2012), *ibid*, Diagram page 87, 'Patent Cooperation Treaty (PCT) patent applications per billion GDP'.

18 Klaffke, Oliver. Ghisalba, Oreste. Alexakis, Domenico. 'Is Swiss biotech sustainable?', 'Figure 1: European Countries innovation performance', Swiss Biotech Report 2011, *ibid*, page 6. See also, Swiss Federal Institute of Intellectual Property (2002) Research and Patenting in Biotechnology- A survey in Switzerland, Publication No.1 (12.03), [https://www.ige.ch/fileadmin/user\\_upload/Juristische\\_Infos/e/j10005e.pdf](https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/j10005e.pdf)

19 Stadler, Renée. 'An innovative decade in Swiss biotech: evidence of patent statistics', in Ernst & Young et al., page 10, Figure 2 'Growth of Biotechnology Patents per Capita'. Swiss Biotech Report 2011, *op.cit*.

20 See <http://www.saworldview.com/article/the-2011-scientific-american-worldview-overall-scores>

21 Bozzi, Anna. 'Swiss Biotech - creating value from innovation', page 7. Swiss Biotech Report 2012, *op.cit*. [http://www.swiss-biotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR\\_2012\\_web.pdf](http://www.swiss-biotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR_2012_web.pdf)

22 See the distinction made by OECD between enterprises active in different areas of biotechnology, described as red, green, white and other types, in Office Fédéral de la Statistique (FSO). Biotechnology R&D in Switzerland. Science and technology indicators. Neuchâtel, February 2008. Graph 1 : Biotechnology applications, page 7. [www.bfs.admin.ch/bfs/portal/en/index/.../15/.../lexi.Document.104191.pdf](http://www.bfs.admin.ch/bfs/portal/en/index/.../15/.../lexi.Document.104191.pdf)

the agricultural and food domains ('green biotech'), as well as industrial and environmental applications ('white biotech').<sup>23</sup>

## Biodefence activities and facilities

### Biodefence programme

There is no set definition of biodefence in and for Switzerland. It is, however, noted that Switzerland together with Germany and Norway submitted a working paper to the Seventh Review Conference in December 2011 which recommended that CBM Form A Part 2(ii) should be amended to read *National research and development programme (civil and military) for protection of humans, animals or plants against the hostile use of biological agents and toxins*. The Swiss biodefence programme, which was initiated in 1995<sup>24</sup>, serves the purpose of adding "research and development mainly benefitting detection and diagnostic techniques", as stated in the 2011 and 2012 CBM returns.

The 2012 CBM reports that 12 civilian facilities are involved in the Swiss biodefence programme. These facilities are listed in Table 2.

As reported in the *BioWeapons Monitor 2011*<sup>25</sup>, the Spiez Laboratory of the Federal Office for Civil Protection (FOCP) within the Federal Department of Defence, Civil Protection and Sports (DDPS), is at

23 See, Office Fédéral de la Statistique (FSO). Biotechnology R&D in Switzerland. Science and technology indicators. *Ibid.* Table 2. Enterprises active in biotechnology by area of application, page 12.

24 Switzerland declared a biodefence programme in the 1996 CBM for the first time.

25 See, Sergio Bonin. "Country report: Switzerland". *BioWeapons Monitor 2011*.

the centre of this programme. As the Swiss centre of expertise for NBC (nuclear, biological, chemical) protection, Spiez Laboratory conducts NBC protection research and is responsible for the provision of protective measures. It is thus in charge of managing CBRN (chemical, biological, radiological and nuclear) emergencies and in this respect works in support of civilian and military resources.

Its Biology Section works on the identification of highly pathogenic microorganisms, the examination of samples for the presence of dangerous biological substances, as well as on biosafety instruction and training.<sup>26</sup>

Finally, some research and development aspects of this biodefence programme are conducted in coordination with various contractors (see Table 1), Spiez Laboratory is supervising these contracted facilities.

In 2010, the Spiez Laboratory started to commission its new BSL-4 high containment facility, which will be fully operational by the end of 2012, according to the 2012 CBM report. The BSL-3 laboratory space (initially within a glove box)<sup>27</sup> will also move to the new facility and be enlarged. The communication strategy surrounding the premises and the activities developed in Spiez Laboratory is based, as far as it is possible, on the principle of transparency.<sup>28</sup> The director Marc Cadisch declared that even though certain aspects of their work can't be made public

26 See, [http://www.labor-spiez.ch/en/lab/pdf/Flyer\\_%20LS\\_E\\_2012.pdf](http://www.labor-spiez.ch/en/lab/pdf/Flyer_%20LS_E_2012.pdf)

27 Cf. <http://www.labor-spiez.ch/en/the/bs/enthebs05.htm>

28 See Marc Cadisch's Editorial in the Spiez Laboratory 2010 annual report "We pursue our public information strategy according to the principle "as transparent as possible"". [http://www.labor-spiez.ch/en/dok/ge/pdf/Jahresbericht\\_LS\\_2010\\_e.pdf](http://www.labor-spiez.ch/en/dok/ge/pdf/Jahresbericht_LS_2010_e.pdf)

**Table 1. Contracted facilities and projects in 2011**

Contractor	Project title
Research Station Agroscope Changting-Wädenswil	<ul style="list-style-type: none"> <li>Development of a DNA Chip for the detection of biological warfare agents</li> </ul>
Cantonal Institute of Microbiology, Bellinzona	<ul style="list-style-type: none"> <li>Microbiological monitoring of mosquitoes in Switzerland that may act as vectors for viruses pathogenic to humans and animals</li> </ul>
Swiss Tropical and Public Health Institute, Basel	<ul style="list-style-type: none"> <li>Production and characterization of monoclonal antibodies against bacterial agents</li> <li>Molecular diagnostics and epidemiology of viruses categorized as possible tools of biological terrorism</li> </ul>
University of Bern, Institute of Infectious Diseases	<ul style="list-style-type: none"> <li>Evaluation of siRNA for antiviral therapy of encephalitogenic viruses: Studies in cell cultures and animal models</li> </ul>
University of Bern, Institute of Parasitology	<ul style="list-style-type: none"> <li>Analysis of mechanisms of pathogenicity in <i>Naegleria Fowleri</i></li> </ul>
University of Zurich, Institute of Social and Preventive Medicine	<ul style="list-style-type: none"> <li>Hantaviral serology of patients exhibiting acute renal failure in regions of Switzerland close to the border</li> <li>Medical concept for the high containment facility</li> </ul>
Zurich University of Applied Sciences, Institute of Chemistry and Biological Chemistry	<ul style="list-style-type: none"> <li>Detection of proteinaceous toxins</li> </ul>
Hannover Medical School	<ul style="list-style-type: none"> <li>Assessing proteolytic stability and transepithelial transport of the proteinaceous toxins ricin, BoNT and SEB</li> </ul>
Miprolab GmbH/ University of Göttingen, Germany	<ul style="list-style-type: none"> <li>Detection and risk assessment of biological toxins</li> <li>Lateral flow assays for the detection of biological agents</li> </ul>
Robert Koch Institute, Centre for Biological Security, Berlin, Germany	<ul style="list-style-type: none"> <li>Expansion of the <i>C. Botulinum</i> culture collection</li> </ul>
Institute for Chemical Biology and Fundamental Medicine, ICBFM, Novosibirsk, Russian Federation	<ul style="list-style-type: none"> <li>Electron microscopy development</li> </ul>

Source: Switzerland 2012 CBMs

“considering the growing antiterrorism implications of NBC protection”, it is their “belief that protecting the public means providing them with exhaustive and easy-to-understand information”. He further added that “transparency is also key to the increased success of efforts in relation to international arms control and the disarmament of weapons of mass destruction, a field in which Spiez Laboratory is heavily involved”.<sup>29</sup>

In this domain, a certain number of initiatives taken demonstrate a level of openness not common elsewhere. The new laboratory space is designed in a way that allows visitors - in a transparent surrounding buffer corridor - to observe Spiez’s staff at work<sup>30</sup>. Moreover, the overall design of the new facility is freely available on their website<sup>31</sup>, and the inauguration of the new containment facility in June 2010 was accompanied by an open day during which the facility was open to the public.

The cost incurred by the construction of the new facility explains the doubling of the total funding for the Swiss biodefence programme in 2010 compared to 2009. The budget of CHF 5 million (excluding the Regional Laboratory Network; see below)<sup>32</sup> then remained stable in 2011, as was expected.<sup>33</sup>

Figure 1 shows the trend in funding for the Swiss biodefence programme between 2002 and 2011. The increase in total funding between 2007 and 2010 is also justified by the expansion and upgrade of the Biology section’s resources and technical capacities. In 2008, a biosafety officer was designated, a new arms control and research coordination unit was

established and clinical diagnostics for special bacterial and viral disease was added to the existing services.<sup>34</sup> In 2009, the laboratory detection capabilities were reinforced through the increase of the range of tests used to analyse special bacterial and viral pathogens. A new member of staff was appointed to strengthen the arms control branch<sup>35</sup>. In 2010, laboratory diagnostics were also expanded in bacteriology. In total, the number of personnel in the Biology Section of the Spiez Laboratory has gone up from 2 in 1995 to 15 in 2011.<sup>36</sup>

29 *ibid.*

30 See 2010 Spiez Laboratory annual report. Editorial, *ibid.*

31 Cf. <http://www.labor-spiez.ch/en/the/sl/entheslpl.htm>

32 Switzerland 2012 CBM.

33 Switzerland 2012 CBM

34 Cf. Spiez Laboratory, Annual Report 2008, Editorial and page 12, <http://www.labor-spiez.ch/en/dok/ge/index.htm>

35 Cf. Spiez Laboratory, Annual Report 2009, Editorial and page 24.

36 Cf. Spiez Laboratory, Annual Report 2011, page 4. [http://www.labor-spiez.ch/en/dok/ge/pdf/spiez\\_laboratory\\_annual\\_report\\_2011.pdf](http://www.labor-spiez.ch/en/dok/ge/pdf/spiez_laboratory_annual_report_2011.pdf)

**Figure 1. Declared funding for the Swiss biodefence programme, 2002-2011.**

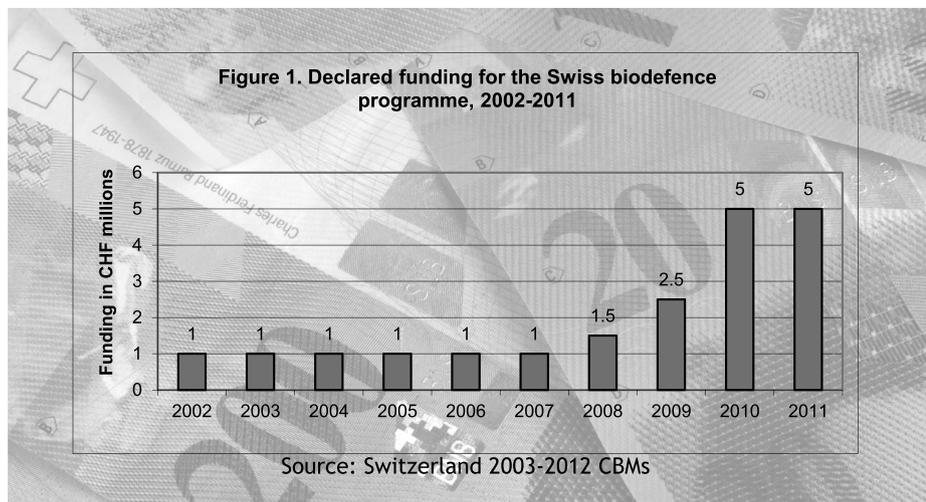
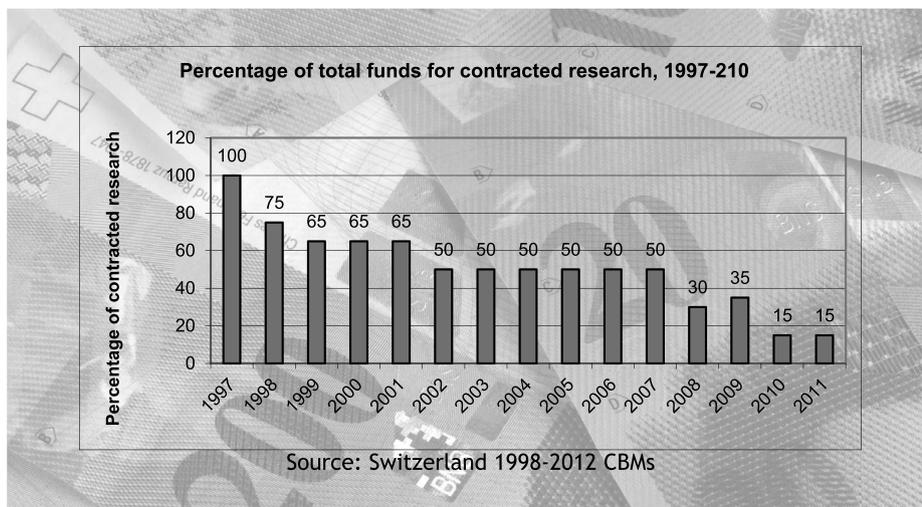


Figure 2 shows the percentage of the total funds for the Swiss biodefence programme that was expended in these contracted facilities between 1997 and 2011. As stated in the *BioWeapons Monitor 2011*, the 20 percent decrease observable in 2010 is the result of the concomitant increase in total funding for the biodefence programme. The amount of funding for contracted research remained quite stable in absolute terms, but it represents a lower percentage of the total funding.

**Figure 2. Percentage of total funds for contracted research, 1997-2011.**



**Table 2. Facilities involved in the Swiss biodefence programme**

Name	Role(s)	Sources of funding	Location	Number of staff	Highest containment level	Agents covered
<b>Centre of Expertise for NBC Protection</b>						
Spiez Laboratory	Centre of Expertise for CBRN Protection/ Regional Laboratory West Central/ National Reference Centre (to be established)	Federal Office for Civil Protection (Federal Department of Defence, Civil Protection and sports)	Spiez	19 (all civilian)	BSL4: 118sqm (square meters), of 727 sqm overall laboratory space; in commissioning phase)	A variety of bacteria, viruses and toxins.
<b>National Reference Centres</b>						
Institute of Virology and Immunoprophylaxis (IVI)	National Reference Centre for highly contagious epizootics and emerging viral diseases	Federal Veterinary Office (Federal Department of Economic Affairs)	Mittelhäusern	55 (all civilian)	BSL3Ag: 10 446 sqm, of 10 700 overall laboratory space	Highly pathogenic Influenza virus, foot-and-mouth disease, classical and african swine fever and porcine circovirus type 2, bluetongue, Rift Valley fever, lumpy skin disease, rinderpest, and others
National Reference Center for Emerging Viral Infections (NAVI) (Virological Laboratory)	National Reference Center for Emerging Viral Infections.	Federal Office of Public Health (Federal Department of Home Affairs)	Geneva	9 (all civilian)	BSL4 (approved for diagnostic purposes only): 22sqm of overall laboratory space	Ebola, Lassa, Marburg, West Nile, Dengue, Yellow fever, SARS, Chikungunya, poliovirus, avian influenza H5N1, Crimean-Congo.
National Reference Center for Anthrax	National Reference Centre for bacteriological agents	Federal Office of Public Health (Federal Department of Home Affairs)	Bern	2 (both civilian)	BSL3: 20sqm of overall 20 sqm laboratory space	Bacillus anthracis, Francisella tularensis, Yersina pestis and Brucella sp.
<b>Regional Competence Centres</b>						
Bacteriological Laboratory-Regional Competence Center West (GE)	Regional Laboratory West	Cantons of West Switzerland	Geneva	5 (all civilian)	BSL3: 58sqm of overall 593sqm laboratory space	Bacillus anthracis, Francisella tularensis, Yersina pestis and Brucella sp.

Virological Laboratory-	Regional Laboratory West	Cantons of West Switzerland	Geneva	Not specified (all civilian)	BSL3: not specified	Various
Diagnostic Laboratory of the Institute of Microbiology	Regional Laboratory West	Cantons of West Switzerland	Lausanne	Not specified (all civilian)	BSL3: not specified	Various
Spiez Laboratory, Regional Competence Center	Regional Laboratory West Central/	Cantons of Bern and Jura	Spiez	19 (all civilian)	BSL4: 118sqm of laboratory space; in commissioning phase)	A variety of bacteria, viruses and toxins.
Department of Medical Microbiology (Cantonal Hospital of Lucerne)	Regional Laboratory East Central	Cantons of Central Switzerland	Lucerne	7 (all civilian)	BSL3:62 sqm, of 778 sqm overall laboratory space	Various
Institute of Medical Microbiology	Regional Laboratory East	Cantons of East Switzerland	Zurich	2 (both civilian)	BSL3: 20sqm of overall 20 sqm laboratory space	Various bacteriological samples
Institute of Medical Virology	Regional Laboratory East	Cantons of East Switzerland	Zurich	2 (both civilian)	BSL3: 20sqm of overall 20 sqm laboratory space	Various viral samples
Cantonal Laboratory of Basel-Stadt	Regional Laboratory North	Cantons of North Switzerland	Basel	4 (all civilians)	BSL3:36sqm of overall 50 sqm laboratory space	Staphylococcus aureus, Pseudomonas aeruginosa, Bacillus anthracis, adenoviruses and lentiviruses.
Cantonal Institute of Microbiology	Regional Laboratory South	Canton of Ticino	Bellinzona	2 (all civilian)	BSL3:36sqm of overall 90 sqm laboratory space	Various

Sources: Switzerland 2012 CBMs and entities' websites

## Regional Laboratory Network

The Regional Laboratory Network was established by the Federal Office of Public Health in collaboration with the cantons in 2006. In the event of a disease outbreak emergency, the Network provides decentralised laboratory capacities for the initial diagnosis of risk group 3 pathogenic organisms<sup>37</sup>. In this respect it is considered part of Switzerland biodefence programme.

As described in the *BioWeapons Monitor 2011*, the Network is composed of four National Reference Centres and six Regional Competence Centres (North, South, East, East Central, West, West Central) that comprise one or more of the nine regional laboratories (see Table 2).

The regional laboratories are tasked with the rapid initial diagnosis of pathogens in the event of an emergency, whereas the reference centres are qualified for both initial as well as confirmative diagnoses. The latter are also responsible for providing information and know-how support to improve diagnostic methods to the regional laboratories.<sup>38</sup>

The Network is jointly funded by the federal state (Federal Department of Home Affairs, Federal Office of Public Health, Federal Department of Economic Affairs, Federal Veterinary Office), all 26 cantons and the Principality of Liechtenstein. The total amount of funding for the network is however not available

37 See, Spiez Laboratory's (Federal Office for Civil Protection) classification of pathogens into three groups according to the risk they represent for human, <http://www.labor-spiez.ch/fr/the/bs/pdf/risikogruppen-viren.pdf>

38 Federal Office of Public Health (2006) Bulletin, 33/06, 14 August. <http://www.bag.admin.ch/dokumentation/publikationen/01435/01795/index.html?lang=de>

because it relies on infrastructure and personnel that are primarily used for and involved in other civil activities.<sup>39</sup>

The activities of the Network are supervised by a coordination committee composed of representatives of the regional laboratories, the national reference centres, the Federal Office of Public Health, the Federal Office of the Environment, from the Swiss Expert Committee for Biosafety and from the Cantonal NBC Coordination platform<sup>40</sup>.

## Armed Forces

The Swiss Armed Forces include CBRN defence forces. Based on a conscript system<sup>41</sup>, the Forces are primarily devoted to the protection and training of troops (Competence Centre NBC- DEMUNEX)<sup>42</sup> and are not engaged in science and research. They consequently rely on the research and expertise developed in the biodefence programme (mainly through the Spiez Laboratory).

All personnel receive basic training in CBRN protection and are equipped accordingly<sup>43</sup>. A

39 Switzerland 2012 CBMs. See Sergio Bonin "Country report: Switzerland". *BioWeapons Monitor 2011*, *op. cit.*

40 See presentation on the Regional Laboratory Network, given by Dr Thomas Binz (Coordination Committee) at the Meeting of Experts of the Biological and Toxin Weapons Convention, 23-27 August 2010. [http://www.opbw.org/new\\_process/mx2010/BWC\\_MSP\\_2010\\_MX\\_Presentation\\_100826-PM\\_Switzerland\\_E.pdf](http://www.opbw.org/new_process/mx2010/BWC_MSP_2010_MX_Presentation_100826-PM_Switzerland_E.pdf)

41 See [http://www.swissinfo.ch/eng/Home/Archive/Militia\\_army.html?cid=5160726](http://www.swissinfo.ch/eng/Home/Archive/Militia_army.html?cid=5160726)

42 See <http://www.vtg.admin.ch/internet/vtg/fr/home/schweizerarmee/organisation/fsta/abc.parsysrelated1.35955.downloadList.59460.DownloadFile.tmp/20110419broschrekompetenzzentrumabckamir2011fbai.pdf> (in French)

43 See Regulation 51.009 on clothing and packs <http://www.vtg.admin.ch/internet/vtg/fr/home/militaerdienst/allgemeines/bekleidung.parsys.18701.downloadList.49909.DownloadFile.tmp/regl51009fweb.pdf> (in French).

specialised NBC Defence Corps (also largely composed of civilian experts who work in comparable professional fields) is maintained and trained by the NBC Centre of Competence of the Armed Forces, also based in Spiez. The latter is responsible for the development of the CBRN defence doctrine, for the management of the military's CBRN resources, and the NBC defence School.<sup>44</sup>

Detailed in the *BioWeapons Monitor 2011*, the NBC Defence Corps is composed of the 320 NBC Defence Armed Forces Staff Section, the NBC Defence Laboratory 1, the NBC Defence Battalion 10, the NBC Defence Intervention Company, and the NBC Defence Battalion 20 (reserve).<sup>45</sup> Together, these units engage in: CBRN reconnaissance and detection; (initial) sampling, analysis and identification of agents; training and medical and technical protection for all troops; and decontamination. These capacities are also offered in support of civilian authorities and international operations.

In addition to the NBC Defence Corps, the Coordinated Medical Service serves as a coordination instrument for the management and provision of human and logistical resources for the organisation of medical care in emergencies<sup>46</sup>. Under the supervision of the head of the Medical Service of the Army, and within the Armed Forces Logistics Organization (AFLO), it provides assistance and mass casualty

44 See <http://www.vtg.admin.ch/internet/vtg/en/home/schweizerarmee/organisation/fsta/abc.html>

45 See <http://www.vtg.admin.ch/internet/vtg/en/home/verbaende/fsta/nbc.html>

46 Cf. <http://www.lba.admin.ch/internet/lba/fr/home/themen/sanit/koordinierter0.html> See also, <http://www.lba.admin.ch/internet/lba/fr/home/themen/sanit/koordinierter0/informationsschrift.parsys.97133.downloadList.94588.DownloadFile.tmp/infoschrift409internet.pdf>

care.<sup>47</sup>

Finally, the International Biodefense handbook 2007 showed that the Pharmacy of the Army, together with the Federal Office for National Economic Supply and the cantonal pharmacies, is responsible for acquiring and stockpiling biological-agent vaccines for military personnel and the general population<sup>48</sup>. Switzerland notably holds stocks of smallpox<sup>49</sup> and anthrax vaccine, antibiotics against anthrax and plague, as well as botulism anti-toxins.<sup>50</sup>

Distribution and vaccination plans exist to make these counteragents available quickly.<sup>51</sup> The Federal Office for Public Health and the B-Section of the Federal Commission for NBC Protection (see below) have established a smallpox vaccination plan which specifies the necessary organization to vaccinate the entire Swiss population within five to six days<sup>52</sup>.

Soldiers are vaccinated against the same traditional

47 See BONIN, Sergio. 'International Biodefense Handbook 2007. An Inventory of National and International Biodefense practices and policies'. Center for Security Studies, ETZ Zurich. 434p. Pages 171 and 174.

48 See BONIN, Sergio. 'International Biodefense Handbook 2007. An Inventory of National and International Biodefense practices and policies', *ibid*.

49 See, Swissinfo. 'La suisse n'oublie pas le bio-terrorisme'. 25 March 2003. [http://www.swissinfo.ch/fre/A\\_La\\_une/Archive/La\\_Suisse\\_noublie\\_pas\\_le\\_bio-terrorisme.html?cid=3234250](http://www.swissinfo.ch/fre/A_La_une/Archive/La_Suisse_noublie_pas_le_bio-terrorisme.html?cid=3234250)

50 [http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch\\_id=20023781](http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch_id=20023781)

51 See, page 25. GUERY, Michael. 'Le Terrorisme Biologique et la Suisse dans une approche juridique'. Zürcher Beiträge zur Sicherheitspolitik und Konfliktforschung, n° 74. See also, BONIN, Sergio. 'International Biodefense Handbook 2007. An Inventory of National and International Biodefense practices and policies', *op.cit*.

52 See, page 143, GUERY, Michael. 'Le Terrorisme Biologique et la Suisse dans une approche juridique', *ibid*.

diseases as the population<sup>53</sup>. They are not vaccinated against anthrax, as the vaccine is not authorised in Europe<sup>54</sup>. In 2003, volunteers that undertook disaster relief work in or near Iraq were vaccinated against smallpox<sup>55</sup>.

## Management of biological emergencies

In Switzerland, as previously noted, a wide range of actors at the cantonal and federal levels, cooperate to ensure NBC protection. The Federal law on epidemics (see below) assigns responsibility to the two levels.

Localised incidents are traditionally managed at the cantonal level through the use of cantonal civil protection resources and means.

In case of a public health event (epizootics, epidemics and pandemics) affecting more than one canton, the Federal government is in charge of coordinating and leading operations associated with the protection of the population<sup>56</sup>.

The Federal Office for Public Health is responsible for the promotion and protection of the health of all the

people living in Switzerland. It therefore provides its expertise and technical support to the development of various activities associated with biological emergency management. It also leads the B-section of the Federal Commission for NBC Protection (ComNBC), the advisory commission for the Federal Council in the preparation and coordination of NBC protection measures<sup>57</sup>. The ComNBC also ensures that the various entities involved at the cantonal and federal levels are prepared to reduce the risks associated with NBC events<sup>58</sup>. In this respect, the Federal Council mandated the ComNBC to establish a Strategy for 'NBC Protection in Switzerland'. It was published in 2007<sup>59</sup>, and it is based on four pillars: reduce the likeliness of the advent of a threat, ensure the quick detection of NBC events, conduct prompt and quality evaluation of the possible consequences of the event for the population, ensure an effective response of experienced intervention authorities.<sup>60</sup>

The Federal Office for Civil Protection (FOCP) also supports the cantons and partner organizations in the coordination of their civil protection activities, so does the Federal Office of Transport, who is responsible for the coordination and harmonisation of

53 See, <http://www.vtg.admin.ch/internet/vtg/fr/home/militaerdienst/rekrut/diensttauglichkeit/medizinische.0013.html>

54 See, <http://www.labor-spiez.ch/fr/the/bs/frthebs0303.htm>

55 See, 'Switzerland prepares for bioterrorism threat'. Swiss info. 30 March 2003. [http://www.swissinfo.ch/eng/Home/Archive/Switzerland\\_prepares\\_for\\_bioterrorism\\_threat.html?cid=3239586](http://www.swissinfo.ch/eng/Home/Archive/Switzerland_prepares_for_bioterrorism_threat.html?cid=3239586)

56 Article 5 of the Federal Law on Civil Protection system and Protection & Support Service enacted on the 1<sup>st</sup> January 2004. <http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/Verbundsystem.parsys.0003.downloadList.00031.DownloadFile.tmp/bzge.pdf>

57 It is composed of experts from the public and private sectors and associated various organizations such as the Veterinary Office, Spiez Laboratory, the medical services of the Swiss Army and the Swiss Army Pharmacy.

58 See, 'How NBC protection is organised in Switzerland'. <http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/abcschutz/organisation.html>

59 See, Commission Fédérale pour le Protection ABC. 'Stratégie de Protection ABC pour la Suisse. 26 June 2007. <http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/strategie.parsysrelated1.30028.downloadList.60659.DownloadFile.tmp/strategieabcchutzch200706f.pdf>

60 See, 'Stratégie de Protection ABC pour la Suisse. 2007. *Ibid.* Page 9.

civil and military transport agencies<sup>61</sup>.

As noted in the *BioWeapons Monitor 2011*, the overall leadership for the management of biological events at the federal level is provided by the Federal NBCN<sup>62</sup> Crisis Management Board, which brings together representatives of the federal and cantonal offices relevant for the type of emergency involved. It is supported by the National Emergency Operations Centre (NEOC), which is responsible for alerting the authorities, warning the public and issuing instructions on measures to be taken by the public for all types of emergencies.

In addition to this overall structure for the management of all NBC events, Switzerland has developed a specific plan to counter pandemic influenza, which sets out the organisation of the measures to implement during the different phases of a pandemic<sup>63</sup>. It serves as a model for the development of cantonal and private sectors specific plans. Hospitals also establish and update plans dedicated to the efficient management of contaminated people<sup>64</sup>. In 2008 the Federal government issued

recommendations for NBC decontamination in hospitals<sup>65</sup> and specific training can also be provided to health staff in particular, so as to improve for example the pre-clinical sort out of patients to accelerate their transfer and treatment<sup>66</sup>.

## Maximum and high biological containment laboratories

As the BSL-4 unit of the Spiez Laboratory is not yet operational, the highest level of containment facility in Switzerland is currently the BSL-4 unit of the National Reference Centre for Emerging Viral Infections (NAVI) in Geneva. It is however solely approved for diagnostic purposes and is not allowed to culture or manipulate viral agents of risk group 4.<sup>67</sup>

All the other laboratories in the Regional Laboratory Network have BSL-3 containment facilities at their disposal (cf. Table 2). The Institute of Virology and Immunoprophylaxis (IVI) is the only laboratory in Switzerland that deals with highly infectious animal diseases and is equipped with a BSL-3Ag containment facility.<sup>68</sup>

As noted in 2011, Switzerland does not officially list

61 See, [http://www.bav.admin.ch/themen/verkehrspolitik/00501/01579/02636/index.html?lang=en&download=N-HzLpZeg7t.lnp6iQNTU042l2Z6ln1ad11Zn4Z2qZpnO2Yuq2Z6gp-JCDd4F6gWym162epYbg2c\\_JjKbNoKSn6A--](http://www.bav.admin.ch/themen/verkehrspolitik/00501/01579/02636/index.html?lang=en&download=N-HzLpZeg7t.lnp6iQNTU042l2Z6ln1ad11Zn4Z2qZpnO2Yuq2Z6gp-JCDd4F6gWym162epYbg2c_JjKbNoKSn6A--).

62 Nuclear (N), biological (B) and chemical (C) incidents as well as natural disasters (N).

63 See, <http://www.bag.admin.ch/influenza/01120/01134/03058/index.html?lang=fr>

64 See, BÜRGI, Ulrich. 'Comment s'organise l'alarme dans un hôpital en cas d'événements majeurs', in Service Sanitaire Coordonné (SSC), Bulletin d'information sur le SSC en Suisse, 1/12, « Plan hospitalier en cas de catastrophe ». Pages 57-62. <http://www.lba.admin.ch/internet/lba/fr/home/themen/sanit/koordinierter0/informationsschrift.parsys.33061.downloadList.38833.DownloadFile.tmp/oldbulletindinformationsurlessc112.pdf>

65 See, 'Recommandations relatives à la décontamination NBC pour les hôpitaux pour les cas aigus et les hôpitaux de décontamination'. 5 February 2008. <http://www.lba.admin.ch/internet/lba/fr/home/themen/sanit/koordinierter0/abc-dekontamination.parsys.0004.downloadList.00041.DownloadFile.tmp/empfehlungendekofdefinitiv.pdf>

66 See, Centre de Formation en Médecine de Catastrophe (CEFO-CA), <http://www.cefoca-sfg.ch/index.php?id=76&L=1>

67 [http://www.hug-ge.ch/library/pdf/Dossiers\\_presse/DPP4D.pdf](http://www.hug-ge.ch/library/pdf/Dossiers_presse/DPP4D.pdf)

68 <http://www.bvet.admin.ch/ivi/03193/index.html?lang=en>

**Table 3. Notifications of risk level 1 to 4 activities in the ECOGEN public register, August 2012**

Biosafety level of the activity	Number of activities (approved and awaiting approval)	Number of organisations
1	1,154	n/a
2	1,255	n/a
3	76	32
4	6	4

Source: Public register ECOGEN which contains the list of notifications and authorizations for activities involving pathogenic or genetically modified organisms in contained use

the biological containment facilities (BSL-1 to BSL-4) on its territory and does not require a prior approval for their creation. It is the projected activities that must satisfy the ordinances on the contained use of organisms, as well as those on occupational safety in the area of biotechnology<sup>69</sup>, and it is within this framework that the appropriateness of a facility's infrastructure for the planned activity is checked<sup>70</sup>.

69 See, in particular, the Ordinance on the Protection of Workforce against Microbiological Risks (Ordonnance sur la protection des travailleurs contre les risques liés aux microorganismes (OPTM)) signed on 35 August 1999. Ordinance on the Prevention of Accidents and Occupational Diseases (Ordonnance du 19 décembre 1983 sur la prévention des accidents et des maladies professionnelles), signed on the 19 December 1983. Ordinance relating to the Act of Labour (Ordonnance 4 du 18 août 1993 relative à la loi sur le travail (OLT 4)) signed on the 18 August 1993.

70 See Annexe 4 to the Ordinance on the Contained Use of Organisms, *ibid.* See also MSP/2012/MX/WP.17. Annex II- "BTWC Compliance Report of Switzerland on oversight of human, animal and plant pathogens in laboratories, animal units, greenhouses and production facilities". 3 August 2012. §18, page76. <http://>

Risk level 3 and 4 activities are subject to approval, whereas only notification is required for risk level 1 and 2 activities<sup>71</sup>. The detailed nature of the information to provide to the authorities depends on the risk level. An official register, ECOGEN, of all approved risk level 1 to 4 activities, as well as all such activities awaiting approval, can be accessed online. Table 3 summarises the number of activities per risk level and the number of organisations requesting them as of August 2012<sup>72</sup>.

Table 4 lists risk level 4 activity notifications, their approval status and the requesting organisations.

[daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/620/51/PDF/G1262051.pdf?OpenElement](http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/620/51/PDF/G1262051.pdf?OpenElement)

71 Articles 8 and 9 of the Ordinance on the Contained Use of Organisms, *ibid.*

72 Cf, <http://www.ecogen.admin.ch/ecogen/Forms/Register/RegisterSearch.aspx>

**Table 4. Risk level 4 activities in the ECOGEN public register, until August 2012**

Title of notification <sup>1</sup>	Organisation <sup>2</sup>	Status
Opsonising antibodies against foot-and-mouth disease virus; characterisation and establishment of a quantitative cell-based test	Institute of Virology and Immunoprophylaxis	Approved
Analysis of viruses in clinical sample using molecular or serological methods	University Hospitals of Geneva	Approved
Veterinary virus diagnostics	Institute of Virology and Immunoprophylaxis	Approved
Storage of rinderpest virus	Institute of Virology and Immunoprophylaxis	Approved
Development of methods of detection and analysis of viral pathogens in risk group 4 (clinical samples, environmental samples including bioterrorist suspect samples) by cultivation, inactivation and molecular biology detection of DNA and RNA from any matrices and maintenance of a culture collection for reference purposes	Spiez Laboratory	Approved
Inactivation of environmental samples and potentially highly pathogenic viruses for diagnostic purposes in the framework of the Regional Laboratory Network	Institute of Medical Virology, University of Zurich	Undergoing assessment by authorities
Quality control of immunobiological products for veterinary medicinal applications	Institute of Virology and Immunoprophylaxis	Approved

Source: Public register ECOGEN

- 1 Translation from the BioWeapons Monitor 2011 version and author's translation from German.
- 2 This shows the organization responsible for the notification. The location of the activity may differ: for instance, if an

institute without BSL-4 capacities is requesting a risk level 4 activity (as it is the case with the Institute of Medical Virology of the University of Zurich), it must collaborate with a project partner that has an appropriate facility available (information on partners/locations, however, is not publicly accessible).

**Table 5. Vaccine production facilities in Switzerland**

Name	Location	Diseases covered/additional information
Crucell Switzerland AG	Bern/Thörishaus	Hepatitis A & B, Influenza (seasonal), Typhoid fever, Measles and Rubella, Cholera, Diphtheria, Tetanus, Pertussis, Haemophilus influenzae. Vaccine in development: Tuberculosis, Malaria, Ebola, Marburg, HIV, HPV, Seasonal Influenza, Respiratory Syncytial Virus <sup>3</sup>
Cytos Biotechnology AG	Schlieren	Development and commercialisation of vaccines against chronic diseases (Immunodrugs) such as nicotine addiction, melanoma, rhino-conjunctivitis, allergic asthma and allergy. <sup>4</sup> Alzheimer's disease, diabetes, multiple sclerosis/psoriasis <sup>5</sup> , hypertension <sup>6</sup> ,
Pevion Biotech Ltd	Ittigen	Development of virosome-based vaccines for clinical trials: Malaria, HIV, Respiratory Syncytial Virus (RSV), Candidiasis. <sup>7</sup>

Sources: Switzerland 2012 CBMs and Companies' websites and annual reports.

3 [http://www.crucell.com/page/images/RandD+pipeline\\_November+2010.JPG](http://www.crucell.com/page/images/RandD+pipeline_November+2010.JPG)

4 <http://www.cytos.com/?id=144>

5 Cf, Cytos 2011 annual report, page 21, [http://www.cytos.com/userfiles/file/AR\\_2011.pdf](http://www.cytos.com/userfiles/file/AR_2011.pdf)

6 Cf, Cytos 2010 annual report, page 19 [http://www.cytos.com/userfiles/file/AR\\_2010.pdf](http://www.cytos.com/userfiles/file/AR_2010.pdf)

7 <http://www.pevion.com/index.php?page=732>

## Vaccine production facilities

According to the 2012 CBM returns, there is one vaccine production facility in Switzerland, and two companies that produce vaccines for clinical trials (see Table 5).<sup>73</sup> In this respect, vaccine production facilities are the same as in 2011.

Crucell has two facilities in the canton of Bern for manufacturing of its hepatitis A, influenza, measles, rubella, and typhoid vaccines. These are the only full-scale vaccine production facilities in Switzerland.

<sup>74</sup>

73 Switzerland 2011 CBM.

74 See the organisation of the floor space in, Crucell (2009) *Bringing Innovation to Global Health*, <http://hugin.info/132631/R/1401132/356214.pdf>. See also the organization of resources of Cytos and Pevion in, Sergio Bonin, BioWeapons Monitor 2011.

In July 2010, Cytos Biotechnology and Singapore's Agency for Science, Technology and Research (A\*STAR) established an influenza collaboration that aims at research, development and commercialisation of a virus-like particle (VLP) vaccines to manage influenza infections. This collaboration was still in effect in October 2011.<sup>75</sup>

According to the Swiss Life Sciences database, Pevion has pre-clinical programmes in universal flu in its proprietary pipeline<sup>76</sup>. It has 24 employees at its location, while Cytos has 10 in Switzerland<sup>77</sup>.

75 See Cytos Annual Report 2011. Page 30. [http://www.cytos.com/userfiles/file/AR\\_2011.pdf](http://www.cytos.com/userfiles/file/AR_2011.pdf)

76 See [http://www.swisslifesciences.com/swisslifesciences/db/a-z\\_search.php?search=1&search\\_char=p](http://www.swisslifesciences.com/swisslifesciences/db/a-z_search.php?search=1&search_char=p)

77 See [http://www.swisslifesciences.com/swisslifesciences/db/detail.php?c=100251k\\$SnMTufZqU7RLM](http://www.swisslifesciences.com/swisslifesciences/db/detail.php?c=100251k$SnMTufZqU7RLM)

## Disease outbreak data

There were no outbreaks of infectious diseases or similar occurrences in Switzerland in 2012 that seemed to deviate from the normal pattern, apart from two cases of Tularaemia<sup>78</sup>.

The following outbreaks of particularly dangerous diseases were recorded in humans in Switzerland in 2009, 2010 and 2011<sup>79</sup>:

Anthrax: none.

Botulism: one case in 2010.

Ebola/Lassa/Machupo/Marburg: none.

Plague: none.

Smallpox: none.

Tularaemia: 5 in 2010, 2 in 2011 and 2 in 2012<sup>80</sup>

## Relevant national laws, regulations and guidelines

Switzerland has a broad range of legislations and regulations in place that enshrine the prohibition to develop, produce, stockpile, acquire or retain biological weapons. At the same time the safe transfers (imports and exports) of micro-organisms as well as biosafety and biosecurity measures (in accordance with the latest WHO Laboratory Biosecurity Guidance) are also covered<sup>81</sup>.

78 Switzerland 2012 CBM and [http://www.bag.admin.ch/k\\_m\\_meldesystem/00733/00804/index.html?lang=fr](http://www.bag.admin.ch/k_m_meldesystem/00733/00804/index.html?lang=fr)

79 Sources : Switzerland 2011 and 2012 CBM and [http://www.bag.admin.ch/k\\_m\\_meldesystem/00733/00813/index.html?lang=de](http://www.bag.admin.ch/k_m_meldesystem/00733/00813/index.html?lang=de)

80 See [http://www.bag.admin.ch/k\\_m\\_meldesystem/00733/00804/index.html?lang=fr](http://www.bag.admin.ch/k_m_meldesystem/00733/00804/index.html?lang=fr)

81 See, MSP/2012/MX/WP.17 Annex II- "BTWC Compliance Report of Switzerland on oversight of human, animal and plant pathogens in laboratories, animal units, greenhouses and production facilities". *Op.cit.* Pages 73-77

The national legal framework that enables Switzerland to deal with threats posed by biological weapons is based on 17 Federal Acts, 3 Codes, 62 Ordinances as well as multiple cantonal texts<sup>82</sup>. The 2012 CBM return enumerates them.

Five of them are seen<sup>83</sup> as the central piece of Switzerland's strategy to combat biological weapons and their consequences.

The first one pertains to the prohibition to disseminate substances -genetically-modified or not- to contaminate drinking water, or a disease responsible for disease in humans or animals. In this respect, the *Swiss Criminal Code* of 1937 makes provisions for custodial sentences in articles 234, 231 and 232.

Then, the *Federal Act on War Material* of 1996 (RS 514.51) prohibits in its article 7, the development, production, acquisition, import, export, transit, storage, and possession of nuclear, biological and chemical weapons in Switzerland or by Swiss citizens, and any assistance in doing so. It also provides for license requirements for the manufacture, import, export, or transit of war material (articles 9 and 17).

Thirdly, the development, export, import, and transit of dual-use and military goods is carried out in accordance with the provisions of *Federal Acts on the Control of Goods Suitable for Civilian and Military Purposes and Specific Military Goods* of 1996 (RS 946.202). The Act details the control measures that

82 Federal legislation can be accessed at <http://www.admin.ch/ch/f/rs.html>

83 François, Garraux (2010). 'Linking Life Sciences with Disarmament in Switzerland', in Brian.Rappert (ed.) *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, [http://epress.anu.edu.au/education\\_ethics/pdf/ch03.pdf](http://epress.anu.edu.au/education_ethics/pdf/ch03.pdf) . See also, Sergio Bonin. *BioWeapons Monitor 2011, op.cit.*

are implemented to counter the risk of proliferation of dual-use goods (authorisation regime, duty to declare and monitoring measures) during the process of research, development, fabrication, stockpiling, transfer, use, import, export and brokering of those goods.

Furthermore, in order to control and limit the spread of disease outbreaks in the country, the 1970 *Federal Act on the Control of Communicable Human Diseases (Federal Act on Epidemics (RS 818.101))*, sets out provisions for disease surveillance through reporting requirements, as well as vaccination and quarantines measures. It also requires authorisations for laboratories (article 5) and individuals that handle pathogens for research or trade purposes (article 29a and 29b). Finally, it allows the government to regulate the use of pathogens (article 29d).

Finally, in order to protect humans, animals and plants, the *Federal Act on the Protection of the Environment* of 1983 (RS 814.01) sets out provisions for biosafety measures. The Act regulates the handling of pathogenic or genetically-modified organisms and the contained use or release of such organisms into the environment (article 29a). In order to facilitate a harmonised implementation of the related ordinances (e.g. Ordinance on the Contained use of microorganisms, Ordinance on the Protection of Workers from the Risks related to exposure to microorganisms), the Federal Office for the Environment regularly issues a classification of microorganisms according to four risk groups.<sup>84</sup>

84 For the lists of organisms, see <http://www.bafu.admin.ch/publikationen/publikation/01614/index.html?lang=fr>

## Codes of conduct, education and awareness-raising

There appears to be no code of conduct in Switzerland that can serve as a successful example of the utility of such documents to promote biosecurity.

However, regarding education in and awareness-raising of dual-use issues, several initiatives have been undertaken in Switzerland and new projects are being pursued.

In 2008, preliminary surveys revealed that even if life scientists in Switzerland had a good understanding of biosafety measures, they were unaware of the dual-use and security issues their work is likely to entail<sup>85</sup>.

Concerned with these results, the Government of Switzerland published a ten pages brochure 'Biology for Peace' in 2008 which sought to raise awareness among life scientists. It presented how advances in life science can be misused and set out the various BWC articles, and Swiss laws, which are relevant to life scientists' work<sup>86</sup>. The publication of the brochure was followed in 2009<sup>87</sup> by a series of awareness-raising seminars conducted by experts from the Universities of Bradford and Exeter in the United Kingdom at various academic institutions

85 Possible approaches to education and awareness-raising among life scientists, BTWC background documentation, submitted by Australia, Japan and Switzerland on behalf of the 'JACKSNNZ' and Sweden, April 2011, §21. [http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/educationand7thRevCon/Possible\\_Approaches\\_to\\_Education\\_and\\_Awareness-Raising\\_among\\_Life\\_Scientists.pdf](http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/educationand7thRevCon/Possible_Approaches_to_Education_and_Awareness-Raising_among_Life_Scientists.pdf)

86 See <http://www.seco.admin.ch/dokumentation/publikation/00035/02291/index.html?lang=en>

87 See the details of the details of the organization of the seminars (target audience, content and educational material, logistical support and budget) in, GARRAUX, François (2010). 'Linking Life Sciences with Disarmament in Switzerland', *op.cit.*

in Switzerland, as well as by the Government of Switzerland itself in 2010<sup>88</sup>.

Even though Switzerland is in the top rank internationally for education in the life sciences<sup>89</sup>, the seminars revealed an almost complete absence of educational modules on biosecurity in regular life-science curricula and a missing link between life science practitioners and the Swiss security community<sup>90</sup>. These experiences showed that there is a need for such educational modules to be continued, ideally in the regular environments of life scientists and in universities<sup>91</sup>.

In April 2012, a two-year research project on 'Ethical issues of dual-use research of concern in Switzerland', financed by the University of Basel, started. Through case scenarios, the investigators of the Institute for Biomedical Ethics (University of Basel) will collect relevant data to assess the "awareness, views and perspectives" of the different Swiss actors involved in such research. The final objective is to suggest governance options for Switzerland.<sup>92</sup>

## CBM participation

Switzerland has submitted CBM declarations regularly every year since 1988 - only in the first year of their establishment, 1987, it did not do so. Since 2006,

88 See Spiez Laboratory annual report 2010, *op.cit.* Page 15.

89 Swiss Biotech Report 2012. Editorial, *op.cit.* See also, 'Swiss biotech- creating value from innovation' page 6,

90 See François Garraux (2010) 'Linking Life Sciences with Disarmament in Switzerland', *op.cit.*

91 François Garraux (2010) 'Linking Life Sciences with Disarmament in Switzerland', *ibid.*

92 [https://forschdb2.unibas.ch/inf2/rm\\_projects/object\\_view.php?r=1167195](https://forschdb2.unibas.ch/inf2/rm_projects/object_view.php?r=1167195)

Switzerland has made its CBM declarations publicly available on the website of the BWC Implementation Support Unit (ISU).

The collection and compilation of the CBM data is performed by Spiez Laboratory (as part of the Federal Office for Civil Protection (FOCP) within the Swiss Federal Department of Defence, Civil Protection and Sport (DDPS)) mandated by the national contact point for all BWC matters - the Division for Security Policy (DSP) within the Swiss Federal Department of Foreign Affairs (FDFA) (see above).

In 2010 the form and content of Switzerland's CBMs report were revised. An information network was established (See Diagram 1) to facilitate the collection of the data needed each year to fill in the forms.

Screening and evaluation of databases and literature is performed by Spiez Laboratory for CBM forms A, B, C, E and G. Furthermore, to ensure correctness and completeness of the data content as well as to maximise efficiency of the process, data collection for forms A, B and G is done in collaboration with the Swiss Federal Offices that have direct access to all relevant information. This process increased Switzerland efficiency in reporting<sup>93</sup>.

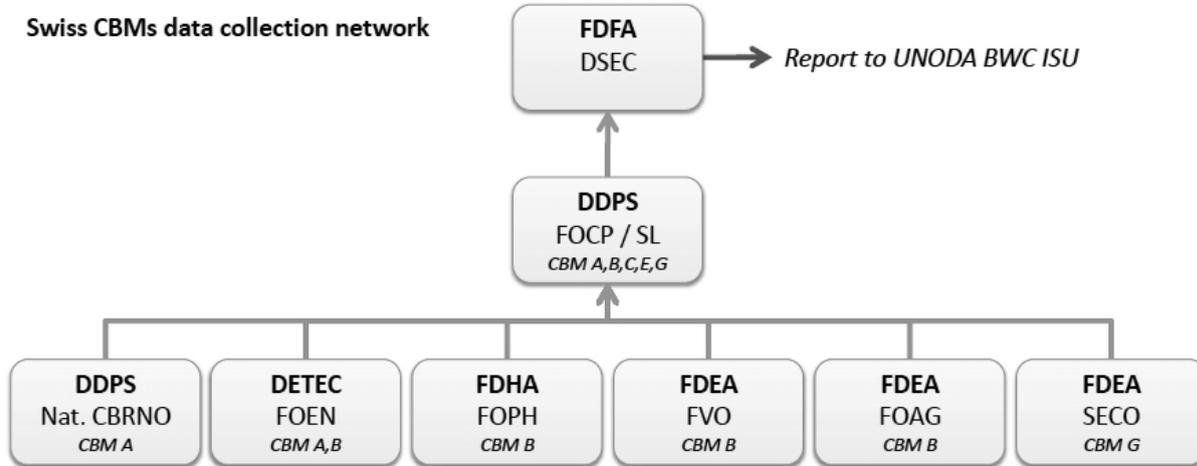
Furthermore Switzerland is an active promoter of the CBM mechanism and its expansion.

In recent years it has funded and submitted several background papers and studies on the topic to the BWC meetings.<sup>94</sup> It has also made regular statements

93 See Spiez Laboratory Annual Report 2010, *op.cit.* Page 10-11.

94 See, for instance, F.Lentzos and R.A. Hamilton (2010) Preparing for a comprehensive review of the CBM mechanism at the Seventh BWC Review Conference, 2009-2010 workshop series report, [http://www2.lse.ac.uk/BIOS/research/biosecurity/pdf/Workshop\\_Report\\_Lentzos\\_Hamilton.pdf](http://www2.lse.ac.uk/BIOS/research/biosecurity/pdf/Workshop_Report_Lentzos_Hamilton.pdf) Also see F.Lentzos and R.A. Hamilton (2009) Compendium of Proposals to Improve the

## Diagram 1- Swiss CBMs data collection network



- BWC: Biological and Toxin Weapons Convention
- DDPS: Federal Department of Defence, Civil Protection and Sport
- DETEC: Federal Department of the Environment, Transport, Energy and Communications
- DSEC: Division for Security Policy and Crisis Management
- FDEA: Federal Department of Economic Affairs
- FDFA: Federal Department of Foreign Affairs
- FDHA: Federal Department of Home Affairs
- FOAG: Federal Office for Agriculture
- FOCP: Federal Office for Civil Protection
- FOEN: Federal Office for the Environment
- FOPH: Federal Office of Public Health
- FVO: Federal Veterinary Office
- ISU: Implementation Support Unit
- Nat. CBRNO: National NBC Protection and Coordination Office
- SECO: State Secretariat for Economic Affairs
- SL: Spiez Laboratory
- UNODA: United Nations Office for Disarmament Affairs

Source: Spiez Laboratory - Federal Office for Civil Protection- Federal Department of Defense, Civil Protection and Sport.

**Table 6. Number of Swiss delegates at the BWC meetings since 2006.**

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012
Number of delegates	10	10	6	8	4	12	9	9	8	6	9	6

Source: UNOG - Implementation Support Unit (ISU). Meetings documents- Lists of participants.

related to the improvement of CBMs at meetings and review conferences<sup>95</sup>.

### Participation in BWC meetings

Switzerland participates regularly in BWC-related meetings in Geneva. Since the Sixth Review Conference in 2006, it has taken part in all relevant meetings (see table 6).

### Past biological weapons activities and accusations

Switzerland never had a biological weapons programme nor has it ever been accused of having one.

There have been numerous white powder instances in Switzerland every year since 2001, all of which turned out to be hoaxes.<sup>96</sup> In the time between the anthrax attacks in the United States in the late 2001 and June 2002 alone, there were more than 1,000 fake anthrax threats recorded in Switzerland, 200 of which were believed to necessitate an intervention by first responders.<sup>97</sup>

CBM Mechanism, <http://www2.lse.ac.uk/BIOS/research/biosecurity/pdf/CBM%20Compendium.pdf>

95 See notably, Statement by Ambassador Alexandre Fasel, 7<sup>th</sup> Review Conference, 5 December 2011, *op.cit.* INVERNIZZI, Cédric. 'How to Enable Fuller Participation in the CBMs'. Meeting of Experts. 18 July 2012. See also, Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 6 December 2010, *op.cit.* See also Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 7 December 2009. See also, 'Actions to Improve Confidence-Building Measures'. Official document submitted by Switzerland at the 6<sup>th</sup> Review Conference. 15 November 2006 BWC/CONF.VI/WP.14

96 Cf., for instance, the Annual Reports of the Spiez Laboratory, <http://www.labor-spiez.ch/en/dok/ge/index.htm> See also, Guery, M. (2004) Biologischer Terrorismus in Bezug auf die Schweiz - Unter besonderer Berücksichtigung rechtlicher Aspekte, Zürcher Beiträge No 74, Center for Security Studies, ETH Zurich, Zurich.

97 See <http://www.admin.ch/ch/d/ff/2003/1832.pdf>, p1896.

## Country report: United Kingdom

### 1972 Biological and Toxin Weapons Convention

Signed: 10 April 1972<sup>1</sup>

Deposit of Ratification: 26 March 1975

### 1925 Geneva Protocol

Signed: 17 June 1925

Deposit of Ratification: 9 April 1930

On 27 September 1991, the UK withdrew the part of its reservation that maintained the UK's right to retaliate in kind if biological weapons were used.<sup>2</sup> Since 20 December 2002, the UK no longer has any reservations to the Geneva Protocol.<sup>3</sup>

### National point of contact

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1 UNODA "Status of Multilateral Arms Regulation and Disarmament Agreements" <http://disarmament.un.org/treatystatus.nsf>

2 UK Parliament (1991) "Biological and Toxin Weapons", Written Answers to Questions, Wednesday 16 October 1991.

3 UN (2004) "*Measures to uphold the authority of the 1925 Geneva Protocol: Note by the Secretary-General*", A/59/179. 23 July 2004. [http://disarmament2.un.org/Library.nsf/67458ce237aeef6785256ebd004b-fee8/6ae6ac038e09307c85256ef9004cfb93/\\$FILE/sg59.179.pdf](http://disarmament2.un.org/Library.nsf/67458ce237aeef6785256ebd004b-fee8/6ae6ac038e09307c85256ef9004cfb93/$FILE/sg59.179.pdf)

## General policy statements on bioweapons and bioweapons/bioterrorism threat perception

The UK is one of the three Depositary Governments for the Biological and Toxin Weapons Convention (BWC) and a long-standing supporter of the international prohibition on biological weapons; as Parliamentary Under-Secretary of State Mr. Alistair Burt stated at the Seventh Review Conference in 2011, the "UK has a keen sense of responsibility for this Convention as the original proposal for a separate ban on biological weapons was made by the United Kingdom back in 1968".<sup>1</sup> Current UK policy on Biological Weapons is influenced by, and influences,<sup>2</sup> a number of regional and like-minded groups, such as

1 UK (2011) "Statement to the Seventh Biological and Toxin Weapons Convention Review Conference", 5 December 2011 [http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/A71C5ADF0263AE43C125795E0048AF29/\\$file/UK+State-ment+7th+BTWC+RevCon.pdf](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/A71C5ADF0263AE43C125795E0048AF29/$file/UK+State-ment+7th+BTWC+RevCon.pdf) see also Walker. J (2012) "Britain and Disarmament: The UK and Nuclear, Biological and Chemical Weapons Arms Control and Programmes 1956-1975", Ashgate publications.

2 UK Parliament (2011) "The Biological and Toxin Weapons Convention", Documents considered by the European Scrutiny Committee on 29 June 2011. <http://www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/428-xxxi/42814.htm>

the EU, NATO and the G8 Global Partnership. National perceptions of the threat of biological weapons have been articulated in a several documents, including the 2010 report, *A Strong Britain in an Age of Uncertainty: the National Security Strategy*, which stated that one of the “four highest priority risks are those arising from ... international terrorism, including through the use of chemical, biological, radiological or nuclear (CBRN) materials...”<sup>3</sup> In late 2011, the threat of bioterrorism was further articulated in an article in the *New Scientist* by Alistair Burt, who wrote:

“Biological weapons are not new: the threat of biological warfare has confronted humanity for centuries...[and]...In the past century, imperial Japan, the Soviet Union, Saddam Hussein’s Iraq and others have developed bioweapons. We now face a new threat in the shape of bioterrorism...[and]... The consequences of future biological attacks could be even worse, from the global release of infectious diseases to effects on public health, business and international travel.”<sup>4</sup>

To respond to the global challenge of biological weapons, the UK has employed a multifaceted strategy that utilises a number of different tools and tracks of activity, ranging from cooperation with the G8 on the fight against infectious diseases and to “work on national implementation” as part of the EU Joint Action in support for the Convention.<sup>5</sup> Amidst

3 HM Government (2010) “A Strong Britain in an Age of Uncertainty: The National Security Strategy”, October 2010, [http://www.direct.gov.uk/prod\\_consum\\_dg/groups/dg\\_digitalassets/@dg/@en/documents/digitalasset/dg\\_191639.pdf](http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_191639.pdf)

4 Burt. A (2011) “Defence against bioweapons demands more action”, *New Scientist*, 15 December 2011. <http://www.newscientist.com/article/dn21290-defence-against-bioweapons-demands-more-action.html>

5 BTWC Compliance Report By The United Kingdom Of Great

all these activities, the BWC has been identified as “a cornerstone of the international approach to combating the threat to international peace and security posed by biological weapons” with Alistair Burt, stating that the Seventh Review Conference “must act now to ensure that the Convention remains up to the task, not only to confront effectively the threats but also to multiply the opportunities”.<sup>6</sup> Specific UK priorities for the Seventh Review Conference included, *inter alia*, securing agreement on a “new substantive programme of annual intersessional meetings”; revising CBMs; agreeing to a more regular review of science and technology and putting in place “practical support for Article VII”.<sup>7</sup> Whilst some of these objectives were secured, the Review Conference proved a challenging negotiating environment. At a workshop on the Seventh Review Conference, hosted by the Harvard Sussex Program (HSP) in association with the UK Foreign & Commonwealth Office (FCO), it was reported that the Review Conference was “a hard fought three weeks” adding that “the results on paper did not capture how difficult the negotiations were behind the scenes”.<sup>8</sup>

Britain And Northern Ireland For The Seventh Review Conference 2011 <http://centralcontent.fco.gov.uk/resources/en/pdf/central-content-pdfs/BTWC/compliancereport>

6 UK (2011) “Statement to the Seventh Biological and Toxin Weapons Convention Review Conference”, 5 December 2011 [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/A71C5ADF0263AE43C125795E0048AF29/\\$file/UK+Statement+7th+BTWC+RevCon.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/A71C5ADF0263AE43C125795E0048AF29/$file/UK+Statement+7th+BTWC+RevCon.pdf)

7 See UK Parliament (2011) op cit ref 4 and FCO (2011) “The Role of the UK in the BTWC” <http://www.fco.gov.uk/en/global-issues/counter-proliferation/biological-and-toxin-weapons-convention/role-of-the-uk-in-btwc/>

8 Revill. J (2012) “Deconstructing the BWC Seventh Review Conference: Workshop Summary”, Harvard Sussex Program “Sussex Day”, University of Sussex, 8th March 2012 <http://hsp.sussex.ac.uk/sandtreviews/uploads/500d730e886cd/hsp%20deconstructing%20the%20bwc%20seventh%20review%20conference.pdf>

In the post Review Conference milieu, UK policy appears to be focused on exploring the potentiality of the third BWC intersessional process.<sup>9</sup> Although Lord Howell of Guildford, Minister for State, Foreign and Commonwealth Office, responded to a parliamentary question in 2012 with the statement that the UK was “keen to see a robust verification mechanism for the Biological and Toxin Weapons Convention (BTWC)”, it was acknowledged that “there remain no signs that the international climate has changed enough to permit universal agreement on verification, particularly given the need to operate by consensus”.<sup>10</sup>

## Life sciences and biotech industry status

According to BWPP’s 2012 global survey, the UK is one of the world’s leading countries in the field of the life sciences and biotechnology. Globally, data from the last five years indicates that the UK ranks third in terms of publications and fifth in terms of biotechnology patents.<sup>11</sup> In terms of finances Ernst and Young’s 2012 report *Global Biotechnology 2012* posits “As in prior years, the UK led Europe in number of financing rounds and venture capital raised”;<sup>12</sup> whilst university ranking metrics indicate that the UK has nine universities in The Times Higher World University Rankings for life sciences.<sup>13</sup> Web of

Science further indicates that many UK universities and research institutes are also particularly active in transnational collaboration across the globe with countries such as the US, Germany, France; however there is evidence of some joint publications between UK author and almost all BWC States Parties. The top 50 instances of transnational authorship in papers related to biotechnology and the life sciences over the last five years where one author was affiliated with a UK institute are illustrated in figure 1. This is based on a topical search of keywords<sup>14</sup> derived from the ISU’s background information document on ‘*New scientific and technological developments relevant to the Convention*’.

As of 2012, the Office for Life Sciences indicated the UK healthcare industry “employs over 100,000 people, largely in highly skilled jobs” and secured £4.4 billion of research and development funding in 2009; whereas in the biotechnology sector, the “UK has 64 companies whose primary business activity is to develop biotechnologies that can be applied to industrial uses. These companies together generate sales of £230m per year based on the latest financial data and employ 1,600 people.<sup>15</sup> Moreover, there has been a concerted effort to promote biotechnology in the UK and the Office for Life Sciences (OLS) has

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London; and University of Bristol

9 Revill. J (2012) *ibid*

10 UK Parliament (2012) “Written Answers”, 7 Feb 2012 : Column WA31, Hansard, <http://www.publications.parliament.uk/pa/ld201212/ldhansrd/text/120207w0001.htm>

11 Aggregated data for BWPP monitor

12 Ernst & Young (2012) “*Beyond borders: global biotechnology report 2012*” <http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders---global-biotechnology-report-2012>

13 University of Cambridge; University of Oxford; Imperial College London; University College London; University of Edinburgh; University of Sheffield; University of Glasgow; King’s College

14 The following search was used in the Web of Science topical search “Genomics OR Genome OR toxicity OR transmission OR infectivity OR virulence OR pathogenicity OR bioreactors OR Neurobio\* OR “synthetic biology” OR Bioprospecting OR transcriptomics OR proteomic OR “Gene sequencing”) Refined by: selected web of science categories and Countries/Territories=( ENGLAND OR UK OR WALES OR NORTH IRELAND OR SCOTLAND ) Timespan=Latest 5 years. For further details please contact the author.

15 Department for Business, Innovation and Skills (2012) „UK life sciences industry overview“, Office for Life Sciences <http://www.bis.gov.uk/policies/innovation/business-support/ols/uk-life-sciences-industry-overview>

**Figure 1. Top 50 countries with which UK researchers have co-authored biotechnology or life science related academic papers.**

Countries	records	Countries	records	Countries	records	Countries	records
USA	5893	JAPAN	629	SINGAPORE	229	CROATIA	112
GERMANY	2593	FINLAND	567	CZECH REPUBLIC	226	TAIWAN	107
FRANCE	2027	IRELAND	538	ISRAEL	219	TURKEY	100
NETHERLANDS	1740	AUSTRIA	392	THAILAND	219	ARGENTINA	94
AUSTRALIA	1430	NORWAY	389	SOUTH KOREA	213	ESTONIA	89
ITALY	1422	SOUTH AFRICA	387	RUSSIA	198	EGYPT	79
CANADA	1345	GREECE	344	ICELAND	154	IRAN	78
SPAIN	1247	BRAZIL	327	HUNGARY	153	SLOVENIA	78
SWEDEN	1051	POLAND	307	TANZANIA	143	GAMBIA	77
SWITZERLAND	1015	PORTUGAL	275	UGANDA	130	MALAYSIA	75
CHINA	799	INDIA	265	MEXICO	124	SAUDI ARABIA	67
BELGIUM	791	NEW ZEALAND	248	PAKISTAN	117	GHANA	66
DENMARK	663	KENYA	239				

identified biotechnology as “an important growth area”<sup>16</sup> and undertaken a number of initiatives to foster life science R&D. Such initiatives include inter alia streamlining “routes to market approval for innovative, breakthrough therapies”; financial investment in “discovery, development and commercialisation of research”; tax incentives for life science research; and the appointment of life science champions.<sup>17</sup>

16 Department for Business, Innovation and Skills (2011) “Office for Life Sciences” <http://www.bis.gov.uk/ols>

17 Department for Business, Innovation and Skills (2010) “Strategy for UK Life Sciences”, Office for Life Sciences, <http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences.pdf>

## Biodefence activities and facilities

There are two UK biological defence research programmes, one civilian programme funded by the Home Office (HO) and a second larger programme funded by the Ministry of Defence (MoD). Research in both programmes is primarily based at the Defence Science & Technology Laboratory (Dstl) facilities in Porton Down. A number of laboratory facilities are included on the Dstl Porton Down site, including a total of 335m<sup>2</sup> of Biosafety Level 4 facilities and 1050 m<sup>2</sup> of Biosafety Level 3 facilities.<sup>18</sup>

18 UK CBM 2012, pg 21

**Figure 2. HO biological defence programme spending and contracted percentage<sup>1</sup>**

Period	Total estimated Spending	Percentage of funding contracted to industry, academic institutions, or in other non-defence facilities
April 1st 2006 - March 31st 2007	£6.7M	88%
April 1st 2007 - March 31st 2008	£7.1 M	85%
April 1st 2008 - March 31st 2009	£7.0M	80%
April 1st 2009 - March 31st 2010	£5.0M	80%
April 1st 2010 - March 31st 2011	£3.0 M	0.05%
April 1st 2011 - March 31st 2012	£2.1M	40%

<sup>1</sup> Data derived from UK CBM returns 2007 - 2011 available from UN Office Geneva BTWC Website

## Home Office biological defence programme

The HO funds a small biodefence programme designed to enhance the UK's capacity to minimise the risk of a CBRN incident through building capabilities in the areas of *inter alia*, detection, medical counter measures, development and assessment of protective equipment, decontamination, hazard assessment and developing an understanding of the impact and spread of biological materials. The relatively small amount of funding for the HO programme is primarily used to fund Dstl activities and has decreased over the last five years - something illustrated in Figure 2 below - in part due to budget reductions but also project completion and an increased focus on answering specific questions related to the operational effectiveness of mature Home Office capabilities".<sup>19</sup> There has been a related decrease in the percentage of funding contracted to industry, academic institutions, or in other non-

defence facilities, however fluctuations in the percentage between 2010 and 2012 are attributed to differing interpretations of the information required under question 4 of CBM Form A, part 2 (ii).

## Ministry of Defence biological defence programme

The MoD's biological defence programme is managed by the MoD's Director of CBRN Policy and aims to support the UK's broader strategic objectives; specifically, it is intended to maintain the UK's "political and military freedom of action despite the presence, threat or use of biological, chemical or radiological agents".<sup>20</sup> There are five components to this approach which have been identified as follows:

- Hazard Assessment
- Detection and diagnostics
- Protection

<sup>19</sup> Personal correspondence.

<sup>20</sup> UK CBM 2011, pg 12

**Figure 3. MoD biological defence programme costs, personnel and external contracts<sup>1</sup>**

Period	Total estimated Spending	Procurement of defence equipment.	Personnel biological defence	extramural contracts: universities academic institutions	extramural contracts: government funded or industrial companies
April 1st 2006 - March 31st 2007	£43.5M	£5.4M	• 207 civilians • 10 military	35	45
April 1st 2007 - March 31st 2008	£55.4M	£13.5M	• 220 civilians • 7 military	35	46
April 1st 2008 - March 31st 2009	£57M	£10.1 M	• 221 civilians • 4 military	45	55
April 1st 2009 - March 31st 2010	£47M	£12.9M	• 216 civilians • 10 military	36	40
April 1st 2010 - March 31st 2011	£51M	£10.25M	• 216 civilians • 4 military	22	49
April 1st 2011 - March 31st 2012	£50M	£9.4M	• 203 civilians • 6 military	24	43

1 Data derived from UK CBM returns 2007 - 2011 available from UN Office Geneva BTWC Website

- Medical Countermeasures
- Hazard Management

In addition to which Dstl staff provide “technical advice on CBW non-proliferation” to inform UK arms control and non-proliferation policies.<sup>21</sup> MoD biological defence funding over the past six years averages roughly £50 million per annum, of which a significant segment is earmarked for activities to

support the procurement of “armed forces biological defence equipment”.<sup>22</sup> A further percentage of this funding goes towards supporting extramural contracts for industrial companies and academic institutions, something that is done, in part, through open calls for proposals in certain issue areas.<sup>23</sup> Estimated spending, personnel and the number of extramural contracts by year are illustrated further in Figure 3.

21 See Center for Arms Control and Non-Proliferation (2009) “Ensuring Compliance With the Biological Weapons Convention Meeting Report” [http://armscontrolcenter.org/policy/biochem/articles/bwc\\_compliance.pdf](http://armscontrolcenter.org/policy/biochem/articles/bwc_compliance.pdf) and the UK’s 2011 CBM return.

22 Data derived from UK CBM returns 2007 - 2011 available from UN Office Geneva BTWC Website

23 See for example the recent Joint Synthetic Biology Initiative (JSBI). <http://www.bbsrc.ac.uk/jointsyntheticbiology>

### Compliance review & transparency

The UK's Ministry of Defence has developed "guidelines to ensure that its biological defence research and development programmes are in compliance with the BTWC".<sup>24</sup> The MoD guidelines are not publicly available, although the objectives have been identified elsewhere as including the following:

- provide guidance on biodefence projects, including joint international projects;
- ensure the work is consistent with UK interpretations of the BWC and associated treaties;
- provide guidance on relevant domestic law that implements UK obligations; and
- demonstrate that the MOD has appropriate guidance in place.<sup>25</sup>

Moreover, Dstl personnel are actively encouraged to publish research when appropriate<sup>26</sup> and publications are evident in a number of different scientific journals including *Vaccine*, *Biosensors Bioelectronics* and *the Journal of Medical Microbiology*.<sup>27</sup> A key word search for the term "bio\*" in publications with one or more authors located at Dstl reveals 87 articles located in more than 60 different publications. Examples of 2012

publications by Dstl affiliated authors include:

- Goodes, L. R., S. P. Dennington, et al. (2012). "Fluorescence microscopy techniques for quantitative evaluation of organic biocide distribution in antifouling paint coatings: application to model antifouling coatings." *Biofouling* 28(6): 613-625.
- Cuccui, J., T. S. Milne, et al. (2012). "Characterization of the Burkholderia pseudomallei K96243 Capsular Polysaccharide I Coding Region." *Infection and Immunity* 80(3): 1209-1221.
- Harper, M. M., J. A. Dougan, et al. (2012). "Detection of SERS active labelled DNA based on surface affinity to silver nanoparticles." *Analyst* 137(9): 2063-2068.
- Morris, C. J., K. Beck, et al. (2012). "Pegylation of Antimicrobial Peptides Maintains the Active Peptide Conformation, Model Membrane Interactions, and Antimicrobial Activity while Improving Lung Tissue Biocompatibility following Airway Delivery." *Antimicrobial Agents and Chemotherapy* 56(6): 3298-3308.
- Rachwal, P. A., H. L. Rose, et al. (2012). "The Potential of TaqMan Array Cards for Detection of Multiple Biological Agents by Real-Time PCR." *Plos One* 7(4).

The subject areas of such publications, many of which are in collaboration with other academic and industrial institutions,<sup>28</sup> are outlined in Figure 4.

In addition to the academic publications produced by Dstl affiliated authors, some unclassified research

24 BWC (2011) "Compliance by States Parties with their obligations under the Convention", BWC/CONF.VII/INF.2, 23 November 2011, page 101.

25 See Center for Arms Control and Non-Proliferation (2009) "Ensuring Compliance With the Biological Weapons Convention Meeting Report" [http://armscontrolcenter.org/policy/biochem/articles/bwc\\_compliance.pdf](http://armscontrolcenter.org/policy/biochem/articles/bwc_compliance.pdf) and the UK's 2011 CBM return.

26 Select Committee on Science and Technology Appendices to the Minutes of Evidence APPENDIX 39 Memorandum submitted by the Defence Science and Technology Laboratory (Dstl) <http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/415/415ap59.htm>

27 Web of Science dataset, contact the author for further details.

28 Select Committee on Science and Technology Appendices to the Minutes of Evidence APPENDIX 39 Memorandum submitted by the Defence Science and Technology Laboratory (Dstl) <http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/415/415ap59.htm>

Figure 4. Life science subject areas dealt with by Dstl Porton Down authors

Research Areas	records
Microbiology	20
Immunology	18
Chemistry	16
Toxicology	10
Biochemistry Molecular Biology	9
Pharmacology Pharmacy	9
Biotechnology Applied Microbiology	7
Infectious Diseases	7
Life Sciences Biomedicine Other Topics	5
Research Experimental Medicine	5

abstracts are also available through the MoDs central repository for S&T research, the ATHENA collection.<sup>29</sup> This includes the *Defence Reporter* publication, the latest edition of which includes titles such as “*Dogs and biological warfare agent (BWA) infections*” and “*molecular viability assays for the verification of surface decontamination - selection of molecular targets*”.<sup>30</sup> In this context, some biodefence research is publicly available either through Athena or academic journals, although the MoD has clearly stated “it will not publish material in the open literature that could ‘potentially jeopardise national security or aid proliferation, or could highlight a deficiency in the UK’s defence posture’”.<sup>31</sup>

29 Dstl (2012) “ATHENA access - Defence Reporter” <http://www.dstl.gov.uk/pages/85>

30 Dstl (2012) “Defence Reporter”, Spring 2012 [https://www.dstl.gov.uk/downloads/Defence%20Reporter\\_Spring%202012.pdf](https://www.dstl.gov.uk/downloads/Defence%20Reporter_Spring%202012.pdf)

31 See Select Committee on Science and Technology “*Security of Research*”, Eighth Report 7, <http://www.parliament.the-stationery-office.co.uk/pa/cm200203/cmselect/cm-sctech/415/41515.htm#note226>

## Maximum and high biological safety level (BSL-3 and 4) facilities and their activities

A Health and Safety Executive (HSE) audit in 2008 identified 10 sites that worked with Containment Level 4 pathogens,<sup>32</sup> all except two of these sites were government run, the two exceptions being private companies working on veterinary vaccines.<sup>33</sup> According to the report, “these facilities vary in capacity and capability, ranging from single rooms to multiple suites

32 This includes both “Specified Animal Pathogen Order” level 4 facilities and Advisory Council for Dangerous Pathogens level 4 agents. The latter being equivalent to the WHO BSL-4 and the EU P-4 standards the former being animal pathogens vary in terms of their biosafety level.

33 The two were identified as private manufacturers of veterinary vaccines, see House of Commons Innovation, Universities, Science and Skills Committee Biosecurity in UK research laboratories Sixth Report of Session 2007-08 Volume I Report, together with formal minutes Ordered by The House of Commons to be printed 16 June 2008 <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmdius/360/360i.pdf>

**Figure 5. Number of UK Laboratories in 2008 by containment level and organisation or site type.**

Containment level	Organisation or site type			
	Government	Private	Research council	University
2	212	230	17	70
3	202	98	7	40
4	5	2	3	0

of CL4 [Containment Level 4] laboratories on a single site”.<sup>34</sup> The number of UK laboratories at containment levels 2, 3 and 4, and the break down by organisation or site type as of 2008 is illustrated in Figure 5 below.

The number of high containment level facilities has evolved considerably as laboratories merge, new research activities are initiated and old projects are concluded. Since the 2008 HSE audit, one government CL4 facility and one CL4 private vaccine manufacturing facility, *Intervet Schering-Plough*, have been de-operationalised and the ... [Specified Animal Pathogen Order]... SAPO license to hold Newcastle disease virus surrendered. Consequently, as of late 2012, there are currently 8 containment level 4 laboratory sites in the UK: three of these work with Advisory Council for Dangerous Pathogens (ACDP) Hazard Group 4 pathogens. Another three work with highly pathogenic avian influenza and operate at ACDP 3+ and SAPO level 4; with two further sites working with SAPO 4 agents.

<sup>35</sup>

## Research on smallpox, allegations of smallpox outbreaks, policy on smallpox destruction

The 2003/04 Annual Reports from the UK’s National Biological Standards Board (NBSB), stipulated one of the objectives of the National Institute for Biological Standards and Control (NIBSC), included “identify[ing] and validat[ing] suitable biological markers for assessment of consistency of production for new generation smallpox vaccines”.<sup>36</sup> This is consistent with earlier UK CBMs, which reported “developing and testing reagents” for smallpox vaccines at the NIBSC facility.<sup>37</sup> The NIBSC, now part of the Health Protection Agency, as the UK’s Official Medicines Control Laboratory, maintains the capacity to analyse smallpox vaccines although it is reported by the NIBSC Director, Dr Stephen Inglis, that “further development of such tests is not an area of active research at this time”.<sup>38</sup>

<sup>36</sup> NBSB (2004) “Annual Report & Accounts”, 1st April 2003 to 31st March 2004 [http://www.nibsc.ac.uk/PDF/NBSB\\_annual\\_report\\_200304.pdf](http://www.nibsc.ac.uk/PDF/NBSB_annual_report_200304.pdf) see also UK CBM returns.

<sup>37</sup> See UK CBM Returns 2007, 2008, 2008.

<sup>38</sup> Personal correspondence, see also the NISBC Annual Reports [http://www.nibsc.ac.uk/PDF/NBSB\\_Annual\\_Report\\_07.pdf](http://www.nibsc.ac.uk/PDF/NBSB_Annual_Report_07.pdf)

<sup>34</sup> House of Commons (2008) “Biosecurity in UK research laboratories” Innovation, Universities, Science and Skills Committee, Sixth Report of Session 2007-08, 16 June 2008

<sup>35</sup> Many thanks to the HSE respondent for assistance here.

**Figure 6. UK CL4 facilities, location, funders, activities and size**

Name	Address	Funder	Activities & Agents	Size
Defence Science and Technology Laboratory (Dstl), Porton Down. <sup>1</sup>	Porton Down, Salisbury, Wiltshire, SP4 0JQ	Primarily the Ministry of Defence.	“Research and development into protective measures as defence against the hostile use of micro-organisms and toxins.” <sup>2</sup>	2 units, 335m <sup>2</sup> total
Health Protection Agency, <sup>3</sup> Colindale.	61 Colindale Avenue, London, NW9 5HT	The Department of Health.	“diagnostic services for highly contagious human pathogens”. <sup>4</sup>	1 unit: 30 m <sup>2</sup>
Health Protection Agency, Porton	Porton Down, Salisbury, Wiltshire, SP4 0JG	The Department of Health.	“Diagnosis and research into various containment level 4 viruses” <sup>5</sup>	2 units: 105m <sup>2</sup> total
National Institute for Biological Standards and Control (NIBSC).	Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG	The Department of Health and the Home Office	“development of assays and testing of reagents”, <sup>6</sup> including work with human pathogens and toxins	2 Containment level 4 units 118m <sup>2</sup> total
National Institute for Medical Research (NIMR), Containment 4 Building C.	The Ridgeway Mill Hill, London, NW7 1AA <sup>7</sup>	UK Medical Research Council (MRC). <sup>8</sup>	Research and diagnostics on highly pathogenic avian influenza virus.	1 unit: 298 m <sup>2</sup> total
The Pirbright Institute [Formerly Institute for Animal Health] <sup>9</sup> , Pirbright Laboratory.	The Pirbright Institute, Pirbright Woking Surrey GU24 0NF	Biotechnology and Biological Sciences Research Council (BBSRC); Department for Environment, Food and Rural Affairs (DEFRA)	Work on exotic animal virus disease. <sup>10</sup>	5,173.87 m <sup>2</sup> Specified Animal Pathogen Order (SAPO) Level 4 total <sup>11</sup>
Animal Health and Veterinary Laboratories Agency (AHVLA)	Woodham Lane Addlestone Surrey KT15 3NB	Primarily Department for Environment, Food & Rural Affairs (DEFRA). <sup>12</sup>	Diagnosis, statutory testing and applied research on the epidemiology and pathology of the disease of farmed, domesticated livestock.	6 SAPO Level 4 Units, 160 m <sup>2</sup> total; plus ~100 m <sup>2</sup> SAPO level 4 capable facilities
Merial Animal Health, Biological Laboratory	Ash Road Pirbright Surrey GU24 0NQ	Privately financed. <sup>13</sup>	The manufacture of viral vaccines. <sup>14</sup>	1 SAPO level 4 facility

1 Defence Science & Technology Laboratory “Contact details”

<http://www.dstl.gov.uk/pages/169>

2 UK CBM 2012, pg 3

3 In accordance with the Health and Social Care Act 2012, Health Protection Agency will be abolished at midnight on 31 March 2013, with all of its functions transferring into a new, larger organisation to be called Public Health England from 1 April 2013.

4 Personal Correspondence, 14th November 201<sup>2</sup>

5 UK CBM 2012, pg 5

6 UK CBM 2012, pg 6

7 NIMR is scheduled to move to the Crick Institute, located on Euston Road, London NW1 2BE upon completion of the new facilities.

8 Medical Research Council (2010) “National Institute for Medical Research “Funding”” <http://www.nimr.mrc.ac.uk/about/funding/>

9 See BBSRC, “Introducing The Pirbright Institute” [http://www.bbsrc.ac.uk/news/policy/2012/121004-pr-introducing-the-pir-](http://www.bbsrc.ac.uk/news/policy/2012/121004-pr-introducing-the-pir-bright-institute.aspx)

[bright-institute.aspx](http://www.bbsrc.ac.uk/news/policy/2012/121004-pr-introducing-the-pir-bright-institute.aspx)

10 The Pirbright Institute, “Scope of Research” <http://pirbright.ac.uk/ISPG/Default.aspx>

11 The Pirbright Institute is the process of expanding their facilities to include a new CL4 building. Personal Correspondence, 14th November 2012.

12 DEFRA (2011) “Veterinary Laboratories Agency Annual Report and Accounts 2010-2011” [http://vla.defra.gov.uk/reports/docs/rep\\_accounts1011.pdf](http://vla.defra.gov.uk/reports/docs/rep_accounts1011.pdf)

13 Merial (2011) “Our Company” [http://uk.merial.com/corporate\\_content/our\\_company/index.asp](http://uk.merial.com/corporate_content/our_company/index.asp)

14 House of Commons (2008) “Memorandum 5 - Submission from Merial Animal Health”, Select Committee on Innovation, Universities, Science and Skills Written Evidence <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmdius/360/360we06.htm>

Elsewhere, the ISI Web of Science database suggests there have been a small number of publications related to Smallpox emerging from UK academic institutions. These draw from a diverse range of disciplinary groupings, including immunology, medical ethics, history of social science and statistics.<sup>39</sup> There is however no evidence of research using the virus *per se* and there are no smallpox stockpiles located in the United Kingdom. In 2011, the Parliamentary Under-Secretary of State for the Department of Health stated the “likelihood of smallpox re-emerging is considered to be low, but the impact upon public health of such an event is assessed as potentially severe... For this reason, the United Kingdom has contingency arrangements in place to protect it against this potential threat”.<sup>40</sup> In 2012, the Parliamentary Under-Secretary of State for the Department of Health indicated “The department’s smallpox policy is currently under review”.<sup>41</sup>

## Vaccine production

The UK is host to a number of pharmaceutical companies, in some cases with several branches or facilities around the country serving different purposes from marketing to manufacturing. Facilities specific to vaccine production are licensed by the Medicines and Healthcare products Regulatory Agency (MHRA), which publishes a Register of Licensed Manufacturing Sites (Human and Veterinary Sites).<sup>42</sup> In the 2012 edition

39 ISI web of science search, further data available from the author.

40 UK Parliament (2010) “*Written Answers*”, Hansard, 16 May 2011  
<http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/110516w0001.htm#1105161000427>

41 UK Parliament (2012) “*House of Lords Summer Recess 2012 Written Answers and Statements*”, Hansard, 31st July 2012, <http://www.publications.parliament.uk/pa/ld201212/ldhansrd/text/120125w0001.htmf>

42 Medicines and Healthcare products Regulatory Agency (2012) “Register of Licensed Manufacturing Sites (Human and Veteri-

of the register, there a small number of facilities stated as being licensed to produce vaccines for the protection of humans. However, correspondents with representatives of these companies and a review of company websites identified indicate that only three companies are actually involved in the production of human vaccines with other companies involved in vaccine development.<sup>43</sup> For example, the Nottingham based Archimedes Development Ltd, is involved in a European Commission FP7 project on the development of an Intranasal Pandemic Influenza Vaccine.<sup>44</sup>

In addition to which a number of private facilities operate in the UK licensed to work the “filling of vaccines”<sup>45</sup> and the manufacture of, *inter alia*, active pharmaceutical ingredients.

## Outbreaks of particularly dangerous diseases

With regard to outbreaks of particularly dangerous diseases, the following data is based on a review of the official data provided in the *Statutory Notifications of Infectious Diseases* in England and Wales, Health Protection Scotland and Public Health Agency

nary Sites)”, Sept 2012 <http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf>

43 Excluding those companies involved in the “filling of vaccines” listed in the MHRA register, eight companies are licensed to manufacture “other biological medicinal products vaccines...”. Of these eight companies, personal correspondence with three companies independently confirmed that they did not currently manufacture vaccines; whereas a review of the available material and product lists on two remaining company websites suggested that they were not actually involved in vaccine production; rather they variously worked on pain management for cancer patients or drug transportation, logistics and storage.

44 European Commission (2012) “*NASSPANVAC Vaccines and Correlates of Protection*”, [http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/182\\_en.html](http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/182_en.html)

45 A number of facilities are licensed for the “filling of vaccines” all of which are identified in the MHRA report, see: *Ibid*

**Figure 7. Licensed manufacturing sites for human vaccines<sup>1</sup>**

Name	Address	Vaccines or License
Health Protection Agency	Porton Down, Salisbury, Wiltshire, SP4 0JG	<ul style="list-style-type: none"> <li>• “The HPA is the sole manufacturer of the UK’s licensed anthrax vaccine.”<sup>2</sup></li> </ul>
MedImmune UK Ltd.	Plot 6 Renaissance Way, Boulevard Industry Park, Speke, Liverpool, L24 9JW	<ul style="list-style-type: none"> <li>• Influenza Vaccine Live<sup>3</sup>, “The egg-based process can produce up to 50 million monovalent vaccine doses per 12-month cycle”<sup>4</sup></li> </ul>
Novartis Vaccines and Diagnostics Limited.	Gaskill Road, Speke, Liverpool, L24 9GR	<ul style="list-style-type: none"> <li>• Bulk manufacture of Influenza vaccine;</li> <li>• Vaccines for meningococcus A, C, W and Y, rabies, Japanese encephalitis, typhoid and diphtheria.<sup>5</sup></li> </ul>

- 1 All information derived from the Medicines and Healthcare products Regulatory Agency (2012) “Register of Licensed Manufacturing Sites (Human and Veterinary Sites)”, Sept 2012 <http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf> and UK CBM return 2011
- 2 HPA (2011) “Anthrax Vaccine”, Biopharmaceutical Manufacturing Capabilities <http://www.hpa.org.uk/ProductsServices/>

- 3 MedImmune (2011) “MedImmune Facilities” [http://www.medimmune.com/about\\_us\\_facilities.aspx](http://www.medimmune.com/about_us_facilities.aspx)
- 4 *Ibid*
- 5 Novartis UK (2011) “Novartis Vaccines and Diagnostics” [http://www.novartis.co.uk/our\\_business/vaccines\\_and\\_diagnostics.shtml](http://www.novartis.co.uk/our_business/vaccines_and_diagnostics.shtml)

(Northern Ireland) in additional Health Protection Agency information between 2007 and 2011.

## Suspicious outbreaks of disease

There have been a small number of outbreaks of infectious diseases that appear to deviate from the normal pattern. Over the course of 2010, heroin laced with anthrax caused 47 cases of so called ‘injectional’ anthrax<sup>46</sup> resulting in 13 reported deaths in Scotland;<sup>47</sup>

46 The term ‘injectional’ is specifically used in some texts see, for example, Ramsay. C. N (2010) “An outbreak of infection with *Bacillus anthracis* in injecting drug users in Scotland” *Euro-surveillance*, Volume 15, Issue 2, 14 January 2010 and C N Holta Ringertz “Injectional anthrax in a heroin skin-popper” *The Lancet*, Volume 356, Issue 9241, Pages 1574 - 1575, 4 November 2000.

47 <http://www.scotland.gov.uk/Publications/2010/07/30140320/3>

and a further five cases and four deaths in England.<sup>48</sup> More recently in 2012, similar outbreaks have also occurred in Germany, Denmark and France, and again in England and Scotland.<sup>49</sup> Whilst generating some alarm, a 2012 article in the *Journal of Emerging Infectious Diseases* concluded that this was caused by accidental contamination:

*“Phylogeographic analysis demonstrated that Ba4599 ...[the strain of anthrax]... was*

48 HPA Anthrax: information for drug users and drug workers <http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutolist-Name/Page/1265637163487>; BBC (2010) “‘Anthrax heroin’ kills drug user in Kent” <http://www.bbc.co.uk/news/uk-england-kent-11685984>; see also Booth, MG et al (2010) “Anthrax infection in drug users”, *The Lancet*, Volume: 375, Issue: 9723, 1345-1346.

49 Health Protectin Scotland (2012) “Anthrax cases among drug users in Europe - update”, <http://www.documents.hps.scot.nhs.uk/ewr/pdf2012/1237.pdf>

**Figure 8. Outbreaks of particularly dangerous diseases in the UK 2007-2011**

	2007 <sup>1</sup>	2008 <sup>2</sup>	2009 <sup>3</sup>	2010	2011
Anthrax	0	1	1	52 <sup>4</sup>	0
Botulism <sup>5</sup>	0	0	0	2 <sup>6</sup>	0
Plague	0	0	0	0	0
Smallpox	0	0	0	0	0
Tularemia	0	0	0	0	0
Viral Hemorrhagic Fevers	1	3	5	3	3 <sup>7</sup>

- 1 HPA Centre for Infections IM&T Dept (2008) “*Final Midi Report For 2007*”, [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1223622641711](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1223622641711) see also HPA (2011) “Foodborne Botulism Laboratory reported cases of Clostridium botulinum intoxication reported to the Health Protection Agency Centre for Infections England and Wales 1980 - 2010”, <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/EpidemiologicalData/botu010FoodborneBotulismLaboratoryreportedcases/>
- 2 HPA Centre for Infections IM&T Dept (2009) “*Final Midi Report For 2008*”, [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1253205364859](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1253205364859)
- 3 Public health Agency [Northern Ireland] (2011) “Notifications of Infectious Diseases”, <http://www.publichealthagency.org/directorate-public-health/health-protection/notifications-infectious-diseases> and HPA Centre for Infections IM&T Dept (2010) “*Final Midi Report For 2009*”, [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1281952671504](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1281952671504)
- 4 HPA has confirmed that there were 5 Cases of anthrax in heroin users in England in 2010 in addition to which there were 47 confirmed cases in Scotland by the 23 December 2010 making a total of 52 cases in 2010. Notably this differs slightly with the CBM return as a result of 5 UK cases being confirmed since the submission in Mar. See Health Protection Scotland <http://www.hps.scot.nhs.uk/anthrax/index.aspx> <http://>

- 5 There have been a small number of cases of infant botulism recorded in 2009 & 2010 and a larger number of cases of “Wound botulism cases in injecting drug users (IDUs)” including a recorded 22 cases in 2009, 4 cases in 2008 and 3 cases in 2007 in England and Wales. Both infant botulism and wound botulism are excluded from these figures, although more details are available from the HPA (2011) “*Botulism*” <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/> and HPA “*Wound botulism cases in injecting drug users (IDUs)*” <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/GeneralInformation/botu020Woundbotulismcasesininjectingdrugusers/>
- 6 See Statutory Notifications of Infectious Diseases in England and Wales Weeks 2010/14 and 2010/15 <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/NotificationsOfInfectiousDiseases/NOIDSReportsAndTables/NoidsPreviousNOIDSReports/Noids2010NOIDSReports/>
- 7 HPA (2012) “*Statutory Notifications of Infectious Diseases (Noids) England and Wales - Annual totals for diseases notifiable under Health protection (Notification) regulations 2010*”, [http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\\_C/1251473364307](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1251473364307)

*closely related to strains from Turkey and not to previously identified isolates from Scotland or Afghanistan, the presumed origin of the heroin. Our results suggest accidental contamination along the drug trafficking route through a cutting agent or animal hides used to smuggle heroin into Europe.*<sup>50</sup>

There have also been a small number of outbreaks of Viral Hemorrhagic Fevers, such as Lassa Fever, which have been brought into the country by infected travellers.<sup>51</sup>

## Allegations and hoaxes

Over the course of the last decade there have been a small number of bioterrorist threats and cases of individuals or groups producing small quantities of agents. Recent examples include:

- The arrest and imprisonment of a South African businessperson, Brian Roach, for threatening to release foot and mouth disease in Britain and the United States. It is unclear whether he had the capacity to carry out the threat.<sup>52</sup>
- The imprisonment in 2010, of Ian Davison of the White Supremacist group, the Aryan Strike

50 “Molecular Epidemiologic Investigation of an Anthrax Outbreak among Heroin Users, Europe” <http://wwwnc.cdc.gov/eid/article/18/8/pdfs/11-1343.pdf>

51 HPA (2010) “Table of Imported Confirmed Lassa Fever Cases in UK Since 1970” <http://www.hpa.org.uk/Topics/InfectiousDiseases/Infection-sAZ/LassaFever/GeneralInformation/lassa005HistoricalTableImportedConfirmedLassaCases/>

52 See <http://www.dailymail.co.uk/news/article-1356766/Man-threatened-biological-weapons-attack-Britain-U-S-arrested.html> and [http://gsn.nti.org/siteservices/print\\_friendly.php?ID=nw\\_20110214\\_7233](http://gsn.nti.org/siteservices/print_friendly.php?ID=nw_20110214_7233) and <http://www.bbc.co.uk/news/world-africa-13894432> and <http://www.thisislondon.co.uk/standard/article-23922816-man-held-over-bio-weapon-threat.do>

Force, who was jailed along with three others - including his son - in 2010 for producing small quantities of Ricin.<sup>53</sup>

Following the ‘Amerithrax’ incident, there have also been a number of hoax letters containing suspicious white powders being distributed to individuals and organisations, including, *inter alia*, then Communities Minister, Shahid Malik,<sup>54</sup> Prince William, Cherie Blair<sup>55</sup> and personnel of the company Barrett Homes.<sup>56</sup> In one recent case, a woman claiming to be a nun was “found guilty of six counts of hoaxes involving noxious substances” after sending senior politicians, including Deputy Prime Minister Nick Clegg, envelopes containing white powders.<sup>57</sup>

## National legislation and regulations

The UK has a number of regulatory and legislative measures designed to prohibit and prevent the development, production, and stockpiling of biological

53 The Telegraph (2010) “White supremacist who manufactured ricin jailed” <http://www.telegraph.co.uk/news/uknews/crime/7724848/White-supremacist-who-manufactured-ricin-jailed.html>; The Guardian (2010) “Neo-Nazi Ian Davison jailed for 10 years for making chemical weapon” <http://www.guardian.co.uk/uk/2010/may/14/neo-nazi-ian-davison-jailed-chemical-weapon>; BBC (2010) “County Durham terror plot father and son are jailed”, <http://news.bbc.co.uk/1/hi/8682132.stm>

54 <http://www.guardian.co.uk/politics/2009/dec/30/shahid-malik-white-powder-anthrax> and <http://www.thepressnews.co.uk/NewsDetails.asp?id=4207> and <http://www.telegraph.co.uk/news/uknews/terrorism-in-the-uk/6912953/Anthrax-scare-at-House-of-Commons.html>

55 See *inter alia*: The News Letter (Belfast, Northern Ireland) November 1, 2003; The Mirror (London, England) September 6, 2003; Daily Mail (London) February 6, 2004

56 Press and Journal, The Aberdeen (UK) August 16, 2006; Andy Philip; The Scotsman; August 16, 2006;

57 Rinne. L (2012) ‘Nun’ sentenced over envelopes containing white powder that were sent to Nick Clegg”, The Independent, Friday 16 November 2012.

weapons that cover human, animal and plant agents. Many of these measures date back to the 1970s, however, concerns over genetic engineering and later, concerns about bioterrorism in the post 9-11, post Anthrax Letter Attacks, have ensured that a number of new measures have been applied and old measures updated to ensure a comprehensive legislative and regulatory landscape in the UK. The key legislative measures include the Biological Weapons Act 1974, which applies to all United Kingdom persons, including bodies corporate, and prohibits “the development, production, acquisition and possession of certain biological agents and toxins and of biological weapons”;<sup>58</sup> and the Anti-terrorism, Crime and Security Act (ATCSA) 2001.<sup>59</sup> Part 7 of ACTSA is designed to secure potentially dangerous agents from hostile exploitation and provides, *inter alia*, “the police with powers to require security measures at laboratories in the UK that hold specified pathogens and toxins”;<sup>60</sup> the Act was extended in 2007 to cover some animal pathogens<sup>61</sup> and revised October 2012 to remove M tuberculosis and add SARS to the list of regulated human pathogens.<sup>62</sup>

The UK has implemented additional measures to fulfil the implementation of Articles III and IV of the BWC. In terms of the implementation of Article III, a number

of measures were applied in the mid-nineties,<sup>63</sup> and export controls were updated more recently through the Export Control Act of 2002 (and the subsequent secondary legislation made under this Act<sup>64</sup>), which includes catch-all controls, end-user certification and, notably, mechanisms to regulate intangible technology transfer.<sup>65</sup> Other regulatory and legislative measures developed in the UK include the Academic Technology Approval Scheme (ATAS), which requires certification for postgraduate study in certain disciplines;<sup>66</sup> and measures to manage health, safety and environmental issues, principally the Control of Substances Hazardous to Health Regulations (COSHH) 2002,<sup>67</sup> which places an obligation on employers “to control substances that can harm workers’ health”.<sup>68</sup> Finally, the Genetically Modified Organisms (Contained Use) Regulations<sup>69</sup> makes provisions for the protection of both workers and the environment in activities related to GMOs, including genetically modified influenza and synthetic biology.

58 Biological Weapons Act 1974 <http://www.legislation.gov.uk/ukpga/1974/6/contents>

59 Anti-terrorism, Crime and Security Act 2001 <http://www.publications.parliament.uk/pa/cm200102/cmbills/049/2002049.pdf>

60 United Kingdom (2008) “Implementation of the UK Anti-terrorism Crime and Security Act (ATCSA) 2001: Biosecurity Aspects“, BWC/MSP/2008/MX/WP.6.

61 The Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007 <http://www.legislation.gov.uk/uksi/2007/926/made>

62 Personal Correspondence, 14<sup>th</sup> November 2012.

63 Including the Export of Goods Order (1994), The Dual-Use and Related Goods (Export Control) Regulations 1996, the Plant Health (Great Britain) Order 1993 See <http://www.vertic.org/pages/homepage/databases/bwc-legislation-database/u.php>

64 Such as the “Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003”

65 See United Kingdom (2003) “Legislation Governing Intangible Technology“, BWC/MSP.2003/MX/WP.65 and United Kingdom (2003) “Two issues in BTWC national implementation: the challenge of intangible technology controls and export licensing enforcement“, BWC/MSP/2007/MX/WP.2

66 FCO “Academic Technology Approval Scheme (ATAS)” <http://www.fco.gov.uk/en/about-us/what-we-do/services-we-deliver/atas/>

67 [http://www.vertic.org/media/National\\_Legislation/United\\_Kingdom/GB\\_Control\\_Substances\\_Hazardous\\_Regulations\\_2002.pdf](http://www.vertic.org/media/National_Legislation/United_Kingdom/GB_Control_Substances_Hazardous_Regulations_2002.pdf)

68 <http://www.hse.gov.uk/coshh/>

69 The Genetically Modified Organisms (Contained Use) Regulations 2000, [http://www.legislation.gov.uk/uksi/2000/2831/pdfs/uksi\\_20002831\\_en.pdf](http://www.legislation.gov.uk/uksi/2000/2831/pdfs/uksi_20002831_en.pdf)

## Codes of conduct, education and awareness raising

In terms of codes, education and awareness raising, as part of a more recent initiative, “the Home Office has a programme of work looking at the protective security of biological agents. This programme is identifying options for increasing the awareness and importance of dual use and/bio-security related issues within the academic community”.<sup>70</sup> Prior to the initiation of this programme, the UK had made modest progress through hosting a small number of seminars with scientists. However, in a working paper submitted to the Seventh Review Conference the UK noted, “there are still considerable difficulties in convincing some members of the academic community that oversight and awareness in the context of the Biological and Toxin Weapons Convention (BTWC) and Chemical Weapons Convention (CWC) are issues deserving attention and action.”<sup>71</sup> Nonetheless, a small number of Universities include discussion on security topics as part of life science related degrees and certainly one study from 2009 reported there were “four discernible references to dual-use ...[and]... six degree courses ... made some form of reference to biological warfare and/or biological weapons [although] the context and framing of discussions varied”.<sup>72</sup> Furthermore, since

2005, major funders of scientific research in the UK now obligate applicants to take dual use issues into consideration when submitting funding proposals although it is unclear how effective this tick box approach has been.<sup>73</sup>

Support for some form of code and aspects of educational provision have emerged from the Royal Society, most notably in the Royal Society’s brainwaves reports, number three of which recommends a “fresh effort by the appropriate professional bodies to inculcate the awareness of the dual-use challenge ... amongst neuroscientists at an early stage of their training.”<sup>74</sup> There has also been a concerted effort by UK academic institutions to promote dual use education for life scientists, particularly through the work of the University of Bradford’s Dual-Use Bioethics project,<sup>75</sup> which has been working with life scientists around the world on issues related to dual use.<sup>76</sup> Yet despite some evidence of progress in the UK activity has been limited, and dual use and/biosecurity related issues

70 Official Correspondence, 14<sup>th</sup> November 2012.

71 Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the “JACKSNNZ” ), and Kenya, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America (2011) “Possible approaches to education and awareness-raising among life scientists”, BWC/CONF.VII/WP.20/Rev.1.

72 Revill. J (2009) Biosecurity and Bioethics Education: A Case Study of the UK Context. “ Research Report for the Wellcome Trust Project on ‘Building a Sustainable Capacity in Dual-use Bioethics’. [http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/docs/UK\\_Biosecurity\\_and\\_Bioethics\\_SurveyLVA.pdf](http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/docs/UK_Biosecurity_and_Bioethics_SurveyLVA.pdf)

73 BBSRC, MRC and Wellcome Trust (2005) “Managing risks of misuse associated with grant funding activities A joint BBSRC, MRC and Wellcome Trust policy statement”, [http://www.bbsrc.ac.uk/organisation/policies/position/public\\_interest/misuse\\_of\\_research\\_joint.pdf](http://www.bbsrc.ac.uk/organisation/policies/position/public_interest/misuse_of_research_joint.pdf)

74 See RS-IAP-ICSU International workshop on science and technology developments relevant to the. Biological and Toxin Weapons Convention <http://royalsociety.org/The-roles-of-codes-of-conduct-in-preventing-the-misuse-of-scientific-research-/>

75 See University of Bradford “Dual-Use Bioethics” <http://www.dual-usebioethics.net/>

76 See BWC/CONF.VII/WP.20 <http://daccess-ods.un.org/access.nsf/Get?Open&DS=BWC/CONF.VII/WP.20&Lang=E>

continue to be considered irrelevant or less relevant by many life science educators and researchers.<sup>77</sup>

## CBM participation

The UK is one of a small number of countries that have regularly submitted CBMs,<sup>78</sup> and was one of the first countries to make its CBMs publicly available firstly through the FCO website beginning in 2003<sup>79</sup> and later, in 2006, through the UNOG BTWC website.<sup>80</sup> The UK has further encouraged more states to submit CBMs and, in a 2011 paper, proposed making CBMs part of an annual agenda item addressed by intersessional task group. Such a group, it was suggested, would look at inter alia, “additional ways of strengthening the CBM regime; to review the CBM process, including levels of annual returns and their quality; and to address any ambiguities and uncertainties in CBM submissions.”<sup>81</sup>

77 Rappert. B, Chevrier. M & Dando. M (2006) *In-Depth Implementation of the BTWC: Education and Outreach, Bradford Review Conference Papers*, No.18, Bradford Project on Strengthening the Biological and Toxin Weapons Convention (BTWC), November 2006. [http://www.brad.ac.uk/acad/sbtwc/briefing/RCP\\_18.pdf](http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_18.pdf) Mancini. G & Revill. J (2008) “*Fostering the biosecurity norm: biosecurity education for the next generation of life scientists*” Research Report of the joint project between Landau Network-Centro Volta and Bradford Disarmament Research Centre. [http://www.centrovolta.it/landau/content/binary/LNCV%20-%20BDRC\\_Fostering%20Biosecurity%20Norm.pdf](http://www.centrovolta.it/landau/content/binary/LNCV%20-%20BDRC_Fostering%20Biosecurity%20Norm.pdf)

78 With the exception of 2001, when records indicate a gap; see “Participation in the BWC Confidence-Building Measures” [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/41BF-3B57E2CB6ED7C12572DD00361BA4/\\$file/CBM\\_Submissions\\_by\\_Form.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/41BF-3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf)

79 Hunger. I and Isla. N (2006) Confidence-building needs transparency: an analysis of the BTWC’s confidence-building measures, Disarmament Forum: Toward A Stronger BTWC, pg 30.

80 UNOG BTWC Meetings and Documents [http://www.unog.ch/80256EE600585943/\(httpPages\)/92CFF2CB73D4806DC-12572BC00319612?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC-12572BC00319612?OpenDocument)

81 United Kingdom (2011) “Illustrative Model Intersessional Work Programme: Task Group Structure and Agenda Items: A UK Proposal”, BWC/CONF.VII/WP.2, 11 October 2011 11 October 2011

## Participation in BWC meetings

The UK has been an active participant in BWC meetings and a UK delegation has been present at every BWC meeting since the Convention entered into force in 1975. The UK has also been active in the production of working papers and background documentation, having produced -independently or with other states- some 51 working papers over the course of the Ad Hoc Group; 20 working papers over the course of the first intersessional process and a further 11 working papers during the intersessional meetings between 2007 and 2010.<sup>82</sup> In preparation for the Seventh Review Conference, the UK co-authored a joint paper on *Possible approaches to education and awareness-raising among life scientists* with a collective other States Parties as well as submitting three independent working papers:

- “Article VII: Options for implementation and proposals for intersessional work” BWC/CONF.VII/WP.1<sup>83</sup>
- “Illustrative model intersessional work programme: a proposal for task group structure and agenda items”;<sup>84</sup> and
- “Decision-making in a future BTWC intersessional work programme”;<sup>85</sup>

In addition, the UK has produced detailed contributions to background documents required for the Review

82 *Ibid*

83 United Kingdom (2011) “Article VII: options for implementation and proposal for intersessional work”, BWC/CONF.VII/WP.1, 11 October 2011

84 United Kingdom (2011) “Illustrative Model Intersessional Work Programme: Task Group Structure and Agenda Items: A UK Proposal”, BWC/CONF.VII/WP.2, 11 October 2011 11 October 2011

85 United Kingdom (2011) “Decision-making in a future BTWC intersessional work Programme” BWC/CONF.VII/WP.10, 14 October 2011

**Figure 9. UK participation in BWC meetings**

Meeting	RevCon 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PrepCom 2011	RevCon 2012
Number of delegates	8	6	6	9	9	12	11	12	8	8	18

Conference. These have included firstly, an article-by-article report of the UK's compliance with the provisions<sup>86</sup> of the Convention submitted as part of the background document on Compliance. Secondly, a summary of the diverse range of "activities and programmes" of relevant to Article X. This paper included an overview of the work conducted through the Department for International Development (DFID) and various other UK organisations, as well as an account of other international collaborative projects of relevance to the Convention and was intended to contribute to the background document on Article X. The third paper provided an overview of salient developments in science and technology and highlighted specific topics that could potentially be addressed in the future.

## Past bioweapons development and use, and accusations of bioweapons development and use

Since the BWC entered into force there have been no official allegations made against the UK regarding the development or use of biological weapons. However, as is the case with a number of other states, there have been a small number of unofficial allegations of the use of biological agents in conflict, most recently

<sup>86</sup> This excludes Article X which is dealt with in a separate document.

from Afghan farmers who have suggested British and US forces used biological agent to cause leaf blight affecting opium poppies in order "to hamper the opium production and trade that is essential for the continued Taliban insurgency in the region".<sup>87</sup> The UK's offensive bioweapons programme is well documented as having concluded in the late 1950s<sup>88</sup> and such unofficial allegations remain unsubstantiated.

<sup>87</sup> See SIPRI Yearbook 2010. Pg 403

<sup>88</sup> Carter, G. B., and Graham S Pearson (1999) "British biological warfare and biological defence, 1925-45", *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*. E. Geissler and J. E. v. C. Moon. Oxford, Oxford University Press for SIPRI: pp 168-189.

## Country report: United States of America

### 1972 Biological Weapons Convention <sup>1</sup>

Signed: 10 April 1972

Deposit of ratification: 26 March 1975

### 1925 Geneva Protocol <sup>2</sup>

Signed: 17 June 1925

Deposit of ratification: 10 April 1975

The US retains a reservation to the Geneva Protocol: 'That the said Protocol shall cease to be binding on the Government of the United States with respect to the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials, or devices, in regard to an enemy State if such State or any of its allies fails to respect the prohibitions laid down in the Protocol'.<sup>3</sup>

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<sup>1</sup> See <http://disarmament.un.org/treatystatus.nsf>

<sup>2</sup> *Ibid.*

<sup>3</sup> *Ibid.*

Regarding its own compliance with the BWC, the USA stated in August 2012: 'All U.S. activities during the reporting period were consistent with the obligations set forth in the BWC. The United States continues to work towards full transparency of biological defence work using the BWC confidence-building measures.'<sup>1</sup>

In 1969, the US National Security Council issued National Security Decision Memorandum 35, which changed US biological weapons policy. The decision stated:

With respect to Bacteriological/Biological programs:

- a. The United States will renounce the use of lethal methods of bacteriological/biological warfare.
- b. The United States will similarly renounce the use of all other methods of bacteriological/biological warfare (for example, incapacitating agents).
- c. The United States bacteriological/biological programs will be confined to research and development for defensive purposes

<sup>1</sup> US Department of State, Adherence to and Compliance With Arms Control, Nonproliferation, and Disarmament Agreements and Commitments, August 2012, <http://www.state.gov/documents/organization/197295.pdf>.

(immunization, safety measures, et cetera). This does not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required.<sup>2</sup>

In the 2009 *National Strategy for Countering Biological Threats*, the US reaffirmed its obligations under the BWC:

[W]e will advance and reinforce as a norm for the safe and beneficial use of the life sciences the exhortation of the BWC that their use as weapons would be 'repugnant to the conscience of mankind'.<sup>3</sup>

Under Secretary of State Ellen Tauscher, in her 2009 address to States Parties of the BWC, reiterated the Bush administration policy that the US does not intend to return to negotiations on a protocol to the treaty:

The Obama Administration will not seek to revive negotiations on a verification protocol to the Convention. We . . . have determined that a legally binding protocol would not achieve meaningful verification or greater security . . . Instead, we believe that confidence in BWC compliance should be promoted by enhanced transparency about activities and pursuing compliance diplomacy to address concerns.<sup>4</sup>

2 National Security Decision Memorandum 35, Washington, November 25, 1969. Foreign Relations of the United States, 1969-1976. Volume E-2, Documents on Arms Control and Non-proliferation, 1969-1972, Document 165. US Department of State, Office of the Historian. <http://history.state.gov/historicaldocuments/frus1969-76ve02/d165>.

3 See [http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf), p. 8.

4 See <http://geneva.usmission.gov/2009/12/09/tauscher-bwc/>

More recently, US Ambassador Laura Kennedy underlined the importance of the BWC in her statement to the April 2011 BWC Review Conference Preparatory Committee meeting:

The BWC provides the premier forum for members of the security, health, scientific and law enforcement communities to come together to better understand and address biological threats.<sup>5</sup>

In December 2011, Secretary of State Hillary Clinton maintained the 2009 position of the Obama administration, noting in her opening remarks to the Seventh Review Conference of the States Parties to the Biological Weapons Convention:

...we need to bolster international confidence that all countries are living up to our obligations under the Convention. It is not possible, in our opinion, to create a verification regime that will achieve this goal. But we must take other steps.

She went on to emphasize the importance of transparency and streamlining the reporting mechanisms to insure that the information shared through the BWC and other forums be as relevant and efficient as possible.<sup>6</sup>

The US government is concerned about the threat of biological attacks from States Parties, and from substate actors or terrorists, whether they are independent or sponsored by states In the cover letter to the 2009 *National Strategy for Countering Biological Threats*, US President Barack Obama highlighted the need to reduce the threats of

5 See [http://www.unog.ch/80256EDD006B8954/%28httpAs-sets%29/9F98E6515ACD48A7C12578770046DFD8/\\$file/BWC-7RC-PC-Statement-110413-USA.pdf](http://www.unog.ch/80256EDD006B8954/%28httpAs-sets%29/9F98E6515ACD48A7C12578770046DFD8/$file/BWC-7RC-PC-Statement-110413-USA.pdf)

6 See <http://www.state.gov/secretary/rm/2011/12/178409.htm>

## bioterrorism and natural disease outbreaks:

Advances within the life sciences hold extraordinary potential for beneficial progress, but they also can empower those who would use biological agents for ill purpose. Economic, political, and religious forces have given rise to a form of fanaticism that seeks to harm free societies. We know that some of these fanatics have expressed interest in developing and using biological weapons against us and our allies. Addressing these unique challenges requires a comprehensive approach that recognizes the importance of reducing threats from outbreaks of infectious disease whether natural, accidental, or deliberate in nature.<sup>7</sup>

## Countering bioterrorism also is a subject of the 2010 'National Security Strategy':

The effective dissemination of a lethal biological agent within a population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, societal, and political consequences. We must continue to work at home with first responders and health officials to reduce the risk associated with unintentional or deliberate outbreaks of infectious disease and to strengthen our resilience across the spectrum of high-consequence biological threats.<sup>8</sup>

Each year the US State Department submits a report to Congress on Adherence to and Compliance with Arms Control agreements. In August 2012, the section of the report devoted to the BWC, the report contains assessments of five countries that are party

to the BWC: China, Iran, North Korea, Pakistan and the Russian Federation. The report also discusses Egypt and Syria, signatories to the BWC that have never ratified the Convention. Each assessment includes three sections, a finding, background and a statement of compliance discussions. The findings for the seven States Parties are as follows:

**China:** Available information indicates China engaged during the reporting period in biological activities with potential dual-use applications; however, the information did not establish that China is engaged in activities prohibited by the BWC.

**Egypt:** During the reporting period, available information did not indicate that Egypt is engaged in activities prohibited to States Parties by the BWC. Egypt is a signatory and not a State Party to the BWC.

**Iran:** Available information indicated Iran continued during the reporting period to engage in activities with potential dual-use BW applications. It remained unclear whether any of these activities were prohibited by the BWC.

**North Korea:** The United States judges that North Korea may still consider the use of biological weapons as an option, contrary to the BWC. North Korea continues to develop its biological research and development capabilities, but has yet to declare any relevant developments as part of the BWC confidence-building measures.

**Pakistan:** Information available through the end of 2011 did not indicate Pakistan is engaged in activities prohibited by the BWC. Pakistan continued during the reporting period to work to improve its biological weapons-related export controls. As of the end of 2011, it had yet to submit an annual confidence-building measure (CBM) declaration.

7 See [http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf)

8 See [http://www.whitehouse.gov/sites/default/files/rss\\_view/national\\_security\\_strategy.pdf](http://www.whitehouse.gov/sites/default/files/rss_view/national_security_strategy.pdf)

**Russian Federation:** Available information during the reporting period indicated Russian entities have remained engaged in dual-use, biological activities. It is unclear that these activities were conducted for purposes inconsistent with the BWC. It also remains unclear whether Russia has fulfilled its BWC obligations in regard to the items specified in Article I of the Convention that it inherited.

**Syria:** Based on information available during the reporting period, the United States is concerned that Syria, a signatory to the BWC, may be engaged in activities that would violate its obligations under the BWC if it were a State Party to the Convention.

Under the sections on Compliance Discussions the report noted that the US discussed the compliance of Iran, North Korea and Syrian with other countries. Regarding Pakistan the report stated that the US and Pakistan continued to “collaborate on improving Pakistan’s BW-related export controls.” Also in these sections the report included statements from the countries under discussion such as the following regarding Iran, “In December 2011, senior Iranian officials publicly renounced the development, production, acquisition and stockpiling of any weapons of mass destruction, including biological and toxin weapons.”

Following Syria’s admission that it possesses a substantial biological and chemical weapons program in July 2012, President Obama announced that the use of such weapons would constitute a “red line for us.” While he stopped short of declaring that Syrian WMD use would automatically prompt US military intervention, it would certainly open the possibility of American action in the ongoing violence, which he has so far opposed. Syrian use of biological or

chemical weapons, and the possibility of hostile non-state actors acquiring such weapons, would change that calculus:

That’s an issue that doesn’t just concern Syria. It concerns our close allies in the region, including Israel. It concerns us...We cannot have a situation where chemical or biological weapons are falling into the hands of the wrong people.<sup>9</sup>

### US Participation in the Seventh Review Conference

The Seventh Review Conference of the BWC took place in from the 5<sup>th</sup> to the 22<sup>nd</sup> of December 2011. The US contributed one working paper, making proposals for the yearly meetings of experts and states parties, known as the intersessional process. While acknowledging the success of the process which began in 2003, the US called for improvements in the process. The paper called for a more ambitious agenda, including “efforts to enhance confidence in effective implementation and compliance, efforts to counter the threat of bioterrorism, efforts to monitor and respond appropriately to developments in science and technology, and efforts to increase both national and international preparedness to detect and respond to sudden outbreaks of infectious disease.”<sup>10</sup> The working paper also called for the process to be more

9 Klapper, Bradley. “Obama warns Syria of ‘enormous consequences’ over use of chemical, biological weapons,” *The Star*, <http://www.thestar.com/news/world/article/1244323--obama-warns-syria-over-chemical-biological-weapons-russia-warns-west>

10 United States of America, Seventh Review Conference 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, “The next intersessional process.” BWC/CONF.VII/wp.23. <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/645/72/PDF/G1164572.pdf?OpenElement>

interactive and results-oriented, recommending that the process be able to “develop specific recommendations, guidelines or best practices to assist and support States Parties and, where practical, establish metrics to document progress.” The US proposed the following topics for the intersessional process: 1) Global health/security to include “action on international cooperation and assistance in detecting, reporting, and responding to outbreaks of disease or biological weapons attacks...” 2) Strengthening implementation of the BWC through “improved transparency,... strengthening the BWC Confidence Building regime,... and options for addressing doubts and ambiguities in accordance with Article V of the Convention...” 3) Science and technology: including, “Identify best practices for supporting the ongoing development of the culture of responsibility, and related oversight mechanisms, within the life sciences community, including the area of education.” The working paper proposed other details under each of these topics.

Tackling the structure for intersessional work the US working paper proposed multi-year working groups, a distinct role for the annual meeting of States Parties, (MSP) different from the meeting of experts. The paper called for 2 weeks of expert meetings in addition to a one-week MSP, the 2003-2005 schedule.

In addition to the working paper on the intersessional process, the US joined with 11 other countries on a Working Paper on “Possible approaches to education and awareness-raising among life scientists.”<sup>11</sup>

One of the agenda items of the Review Conference is to review new scientific and technological developments relevant to the Convention. The

US submitted a 10-page paper on the topic. The paper’s principal focus was on developments that alter or mitigate the biological threat. Developments that could alter the threat included, four broad categories 1) “Advances in manipulation of genetic material and microorganisms and in understanding of pathogenicity;” 2) “Advanced therapeutic delivery systems;” 3) Nanotechnology and chemically engineered nanoparticles, and 4) “Industrial application of biotechnology - disposable equipment.” The US paper contained a great deal of specific information that fell into these categories. Among the advances that could tend to mitigate the biological threat the US again provided four broad areas, with detailed information included under each: 1) Disease surveillance, sensor and detection technologies” 2) “Microbial forensics,” 3) “Medical countermeasures, and 4) “Export control and border security technologies. The US paper concluded with a section on other developments including: “Information technology and advanced computational systems,” Awareness-raising communication, confidence-building, and scientific conduct,” and “Improvements in biosafety and biosecurity practices.”<sup>12</sup>

### US Participation at the 2012 Meeting of Experts

The Seventh Review conference also set the agenda for the 2012 Meeting of Experts to include:

- Cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X;
- Review of developments in the field of science and technology related to the Convention;

11 <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/650/58/PDF/G1165058.pdf?OpenElement>.

12 <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/651/16/PDF/G1165116.pdf?OpenElement>.

- Strengthening national implementation...
- [and]...how to enable fuller participation in the Confidence-building Measures (CBMs)<sup>13</sup>

The Meeting took place from July 16<sup>th</sup> to July 20<sup>th</sup> of 2012, for which the United States submitted four papers directly related to these agenda items. The paper on promoting cooperation and assistance between States Parties, especially with regard to Article X, noted that many fields of concern to the BTWC fell more directly under the purview of other fora, and that the BWTC should respect the primacy of their jurisdiction. The paper urged comprehensive understanding, particularly via discussion of national implementation reports in order to identify and narrowly target areas of need. The paper emphasized the role of international encouragement and assistance in maintaining biosafety standards, achieving compliance with the 2005 International Health regulations, and promoting CBM submissions.<sup>14</sup>

Another paper focused specifically on challenges, benefits, and potential improvements of the CBM system. This paper identified the dual problem of CBMs as it currently stands thus “...fewer than half of all BTWC States Parties submit CBMs. All available evidence suggests that far fewer States Parties actually make use of the CBMs by reviewing the submissions of other States Parties.”<sup>15</sup> In order to combat these issues, the United States proposes further streamlining the information requests and facilitating electronic submission - both processes

13 See [http://www.unog.ch/\\_80256ee600585943.nsf/\(httpPages\)/26e4793f76daf81ec1257a87002c4700?OpenDocument&ExpandSection=1#\\_Section1](http://www.unog.ch/_80256ee600585943.nsf/(httpPages)/26e4793f76daf81ec1257a87002c4700?OpenDocument&ExpandSection=1#_Section1)

14 United States, “Cooperation and Assistance,” official document of the Meeting of Experts 2012, BWC/MSP/2012/MX/WP.3.

15 United States, “Confidence Building Measures,” official document of the Meeting of Experts 2012, BWC/MSP/2012/MX/WP.4.

begun by the Seventh Review Conference - with an eye to keeping the submissions pertinent while making the generation of CBMs an easier task for States Parties. The paper suggests the ISU should set up a network specifically to facilitate assistance between nations producing, translating, and otherwise working on CBMs. Lastly, it points out the value of academia in processing, analyzing, and improving the accessibility of the data made available in CBMs, and consequently urges the BTWC and States Parties to make CBMs publicly available as much as possible while commensurate with biosecurity concerns.<sup>16</sup>

The paper “National Implementation” focused most heavily on Articles III and IV, providing long lists of granular policy steps necessary to upholding them. The paper expresses approval for both a new “accountability framework” system and a bilateral peer review-style system (proposed by the Canadians and Swiss, and French, respectively), either separately or in conjunction with each other. The United States takes a clear stand on the purpose of any such system, stating:

It is thus essential that BTWC States Parties enhance their collective understanding of the state of implementation around the world. Constructive proposals have been advanced in this area in recent years, ranging from a BTWC implementation/legislation database to the Canadian/Swiss idea of an “accountability framework” and the French proposal for bilateral “peer review.” These ideas appear to have merit, and might even work well in concert. It must remain clear, however, that the purpose of such efforts is not punitive; rather, they are a means of reassuring States Parties that everyone’s security

16 Ibid.

needs are being met by their treaty partners, and of identifying gaps and needs, and developing means to redress them.<sup>17</sup>

“National Implementation” also points out the value of regional and subregional systems for maintaining and overseeing biosafety.<sup>18</sup>

Lastly, the United States’ submission “Developments in Science and Technology” highlights several “enabling technologies” that drive the pace of wide swathes of advancement and research, notably gene sequencing, gene synthesis, computational processing power (including innovations in distributed and crowd-sourced processing) and data storage and bandwidth for storing and accessing the wealth of shared biological data. Gene synthesis is further noted as posing the most risk for abuse, and therefore meriting attention when crafting Dual Use policy. All such policy should be specifically tailored to the risks and benefits of the activities involved, necessitating a thorough understanding of the technologies involved, even those from outside the life sciences. The paper welcomes the insights and advice of various academic societies, particularly in response to the recent H5N1 controversy (on which more later), and underscores the importance of education and awareness in order to handle evolving scientific obstacles, opportunities, and hazards most effectively.<sup>19</sup>

## Status of the life sciences and biotechnology industry

17 United States, “National Implementation,” official document of the Meeting of Experts 2012, BWC/MSP/2012/MX/WP.5.

18 Ibid.

19 United States, “Developments in Science and Technology,” official document of the Meeting of Experts 2012, BWC/MSP/2012/MX/WP.6.

According to BWPP’s 2011 global survey, the US is the world’s leading country in the field of the life sciences and biotechnology. Globally, the country ranks first in terms of publications and, together with Japan, first in terms of patents.<sup>20</sup>

According to Ernst & Young<sup>21</sup>, the US had 318 public biotechnology companies and 1,552 private companies in 2011, a small decline from 2010, when the US boast 320 public and 1,594 private biotechnology companies. This appears to be a fairly constant number of companies compared to 331 public and 1,475 private companies seven years ago in 2005<sup>22</sup>, but such an observation conceals the true picture. The biotechnology industry in the US grew considerably during the first half of that interval, peaking at 371 public companies and 1,754 private companies in 2008. At that time, the total number of public and private companies worldwide was 4,414,<sup>23</sup> indicating that the US was home to approximately 39 per cent of the world’s biotechnology companies. After the economic crisis of 2008, the number of biotechnology companies dropped sharply to their current levels and are currently holding steady.

20 Bioweapons Prevention Project (2011) *BioWeapons Monitor 2011*, <http://www.bwpp.org/documents/BWM%202011%20WEB.pdf>

21 Ernst & Young (2011) *Beyond Borders: Global Biotechnology Report 2011*, 25<sup>th</sup> anniversary edition, [http://www.ey.com/Publication/vwLUAssets/Beyond\\_borders\\_global\\_biotechnology\\_report\\_2011/\\$FILE/Beyond\\_borders\\_global\\_biotechnology\\_report\\_2011.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_global_biotechnology_report_2011/$FILE/Beyond_borders_global_biotechnology_report_2011.pdf)

22 Ernst & Young (2007) *Beyond Borders: Global Biotechnology Report 2011*, 21<sup>st</sup> edition, <http://www.successformula.ru/file.php/1/stuff/BeyondBorders2007.pdf>

23 Ernst & Young (2009) *Beyond Borders: Global Biotechnology Report 2009*, 23<sup>rd</sup> edition, which is no longer available online through Ernst & Young’s website, but can be accessed publicly through the Massey University online library at <http://www.massey.ac.nz/~ychisti/E&Y09.pdf>

Table 1. United States biodefence funding, 2001-13<sup>1</sup>

Federal agency	Funding (USD millions)													Totals
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011 (actual)	2012 (est.)	2013 (budget)	
Department of Health and Human Services	271	2,940	3,738	3,819	4,148	4,132	4,069	3,993	4,369	4,068	4,150	3,936	3,964	47,598
Department of Defense	274	824	422	417	430	583	555	578	718	675	789	950	831	8,045
Department of Homeland Security	N/A	N/A	422	1,788	2,981	567	354	359	2,550	478	390	307	364	10,561
Other <sup>a</sup>	89	332	508	400	571	508	467	494	512	432	405	383	380	4,716
<b>Total:</b>	<b>633</b>	<b>4,096</b>	<b>5,090</b>	<b>6,424</b>	<b>8,130</b>	<b>5,790</b>	<b>5,445</b>	<b>5,425</b>	<b>8,148</b>	<b>5,653</b>	<b>5,734</b>	<b>5,576</b>	<b>5,539</b>	<b>70,920</b>

Notes:

a. Other is the Environmental Protection Agency, National Science Foundation, and Departments of Agriculture, Commerce, and State.

- 1 Franco, C. and T.K. Sell (2010) 'Federal Agency Biodefence Funding, FY2010-FY2011', *Biosecurity and Bioterrorism*, Vol. 8, No. 2, <http://www.upmc-biosecurity.org/website/resources/publications/2010/pdf/2010-06-14-biodeffunds.pdf> and Franco, C. and T.K. Sell (2012) 'Federal Agency Biodefence Funding, FY2012-FY2013', *Biosecurity and Bioterrorism*, Vol. 10, No. 2, <http://www.upmc-biosecurity.org/website/resources/publications/2012/2012-06-12-biodeffunds.html>

## Biodefence funding, activities and facilities

### Funding

Biodefence funding in the US is spread across a number of departments and agencies. Table 1 shows biodefence funding between 2001 and 2011.

The data in Table 1 were compiled by the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC). The total amount of funding for biodefence between 2001 and 2012 is over USD 66 billion. Funding increased dramatically after 2001 due to the anthrax-containing letters posted to media representatives and members of Congress. Annual funding remains high today.<sup>24</sup> The Department of Health and Human Services (HHS) received the largest amount, close to USD 44 billion, for both in-house projects and private sector grants and contracts, much of it related to countermeasure

<sup>24</sup> Ibid.

research and development (see below).

Up to and including 2007, the Center for Arms Control and Non-Proliferation (CACNP) also compiled biodefence funding.<sup>25</sup> The 2007 CACNP study pointed up significantly higher funding than the UPMC study.<sup>26</sup> The CACNP study includes three categories not in the UPMC study: Department of Energy; Department of Veterans Affairs; and the US Postal Service. A comparison of the two studies is presented in Table 2.

Over the seven years common to both studies, CACNP total funding is 24 per cent greater than that of the UPMC. Therefore, US biodefence funding from 2001-12 is perhaps closer to USD 82 (1.24 x 66) billion.

<sup>25</sup> Pearson, A. (2008) 'Federal Funding for Biological Weapons Prevention and Defense', Center for Arms Control and Non-Proliferation. [http://armscontrolcenter.org/resources/fy2008\\_bw\\_budget.pdf](http://armscontrolcenter.org/resources/fy2008_bw_budget.pdf)

<sup>26</sup> C Franco and TK Sell *Op. Cit.*

**Table 2 Comparison of the CACNP and UPMC studies of US biodefence funding**

Study	Funding (USD millions)							Totals
	2001	2002	2003	2004	2005	2006 <sup>b</sup>	2007 <sup>b</sup>	
Center for Arms Control <sup>a,b</sup>	1,624	5,295	6,150	7,515	7,556	7,904	8,016	44,060
UPMC Medical Center	633	4,096	5,090	6,424	8,130	5,790	5,445	35,608

Notes:

a. The Center for Arms Control study includes three categories not in the UPMC study: Department of Energy; Department of Veterans Affairs; and the US Postal Service.

b. In the Center for Arms Control Study, 2006 funding is estimated and 2007 funding is requested.

**Table 3 Selected items from the HHS Emergency Preparedness Budget (estimated) for 2013<sup>1</sup>**

Agency/programme	Funding (USD millions)	
Centers for Disease Control and Prevention (CDC)		1,275
<i>State and local preparedness and response capability</i>	642	
<i>(National) Preparedness and response capability</i>	147	
<i>Strategic national stockpile</i>	486	
National Institutes of Health		1,308
<i>Biodefence research</i>	1,308	
Food and Drug Administration		346
<i>Food defence</i>	218	
<i>Vaccines/drugs/diagnostics</i>	121	
<i>Physical security</i>	7	
ASPR		862
<i>National Disaster Medical System (NDMS)</i>	52	
<i>Hospital preparedness</i>	255	
<i>BARDA</i>	457	
<i>Other</i>	98	
Other		140
Project BioShield Fund from DHS to HHS		415

Notes:

ASPR stands for Assistant Secretary for Preparedness and Response.

BARDA stands for Biomedical Advanced Research and Development Authority.

1 Ibid.

**Table 4 NIAID extramural and intramural research budgets, 2010, 2011 and 2012 (requested)<sup>1</sup>**

	Funding (USD millions)			
	2010	2011 (actual)	2012 (enacted)	2013 (President's Budget)
Extramural research				
<i>HIV/AIDS</i>	1,326	1,313	1,323	1,330
<i>Biodefence and emerging infectious diseases</i>	1,316	1,306	1,306	1,308
<i>Infectious and immunological diseases</i>	1,350	1,333	1,039	1,040
Intramural research	542	536	536	536
Research management and support	283	283	286	

1 See <http://www.niaid.nih.gov/about/whoWeAre/budget/Documents/fy2012cj.pdf>

## Department of Health and Human Services funding

HHS funding for biodefence is divided between nearly 1 billion specifically targeted to bioterrorism and emergency preparedness, requested through the Assistant Secretary for Emergency Preparedness and Response (ASPR, formerly and still sometimes listed as the Public Health and Social Services Emergency fund), and a little under 3 billion for biodefence related projects in other departments.

Relevant portions of the budget are listed in Table 3.

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention are slated to receive most of the requested funding, more than USD 2.5 billion. The Project BioShield budget item is a Special Reserve Fund that was approved by Congress in 2004, so it does not represent new or requested funding. The Project BioShield funding was transferred from the Department of Homeland

Security (DHS) to the HHS in 2010.<sup>27</sup>

Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is the recipient of most of the funding (see Table 4).

Requested funding for biodefence in 2012—more than USD 1.3 billion—is about the same as that requested for HIV/AIDS or for infectious and immunological diseases.

## Department of Defense (DoD) funding

The DoD budget does not separate chemical and biological defence, so reported funding includes both. DoD funding for its Chemical and Biological Defense Program from 2001 to 2013 (requested) is presented in Table 5.<sup>28</sup>

27 Consolidated Appropriations Act, 2010 (P.L. 111-117)

28 The RTD&E and Procurement budgets for any fiscal year may be found from the following URL by changing either the gray-highlighted year and using the letters r or p for RTD&E or

**Table 5 DoD Chemical and Biological Defense Program (CBDP) funding, 2001-2013 (requested)**

Budget category	Funding (USD millions)												
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013(req)
CBDP funding in the RTD&E budget	405	595	638	703	715	1,048	983	1,051	1,081	1,223	1,140	1,140	1,106
CBDP funding in the Procurement budget	470	512	658	545	707	713	522	519	456	356	355	247	299
Totals:	875	1,107	1,296	1,248	1,422	1,761	1,505	1,570	1,537	1,578	1,494	1,387	1,405

Notes:

RTD&E stands for Research, Development Test & Evaluation.; CBDP stands for Chemical and Biological Weapons Defense Program.

The CBDP programme was well funded both prior to 2002 and afterwards,<sup>29</sup> in contrast to the biodefence-related sections of the HHS budget, which increased substantially in 2002. In the wake of the September 11<sup>th</sup> terrorist attacks and the 2001 anthrax letters, biodefence became more relevant to agencies overseeing the health of civilian populations in addition to a military concern.

Of the many DoD budget sections, biodefence funding appears only in the Research, Development Test & Evaluation (RTD&E) and the Procurement budgets. CBDP and other biodefence programme funding in these two budgets are shown in more detail in Table 6, where entries are divided into two sections: the Chemical and Biological Defense Program (CBDP); and ‘Other’, which includes the Army, the Navy, the Defense Advanced Research Projects Agency, and the Defense Threat Reduction Agency.

Most items in the 172-page detailed budget, including

transportable decontamination systems, general purpose masks, and protective clothing technology, shelters, and field hospitals, pertain to both biological and chemical defence, as they are in many capacities effective against both threats.<sup>30</sup> Given this overlap, the DoD budget itself does not separate them, and the *BioWeapons Monitor 2012* cannot estimate how much of the USD 1.404 billion for 2013 (requested funding) is specifically for biodefence and how much for chemical defence.<sup>31</sup>

However, major biodefence projects under the DoD auspices include:

- Creating and improving systems and equipment to detect and identify aerosolized biological agents, in the field and at various distances, approximately \$101 million
- Developing reactive self-decontaminating materials to be used as protective gear or part of other standard equipment,

30 See [http://comptroller.defense.gov/defbudget/fy2010/budget\\_justification/pdfs/02\\_Procurement/Vol\\_4\\_CBDP/CBDP\\_PDW\\_PB10.pdf](http://comptroller.defense.gov/defbudget/fy2010/budget_justification/pdfs/02_Procurement/Vol_4_CBDP/CBDP_PDW_PB10.pdf)

31 See [http://comptroller.defense.gov/defbudget/fy2013/budget\\_justification/pdfs/02\\_Procurement/Chemical\\_and\\_Biological\\_Defense\\_Program\\_PB\\_2013.pdf](http://comptroller.defense.gov/defbudget/fy2013/budget_justification/pdfs/02_Procurement/Chemical_and_Biological_Defense_Program_PB_2013.pdf)

Procurement, respectively: [http://comptroller.defense.gov/defbudget/fy2008/fy2008\\_r1.pdf](http://comptroller.defense.gov/defbudget/fy2008/fy2008_r1.pdf)

29 ‘Department of Defense Budget Fiscal Year 2001: RDT&E PRO-GRAMS (R-1)’ (February 2000), [http://comptroller.defense.gov/defbudget/fy2001/fy2001\\_r1.pdf](http://comptroller.defense.gov/defbudget/fy2001/fy2001_r1.pdf)

**Table 6. Chemical and biological DoD funding**

	Funding (USD millions)			
	2010	2011	2012(base)	2013(req)
Chemical and Biological Weapons Defence Program				
Basic research CBW defence	64	49	53	51
Applied research CBW defence	233	171	220	223
RDT&E management support, CBW defence	113	133	93	93
RDT&E management support, SBIR grants	15	0	0	0
Operational systems development, CBW defence	6	7	16	15
Advanced technology development, CBW defence	305	218	229	234
Advanced component development and prototypes, CBW defence	248	268	213	179
System development and demonstration, CBW defence	238	295	317	311
Procurement installation force protection system cost	67	89	16	24
Procurement individual protection system cost	98	71	71	74
Procurement decontamination system cost	29	23	6	1
Procurement joint bio defence programme - medical system cost	13	10	4	33
Procurement collective protection system cost	33	25	9	3
Procurement contamination avoidance system cost	117	134	140	165
Subtotal:	1,578	1,492	1,387	1,404
Other (Army, Navy, DARPA, DTRA)				
SD&D medical materiel and defence equipment (Army)	38	33	27	43
Applied research biological warfare defence (DARPA)	41	35	30	19
Applied research materials and biological technology (DARPA)	256	279	220	166
Applied research WMD defeat technologies (DTRA)	219	298	196	172
SD&D WMD defeat technologies (DTRA)	9	8	6	6
ACD&P counterdrug RDT&E projects (Navy)	15	9	0	0
Procurement of support equipment CBRN soldier protection (Army)	180	179	12	9
Subtotal:	758	841	491	416
<b>TOTALS:</b>	<b>2,336</b>	<b>2,333</b>	<b>1,878</b>	<b>1,820</b>

**Notes:**

ACD&P stands for Advanced Component Development & Prototypes; CBDP stands for Chemical and Biological Weapons Defense Program  
 CBW stands for Chemical and Biological Weapons; DARPA stands for Defense Advanced Research Projects Agency  
 DTRA stands for Defense Threat Reduction Agency; RTD&E stands for Research, Development Test & Evaluation  
 SBIR stands for Small Business Innovation Research; SD&D stands for Systems Development & Equipment

approximately \$1 million

- 7-Day Biodefense, a program innovating new ways to increase survival and create immunity in the face of unknown and emerging pathogens, approximately \$36 million (under DARPA)
- Developing and acquiring vaccines for use as countermeasures, approximately \$88 million
- Emerging Infectious Diseases Flu countermeasures (EID-Flu), a program focusing on protecting service members from natural or artificial influenza viruses, approximately \$307 million
- Hemorrhagic Fever Virus (HFV) Medical Countermeasures (MCM) Acquisition Program, which seeks to develop vaccines and treatments for agents in the deadly Filoviridae family (Ebola, Marburg, etc), for which no such medical countermeasures currently exist, approximately \$374 million<sup>32</sup>

•

Taken together, these programs account for \$907 million in confirmed, primarily biodefense spending through the DoD, only a very small fraction of the total allocated to amalgamated biological and chemical concerns.

## Department of Homeland Security funding

Biodefence programmes and funding requests are located in several DHS budget documents.<sup>33</sup> Some

programmes do not appear explicitly as line items in the budgets, but instead appear in DHS budget discussions. A summary of biodefence programmes gleaned from these sources is presented in Table 7. The budget items in Table 7 may not capture all DHS biodefence funding requests, as biodefence items are not broken down in some budget categories. It is likely, though, that all of the major programmes are shown in Table 7.

Science and Technology Directorate is of particular interest to the *Bioweapons Monitor*. Its total requested funding for 2013 is USD 832 million.<sup>34</sup> Almost half, USD 369 million (USD 100 + USD 135 million), is targeted at biodefence activities. This is a similar proportion to last year, although total funding for the program has been reduced by almost 350 million.<sup>35</sup> Most biodefence funding is to be found in two programme areas: Laboratory facilities; and Research, Development & Innovation.

A summary of requested biodefence funding for 2013 for the HHS, DoD and DHS is provided in Table 8. Total requested funding of USD 6.1 billion is comparable to funding for 2013 in the UPMC study (see Table 1), raising confidence that most biodefence funding and activities that it supports have been captured in this *BioWeapons Monitor*. One caveat, however, is that the biodefence funding contain some money earmarked for chemical weapons programmes, as chemical defence is not broken down in some budgets (such as the DoD CBDP

32 United States of America, "Confidence Building Measure covering 2011," submitted to the United Nations on July 9th, 2012, accessed at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/DBE5A41DDFEAC499C1257A370036DA5D/\\$file/BWC\\_CBM\\_2012\\_USA-Public.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/DBE5A41DDFEAC499C1257A370036DA5D/$file/BWC_CBM_2012_USA-Public.pdf).

33 See <http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012-overview.pdf>, <http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012-overview.pdf>.

[http://www.dhs.gov/ynews/testimony/testimony\\_1301519363336.shtm](http://www.dhs.gov/ynews/testimony/testimony_1301519363336.shtm)

34 See <http://www.dhs.gov/news/2012/03/29/written-testimony-science-and-technology-directorate-under-secretary-dr-tara-otoole>.

35 [http://www.dhs.gov/ynews/testimony/testimony\\_1301519363336.shtm](http://www.dhs.gov/ynews/testimony/testimony_1301519363336.shtm)

**Table 7. DHS biodefence programme funding in 2012 and 2013 (requested)**

DHS division Programme	2012 (Est) (USD millions)	2013 (req) (USD millions)
Office of Health Affairs		
BioWatch	115	125
<i>BioWatch Gen-1/2</i>	90	85
<i>BioWatch Gen-3</i>	25	40
National Biosurveillance Integration Center	7	8
Science and Technology Directorate		
Laboratory facilities	277	100
<i>National Bio and Agro Defense Facility (NBAF) construction</i>	150	0
<i>Infrastructure upgrades</i>	18	15
<i>Laboratory operations</i>	77	53
<i>NBACC operations<sup>a</sup></i>	31	32
Research, Development & Innovation (RD&I)	147	135
<i>Viable Bioparticle Capture Project</i>	2	0
<i>Bioagent Threat Assessment</i>	44	33
<i>Bioagent Detection</i>	50	41
<i>Bioagent Attack Resiliency</i>	50	61
Federal Emergency Management Agency (FEMA)		
Regional Catastrophic Event Planning <sup>b</sup>	9	0
<b>TOTAL:</b>	<b>554</b>	<b>369</b>

Notes:

- a. NBACC stands for National Biodefence Analysis and Countermeasures Center
- b. The focus is on plans for responding to biological events and earthquakes

budget). The discrepancy between total biodefence funding in Table 8 and the total given for 2013 in the UPMC study comes from the inclusion of more items from the DoD budget as biodefence-related.

## Activities

One should note at the outset that many biodefence activities, such as broad-spectrum countermeasure development and strengthening local responses to epidemics, have public-health value for protection against natural diseases, in addition to defence against bioweapons.

Information on many US biodefence activities can be derived from programme titles in the budget tables. Some activities are expanded upon below.

NIAID funding, mainly for protecting civilians, is for research on bioweapons agents and the discovery and development of countermeasures. According to the 2012 requested budget description:

Since 2003, NIAID has led the NIH research and development program for medical countermeasures against terrorist threats of infectious diseases, chemical weapons, and radiation . . . NIAID supports basic research both to assess the mechanisms that lead infectious

**Table 8. Summary of requested biodefence funding for 2012 for the HHS, DoD and DHS**

Agency/Programme	FY 2013 (USD millions)
<b>HHS</b>	
Centers for Disease Control and Prevention	1,275
National Institutes of Health (includes NIAID)	1,308
Food and Drug Administration	346
Assistant Secretary for Preparedness and Response	862
Other	140
<b>DoD</b>	
Chemical and Biological Weapons Defense Program	1,404
Other (Army, Navy, DARPA, and DTRA)	416
<b>DHS</b>	
Office of Health Affairs	125
Science and Technology Directorate	235
Federal Emergency Management Agency	0
<b>Total:</b>	<b>6,111</b>

agents to cause diseases and to determine how the immune system can combat them. NIAID also is developing countermeasures that are effective against a variety of infectious microorganisms and other countermeasures that are effective against radiological and nuclear threats . . . To date, NIAID has tested numerous candidate interventions for public health threats such as smallpox, Anthrax, Ebola, Marburg, botulinum toxin, and pandemic influenza, many of which pose threats against U.S. and international communities . . .<sup>36</sup>

The military defensive purpose of the DoD Chemical and Biological Defense Program is described as

follows:

The DoD Chemical and Biological Defense Program (CBDP) is a key part of a comprehensive national strategy to counter the threat of chemical and biological weapons . . . The military mission is to dissuade, deter, defend, and defeat those who seek to harm the United States, its allies, and its partners through WMD [weapons of mass destruction] use or threat of use and, if attacked, mitigate the effects and restore deterrence . . . This budget includes support of a comprehensive science and technology base program . . . including research into advanced chemical and biological detection systems, advanced materials for improved filtration systems and protection systems, advanced decontaminants, investigations into the environmental fate of chemical warfare

<sup>36</sup> See <http://www.niaid.nih.gov/about/whoWeAre/budget/Documents/fy2012cj.pdf>, p. 18.

agents, advanced information technologies, medical biological defense research.<sup>37</sup>

Parallel to NIAID funding in the HHS budget, the CBDP may also fund 'therapeutics, and vaccines for viral, bacterial, toxin, and novel threat agents'. The one difference in the CBDP budget is that it provides funding for development of countermeasures for novel (previously unidentified) threat agents.

A few of the programme titles in the DHS budget do not adequately depict activities:

- The 'BioWatch detection network [is] a federally-managed, locally-operated, nationwide bio-surveillance system designed to detect the intentional release of aerosolized biological agents in more than 30 cities'.<sup>38</sup> Gen-1/2 and Gen-3 describe the different generations of the system.
- The National Bio and Agro Defense Facility is 'a new, state-of-the-art biosafety level 3 & 4 facility. Work performed at NBAF will lead to the development of vaccines and anti-virals and enhanced diagnostic capabilities for protecting our country from numerous foreign animal and emerging diseases'.<sup>39</sup> The requested funding is for construction of the facility.
- The National Biodefense Analysis and Countermeasures Center (NBACC) was established 'to be a national resource to understand the scientific basis of the risks posed by biological threats and to attribute

their use in bioterrorism or biocrime events'.<sup>40</sup> The NBACC is actually two centres: the National Bioforensic Analysis Center (NBFAC) which 'conducts bioforensic analysis of evidence from a biocrime or terrorist attack to attain a "biological fingerprint" to help investigators identify perpetrators and determine the origin and method of attack'<sup>41</sup>; and the National Biological Threat Characterization Center (NBTCC) which 'conducts studies and laboratory experiments to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities and conduct risk assessments; and to determine potential impacts to guide the development of countermeasures such as detectors, drugs, vaccines, and decontamination technologies'.<sup>42</sup>

The activities of the NBACC and particularly those of the NBTCC have been surrounded by concern about possible violations of the BWC. In 2004, a presentation on the NBTCC<sup>43</sup> outlined a number of proposed activities, including studies of aerosol dynamics, aerosol animal-model development, novel delivery of an agent, innovative packaging, genetic engineering, and environmental stability. In a guest commentary in the journal *Politics and the Life Sciences*, three arms control experts noted that, '[t]aken together, many of the activities . . . may constitute development (of bioweapons) in the

37 See [http://comptroller.defense.gov/defbudget/fy2011/budget\\_justification/pdfs/03\\_RDT\\_and\\_E/CBDP\\_RDT\\_E\\_PB11.pdf](http://comptroller.defense.gov/defbudget/fy2011/budget_justification/pdfs/03_RDT_and_E/CBDP_RDT_E_PB11.pdf), p. 2.

38 See <http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012-overview.pdf>, p. 8.

39 *Ibid.*, p. 9.

40 See [http://www.dhs.gov/files/labs/gc\\_1166211221830.shtm](http://www.dhs.gov/files/labs/gc_1166211221830.shtm)

41 *Ibid.*

42 *Ibid.*

43 Presentation by George Korch, 'Leading Edge of Biodefense – The National Biodefense Analysis and Countermeasures Center', at the Department of Defense Pest Management Workshop, February 2004.

guise of threat assessment, and they certainly will be interpreted that way'.<sup>44</sup> Development of bioweapons is prohibited under the BWC.

In response to this concern, the Government of the US issued a Directive to the DHS stating that '[a]ll relevant research, development, and acquisition projects shall be assessed for arms control compliance at inception, prior to funding approval, whenever there is significant project change, and whenever in the course of project execution an issue potentially raises a compliance concern'.<sup>45</sup>

Nevertheless, as noted by the US Congressional Research Service, concerns remain:

While such an internal compliance review process may be robust, some arms control experts have been critical of compliance processes that remain entirely internal to a single agency. Such critics assert that interagency review, or review performed or coordinated through the White House, for example through the National Security Council or the Homeland Security Council, would provide greater expert input and further divorce the compliance review from the programmatic and budgetary aspects of a research program.<sup>46</sup>

## Commercial sector biodefence activities

Sixty-one biodefence biotechnology companies are listed on the Biodefence Stocks Directory website,<sup>47</sup> four more than last year, and too many for the *BioWeapons Monitor* to detail their biodefence activities. Since the reason for their inclusion in the Directory is that they are listed on some US stock exchanges, they are all public companies. The Directory provides no information on potentially many more private biodefence biotechnology companies. Many included in the Directory have their headquarters in the US. Most are developing medicines for natural infectious diseases which can be employed-against potential bioweapon agents as well.

The Biomedical Advanced Research and Development Authority (BARDA) have contracted with a number of companies to supply countermeasures to the Strategic National Stockpile (SNS). The SNS warehouses countermeasures at multiple locations in the US, so they can be delivered quickly to victims in case of a bioweapon attack. These companies are listed, along with information on BARDA contracts, in Table 9.

## Facilities

### *Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (BSL3)*

The NIAID offers the following description of the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs):

<sup>47</sup> See [http://www.investorideas.com/BDS/Stock\\_List.asp](http://www.investorideas.com/BDS/Stock_List.asp)

<sup>44</sup> Leitenberg, M., J. Leonard and R. Spertzel (2004) 'Biodefense crossing the line', *Politics and the Life Sciences*, Vol. 22, No. 2, p. 2.

<sup>45</sup> See <http://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-041-01-compliance-with-and-implementation-of-arms-control-agreements.pdf>

<sup>46</sup> Shea, D.A. (2007) *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, Congressional Research Service, Washington, DC, <http://www.fas.org/sgp/crs/homesec/RL32891.pdf>, p. 9.

**Table 9. Bioweapon agents contracted for the Strategic National Stockpile<sup>1</sup>**

Biodefense company	Name of countermeasure	Type of countermeasure (disease target)	Number of treatment courses or doses (thousands)	Contract price (USD millions)
Emergent BioSolutions	Anthrax Vaccine Adsorbed (BioThrax)	vaccine (B. anthracis infection - anthrax)	28750	691
Human Genome Sciences	Raxibacumab (Abthrax)	humanized Mab (B. anthracis infection - anthrax)	65	326
Cangene Corporation <sup>a</sup>	Anthrax Immune Globulin (AIG)	passive immunization (B. anthracis infection - anthrax)	10	144
Cangene Corporation <sup>a</sup>	Botulism Antitoxin Heptavalent	polyclonal antibody (botulinum toxin poisoning)	200	414
Bavarian Nordic <sup>b</sup>	IMVAMUNE®, MVA vaccine	vaccine (Variola virus - smallpox)	10,000 or 20,000 <sup>c</sup>	505
SIGA Technologies	ST-246	oral proteinase inhibitor antiviral (Variola virus - smallpox)	1,700 <sup>d</sup>	500

**Notes**

a. Cangene is a Canadian Company

b. Bavarian Nordic is headquartered in Denmark, with a non-biodefense US facility in California

c. Two sources for the data report different doses (10 million vs. 20 million) for the smallpox vaccine

d. The 1,700 number is treatment courses - each course consists of 14 doses

1 US Department of Health and Human Services (2010) *Project BioShield Annual Report to Congress, January 2009-December 2009*, <https://www.medicalcountermeasures.gov/BARDA/documents/2009%20BioShield%20Report%20FINAL.pdf>; Gottron, F. (2010) *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, Congressional Research Service, [http://assets.opencrs.com/rpts/R41033\\_20100707.pdf](http://assets.opencrs.com/rpts/R41033_20100707.pdf); and United States Securities and Exchange Commission, 'Form 10K for the year 2010', submitted by Sigma Technologies, [http://www.sec.gov/Archives/edgar/data/1010086/000120677411000458/siga\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1010086/000120677411000458/siga_10k.htm)

The NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs) support research focused on countering threats from bioterror agents and emerging infectious diseases. Each Center is comprised of a consortium of universities and research institutions serving a specific geographical region.<sup>48</sup>

The names and states served by the 11 RCEs are listed below:

- New England Regional Center for Excellence (NERCE) - Region I (CT, ME, MA, NH, RI, VT);
- Northeast Biodefense Center (NBC) - Region II (NJ, NY, PR, VI);
- Middle Atlantic Regional Center of Excellence (MARCE) - Region III (DE, D.C., MD, PA, VA, WV);
- Southeast Regional Center of Excellence (SERCEB) - Region IV (KY, MS NC, TN, AL, FL, GA, SC);
- Great Lakes RCE (GLRCE) - Region V (IL, IN, MI, MN, OH, WI);

48 See <http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx>

**Table 12. US government biodefence facilities of special interest**

Facility name	Location	Research laboratories (square metres)	Researched agents (A, B, other select agents)	Aerosol research (Y or N)	Outdoor Research (Y or N)
Lothar Salomon Test Facility	Dugway, UT	1,158 m2 (BSL2, 3)	A, B, other	Y	Y
Plum Island Animal Disease Center	Greenport, NY	17,877 m2 (BSL2, 3)	not available	not available	not available
Battelle Biomedical Research Center	West Jefferson, OH	8,032 m2 (BSL2, 3)	A, B, other	Y	N
US Army Medical Research Institute of Infectious Diseases	Fort Detrick, Frederick, MD	30,258 m2 (BSL2, 3, 4)	A, B, other	Y	N
Centers for Disease Control and Prevention, Office of Infectious Diseases	Atlanta, GA	3,162 m2 (BSL2, 3, 4)	A, B, other	N	N
Centers for Disease Control and Prevention, Division of Vector Borne Diseases	Fort Collins, CO	1,208 m2 (BSL2, 3)	A, B, other	N	N
Lawrence Livermore National Laboratory	Livermore, CA	1,474 m2 (BSL2, 3)	A, B, other	Y	N

- Western Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research - Region VI (AR, LA, NM, OK, TX);
- Midwest Regional Research Center of Excellence for Biodefense and Emerging Infectious Diseases (MRCE) - Region VII (MO, KS, IA, NE)
- Rocky Mountain Regional Center of Excellence (RMRCE) - Region VIII (CO, UT, WY, MT, ND, SD);
- Pacific-Southwest Regional Center of Excellence (PSRCE) - Region IX (AZ, CA, HI, NV);
- Northwest Regional Research Center of Excellence for Biodefense and Emerging Infectious Diseases (NWRCE) - Region X (AK, ID, OR, WA); and
- Pacific Northwest Regional Center of Excellence (PNWRCE) - Region X (OR, WA, AK,

ID).<sup>49</sup>

Size information is not readily available. Additional information is available on the NIAID website.<sup>50</sup>

### Government biodefence laboratories/facilities of special interest

In testimony to the US Congress, the General Accountability Office reported in 2007 that 1,356 BSL3 labs in the US have registered under the Select Agent Regulations.<sup>51</sup> CDC (Centers for Disease Control

49 See <http://mrce.wustl.edu/index.php?page=resources&category=5>

50 See <http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx>

51 'High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States', *op.cit.* Testimony at

and Prevention) and NIH representatives testifying at the congressional hearing were unable to tell Congress what the labs were researching. All that the *BioWeapons Monitor 2012* can say about them is that they research or plan to research select agents.

There are, however, a number of high-profile government biodefence facilities that are not on the list of RCEs. Key data regarding these facilities is summarised in Table 12. They are identified and described in some detail in the ‘United States of America Confidence Building Measure Return covering 2011’ (hereafter called USA CBM 2012) and are described briefly below:

### Lothar Salomon Test Facility

At the Lothar Salomon Test Facility in Dugway, Utah, biological defence research includes:

testing of battlefield detection and identification methods, protective equipment, and decontamination systems, to include interferent testing of biological detectors and to develop/validate aerosol particle dispersion models . . . using simulants.<sup>52</sup>

Agents studied include Category A and B bioweapon agents. The rural location of and outdoor aerosol experimentation at the Dugway facility are particularly noteworthy in the context of the *Bioweapons Monitor 2012*.

the Congressional hearing on ‘Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States’, *op. cit.*

52 *Ibid.*, pp. 74-76.

### Plum Island Animal Disease Center (PIADC)

The PIADC in Greenport, New York, is a formerly DHS-administered facility, now under the jurisdiction of the USDA, which researches animal diseases. It has three enhanced BSL3 areas (2,630 square metres of laboratory space; 2,961 square metres of animal space; and 12,052 square metres of support space) and can work with large animals, such as cattle.<sup>53</sup>

PIADC provides the only research and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock. The focus of the research is on pathogens that infect animals, not those of humans. The facility maintains a reference repository of animal disease agents (and diagnostic capabilities to recognize them should they occur in the US). The facility also trains veterinarians to field diagnose high consequence foreign animal disease.<sup>54</sup>

The PIADC resides on an island located a fair distance from the mainland, thereby providing an environment where the probability of escape of highly contagious animal diseases is minimised.

Because Congressional law stipulates live foot-and-mouth disease virus cannot be studied on the mainland, PIADC is unique in that it is the only laboratory in the United States equipped with research facilities that permit the study of foot-and-mouth disease. Foot-and-mouth disease is an

53 United States of America, “Confidence Building Measure covering 2011,” submitted to the United Nations on July 9th, 2012, accessed at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/DBE5A41DDFEAC499C1257A370036DA5D/\\$file/BWC\\_CBM\\_2012\\_USA-Public.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/DBE5A41DDFEAC499C1257A370036DA5D/$file/BWC_CBM_2012_USA-Public.pdf).

54 “*High-Containment Biosafety Laboratories*”.

extremely contagious disease of cloven-hoofed animals. Accidental outbreaks of the disease have caused catastrophic livestock and economic losses in many countries throughout the world, most notably and most recently in the United Kingdom in 2001.<sup>55</sup>

The PIADC receives significant government funds through the USDA and DHS for its operations, but it no longer operates any BSL4 laboratory space; in this capacity it will be replaced by a BSL3/BSL4 facility at Manhattan, Kansas. The US Congress has approved financing for construction of the Kansas facility. More information is available on US Department of Agriculture (DoA) website.<sup>56</sup>

## Battelle Biomedical Research Center

The Battelle Biomedical Research Center in West Jefferson, Ohio, conducts experiments using its aerosol capabilities and BSL3 containment facility. Battelle does not perform outdoor experiments.

Its research objective is to test and evaluate medical countermeasures against biological threats/terrorism agents,<sup>57</sup> which requires infecting animals with pathogens. According to its list of 2010 publications,<sup>58</sup> it carries out experiments that involve infecting monkeys with viral agents that are potentially highly contagious among humans—as indicated by the publication title ‘Macaque Proteome Response to Highly Pathogenic Avian Influenza and 1918

Reassortant Influenza Infections’.<sup>59</sup> Battelle also conducts aerosol experiments with Category A and B bacterial bioweapon agents, as evidenced by the publication title ‘CpG oligodeoxyribonucleotides protect mice from *Burkholderia pseudomallei* but not *Francisella tularensis* Schu S4 aerosols’.

## US Army Medical Research Institute of Infectious Diseases (USAMRIID)

The USAMRIID, located at Fort Detrick in Frederick, Maryland, is the leading military biodefence research institution. It has a number of BSL4 (1,186 square metres) and BSL3 (3,139 square metres) laboratories<sup>60</sup> for internal use, including a newly constructed laboratory with a BSL4 capability<sup>61</sup> to accommodate animal testing for countermeasures developed elsewhere.

Its research focus is:

[t]o develop medical countermeasures, to include candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents. Perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies.<sup>62</sup>

The USAMRIID conducts research and countermeasure development with Category A and B bioweapon agents. It does not conduct outdoor experiments.

55 See <http://www.ars.usda.gov/AboutUs/AboutUs.htm?modecode=19-40-00-00>

56 USA CBM 2012. Also see [http://www.dhs.gov/files/labs/editorial\\_0901.shtm](http://www.dhs.gov/files/labs/editorial_0901.shtm), <http://www.ars.usda.gov/research/projects/programs.htm?modecode=19-40-00-00>, and [http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/about\\_faddl.shtml](http://www.aphis.usda.gov/animal_health/lab_info_services/about_faddl.shtml)

57 USA CBM 2012, 71.

58 *Ibid.*, 71-72.

59 Brown, J.N. et al. (2010) ‘Macaque Proteome Response to Highly Pathogenic Avian Influenza and 1918 Reassortant Influenza Infections’, *Journal of Virology*, Vol. 84, pp. 12058-12068. Reported in *ibid.*, 71.

60 USA CBM 2012, 99.

61 See [http://gsn.nti.org/siteservices/print\\_friendly.php?ID=nw\\_20110722\\_1487](http://gsn.nti.org/siteservices/print_friendly.php?ID=nw_20110722_1487)

62 USA CBM 2011, 114.

## Centers for Disease Control and Prevention, Office of Infectious Diseases (CDC-OID)

The CDC-OID in Atlanta, Georgia, has BSL4 (543 square metres) and BSL3 (2,325 square metres) laboratories.<sup>63</sup> All personnel are civilians. While the CDC's main mission is non-biodefence public health, it does have a biodefence mission as well:

CDC's strategic plan for biodefence is based on the following five focus areas, with each area integrating training and research: preparedness and prevention; detection and surveillance; diagnosis and characterization of biological and chemical agents; response; and communication. ...Activities include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefence activities include those with select agents."<sup>64</sup>

The CDC-OID facility is one of the two World Health Organization sanctioned depositories for smallpox virus.

## Centers for Disease Control and Prevention, Division of Vector Borne Diseases (CDC-DVBD)

The CDC-DVBD in Fort Collins, Colorado:

...strives to protect the nation from bacterial and

viral diseases transmitted by mosquitoes, ticks and fleas. DVBD's biodefence work focuses on development and implementation of epidemiology and surveillance; prevention, control and decontamination; vaccine development and improved diagnostics for diagnosis, detection and characterization of several vector-borne pathogens including various bacteria and alphaviruses. Additionally, DVBD serves as the national reference laboratory for these pathogens.<sup>65</sup>

The CDC-DVBD has BSL3 (1,142 square metres) laboratories.<sup>66</sup> It does not conduct outdoor experiments.

Some Category A and B bioweapon agents are transmitted through insect vectors. Plague is transmitted by fleas and encephalitis is transmitted by mosquitoes. Although not mentioned in the US 2012 CBM, the CDC-DVBD likely researches avian vectors as well.

## Lawrence Livermore National Laboratory (LLNL)

The LLNL in Livermore, California, is one of at least four major nuclear-weapon laboratories in the US. While the others—Brookhaven National Laboratory, Los Alamos National Laboratory, and Sandia National Laboratory—engage in biodefence activities, they are of little interest to the *BioWeapons Monitor 2012*. All are described in detail in the US 2012 CBM.

The LLNL conducts the most biodefence R&D of

63 *Ibid.*, 10.

64 *Ibid.*, 44, and United States of America, "Confidence Building Measure Covering 2010", (USA CBM 2010), 177.

65 USA CBM 2010, 167.

66 USA CBM 2011, 171.

the four, but has minimal BSL3 space (60 square metres)<sup>67</sup>.

LLNL is performing work in the area of biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, restoration, and forensics . . . In addition to the detection platforms LLNL is also working on tools that will help to restore normal activities in the event that a biological agent is used. These include developing rapid viability testing, decontamination strategies, and biological response plans for DHS, DOD, and EPA [Environmental Protection Agency]. We also have substantial activities in developing forensic assays to help determine where an agent may have come from and who might be responsible for the use of that agent.<sup>68</sup>

The LLNL has been cited for biosafety violations. These were catalogued in a statement by the watchdog organisation Tri-Valley CAREs to the BWC 2008 Meeting of Experts:

The LLNL was recently fined \$450,000 for a shipping mishap that led to the exposure of several workers at another facility to anthrax. A subsequent investigation uncovered lax oversight at the LLNL, including the failure to comply with applicable regulations governing the possession and transfer of select agents. . . [A]n unauthorized individual was allowed to package the anthrax, a . . . violation of the select agent regulations.<sup>69</sup>

There are a few dozen lower-profile facilities

67 *Ibid.*, 128.

68 *Ibid.*, 134.

69 See <http://www.trivalleycares.org/comments/BWCstatement-TVC.pdf>

fully described in the US 2012 CBM that have biodefence activities. Some have only BSL1 and BSL2 biocontainment laboratories. For the most part, these facilities carry out research that is of little interest to the *BioWeapons Monitor 2012*—refer to the US 2012 CBM for details.

## Maximum and high biological containment laboratories

There are eight operational and three planned or under construction Biosafety Level 4 (BSL-4) laboratories in the US, as the NBACC facility in Fort Detrick is now operational.<sup>70</sup> BSL-4 is the highest level of biosafety or biocontainment, and BSL-4 laboratories are designed to research the world's most deadly pathogens for which there is no cure. In addition, there are some 1,356 BSL-3 laboratories (the second highest level) in the US.<sup>71</sup> Table 10 lists the operational BSL4 laboratories, along with descriptive information, and Table 11 lists the planned or under construction BSL4 laboratories.

70 See <http://www.fas.org/programs/bio/research.html> and <http://www.upmc-biosecurity.org/website/resources/publications/2007/2007-04-04-highcontainmentbioresearchlabtable1.html> and [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/DBE5A41DDFEAC499C1257A370036DA5D/\\$file/BWC\\_CBM\\_2012\\_USA-Public.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/DBE5A41DDFEAC499C1257A370036DA5D/$file/BWC_CBM_2012_USA-Public.pdf)

71 'High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States', written statement of Keith Rhodes, United States Government Accountability Office, p. 10. Testimony at the Congressional hearing on 'Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States', 4 October 2007.

Table 10. Operational BSL4 laboratories in the US <sup>1</sup>

Institution	Location	Name of Facility	Size of BSL 4 labs	Financing Sources
Georgia State University	Atlanta, GA	Viral Immunology Center, National B Virus Resource Laboratory	60m2	NIH, Immunology Core Support Georgia Research Alliance, private foundations
Texas Biomedical Research Institute*	San Antonio, TX	The Betty Slick and Lewis J. Moor- man, Jr. Laboratory Complex	114 m2	DoD, NIH, DHS, private companies & donors
US Army Medical Research Institute of Infectious Diseases	Fort Detrick, Frederick, MD	U.S. Army Medical Research and Materiel Command	1,186 m2	DoD
Centers for Disease Control and Prevention	Atlanta, GA	Office of Infectious Diseases (OID)	136m2, 271m2 136m2	DHS, HHS, EPA other governmental agencies
Rocky Mountain Laboratories Integrated Research Facility	Hamilton, MT	NIH, Integrated Research Facility (IRF) 631m2 Rocky Mountain Laboratories (RML)	631m2	HHS (NIAID)
The University of Texas Medical Branch	Galveston, TX	Galveston National Laboratory (GNL)	186 m2, 1,022 m2	NIH, DHS, DoD, DoE, USDA, universities pharmaceutical industry, private foundations
Virginia Division of Consolidated Laboratory Services	Richmond, VA	Biotech Six	Info. not available	CDC, USDA, EPA, others
US Department of Homeland Security Science and Technology Directorate	Fort Detrick, MD	National Biodefense Analysis and Countermeasures Center (NBACC)	976 m2	DHS

\* Previously the Southwest Foundation for Biomedical Research

- 1 Additional information on the various laboratories is available at <http://www.upmc-biosecurity.org/website/resources/publications/2007/2007-04-04-highcontainmentbioresearchlabtable1.html>; <http://www.fas.org/programs/bio/research.html>; <http://www.utmb.edu/gnl/>; <http://www.niaid.nih.gov/about/organization/dir/rml/pages/default.aspx>; [http://www.news.vcu.edu/news/One\\_of\\_most\\_advanced\\_labs\\_in\\_US\\_is\\_latest\\_addition\\_to\\_new\\_East](http://www.news.vcu.edu/news/One_of_most_advanced_labs_in_US_is_latest_addition_to_new_East); [http://txbiomed.org/About/resources\\_3.aspx](http://txbiomed.org/About/resources_3.aspx); and <http://www2.gsu.edu/~wwwvir/Research/Index.html>

Table 11. Planned or under construction BSL4 laboratories in the US <sup>1</sup>

Institution	Location	Name of Facility
National Institute of Allergy and Infectious Diseases	Fort Detrick, Frederick, MD	Integrated Research Facility
Kansas State University	Manhattan, KS	National Bio- and Agro-Defense Facility
Boston University	Boston, MA	National Emerging Infectious Diseases Laboratory

- 1 See <http://www.fas.org/programs/bio/research.html> and Gronvall, G.K. et al. (2007) 'High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations', *Biosecurity and Bioterrorism*, Vol. 5, No. 1, pp.75-85.

## Vaccine production facilities

### *Human vaccines*

The US 2012 CBM itemises vaccine production facilities for human diseases only.<sup>72</sup> It appears to rely on the US Food and Drug Administration (FDA)'s 'Complete List of Vaccines Licensed for Immunization and Distribution in the US'.<sup>73</sup> The US 2012 CBM does not itemise veterinary vaccine production facilities, but the US 2011 CBM refers to the DoA document on veterinary vaccine and biological product manufacturers.<sup>74</sup> Although CBM 2012 does not direct readers to this list a second time, the list itself has been updated to reflect the most recent information on the US animal vaccine industry, as of July 2012.<sup>75</sup> The human vaccine producers are, for the most part, large, high-profile companies. A number of the companies licensed to sell human vaccines in the US do not produce their vaccines inside the country, although they may have packaging and distribution facilities there. From a bioweapons viewpoint, the production facilities are the ones of interest. Correctly, the US 2012 CBM does not list the companies producing outside of the country, except in relation to two possible errors (see below).

US human vaccine producers are listed in Table 13, along with the city and state where the production facility is located, the company's relevant website,

72 USA CBM 2011, pp. 275-284.

73 See <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

74 US Department of Agriculture (2011) *Veterinary Biological Products: Licensees and Permittees*, 23-46, [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/Current-ProdCodeBook.pdf](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/Current-ProdCodeBook.pdf).

75 US Department of Agriculture (2012) *Veterinary Biological Products: Licensees and Permittees*, 23-46, [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/Current-ProdCodeBook.pdf](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/Current-ProdCodeBook.pdf).

the size of the facility by either area or number of employees, and other information.

The US 2012 CBM lists MedImmune's FluMist® vaccine, which is produced in Speke in the United Kingdom. It is blended and packaged in the US (Philadelphia, PA),<sup>76</sup> so it should not be listed in the Return.

Information for one CBM-declared production facility, Organon Teknika, is confusing. The facility does not appear to have a website, but according to one business website,<sup>77</sup> it is a subsidiary of Schering-Plough and has very few employees. On another business website,<sup>78</sup> it is listed as a subsidiary of Merck. Its status as a vaccine production facility is therefore somewhat dubious.

Two new large facilities dedicated to influenza vaccine are listed at the bottom of Table 13. The Novartis facility will produce vaccines while the GlaxoSmithKline facility only packages and fills syringes at present. It is unclear if the latter will become a production site.

The human vaccine business appears to be expanding rapidly because of concern about pandemic influenza, new recombinant vaccine technologies, and new uses for vaccines. The Barr Laboratories facility is a new addition this year, and the number of US vaccine production facilities is expected to increase over the next several years.<sup>79</sup>

76 See [http://www.medimmune.com/about\\_us\\_facilities.aspx](http://www.medimmune.com/about_us_facilities.aspx)

77 See <http://www.manta.com/c/mmjs6yr/organon-tekника-corp>

78 See <http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=116535033>

79 USA CBM 2012, 250.

**Table 13. Human vaccine production facilities in the US**

Facility (location)	Website	Size (area or employees)	Biodefence Vaccines (Y or N)	Example Vaccine targets
<i>From US 2012 CBM submission</i>				
Barr Laboratories Inc. (Forest, VA)	<a href="http://www.pharmaceutical.org.uk/barr/index.html">http://www.pharmaceutical.org.uk/barr/index.html</a>	Not readily available	N	Adenovirus, types 4 and 7
Emergent BioDefense Operations (Lansing, MI)	<a href="http://www.emergentbiosolutions.com/">http://www.emergentbiosolutions.com/</a>	214,000 square feet	Y	Anthrax
MassBiologics (Boston, MA)	<a href="http://www.umassmed.edu/massbiolabs/index.aspx">http://www.umassmed.edu/massbiolabs/index.aspx</a>	Not readily available	N	Diphtheria, tetanus
MedImmune (Vaccine mfg. in Speke, UK, packaging in Philadelphia, PA)	<a href="http://medimmune.com/">http://medimmune.com/</a>	Not readily available	N	Influenza
Merck & Co (Vaccines and drugs, West Point, PA (70% of vaccine mfg. will move to new facility in Durham, NC, which opens in 2011)	<a href="http://www.merck.com/index.html">http://www.merck.com/index.html</a>	8,500 employees (West Point) 272,000 square feet (Durham)	N N	Hepatitis, measles, mumps, cervical cancer
Organon Teknika Corporation (Durham, NC)	No website	10-19 employees	N	Tuberculosis
Sanofi Pasteur Biologics/Acambis (Cambridge, MA)	<a href="http://www.sanofipasteur.us/sanofi-pasteur2/front/index.jsp?codeRubrique=73&amp;site-Code=SP_US">http://www.sanofipasteur.us/sanofi-pasteur2/front/index.jsp?codeRubrique=73&amp;site-Code=SP_US</a>	100-250 employees	Y	Smallpox
Sanofi Pasteur (Swiftwater, PA)	<a href="http://www.sanofipasteur.us">http://www.sanofipasteur.us</a>	3,200 employees	N	Influenza, diphtheria, tetanus, yellow fever
Wyeth Pharmaceuticals (now Pfizer) (New York, NY - main office)	<a href="http://www.pfizer.com/welcome/">http://www.pfizer.com/welcome/</a>	115,000-345,000 square feet	N	<i>Streptococcus pneumoniae</i>
<i>From CDC &amp; FDA list of vaccines</i>				
GlaxoSmithKline (Marietta, PA, influenza vaccine) now only packaging and filling)	<a href="http://www.gsk.com/products/vaccines/index.htm">http://www.gsk.com/products/vaccines/index.htm</a>	656,000 square feet	N	Influenza
Novartis Vaccines and Diagnostics (Holly Springs, NC)	<a href="http://www.novartis.com/products/vaccines.shtml">http://www.novartis.com/products/vaccines.shtml</a>	300,000 square feet (operational 2013)	N	Rabies, influenza, meningitis

## Veterinary vaccines

In the DoA document on veterinary vaccine and biological manufacturers,<sup>80</sup> the table listing veterinary vaccines takes up 23 pages and includes several hundred vaccines, many of which employ live, attenuated or killed viruses. Furthermore, the document lists more than 100 producers of vaccines and biologicals. In theory, most of the facilities could be used to produce potential animal or human bioweapon agents.

To illustrate the bioweapons potential, Table 14 lists companies and other organisations that produce vaccines and biologics for Category A & B bioweapon agents for animal health purposes. The producers are listed by their DoA license number to identify them concisely. The most notable change since the 2011 BioWeapons Monitor is the increase in producers working with killed West Nile virus. In Table 15, the license number is correlated with the companies and their location.<sup>81</sup>

Most of these producers are located in the mid-west, farm-belt area of the US. Some are subsidiaries of large human pharmaceutical companies.

## Research on smallpox

The CDC in Atlanta, Georgia, and the State Research Institute for Viral Preparations in Moscow, Russia, are the sole authorised repositories of the smallpox virus. In the US, research with live smallpox virus is carried out only at the CDC. Research activities include strain evaluation, serologic assays, nucleic acid-based diagnostics, antiviral drugs, and animal

models.<sup>82</sup>

With the development of a new smallpox vaccine and of an effective smallpox antiviral, calls for the destruction of these two remaining smallpox stocks have intensified.<sup>83</sup> Kathleen Sebelius, the US Secretary of Health and Human Services, rejected the demand at least for now because of the US perception of the need for additional research and countermeasure development:

We fully agree that these samples should – and eventually will – be destroyed. However, we also recognize that the timing of this destruction will determine whether we continue to live with the risk of the disease re-emerging through deliberate misuse of the virus by others . . . Although keeping the samples may carry a miniscule risk, both the United States and Russia believe the dangers of destroying them now are far greater.<sup>84</sup>

Smallpox vaccine is being acquired for the SNS (see above), and many first responders and perhaps more than two million military personnel have been vaccinated.<sup>85</sup>

80 US Department of Agriculture (2012) *Veterinary Biological Products: Licensees and Permittees*, op. cit.

81 Ibid.

82 LeDuc, J.W. and P.B. Jahrling (2001) 'Strengthening National Preparedness for Smallpox: an Update', *Emerging Infectious Diseases*, Vol. 7, No. 1, [http://wwwnc.cdc.gov/eid/article/7/1/70-0155\\_article.htm](http://wwwnc.cdc.gov/eid/article/7/1/70-0155_article.htm)

83 See [http://www.gazettetimes.com/news/local/article\\_3bae4488-a120-11e0-8793-001cc4c03286.html](http://www.gazettetimes.com/news/local/article_3bae4488-a120-11e0-8793-001cc4c03286.html)

84 Sebelius, K. (2011) 'Why We Still Need Smallpox', *The New York Times*, 25 April, <http://www.nytimes.com/2011/04/26/opinion/26iht-edsebelius26.html>

85 Center for Infectious Disease Research and Policy, University of Minnesota (2008) 'US military switching to new smallpox vaccine', 11 February, <http://www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/feb0808smallpox.html>

**Table 14. Producers of veterinary vaccines against bioweapon agents and other pathogens of interest**

License number of producer	Vaccine target	Type of vaccine	Type of agent
<b>Category A and B bioweapon agents</b>			
188	<i>Bacillus anthracis</i>	Live culture	Category A bioweapons agent
188	<i>Brucella abortus</i>	Live culture	Category B bioweapons agent
188, 597	Eastern, Western and Venezuelan Encephalomyelitis	Killed virus	Category B bioweapons agent
165A, 245	<i>Clostridium botulinum</i> poisoning?	Botulinum type C bacterin-toxoid	Category A toxin
165A, 112, 124	<i>Chlamydia Psittaci</i>	Modified live and killed virus	Category B bioweapons agent
124, 165A, 303, 337, 189, 196, 368	<i>Salmonella sp.</i>	Avirulent live & live culture	Category B bioweapons agent
455	<i>Brucella Suis</i> Bacterin		Category B bioweapons agent
<b>Other pathogens of interest</b>			
368, 196, 112, 189, 279	Avian influenza (14 HxNy subtypes, no H5N1)	Killed virus	Strains of H5N1 deadly
165A, 189, 303,	Swine influenza (H1N1, H1N2, H3N2 subtypes)	Killed virus	Strains of H1N1 and H3N2
112, 124, 189, 597	West Nile Virus	Killed virus	Emerging infectious disease

**Table 15. License numbers of some veterinary vaccine producers, the companies, and their location**

License number	Producer	Location
112	Fort Dodge Laboratories, Inc.	Fort Dodge, IA
124	Boehringer Ingelheim Vetmedica, Inc.	St. Joseph, MO
165A	Intervet Inc.	Elkhorn, NE
188	Colorado Serum Company	Denver, CO
189	Embrex, Inc.	Lincoln, NE
196	Lohmann Animal Health International	Winslow, ME
245	United Vaccines, Inc.	Madison, WI
279	Merial, Inc.	Gainesville, GA
303	Novartis Animal Health US, Inc.	Larchwood, IA
337	Arko Laboratories Ltd.	Jewell, IA
368	Biomune Company	Lenexa, KS
455	Newport Laboratories, Inc.	Worthington, MN
597	Hennessy Research Associates, LLC	Shawnee, KS

## Dual-use research of immediate misuse potential

Many experiments in molecular biology may have dual-use potential, and dozens of experiments may be under way in the US and elsewhere that are of concern as identified in the Fink Report.<sup>86</sup> Reported here are some lines of experiments involving pathogenic viruses that are of high dual-use concern because purposeful release or accidental escape from the laboratory could cause a very large number of casualties. Of most concern are experiments that involve live 1918 pandemic influenza virus, Severe Acute Respiratory Syndrome (SARS), and laboratory-made 'reassortments' or combinations of avian H5N1 influenza virus and a common human H3N1 influenza virus.

In 2005, the 1918 flu virus was reconstructed from old pathology samples obtained through resurrected tissue from victims' graves. Pathogenicity experiments with the live reconstructed virus then began.<sup>87</sup> A 2009 publication reviews the animal pathogenicity experiments conducted with the live 1918 flu virus in Canada and the US.<sup>88</sup> The research institutions conducting experiments with live virus identified in that publication and from a general internet search are the CDC, the School of Medicine

at the University of Washington, the National Centre for Foreign Animal Disease (Canada), the Mount Sinai School of Medicine,<sup>89</sup> and the NIAID.<sup>90</sup>

Experiments with viruses that increase their pathogenicity are included in the Fink Report's list of experiments of concern. Experiments at Yoshihiro Kawaoka's laboratory at the University of Wisconsin-Madison fall into the increased pathogenicity category. In one experiment published in 2004, a mild influenza A virus was engineered using two 1918 genes; the resulting virus was more pathogenic.<sup>91</sup> In another experiment at the University of Wisconsin laboratory,<sup>92</sup> all possible reassortments between avian H5N1 and human H3N2 influenza viruses were made and tested in mice. Researchers found some highly pathogenic reassortments.

During 2011 and 2012, the most prominent case of Dual Use Research of Concern involved experiments on H5N1, or avian flu. Dr. Kawaoka, at the University of Wisconsin and Dr. Fouchier of the Erasmus Medical Center in the Netherlands, both with funding from the US National Institutes of Health (NIH) demonstrated that H5N1, normally transmissible only through birds, could achieve transmissibility in mammals with only a handful of naturally occurring mutations. However, in both cases its lethality

86 Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, National Research Council (2004) *Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma*, National Academies Press, Washington, DC, [http://www.nap.edu/catalog.php?record\\_id=10827#toc](http://www.nap.edu/catalog.php?record_id=10827#toc)

87 T.M. Tumpey et al. (2005) 'Characterization of the reconstructed 1918 Spanish influenza pandemic virus', *Science*, Vol. 310, No. 5745, <http://www.sciencemag.org/content/310/5745/77.full.pdf>, pp. 77-80.

88 The scientific paper found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2763968/?tool=pubmed> was used to identify several laboratories researching live 1918 pandemic flu.

89 See <http://vir.sgmjournals.org/content/91/2/339.full>

90 The NIAID is conducting experiments with chimeric live flu viruses that contain some 1918 pandemic flu genes for which pandemic potential is not known. It is unclear whether it is experimenting with the live 1918 pandemic flu virus itself.

91 Devitt, T. (2004) 'Gene From 1918 Virus Proves Key To Virulent Influenza', 6 October, <http://www.wisconline.com/feature/flu.html>

92 C. Li et al. (2010) 'Reassortment between avian H5N1 and human H3N2 influenza viruses creates hybrid viruses with substantial virulence', *Proceedings of the National Academy of Sciences*, Vol. 107, No. 10, pp. 4687-4692.

decreased substantially. The researchers planned to submit their papers to *Nature* and *Science* respectively. In October 2011, the US National Advisory Board on Biosecurity (NSABB) convened to review both papers. The next month, the NSABB recommended that they be published, but with alterations that emphasized the beneficial purposes and aspects of the research and acknowledged biosecurity measures and concerns; it also recommended that specific mutation data be shared with responsible researchers on a selective basis, but not published freely.<sup>93</sup>

Benefits of the experiments included forming a more accurate picture of the risk H5N1 poses, providing information to improve future pandemic flu preparedness efforts, and gaining a deeper understanding of viral evolution and transmissibility, among others. Nevertheless, the experiments continued to draw censure and scrutiny, both from the popular press and the worried international biological community. Due to the high lethality of H5N1 (60% in identified human cases), the possibility of an accidental or malicious release of an aerosol-transmissible form of the disease would present a high biosecurity risk.<sup>94</sup> Furthermore, the experiments succeeded at improving both transmissibility and expanding the host range of the virus, areas of research identified by the Fink committee as “of sufficient concern to warrant oversight prior to being undertaken or published in full after being

carried out.”<sup>95</sup> In response to these concerns, both researchers agreed to halt experiments on H5N1 in mammals, and any other H5NA viruses already shown to be transmissible in mammals. This voluntary moratorium was set at 60 days to allow the scientific and international communities to discuss the best possible security measures for the pathogens and the process for disseminating the research safely afterwards.<sup>96</sup>

Throughout February 2012, the New York Academy of Sciences, the Harvard School of Public Health, and the WHO all held meetings between various officials and experts to discuss the prudence of conducting the research to begin with, and the subsequent decision by the NSABB regarding publication. The first two meetings were unable to come to any consensus, while the WHO talks resulted in a call for an extension of the ongoing research moratorium on H5N1 in mammals, but full publication of both papers in the long term. Additional major points included general agreement that BSL3+ was the correct level of biosecurity that ought to be required for H5N1 transmissibility research, and concern over the accuracy and usefulness of ferrets as model organisms. In previous experiments with the same family of viruses, ferrets failed to respond similarly to humans in response to influenza infection patterns in particular.<sup>97</sup>

93 “Making avian influenza aerosol-transmissible in mammals,” An official document of the 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. BWC/MSP/2012/MX/INF.2. Accessible from [http://www.unog.ch/\\_\\_80256ee600585943.nsf/\(httpPages\)/f837b6e7a401a21cc1257a150050cb2a?OpenDocument&ExpandSection=1#\\_Section1](http://www.unog.ch/__80256ee600585943.nsf/(httpPages)/f837b6e7a401a21cc1257a150050cb2a?OpenDocument&ExpandSection=1#_Section1).

94 Ibid.

95 Tatyana Novossiolova *et al.* “The Creation of a Contagious H5N1 Influenza Virus: Implications for the Education of Life Scientists,” *Journal of Terrorism Research* 3.1 (2012), accessed at <http://ojs.st-andrews.ac.uk/index.php/jtr/article/view/417/378>.

96 Ron A. M. Fouchier *et al.* “Pause on avian flu transmission studies,” *Nature*, 448 (2012): 443, doi 10.1038/481443a, accessed at <http://www.nature.com/nature/journal/v481/n7382/full/481443a.html>.

97 “Making avian influenza aerosol-transmissible in mammals”.

By the end of March 2012, the NSABB presented a new series of recommendations:

- (a) The revised Kawaoka manuscript should be communicated in full;
- (b) The data, methods, and conclusions presented in the revised Fouchier manuscript should be communicated, but not as currently written;
- (c) Development of national, and participation in the development of international, policies for the oversight and communication of dual use research of concern; and
- (d) Expedient development of a mechanism to provide controlled access to sensitive scientific information.<sup>98</sup>

NIH also released a new set of policy guidelines intended to regulate and clarify situations of Dual Use Research of Concern, but the guidelines in question explicitly apply only to pathogens classified as Tier 1 Select Agents and Toxins. Carrie Wolinetz argues that this is counterproductive on two levels: first, all work with Tier 1 agents is already highly restricted, monitored, and regulated; and second, many if not most of the most prominent Dual Use cases, including the H5N1 debate that prompted the new policy, did not involve Tier 1 agents and therefore would not fall under the policy's purview.<sup>99</sup>

Furthermore, the particular requirements of the policy are difficult both to define and execute. It calls upon all "Federal departments and agencies

that conduct or fund life sciences research"<sup>100</sup> to carry out the following:

- a) Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
- b) Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
- c) Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
- d) Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures<sup>101</sup>

Nowhere, however, does the policy specify whom within federal agencies would be responsible for funding, coordinating, and carrying out such assessments, what qualifications they might require to do so, or what sort of timeline such a project would follow. This last oversight is noteworthy in light of how many months transpired between the submission of the H5N1 research and the eventual, much-equivocated verdict on the papers' publication. The policy ultimately relies on highly subjective

<sup>100</sup> Ibid.

<sup>101</sup> National Institutes of Health, "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," accessed at [http://oba.od.nih.gov/oba/biosecurity/PDF/United\\_States\\_Government\\_Policy\\_for\\_Oversight\\_of\\_DURC\\_FINAL\\_version\\_032812.pdf](http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf).

<sup>98</sup> Ibid.

<sup>99</sup> Carrie D. Wolinetz, "Implementing the New US Dual-Use Policy," *Science*, 336 no. 6088 (2012): 1525-1527, accessed at <http://www.sciencemag.org/content/336/6088/1525.full>.

judgment calls, but fails to provide for a system of appeals to oversee those decisions. The policy also leaves ambiguous what would constitute sufficient “ongoing review” at the institutional level. Wolinetz worries that assigning burdensome administrative duties to universities in exchange for the opportunity to work on select agents could potentially backfire by discouraging critical biosecurity research on Select Agents.<sup>102</sup>

## Disease outbreak data

The US 2012 CBM no longer lists reportable diseases that do not constitute unusual disease outbreaks. It lists two entirely nonfatal outbreaks of salmonella poisoning and one unusually clustered outbreak of Guillain-Barré syndrome, the first such cluster in North America. All cases were the result of *Campylobacter* infections, which frequently precedes GBS. Out of 26 cases meeting the Brighton criteria, only one resulted in death.<sup>103</sup>

Although not included in the CBM 2012, an outbreak of West Nile virus spread widely in late summer months of 2012, with West Nile activity reported in all of the lower 48 states, and human cases reported in 43 states. As of August 29<sup>th</sup>, reported cases in the US reached 1,590, with 66 deaths. Over half of the deaths and 70% of total cases occurred in Texas. More than half of the reported cases featured the more dangerous, neuroinvasive form of the virus, with a 10% fatality rate and a high incidence of long-lasting neurological damage in survivors. Officials at the Texas Department of State Health Services expect the number of cases to continue to rise, potentially culminating in the worst West Nile season the US has

102 Wolinetz, “Implementing the New Dual Use Policy”.

103 USA CBM 2012, 221-233.

weathered so far.<sup>104</sup>

## National legislation and regulations

The Biological Weapons Antiterrorism Act of 1989 establishes any violation of the BWC by a private party as federal crime, fulfilling the United States’ commitments under Article IV. It is illegal to

use a biological agent, toxin, or delivery system as a weapon, or are in possession of any biological agent without justifiable research or peaceful purpose...It is also a crime to knowingly possess a Select Agent or toxin, regardless of intent, if the individual does not have legitimate access...<sup>105</sup>

The Federal Bureau of Investigations conducted several investigations of biological material under this statute in the last year, some of which lead to prosecution.

The ‘Patriot Act’ of 2001<sup>106</sup> was enacted to ‘intercept and obstruct terrorism’. It contains one section, Section 817, which is relevant to the *BioWeapons Monitor*:

SEC. 817. EXPANSION OF THE BIOLOGICAL WEAPONS STATUTE . . .

(b) ADDITIONAL OFFENSE.—Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a

104 Falco, Miriam. “West Nile cases rising; 66 dead,” *CNN*, August 29, 2012, <http://www.cnn.com/2012/08/29/health/west-nile-virus/index.html>.

105 USA CBM 2012, 242.

106 See <http://www.gpo.gov/fdsys/pkg/PLAW-107publ56/pdf/PLAW-107publ56.pdf>

prophylactic, protective, *bona fide* research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both.<sup>107</sup>

The language closely parallels that of the BWC prohibitions. The Patriot Act makes explicit that the BWC prohibitions apply to domestic and foreign violators as well. In addition, it prescribes fines and jail sentences for violations of the Act.

A second relevant document is the 2005 ‘Select Agent Regulations’,<sup>108</sup> which describes in detail the rules on storing, handling, transferring, and working with more than 80 ‘select’ biological agents and toxins. The list is composed of pathogens that have ‘the potential to pose a severe threat to public health and safety’.<sup>109</sup> The Office of Inspector General can levy civil or criminal penalties for a violation of the Select Agent Regulations. Category A and B bioweapon agents<sup>110</sup> are among the pathogens on the list.

The Select Agent list was revised in 2008<sup>111</sup>—recommendations issued in 2011 by the Federal Experts Security Advisory Panel propose radical alterations to the list.<sup>112</sup> The revised list identifies

107 *Ibid.* SEC. 817: Expansion of the Biological Weapons Statute.

108 Office of Inspector General (2005) ‘Possession, Use, and Transfer of Select Agents and Toxins; Final Rule’, 42 CFR Parts 72 and 73, *Federal Register*, Vol. 70, No. 52, 18 March, pp. 13294-13325, [http://www.selectagents.gov/resources/42\\_cfr\\_73\\_final\\_rule.pdf](http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf)

109 *Ibid.*, p. 13297.

110 See <http://www.bt.cdc.gov/agent/agentlist-category.asp>

111 Centers for Disease Control and Prevention (2008) ‘Possession, Use, and Transfer of Select Agents and Toxins’, 42 CFR Part 73, *Federal Register*, Vol. 73, No. 201, 16 October, pp. 61363-61366, [http://www.selectagents.gov/resources/Biennial%20Review\\_CDC\\_20081016.pdf](http://www.selectagents.gov/resources/Biennial%20Review_CDC_20081016.pdf)

112 Federal Experts Security Advisory Panel (2010) ‘Recommen-

11 agents—so-called Tier 1 agents—that present the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence’:<sup>113</sup>

The following agents are recommended to comprise the list of Tier 1 BSAT [biological select agents and toxins]:

*Bacillus anthracis*

*Burkholderia mallei*

*Burkholderia pseudomallei*

Ebola virus

Foot-and-mouth disease virus

*Francisella tularensis*

Marburg virus

Variola major virus

Variola minor virus

*Yersinia pestis* . . .<sup>114</sup>

Botulinum toxin and/or toxin-producing strains of *Clostridium botulinum* were added later to the list.

It is noteworthy that one Category A bioweapons agent (Lassa virus) is not on the Tier 1 list. A number of Category B and C agents (foot-and-mouth-disease virus, *Burkholderia mallei*, and *Burkholderia pseudomallei*) have been placed on the Tier 1 list, and a few Category B agents have been removed from the list (Eastern and Venezuelan equine encephalitis viruses). Approximately 25 agents and toxins have been recommended for removal from the

dations Concerning the Select Agent Program’, 2 November (revised 20 December 2010 and 10 January 2011), <http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf>

113 *Ibid.*, p. 3.

114 *Ibid.*

list, reducing its size substantially. Work with Tier 1 agents would be governed by strict regulations, whereas regulations concerning work with other agents will be relaxed compared to specifications in the 2005 Select Agent Regulations.

Between the Patriot Act and the Select Agent Regulations, close oversight is achieved with respect to working with select agents and who can work with them. The USA CBM 2011<sup>115</sup> highlights an additional key regulation aimed at ensuring appropriate oversight for other diseases not subject to Select Agent restrictions:

**Control of Communicable Diseases: Foreign and Possessions**

. . . By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another . . . This rule . . . [creates] a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC [Centers for Disease Control and Prevention] contacting travelers in the event of an exposure to a communicable disease . . .

The Select Agent Program puts forward various recommendations to institutions licensed to work with Select Agents on best practices and current regulations. The CDC regulations on Select Agents,

115 USA CBM 2011, pp. 266-272.

published in 2008, require all individuals or institutions working with Select Agents to receive a certificate of registration from the secretary of HHS. Exemptions are permitted in cases of manipulated agents that do not pose the same threat as their wild-type counterparts, certain extremely small amounts of particular agents, and urgently needed research into an ongoing emergency outbreak. Otherwise, all individuals with access to or control over Select Agents must be subject to security checks and evaluations; biosafety procedures and physical security plans must be submitted and approved by the secretary; response plans in the case of release, loss, or theft must be submitted and approved by the secretary; inspections and drills must be performed at least annually; and non-exempt transport is subject to similar regulations.<sup>116</sup>

Fourteen official guidance statements pertaining to the execution of Select Agents regulations were issued in 2011, all of which may be found in the USA CBM 2012. According to the Bioterrorism Preparedness Act, the HHS Secretary must re-evaluate the Select Agents list every two years. The revised and updated list of Select Agents presented in October 2012 simultaneously fulfilled Executive Order 13546: Optimizing the Security of Biological Select Agents and Toxins in the United States, which was issued in order to:

review, tier, and reduce the Select Agent List; establishing personal reliability standards for BSAT workers; and establishing physical security standards for identified Tier 1 select agents and toxins.<sup>117</sup>

116 *CDC Select Agents Regulations (42 CFR Part 73)*, accessed here: <http://www.selectagents.gov/resources/42%20CFR%2073.pdf>.

117 *Ibid* 246.

On October 5, the HHS Federal Register declared

As a result of our review, we have added Chapare virus, Lujo virus, and SARS-associated coronavirus (SARS-CoV) to the list of HHS select agents and toxins. We have also removed from the list of HHS and overlap select agents and toxins, or excluded from compliance with part 73, the agents and toxins described in the Executive Summary... [this HHS review] established new security requirements for entities possessing Tier 1 agents, including the requirement to conduct pre-access assessments and on-going monitoring of personnel with access to Tier 1 agents and toxins; and made revisions to the regulations to clarify regulatory language concerning security, training, biosafety, and incident response.<sup>118</sup>

USA CBM 2012 also reports several other new or amended regulations that are of less interest to the Bioweapons Monitor, or are discussed elsewhere.

## Codes of conduct, education and awareness-raising

### *US government activities*

The 2009 *National Strategy for Countering Biological Threats* pays attention to codes of conduct, education and awareness-raising:

Life scientists are best positioned to develop, document, and reinforce norms regarding the beneficial intent of their contribution to the global community as well as those activities that are fundamentally intolerable. Although other communities can make meaningful contributions,

only the concerted and deliberate effort of distinguished and respected life scientists to develop, document, and ultimately promulgate such norms will enable them to be fully endorsed by their peers and colleagues. We will seek to facilitate these efforts by:

- Encouraging the constituencies of the global life sciences community to engage in a robust and sustained dialogue as to the development of behavioral norms and options for their codification;
- Encouraging professional societies in the life sciences to develop and communicate codes of ethics and consider how their membership policies can best reflect community norms;
- Assisting professional societies and other representatives of the life sciences community in the development of relevant educational and training materials;
- Ensuring the availability of tools and resources needed to document, communicate, and reinforce norms during the education and throughout the career of life scientists in academia, industry, or government; and
- Supporting efforts by life scientists to explore community-based approaches for identifying and addressing irresponsible conduct.<sup>119</sup>

Aside from FBI enforcement of BWAT, there appear to be no US government agencies that have programmes

118 Secretary of HHS, *Federal Register*, Volume 77. No. 194, October 5, 2012, accessed at <http://www.selectagents.gov/resources/CDC%20Select%20Agent%20Biennial%20Review%20Final%20Rule%2010%2005%202012.pdf>.

119 National Security Council (2009) *National Strategy for Countering Biological Threats*, [http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf), p. 8.

dealing explicitly with hostile exploitation of life sciences, such as the development of offensive bioweapons. There are, however, a number of agencies that deal with research misconduct, whistle-blowing, and bioethics.<sup>120</sup> Hostile exploitation could fall under misconduct. In particular, the NSABB, within NIH, provides a number of education materials on dual-use dilemmas and the responsibilities of life scientists.<sup>121</sup> Furthermore, the NSABB also conducts its own outreach; in 2011 they published a report on outreach strategies targeting amateur biologists and non-life scientists now contributing to or interacting with biological dual use activities.<sup>122</sup>

In the past year the FBI has also conducted a variety of outreach and education events. Ten such events targeted to research communities focused on promoting threat awareness and building a framework to encourage academics in the life sciences field to report any dubious activity. Outreach to the quickly growing sector of synthetic biology centered around proactive cooperation to mitigate misuse of new developing technologies, while another event aimed at the growing amateur biologist community echoed the concerns presented in the academic outreach.<sup>123</sup>

120 See <http://ori.hhs.gov>; See [http://ori.hhs.gov/education/products/rcr\\_misconduct.shtml](http://ori.hhs.gov/education/products/rcr_misconduct.shtml); *Ibid*; <http://oig.hhs.gov/fraud/hotline>; <http://www.osc.gov/intro.htm>; <http://www.osc.gov/intro.htm>; Government Accountability Project (2007) 'Senate Panel Approves Whistleblower Protections for Defense Contractors', Press Release, 25 <http://www.whistleblower.org/press/press-release-archive/2007/1354-senate-approves-whistleblower-protections-for-defense-contractors>; <http://bioethics.od.nih.gov/specific.html>

121 See [http://oba.od.nih.gov/biosecurity/biosecurity\\_education-al.html](http://oba.od.nih.gov/biosecurity/biosecurity_education-al.html)

122 See [http://oba.od.nih.gov/biosecurity/pdf/finalnsabbreport-amateurbiologist-nonlifescientists\\_june-2011.pdf](http://oba.od.nih.gov/biosecurity/pdf/finalnsabbreport-amateurbiologist-nonlifescientists_june-2011.pdf)

123 USA CMB 2012, 242.

## *Activities by non-governmental organisations (NGOs)*

There are two sets of awareness-raising materials on the internet: one hosted by the Federation of American Scientists (FAS) and the other by the CACNP. The FAS strategy is to provide students with 'case studies in dual-use biological research' based on real research papers,<sup>124</sup> whereas the CACNP offering<sup>125</sup> consists of multimedia units each consisting of photographs, charts, tables and bulleted lists and other learning aids, all with voice-over.

The Biotechnology Industry Organization composed the 'BIO Statement of Ethical Principles' that explicitly opposes the development of bioweapons:<sup>126</sup>

We support the Biological Weapons Convention, a treaty signed by the United States and many other nations banning development and use of biological weapons. We will not undertake any research intended for use in developing, testing or producing such weapons."<sup>127</sup>

The Organization does not provide any materials, though, for training or awareness-raising.

The National Academy of Sciences conducted a survey in 2007 on the awareness of dual use concerns in the life sciences community: many respondents indicated that they took voluntarily took measures

124 <http://www.fas.org/biosecurity/education/dualuse/index.html>

125 [http://www.politicsandthelifesciences.org/Biosecurity\\_course\\_folder/base.html](http://www.politicsandthelifesciences.org/Biosecurity_course_folder/base.html)

126 <http://bio.org/content/bio-statement-ethical-principles>

127 <http://bio.org/content/bio-statement-ethical-principles?page=3>

to prevent misuse of their research.<sup>128</sup> The NAS also convened the Committee on Education on Dual Use Issues in the Life Sciences in 2009, which held a workshop entitled The Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences. Experts from 30 different countries:

...sought to identify a baseline about (1) the extent to which dual use issues are currently being included in postsecondary education (undergraduate and postgraduate) in the life sciences; (2) in what contexts that education is occurring (e.g. in formal coursework, informal settings, as stand-alone subjects or part of more general training, and in what fields); and (3) what online education materials addressing research in the life sciences with dual use potential already exist.<sup>129</sup>

The Committee produced a textbook, *Challenges and Opportunities For Education About Dual Use in the Life Sciences*, synthesizing the ideas from the workshop into a thorough guide, which was published in 2010 and is available online for free as a PDF.<sup>130</sup>

No material relevant to the *BioWeapons Monitor 2012* was found on the Pharmaceutical Research and Manufacturers of America (PhRMA) website, despite searches for several key phrases, such as ‘Biological Weapons Convention’, ‘bioethics’, and ‘biological weapons’.<sup>131</sup>

128 See <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12460>

129 See [http://www.nap.edu/catalog.php?record\\_id=12958#-description](http://www.nap.edu/catalog.php?record_id=12958#-description) and <http://www.interacademies.net/File.aspx?id=15715>

130 Ibid.

131 <http://www.phrma.org/>

## CBM participation

The US has submitted CBM declarations regularly—it is one of nine states to have filed CBM declarations in each of the 25 years since their establishment in 1987. The US has made its CBM declarations publicly available since 2010 via the website of the BWC Implementation Support Unit. The publicly available version of the US 2010 CBM is reportedly 13 pages shorter than the restricted version available to BWC member states.<sup>132</sup> In 2011, the US submitted a public version of its CBM declaration and placed an additional 18 pages on the restricted CBM website.<sup>133</sup>

## Participation in BWC meetings

The US participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference of the BWC in 2006, the US has taken part in all relevant meetings (see Table 16).

In conjunction with President Obama’s commitment to cooperative and preventative global biosecurity, the United States’ participation with the BWC has only increased. Not only did the United States send more delegates to the 7<sup>th</sup> Review Conference than any previous meeting, but the delegation was helmed by Secretary of State Hillary Clinton, the highest-ranking US official ever to address a BWC review conference on the nation’s behalf.<sup>134</sup> At the

132 See <http://www.biological-arms-control.org/publications/CB-MReader2010-finalannex.pdf>

133 Telephone interview by Iris Hunger with a governmental representative, August 2011.

134 Gregory Koblenz, “From biodefence to biosecurity: the Obama administration’s strategy for countering biological threats,” *International Affairs* 88.1 (2012): 131-148, doi: 0.1111/j.1468-2346.2012.01061.x, accessed at <http://onlinelibrary.wiley.com/store/10.1111/j.1468-2346.2012.01061.x/asset/j.1468-2346.2012.01061.x.pdf;jses->

Table 16. Number of US delegates at BWC meetings since 2006 <sup>1</sup>

Meeting	RC 2006	MX 2007	MSP 2007	MX 2008	MSP 2008	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012
Number of delegates	14	10	12	12	15	14	12	17	16	8	21	17

Notes: RC stands for Review Conference; MX stands for Meeting of Experts; MSP stands for Meeting of States Parties; PC stands for Preparatory Committee (PrepCom)

<sup>1</sup> See the Lists of Participants under the official documents for the Meeting of Experts at [http://www.unog.ch/\\_80256ee600585943.nsf/\(httpPages\)/26e4793f76daf81ec1257a87002c4700?OpenDocument&ExpandSection=1#\\_Section1](http://www.unog.ch/_80256ee600585943.nsf/(httpPages)/26e4793f76daf81ec1257a87002c4700?OpenDocument&ExpandSection=1#_Section1) and for the Seventh Review Conference at [http://www.unog.ch/\\_80256ee600585943.nsf/\(httpPages\)/f1cd974a1fde4794c125731a0037d96d?OpenDocument&ExpandSection=1#\\_Section1](http://www.unog.ch/_80256ee600585943.nsf/(httpPages)/f1cd974a1fde4794c125731a0037d96d?OpenDocument&ExpandSection=1#_Section1).

conference, Secretary Clinton proposed opening the doors of America’s Interagency Biodefense Campus at Fort Detrick, Maryland to representatives of the Convention, in order to promote transparency and international trust.<sup>135</sup> On July 24<sup>th</sup>, 2012, Special Representative for BWC Issues Laura Kennedy led a group of Conference on Disarmament ambassadors, including Algerian Ambassador Delmi, the current BWC chairman, on a tour of the facility. They visited the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the National Biodefense Analysis and Countermeasures Center (NBACC) of the Department of Homeland Security as well.<sup>136</sup>

sionid=78D43E37B90041D74995D97B08F3AEA4.d03t02?v=1&t=h-6dz5gax&s=d74b8bb4f4967b04e25e4fd0ebb6e30905f10618.

<sup>135</sup> See <http://www.state.gov/t/avc/rls/197379.htm>

<sup>136</sup> See <http://geneva.usmission.gov/2012/08/03/ft-detrick/>

## Past biological weapons activities and accusations

The past offensive biological weapons programme of the US is well documented.<sup>137</sup> It was dismantled in 1969 following the US decision to abandon offensive bioweapons.

### *Accusations of US bioweapons use or BWC violations*

The listings here of accusations of US bioweapons use are restricted to after 1972 when the BWC entered into international law and to accusations of state origin or likely state influence. There have been numerous allegations of US bioweapons use and offensive bioweapons research, some of which have proven to be false and some of which have been

<sup>137</sup> G.W. Christopher et al. (1997) ‘Biological Warfare: A Historical Perspective’, *Journal of the American Medical Association*, Vol. 278, No. 5, <http://jama.ama-assn.org/content/278/5/412.abstract>, pp. 412-417. For a summary, see <http://www.fas.org/nuke/guide/usa/cbw/bw.htm>

shown to be politically motivated. Accusations are hard to prove because of:

difficulties in verification of alleged or attempted biological attacks, the use of allegations of biological attacks for propaganda purposes, the paucity of pertinent microbiological or epidemiologic data, and the incidence of naturally occurring endemic or epidemic diseases during hostilities.<sup>138</sup>

A 1997 paper describes Soviet allegations of US offensive bioweapons research and use in the 1970s and 1980s.<sup>139</sup> The key allegations are as follows:

- the US was using the Malarial Control Research Unit in New Delhi, India, to study mosquitoes, birds and chemical spraying for the dispersal of BW agents;
- the United States Agency for International Development funded the Pakistani Medical Studies Center in Lahore to develop disease-carrying mosquitoes for use in Afghanistan and Cuba;
- the US used biological weapons during the Korean War of 1950-53.<sup>140</sup> These allegations had been dismissed years before; and

138 *Ibid.* The quote was made in reference to the history of biological warfare, but is equally applicable to accusations of bioweapons use.

139 M. Leitenberg (1997) 'Biological Weapons, International Sanctions and Proliferation', *Asian Perspective*, Vol. 21, No. 3, pp. 22-31.

140 "New Evidence on the Korean War," Cold War International History Project Bulletin 11," p176-199; M Leitenberg 'False Allegations of U.S. Biological Weapons Use during the Korean War,' Chapter 6 in *Terrorism, War, or Disease? Unraveling the Use of Biological Weapons*, AL Clunan, *et al.* eds (Palo Alto, CA, Stanford University Press, forthcoming); M Leitenberg (2000) 'The Korean War Biological Weapons Allegations: Additional Information and Disclosures', *Asian Perspective*, Vol. 24, No. 3 p159-172.

- biological weapons use in Cuba and Indochina.

Other allegations of US biological weapons use before 1998 are briefly described in a 1997 paper and on the FAS website:<sup>141</sup>

- [I]n January 1988 . . . a report by Tass that the US was developing 'ethnic' weapons.
- On September 2, 1995 the Iraqi mission to the United Nations charged that 'The Allies used an extremely advanced chemical and biological compound named "tricoticine" which has long-term effects on human beings, animals, and even on plants'. The allegation obviously refers to tricothecene mycotoxins.
- The outbreak of plague in Surat, India, in September 1994 resulted in a whispering campaign by Indian authorities that the plague strain was 'a genetically engineered microbe intended for biological warfare,' and the suggestion in the Indian media was that the US was responsible.

By far most of the allegations originate in Cuba. Between 1994 and 1997, Cuba made numerous allegations of US bioweapon attacks against people, animals and crops, including a 1981 outbreak of dengue fever that sickened more than 300,000.<sup>142</sup> None of the allegations were ever proved, and the disease episodes probably were due to natural causes.

141 *Ibid.* Also see <http://www.fas.org/bwc/papers/review/under.htm>

142 R. Zilinskas (1999) 'Cuban allegations of biological warfare by the United States: assessing the evidence', *Critical Reviews in Microbiology*, Vol. 25, No. 3, pp. 173-227; Levy, B.S. and V.W. Sidel (2000) *War and Public Health*, American Public Health Association, Washington, DC, pp. 110-111. Also see <http://www.globalsecurity.org/wmd/world/cuba/bw.htm> and M. Leitenberg (1997) 'Biological Weapons, International Sanctions and Proliferation', *op. cit.*

One particular Cuban allegation was taken up in 1997 by the BWC States Parties under Article V of the BWC. The allegation claimed that an insect, *Thrips palmi*, was dropped from a US crop-dusting airplane in October 1996. *Thrips palmi* is a major pest with respect to vegetable crops and it spread from Asia to the Caribbean in the 1980s.<sup>143</sup> Cuba asserted that a Cuban pilot observed an American cropduster aircraft releasing some kind of substance over the area that was subsequently the source of the infestation, despite its distance from other Caribbean regions with populations of *Thrips palmi*.<sup>144</sup> Cuba presented further information stating that the American pilot's explanation was not consistent with standard aviation procedure, typical mechanical features of his aircraft model, or with the US State Department's explanations of the incident.<sup>145</sup> The report of a BWC States Parties Committee concluded that 'it has not proved possible to reach a definitive conclusion with regard to the concerns raised by the Government of Cuba'. It did not recommend any follow-on actions.<sup>146</sup>

The two allegations of US BWC violations from 1998 to the present summarised below were gleaned from a secondary source: *The CBW Conventions Bulletin*.<sup>147</sup>

143 See [http://entomology.ifas.ufl.edu/creatures/veg/melon\\_thrips.htm](http://entomology.ifas.ufl.edu/creatures/veg/melon_thrips.htm)

144 "Information about the appearance in Cuba of the *Thrips palmi* plague," a document presented to the General Assembly of the United Nations on April 29, 1997, A/52/128, accessed at [http://www.un.org/ga/search/view\\_doc.asp?symbol=A%2F52%2F128&Submit=Search&Lang=E](http://www.un.org/ga/search/view_doc.asp?symbol=A%2F52%2F128&Submit=Search&Lang=E)

145 Ibid, and "Technical considerations regarding the statements by the United States Department of State on the activities of the United States S2R aircraft while overflying Cuban national territory on 21 October 1996," submitted on June 27, 1997, A/52/213, accessed at [http://www.un.org/ga/search/view\\_doc.asp?symbol=A%2F52%2F213&Submit=Search&Lang=E](http://www.un.org/ga/search/view_doc.asp?symbol=A%2F52%2F213&Submit=Search&Lang=E)

146 See <http://www.globalsecurity.org/wmd/world/cuba/bw.htm>

147 See <http://www.sussex.ac.uk/Units/spru/hsp/pdfbulletin.html>

- In 2008, Indonesian Minister of Health, Siti Fadilah Supari, alleged that the US and the World Health Organization had conspired against developing countries by seizing control of samples of the H5N1 bird flu virus, in order to use the material for vaccines or biological weapons development.<sup>148</sup>
- In 2001, Iranian parliamentary deputies accused the US of being the producer of the world's most dangerous biological weapons.<sup>149</sup>

Some arms control experts believe that three US biodefence projects undertaken in the 1990s could be viewed as violations of the BWC. The three projects are described in a 2001 British American Security Information Council (BASIC) report:<sup>150</sup>

- **The Jefferson Project:** the US government planned to develop a genetically modified anthrax strain to test its existing vaccines. It is unclear whether the strain was developed.<sup>151</sup>
- **Project Bacchus:** the US built a biological agent production facility in the State of Nevada using commercially available parts to see how easily it could be done. The facility

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148 See <http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb80.pdf>, p. 24.

149 See <http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb53.pdf>, p. 50.

150 M. Crowley (2001) *Disease by Design: De-mystifying the Biological Weapons Debate*, Research Report 2001.2, British American Security Information Council, London and Washington, DC, [http://www.911investigations.net/IMG/pdf/BASIC-Biological\\_Weapons.pdf](http://www.911investigations.net/IMG/pdf/BASIC-Biological_Weapons.pdf)

151 *Ibid.*, p. 50 and M. Scherer (2004) 'The Next Worst Thing', March/April, <http://motherjones.com/politics/2004/03/next-worst-thing>

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produced a benign, simulated bioweapons agent.

- **Project Clear Vision:** the US Central Intelligence Agency built and tested a ‘mock’ biological bomb patterned on a Soviet-designed biological bomb to see how well it dispersed agents.

## Hoaxes

Hoax anthrax letters are a weekly phenomenon in the US. *The Los Angeles Times* reported in 2009 that

The FBI [Federal Bureau of Investigation] has investigated about 1,000 such ‘white powder events’ as possible terrorist threats since the start of 2007 . . . The bureau responds if a letter contains a written threat or is mailed to a federal official . . . Among the recent targets: nearly all 50 governors’ offices; about 100 U.S. embassies abroad; 52 banks; 36 news organizations; ticket booths at Disneyland; Mormon temples in Salt Lake City and Los Angeles; town halls in Batavia, Ohio, and Ellenville, N.Y.; a funeral home and day-care center in Ocala, Fla.; a sheriff’s office in Eagle, Colo.; and homes in Ely River, N.M.<sup>152</sup>

## Biological Defence and Emergency Preparedness

In the case of a biological attack or natural disease outbreak, the National Notable Diseases Surveillance System (NNDSS) is designed to ensure a quick, coordinated response. Local health care practitioners provide information that can be acted upon at the local and state level, or reported efficiently to the CDC if a national response is required:

Each state has laws mandating that providers report cases of certain diseases to state and/or local health departments. These data provide the direction and scope of many state and local health department activities, from detecting individual cases and controlling outbreaks to implementing prevention and intervention activities. State health departments support national public health surveillance by voluntarily sharing a portion of their data with CDC. The data from states are used by CDC to monitor disease trends, assess the effectiveness of prevention and control measures, identify populations or geographic areas at high risk, formulate prevention strategies, develop public health policies, and work with the international community to identify and contain global outbreaks.<sup>153</sup>

A key element in sharing this data swiftly and effectively is the National Electronic Diseases Surveillance System (NEDSS). The NEDSS allows for secure, immediate internet-based reporting in standardized, mutually compatible formats. Consequently, information can be compared, organized, and analyzed more quickly, while also creating a permanent, searchable database of geographic cases, lab reports, and other relevant medical information for reference and research. The NEDSS is in use in 46 states, as well as New York City and the District of Columbia.<sup>154</sup>

If the NNDSS discovers a severe outbreak, the Strategic National Stockpile (SNS) can respond near-immediately by delivering Push Packages anywhere in the United States or its territories. Push Packages are

152 B. Drogin (2009) ‘Anthrax hoaxes pile up, as does their cost’, *The Los Angeles Times*, 8 March, <http://articles.latimes.com/2009/mar/08/nation/na-anthrax-threats8>

153 See <http://wwwn.cdc.gov/nndss/default.aspx>

154 See <http://wwwn.cdc.gov/nndss/script/nedss.aspx>

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caches of pharmaceuticals, antidotes, and medical supplies designed to provide rapid delivery of a broad spectrum of assets for an ill defined threat in the early hours of an event. These Push Packages are positioned in strategically located, secure warehouses ready for immediate deployment to a designated site within 12 hours of the federal decision to deploy SNS assets.<sup>155</sup>

Push Packages are stored in pre-configured units designed for maximum ease of transport by truck or airplane, and materials are rotated in according to their shelf life, ensuring that all components retain their potency. If more specific medicines, equipment, or supplies are necessary, Vendor Managed Inventory (VMI) will begin shipping the necessary items between 24 and 36 hours. If the outbreak consists of a known or suspected pathogen with available medical countermeasures, the VMI system will provide the first response of targeted vaccines, pharmaceuticals, and/or specialized equipment as required. In the case of an outbreak, the Surgeon General has the authority to detain and quarantine individuals “reliably believed to be infected” to prevent the spread of disease.<sup>156</sup> In accordance with the 2004 Cities Readiness Initiative (CRI), the public health departments of individual states and large metropolitan areas must formulate plans capable of providing antibiotics to their citizens within a minimum of 48 hours after a bioterrorist attack.<sup>157</sup>

In the case of an unknown or highly modified pathogen, the SNS provision of generic medical supplies may be of limited usefulness while the CDC and other medical research facilities work to develop

countermeasures for the new threat, potentially leaving populations vulnerable “for days or weeks”. In this scenario, a response capable of defeating various threats, identified or not, would be ideal, but current medical countermeasures are developed for specific agents most likely to become future threats, and they must be proven safe and effective to the satisfaction of FDA licensing requirements prior to stockpiling for emergency use.<sup>158</sup>

155 See <http://www.cdc.gov/phpr/stockpile/stockpile.htm>

156 See <http://www.bt.cdc.gov/legal/42USC264.pdf>

157 Ibid.

158 Global Security Newswire Staff, “HHS Official Warns of Biodefense Vulnerabilities,” *National Journal*, July 25, 2011, accessed at <http://www.nationaljournal.com/nationalsecurity/hhs-official-warns-of-biodefense-vulnerabilities-20110725>.