BWPP

BioWeapons Prevention Project

BioWeapons Monitor 2011

The BioWeapons Prevention Project

The BioWeapons Prevention Project (BWPP) is a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence. It was launched in 2003 by a group of non-governmental organizations concerned at the failure of governments to fortify the norm against the weaponization of disease. BWPP monitors governmental and other activities relevant to the treaties that codify that norm.

www.bwpp.org

BioWeapons Monitor 2011

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Editor

Iris Hunger (irishunger@versanet.de)

Copy-editor, design and layout

Rick Jones (rick@studioexile.com)

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About the *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, which the current treaty regime does not accomplish sufficiently.

Preventing states and non-state actors from acquiring and using biological weapons is an urgent, unmet need. The *BioWeapons Monitor* seeks to provide factual information that will enhance discussions on strengthening implementation of the BWC and other national and international measures that support the biological weapons prohibition. It works in good faith in order to benefit the international community as a whole.

The *BioWeapons Monitor* is not a technical verification system, but an effort of civil society to hold governments accountable for their obligations to eliminate permanently biological weapons and to prevent their re-emergence. It is meant to complement BWC States Parties' reporting requirements under the BWC confidence-building measures (CBMs). While some states have chosen to make their CBMs available to the public, this is not the case for most states, with the result that civil society is unable, except through the *BioWeapons Monitor,* to assess treaty compliance.

The *BioWeapons Monitor 2011* contains country reports on BWC-relevant activities in eight states: Germany, India, Japan, Kenya, South Africa, Switzerland, the United Kingdom, and the United States. In-country researchers collected and analysed relevant information that is distributed through the publication. The researchers used open sources and actively sought to procure information from government departments, research institutions, industry, scientific societies and other entities. This wide range of sources helps to ensure the project's success—that is, it does not rely solely on governments being forthcoming with information.

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, 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 2011* provide factual information and are critical but constructive in their analysis. As a rule, any controversial piece of information is backed by two different sources. More importantly, countries were given the opportunity to respond to information prior to publication.

This second edition of the *BioWeapons Monitor* builds on experience obtained during work on the inaugural issue in 2010. While the *BioWeapons Monitor 2011* utilised refined data collection and analysis procedures, limitations still exist in this regard, particularly with respect to countries covered for the first time. This second edition was, and future editions will be, able to build on relationships established by the in-country researchers with relevant experts on the ground and experience of finding and using data sources, allowing, over time, reports to be more comprehensive, and the painting of 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 failed negotiations on a legally-binding protocol to the BWC 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, and 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.

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List of researchers and advisers

The following in-country researchers were responsible for researching and writing the country reports:

- Animesh Roul, Society for the Study of Peace and Conflict, India.
- Bilkis Omar, African Research Insight, South Africa.
- Eucharia Kenya and Margaret Muturi, International Centre for Health Intervention and Research in Africa (ICHIRA), Kenya.

- Iris Hunger, Research Group for Biological Arms Control, Germany.
- James Revill, Harvard Sussex Program on Chemical and Biological Weapons, UK.
- Lynn Klotz, Scientists Working Group on Biological and Chemical Weapons, US.
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- Sergio Bonin, Center for Security Studies at ETH Zurich, Switzerland.

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Introduction

State of the biological weapons control regime

The centrepiece of the multilateral biological weapons control regime is the Biological Weapons Convention (BWC) of 1972, which entered into force in 1975. Since the release of the *BioWeapons Monitor 2010,* Burundi has ratified and Mozambique has acceded to the BWC, bringing the number of members and signatories to 165 and 12, respectively. 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 to achieve universality.

States that signed the BWC but have yet to ratify

1. Central African Republic
2. Côte 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. Marshall Islands
12. Mauritania
13. Micronesia (Federated States of)
14. Namibia
15. Nauru
16. Niue
17. Samoa
18. South Sudan
19. Tuvalu

Biological arms control currently has the chance to leave behind the shadows of its deepest crisis since the signing of the BWC in 1972. Efforts to strengthen and improve the Convention by adding transparency and verification measures ended unsuccessfully in summer 2001 after 6.5 years of negotiations. At the Fifth BWC Review Conference in 2001 and 2002 states were unable to agree on reopening multilateral negotiations on a legally-binding Protocol to the BWC. Instead, they agreed on regular meetings to discuss a specific range of issues, including national implementation, disease surveillance, and the role of the scientific community.

These intersessional discussions took place twice a year and continued after the Sixth BWC Review Conference in 2006. They have resulted in the unprecedented opening of proceedings in Geneva, Switzerland, to international and non-governmental organisations (NGOs), and in bringing in new expertise, primarily from the public health sector. The intersessional process has increased common understanding on a variety of issues, but it has not produced any collective action, such as multilaterally agreed decisions, recommendations, or guidelines.

The Seventh BWC Review Conference in December 2011 presents an opportunity to translate common understanding into collective action in relation to the topics under discussion in the intersessional process and to revisit the pressing issue of verification of the BWC.

The central norm of the BWC is written down in Article I of the treaty:

> 'Each State Party to this Convention undertakes never in any circumstances 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 conflict'.

While there have been violations of this central norm in the past, 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. During the BWC Review Conference in 2006, the United States accused Iran, North Korea and Syria (a signatory) of non-compliance with the BWC.[1] Iran and Syria rejected the accusation; North Korea was not represented at the conference.[2] A number of States Parties voiced general concerns at the

1 Statement by the representative of the US during the opening plenary of the Sixth BWC Review Conference, 20 November 2006, http://www.opbw.org

2 Statements by the representatives of Iran and Syria during the General Debate of the Sixth BWC Review Conference, 20–21 November 2006, http://www.sussex.ac.uk/Units/spru/hsp/documents/CBWCB74.pdf; also see the list of participants for the Sixth BWC Review Conference at http://www.opbw.org

2006 Review Conference about the use of biological weapons by non-state actors such as terrorist groups or individuals.

Why transparency is important

Compliance with the prohibition is about more than verifying the absence of biological weapons. Perhaps more importantly, it is also about verifying the peaceful nature of activities that could contribute to biological weapons development efforts. A large number of the peaceful activities in the area of the life sciences and biotechnology could be harnessed without major alteration to advance biological weapons development. The 'dual-use' character of many activities in the biological area thus makes verification of compliance with the BWC difficult. It is insufficient simply to confirm the presence or absence of certain items of equipment or materials; one also has to determine the intentions behind the use of such items.

Owing to the widespread dual-use problem in the life-science and biotechnology sphere, transparency is an important precondition for assessing compliance with the BWC. Political scientists and diplomats have repeatedly and consistently stressed the importance of transparency for the effectiveness of multilateral control regimes. Transparency refers to the availability of relevant information and, more extensively, to the openness of a system (such as a government or a private company) to external observers. To regulate the behaviour of states and to assess regime effectiveness, actors simply must have information on the activities they are trying to control. A sufficient degree of transparency also helps to deter violations of norms and reassures actors that others are not misusing technologies and materials.

Transparency about and the willingness to explain the biological activities performed in a given country are of the utmost importance for increasing confidence in their peaceful nature. Excessive secrecy of activities in the biological field, particularly if carried out in military facilities, is likely to lead to misinterpretation and suspicion, and may result in a new biological arms race. In 2005, then United Nations (UN) Secretary-General Kofi Annan called on all states 'to increase the transparency of biodefence programmes'.[3]

Existing transparency-building efforts under the BWC

The existing biological weapons control regime includes a number of formal and informal, intrusive and non-intrusive multilateral mechanisms to foster transparency. States agreed in 1980 to report on the destruction of existing biological and toxin weapon stockpiles. The consultative mechanism under Article V of the BWC allows for multilateral meetings to consider problems and to clarify ambiguities regarding BWC compliance. Serious biological weapons-related compliance concerns can be addressed through on-site inspections. The current annual BWC meetings are a forum for face-to-face

3 See http://www.un-ngls.org/orf/UNreform/UBUNTU-1.pdf, para. 103, p. 19.

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). The existing transparency enhancement measures have, however, limited utility. Only one state has ever taken advantage of the consultative process under Article V in a multilateral setting;[4] many states do not submit the politically-binding CBMs; and there is little follow-up after the initial data-gathering step.

Confidence-building measures

CBMs are the only permanent transparency mechanism under the BWC that a large number of states are using regularly. Every BWC State Party is under the obligation to submit a CBM declaration by 15 April of each year, providing information on a range of activities and facilities. As of 20 November 2011, 68 states had submitted their CBM for the year, a few less than in 2010, and still less than 50 per cent of the 165 BWC States Parties. The BWC Implementation Support Unit collects the CBM returns and makes them available to States Parties.[5]

CBMs were agreed in 1986 'to prevent or reduce the occurrence of ambiguities, doubts and suspicions'[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. The topics that were agreed in 1991 are the ones under which information still is requested today:[7]

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 publication of results and promotion of the use of knowledge.

D. Active promotion of contacts.

E. Declaration of legislation, regulations and other measures.

F. Declaration of past activities in offensive and/or defensive biological research and development programmes.

G. Declaration of vaccine production facilities.

CBM declarations are available to BWC States Parties only. A limited but increasing number of

4 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://bwc.unog.ch/1997-08-FCP/BWC_CONS_01.pdf; and Zilinskas, 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.

5 Detailed guidance on how to collect information, complete the forms and submit the CBM declaration to the United Nations is available at http://www.unog.ch/bwc/cbms

6 See http://bwc.unog.ch/1986-09-2RC/BWC_CONF.II_13.pdf, Part II, p. 6.

7 For the current CBM forms see http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/3CFFA8AC4E497426C12572DB00514912/$file/CBM_Forms_Static_E.pdf

states—21 of the 68 having handed in CBMs as of 20 November 2011—provide them to the public.[8]

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 verification of the BWC. The objective is to demonstrate that transparency of relevant activities can be increased through open-source information alone.

We selected countries (Germany, India, Japan, Kenya, South Africa, 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 a common methodology are extremely rare. One effort to develop such a ranking system was published in 2005.[9] The *BioWeapons Monitor* has used the methodology suggested in that publication and updated the listing. Detailed information is available in the Annex.

8 See http://www.unog.ch/__80256ee600585943.nsf/%28httpPages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=25#_Section25

9 See http://www.biological-arms-control.org/publications/hunger_CBM.pdf, pp. 46–51.

We selected two countries each from Africa, the Americas, Asia, and Europe to sustain the *BioWeapons Monitor*'s principle of global distribution. Unfortunately, one of the two countries from the Americas, Brazil (which was covered in the *BioWeapons Monitor 2010*), could not be included this year, because of organisational difficulties. In addition, the Swiss Federal Department of Foreign Affairs suggested that the *BioWeapons Monitor* include Switzerland in the 2011 edition; the *BioWeapons Monitor* was happy to do so.

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 control. 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. As in the first edition, not all topics could be covered in all of the country reports.

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
- work on (bio)chemical non-lethal weapons.

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, tularemia, and viral hemorrhagic 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. ■

Findings

The *BioWeapons Monitor 2011* found no evidence in the public domain of non-compliance with the 1972 Biological Weapons Convention (BWC) by the countries surveyed in the year under review.

This second edition of the *BioWeapons Monitor* increased further transparency of BWC-relevant activities globally. Five new countries were surveyed in 2011: Japan, South Africa, the United Kingdom, and the United States (all global or regional biotechnology leaders on different continents), as well as Switzerland (at the suggestion of the Swiss Federal Department of Foreign Affairs). The country reports of three of the four countries covered in 2010 were updated and expanded in 2011 (Germany, India, and Kenya).

The *BioWeapons Monitor 2011* builds on experience gained during production of the first edition. Experience of data-source identification and data-gathering, and the relationships established by the in-country researchers with relevant experts on the ground, allowed for more extensive data-gathering (especially for those countries surveyed for a second time), making it possible to fill gaps in last year's reports. Notable findings include those detailed below.

Four of the countries covered (Germany, Switzerland, the UK, and the US) have submitted their 2011 CBM (confidence-building measure) declarations and made them publicly available. The type and amount of data collected and compiled in the country reports are more extensive than what is covered in those CBMs. Three countries (India, Japan, and South Africa) have submitted their 2011 CBM declarations but not made them public. Kenya's 2011 CBM declaration, although reportedly having been submitted in September, had not yet been listed on the Implementation Support Unit (ISU) website by 20 November 2011.

The global distribution of capabilities in the sphere of the life sciences and biotechnology is changing. The *BioWeapons Monitor 2011*'s survey indicates, for example, that a number of countries outside of Europe and North America, such as Colombia, India, Iran, the Republic of Korea, Thailand and Tunisia, have climbed up many rungs of the ladder of science and technology holders over the past six years.

Military activities in the life-science field were identified in all eight countries. In Kenya, there is no regular biodefence programme; instead, the

Kenyan military is cooperating with the US Army on health research, mainly on malaria and HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome). The other seven countries have military biodefence programmes of extremely diverging size and age, with the US programme being by far the biggest. Except for Kenya, all of the countries surveyed also have civilian biodefence activities. The ratio between military and civilian defence activities ranges from 'mostly civilian' (Japan and Switzerland) to 'a greater extent civilian' (Germany, India, South Africa, and the US) to 'a greater extent military' (the UK). What remains unclear is definition of the term biodefence. It seems to differ from country to country, influencing what is counted as biodefence (and not, for instance, public health) and what is not, and the distinction between civilian and military biodefence activities. By way of illustration, Switzerland declared in its 2011 CBM regional diagnostic laboratories as biodefence facilities, whereas Germany does not consider the 'biosecurity projects' conducted in its central public health institution to be biodefence activities, and hence does not declare them in its CBM.

The *BioWeapons Monitor 2011* identified operational BSL-4 laboratories in six of the eight countries surveyed:

- Germany has two fully operational BSL-4 laboratories, one more will be fully operational in the near future, two more are planned or in the early stages of construction;
- India has one fully operational BSL-4 laboratory, one more will be fully operational in the near future;
- Japan has two BSL-4 laboratories, which are not being operated at the maximum safety level due to local public opposition;
- Kenya has no BSL-4 laboratories;
- South Africa has one fully operational BSL-4 laboratory;
- Switzerland has one operational BSL-4 laboratory that is for diagnostic purposes only, one more will be fully operational in the near future;
- the UK has four fully operational BSL-4 laboratories; and
- the US has seven fully operational BSL-4 laboratories, four more are planned or in the early stages of construction.

The *BioWeapons Monitor 2011* was able to pinpoint approximately half-a-dozen BSL-3 facilities each in India, Kenya, and South Africa, as well as at least 97 operational BSL-3 facilities in Germany, approximately 200 in Japan, at least 36 in Switzerland, 347 in the UK, and 1,356 in the US.

All of the countries surveyed have vaccine production facilities. Kenya and South Africa are currently producing animal vaccines only. The biggest vaccine producers are India, Japan, and US, where 10, 9 and 22 facilities respectively could be discerned.

Two unusual disease outbreaks were identified for the past two years. Human cases of anthrax occurred in Germany and the UK due to contaminated heroin. The other was an outbreak in Germany of enterohaemorrhagic *Escherichia coli* with unusual properties; bioterrorism concerns were voiced, but the source turned out to be fenugreek sprouts with no indication of deliberate contamination.

With the exception of South Africa, there is no evidence in the public domain of any of the countries surveyed ever having been involved in biological weapons activities after the signing of the BWC in 1972. India, the UK, and the US have been the targets of unsubstantiated allegations of biological weapons development or use. Compliance concerns were voiced in relation to some aspects of the US biodefence programme in the early twenty-first century.

The *BioWeapons Monitor* remains the only public document that presents a comprehensive overview of the capabilities and activities of selected states in the area of the life sciences and biotechnology with relevance to the BWC. The *BioWeapons Monitor 2011* demonstrates the potential of continuous monitoring by civil society for painting complex and comprehensive pictures of BWC-relevant activities in countries with very different levels of technological development. While not yet possible, continuous monitoring will, in the future, be able to point up trends in biodefence activities, vaccine production, and bioterrorist events. The *BioWeapons Monitor* will work towards covering more countries in years to come, particularly leading global and regional biotechnology holders, in order to develop a more complete assessment of BWC-relevant activities around the world. ■

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, Werderscher Markt 1, Berlin 10117, Germany

Tel.: +49 30 5000 4583

E-mail: 243-rl@diplo.de

Germany is a long-standing supporter of the international prohibition on biological weapons. Its policy is guided by European Union (EU) policy on the issue, which is set down in the 2003 European Security Strategy (*A Secure Europe in a Better World*)[1] and more specifically in the 2003 *EU Strategy Against Proliferation of Weapons of Mass Destruction.*[2] The EU views terrorism and the proliferation of weapons of mass destruction (WMD) as major threats to its security. It believes that '[a]dvantages in the biological sciences may increase the potency of biological weapons in the coming years'[3] and that biological weapons 'may have particular attractions for terrorists'[4]. 'Effective multilateralism' is the EU's mechanism of choice for countering the proliferation of WMD. According to the Council Decision of 18 July 2011 relating to the EU's position on the Seventh BWC Review Conference in December 2011,

1 See http://www.consilium.europa.eu/uedocs/cmsUpload/78367.pdf

2 See http://register.consilium.europa.eu/pdf/en/03/st15/st15708.en03.pdf

3 See http://www.consilium.europa.eu/uedocs/cmsUpload/78367.pdf, pp. 3–4.

4 See http://register.consilium.europa.eu/pdf/en/03/st15/st15708.en03.pdf, p. 4.

the EU aims 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', and reviewing the implementation of Article X.[5]

Together with Switzerland and Norway, Germany has focused its preparatory efforts for the Seventh BWC Review Conference on the BWC confidence-building measures (CBMs). Besides organising a series of workshops on the topic in 2009 and 2010, Germany has co-sponsored one and submitted another working paper on CBMs.[6] Germany also sponsored one of the international workshops in preparation for the Seventh BWC Review Conference—in Berlin in June 2011.

Status of the life sciences and biotechnology industry

According to the 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.[7]

The auditing company Ernst & Young cites 400 German biotechnology companies.[8] The German Biotech Database, a directory and information platform comprising data on life-science and biotechnology companies and institutes in Germany, lists 1,919 such companies and institutes.[9] 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 761 companies and 93 universities and research institutes in Germany.[10]

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 218 members.[11] Bio Deutschland, the sector association of the German biotechnology industry, has 282 members.[12]

Biodefence activities and facilities

Germany's military biodefence programme dates from the 1950s.[13] Germany started to declare information on its biodefence programme in 1992, when this

5 See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:188:0042:0046:EN:PDF

6 See http://www.unog.ch/80256EE600585943/%28httpPages%29/BF4050089BB59EEDC12579300045A924?OpenDocument

7 See the Annex to this report.

8 Ernst & Young (2011) *Deutscher Biotechnologie-Report 2011*, http://www.ey.com/Publication/vwLUAssets/Deutscher_Biotechnologie-Report_2011/$FILE/German_Biotechreport_2011_SEO.pdf

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

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

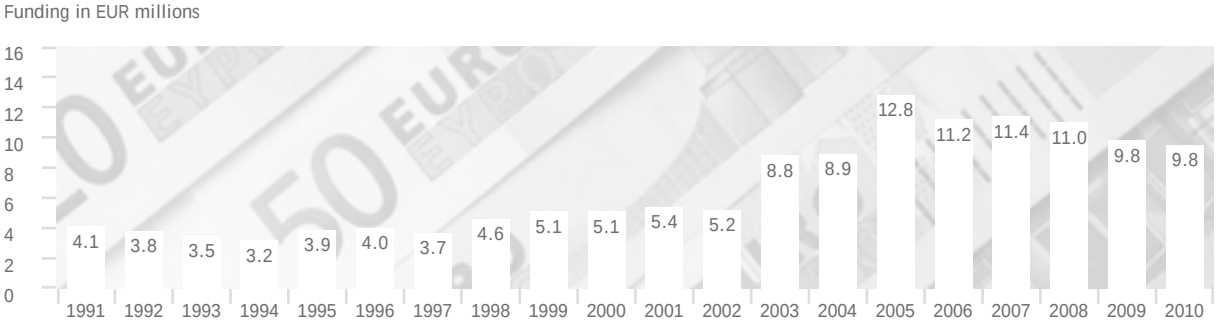
11 See http://www.v-b-u.org/Mitglieder/Unsere+Mitglieder.html

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

13 Germany 1992 CBM.

information was first required under the CBMs of the BWC. Funding for this programme, roughly speaking, tripled between the early 1990s and 2005. In 2010, EUR 9.52 million was spent on Germany's military biodefence programme. Figure 1 shows the trend in funding for this programme between 1991 and 2010.

Figure 1. Declared funding for the German military biodefence programme, 1991-2010



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 1992–2011 CBMs.

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	4 (all 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 flavi-viruses, 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
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)	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, ricin

According to Germany's 2011 CBM declaration, the same four facilities as in 2009 were involved in the military biodefence programme in 2010 (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 2010 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.[14]

In 2010, approximately 15 per cent of the Ministry of Defence (MoD)'s funding went to contracted facilities.[15] 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 Biodefense 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.[16]

Germany describes the aims and activities of its military biodefence programme as follows: 'The RD [research and development] activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection'.[17] Short descriptions of all research and development projects on medical biodefence are available online.[18] 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 Munster. The latter presented its work at the 2011 Medical Biodefense Conference in Munich; projects presented were titled 'Lateral flow assays for the rapid detection of biological threat agents in the field', 'Photochemical inactivation allows rapid diagnostics of alpha- and poxviruses', 'Microbial inactivation for safe and rapid diagnostics of infectious samples', 'Effective sampling of B-agents using different swabs', and 'Inactivation methods for pathogens affect detection assays'.[19]

Since 1989, the German MoD has informed the Bundestag (national parliament) annually about

14 Germany 2011 CBM.

15 Germany 2011 CBM.

16 2011 Medical Biodefense Conference, Munich, 25–28 October, list of participants.

17 Germany 2011 CBM.

18 See http://www.sanitaetsdienst-bundeswehr.de/portal/a/sanitaetsdienst/!ut/p/c4/04_SB8K8xLLM9MSSzPy8xBz9CP3I5EyrpHK9quLEPL3c1JTMqsw8vbT8ouLkjNK8dL3EpGQQq6RKvyDbUREAGIhxFw!!/

19 2011 Medical Biodefense Conference, *op. cit*, abstracts.

MoD-funded projects involving genetic engineering work. According to the 2011 report, 23 such projects were conducted in 2010.[20] Nine of these 23 projects focused on chemical defence measures, while two dealt with non-biodefence health issues. The remaining 12 were all carried out under BSL-1 or BSL-2 conditions:

- Development and testing of equipment and procedures for field use for sampling and identification of biological weapon agents and other highly contagious human pathogens.
- Development of a real-time, polymerase chain reaction (PCR)-based, field-usable detection system with automated sample preparation for the detection of different biological weapon agents.
- Development of gene probes (project paused in 2010).
- Diagnosis, prophylaxis and epidemiology of anthrax.
- Diagnosis, prophylaxis and epidemiology of orthopox viruses.
- Diagnosis, prophylaxis and epidemiology of glanders and mellioidosis.
- Diagnosis, prophylaxis and epidemiology of selected bunyavirus and flavivirus infections.
- Diagnosis, prophylaxis and epidemiology of diseases caused by alphaviruses.
- Diagnosis, prophylaxis and epidemiology of diseases caused by rickettsia.
- Evaluation of biological weapon detection systems (project paused in 2010).
- Evaluation of defined phagemid clones and construction of scFv-expressing organisms.
- Identification of known and unknown biological weapon-relevant viruses by genomic hybridisation.

Besides its long-standing military biodefence programme, Germany has declared a small civilian biodefence programme since 2005, aimed at improving preparedness and the 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. Funding in 2010 amounted to EUR 125,205, almost one-quarter less than in 2009. Two projects were conducted: one on 'efficacy testing of disinfectants on surfaces of personal protection equipment' and one on the 'evaluation of real-time PCR assays by a round-robin test'.[21]

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'.[22] Five additional projects that are completely or partly biodefence projects were

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

21 Germany 2011 CBM.

22 See http://www.bmbf.de/pub/Zivile_Sicherheit_Gefahrstoffe.pdf

Table 2. Selected projects that are completely or partly biodefence projects conducted under the Research for Civil Security programme of the Ministry of Education and Research[23]

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

Table 3. Projects that are completely or partly biodefence projects funded by the European Commission's Seventh Framework Programme FP7-Security[24]

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	As of 1 November 2011: under negotiation.		
CBRNEMAP	Road-mapping study of CBRNE demonstrator	14	1.4	June 2010–September 2011
CREATIF	CBRNE-related testing and certification facilities	7	0.8	February 2009–July 2011
DECOTESSC	Demonstration of counterterrorism system-of-systems against CBRNE	9	1.0	April 2010–June 2011
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

identified under different programme lines (see Table 2).

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

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 involving smallpox. The smallpox preparedness plan also constitutes the basis for dealing with other epidemics resulting from a bioterrorist attack.[25]

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.[26] In 2010–11, the ZBS conducted 60 projects. Only 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.[27]

To support the states in preparing for disaster management, the federal government has built up stocks of medication and medical supplies. Supplies for general medical emergencies are to be stored at 100 different locations, and they are to be complemented by specific supplies for protection in the event of an NBC (nuclear, biological, chemical) scenario. In particular, the antibiotic Ciprofloxazin is being stored to protect people from or to treat people after an outbreak of anthrax or plague.[28] 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).[29]

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

23 See http://www.bmbf.de/en/12874.php

24 See http://cordis.europa.eu/fp7/home_en.html

25 See http://www.rki.de/cln_178/nn_216446/EN/Content/Prevention/Bioterrism/bioterrism__node__en.html?__nnn=true

26 See http://www.rki.de/DE/Content/Institut/OrgEinheiten/ZBS/zbs__node.html

27 See http://www.rki.de/cln_160/nn_199408/DE/Content/Institut/OrgEinheiten/ZBS/Projekte,templateId=raw,property=publicationFile.pdf/Projekte.pdf

28 See http://www.bbk.bund.de/DE/AufgabenundAusstattung/GesundhBevschutz/Allgemeines/Sanitaetsmaterialbevorratung/sanitaetsmaterialbevorratung_node.html

29 Pockenimpfstoff für die gesamte Bevölkerung in Deutschland gesichert, 10 November 2003, http://www.denis.bund.de/aktuelles/04332/index.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, 220 sqm.	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[30]
Robert Koch Institute	Berlin	In early construction	n/a	Building permit issued in 2007; construction started in autumn 2010; start of operations planned for 2014[31]
Institute of Microbiology of the Federal Armed Forces	Munich	Planned	n/a	–

Table 5. Number of BSL-1, 2 and 3 facilities engaged in genetic engineering work

Biosafety level	Public	Private	Total (2011)	Total (2010)
1	3,583	906	4,489	4,397
2	1,266	191	1,457	1,387
3	87	10	97	97

30 See http://www.fli.bund.de/no_cache/de/startseite/presse/presse-informationsseite/Pressemitteilung/fli-gibt-startschuss-fuer-den-umzug-in-den-neubau.html

31 See http://www.rki.de/nn_753518/SharedDocs/FAQ/Hochsicherheitslabor/FAQ__12.html

Table 6. Vaccine production facilities

Name	Location	Diseases covered/additional information
Novartis Vaccines and Diagnostics GmbH[32]	Marburg	Botulism (antitoxin), diphtheria, influenza, meningococcal meningitises, pertussis, rabies, tetanus, tick-borne encephalitis
GlaxoSmithKline Biologicals[33]	Dresden	Influenza
IDT Biologika GmbH[34]	Dessau-Rosslau	Production of bacterial and viral vaccines for clinical trial: filoviruses, human immuno-deficiency virus (HIV), malaria, Salmonella typhi, smallpox, tuberculosis
Rhein Biotech GmbH. Dynvax Europe[35]	Düsseldorf	Hepatitis B (commissioned production)
Bavaria Nordic GmbH[36]	Berlin	Pilot production plant, established in 2003; for production of vaccines for clinical trials: anthrax, HIV, smallpox, fowlpox, respiratory syncytial virus (RSV), other infectious diseases, cancer
Vibalogics GmbH[37]	Cuxhaven	Tuberculosis (commissioned production for clinical trials), other bacterial and viral vaccines

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.[38]

Besides the BSL-4 facilities, there are many facilities with lower containment, which are managed at the state level. Table 5 provides an overview of such facilities that are engaged in genetic engineering work.[39]

32 See http://www.novartis-vaccines.de/about/uebernovartis vaccines_marburg.php

33 See http://www.glaxosmithkline.de/html/unternehmen/dresden_standort.html

34 See http://www.idt-biologika.de

35 See http://www.rheinbiotech.de/products.0.html

36 See http://www.bavarian-nordic.com

37 See http://www.vibalogics.com

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

39 See http://www.bvl.bund.de/DE/06_Gentechnik/02_Verbraucher/03_Genehmigungen/03_GentArbeitenAnlagen/gentechnik_GenehmigungGentArbeitenAnlagen_node.html

Vaccine production facilities

Six licensed human vaccine production plants were active in Germany in 2010 (see Table 6).[40]

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;[41]
- 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;[42] and

40 Germany 2011 CBM.

41 See http://www.glaxosmithkline.de/docs-pdf/unternehmen/Folder_dt_eng.pdf

42 See http://www.idt-biologika.de

- Vibalogics GmbH in Cuxhaven runs a '2,500 m^2 facility with 1,100 m^2 classified rooms' and has '3 bioreactors up to 30 l working volume (1 single-use)'.[43]

Disease outbreak data

With regard to particularly dangerous diseases, the following outbreaks were recorded in Germany in 2010[44] and 2011[45]:

- Anthrax: two cases of anthrax in 2010 due to contaminated heroin; both recovered.[46]
- Botulism: four cases in 2010, six cases in 2011 (as of October 2011).
- Lassa/Ebola/Marburg: none.
- Plague: none.
- Smallpox: none.
- Tularaemia: 31 cases in 2010; 12 cases in 2011 (as of October 2011).

One unusual disease outbreak affected Germany in summer 2011. Starting in early May 2011, there was an unusually high number of HUS (haemolytic-ureamic syndrom) and bloody diarrhoea cases caused by enterohaemorrhagic Escherichia coli (EHEC) of serotype O104:H4. The EHEC outbreak was declared ended on 26 July 2011. 855 HUS cases and 2,987 cases of acute gastroenteritis were recorded. 53 people died. Unusually, it was mostly adults who suffered. The source of infection was contaminated fenugreek sprouts.[47] During the outbreak there was speculation that it was the result of a bioterrorist attack.[48]

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).[49] The central legal instruments are:

1) the War Weapons Control Act of 1961, which prohibits any activity relating to biological weapons, including development, trade, trans-

43 See http://www.vibalogics.com

44 See http://www.rki.de/cln_160/nn_2019956/DE/Content/Infekt/Jahrbuch/Jahresstatistik__2010,templateId=raw,property=publicationFile.pdf/Jahresstatistik_2010.pdf

45 See http://www3.rki.de/SurvStat (19 October 2011).

46 See http://www.rki.de/cln_160/nn_205760/DE/Content/Infekt/EpidBull/Archiv/2010/49__10,templateId=raw,property=publicationFile.pdf/49_10.pdf

47 See http://www.rki.de/DE/Content/InfAZ/E/EHEC/EHEC-Abschlussbericht.html

48 See, for instance, http://www.tagesspiegel.de/meinung/ehec-ausbruch-gibt-raetsel-auf-auch-unheimliche/4213684.html or http://www.spiegel.de/wissenschaft/medizin/0,1518,766430,00.html

49 See http://www.un.org/sc/1540/nationalreports.shtml

fer, 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.[50]

(Bio)chemical non-lethal weapons

After the Kosovo crisis in 2004, the Government of Germany decided to allow the country's military forces to employ riot-control agents, such as pepper-spray, in United Nations (UN)-, European Union (EU)-, and North Atlantic Treaty Organization (NATO)-mandated missions.[51] The Parliament has to be informed should newly-developed agents be introduced as non-lethal weapons into the arsenal of the military forces.[52]

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.[53] The DFG 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 co-

50 See http://www.unog.ch/80256EE600585943/(httpPages)/4ADF8E868AAE82B3C1257578005563E1?OpenDocument

51 Erstes Gesetz zur Änderung des Ausführungsgesetzes zum Chemiewaffenübereinkommen, 11 October 2004, and Drucksache 15/3447, Deutscher Bundestag.

52 See http://www.spiegel.de/politik/deutschland/0,1518,311

53 See http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2008/codex_dualuse_0804.pdf

operation 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.[54]

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.[55] 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.[56] 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.[57]

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.[58]

CBM participation

Germany has submitted CBM declarations regularly—it is one of nine states that have filed CBM declarations in each of the 25 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 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

54 See http://www.biodeutschland.org/position-papers-and-statements.html

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

56 See http://www.mpg.de/pdf/procedures/researchFreedomRisks.pdf

57 Interacademy Panel on International Issues (2005) 'IAP Statement on Biosecurity', 1 December, http://sites.nationalacademies.org/xpedio/groups/pgasite/documents/webpage/pga_054651.pdf

58 See http://www.biological-arms-control.org/publications/2010BiosecurityUmfrage-Publikation-Final-English.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
Number of delegates	18	7	8	8	10	11	6	9	8	6

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

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.[59] ■

59 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.[1] 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 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'.[2]

India also agreed to the 'Final Document' of the BWC Sixth Review Conference, which includes the following declarations:

'41. The Conference stresses the importance of the withdrawal of all reservations to the 1925 Geneva Protocol related to the Convention.

42. The Conference welcomes the actions which States Parties have taken to withdraw their reservations to the 1925 Geneva Protocol related to the Convention, and calls upon those States Parties that continue to maintain pertinent reservations to the 1925 Geneva Protocol to withdraw those reservations, and to notify the Depositary of the 1925 Geneva Protocol of their withdrawals without delay.

43. The Conference notes that reservations concerning retaliation, through the use of any of the objects prohibited by the Convention, even conditional, are totally incompatible with the absolute and universal prohibition of the development, production, stockpiling, acquisition and retention of bacteriological (biological) and toxin weapons, with the aim to exclude completely and forever the possibility of their use.'[3]

National point of contact

D.B. Venkatesh Varma, Joint Secretary (Disarmament and International, Security Affairs), Ministry of External Affairs, South Block, New Delhi 110001, India

Tel.: +91-11-23014902
+91-11-23015626

E-mail: jsdisa@mea.gov.in

India has neither the military intention nor the political will to develop and use biological weapons 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'.[4]

India takes the biological weapons 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.[5] In 2007, Prime Minister Manmohan Singh underscored the fact that the Government of India is working towards mitigating biological weapon threats.[6] 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.[7]

In early October 2011, a team of DRDO scientists led by Chief Controller W. Selvamurthy visited the United Kingdom and shared recent Common Wealth Games(CWG) experience,[8] mostly pertaining to preparedness to handle CBRN (chemical, biological, radiological, nuclear) situations and technologies developed by the DRDO for CBRN defence. The Indian delegation reportedly had extensive interactions with the relevant unit of the Office for Security and Counter-Terrorism (OSCT)—under the Home Office—to explore possibilities for cooperation in developing CBRN and other defence technologies.[9]

1 See http://www.icrc.org/customary-ihl/eng/docs/v1_rul_rule73#Fn3

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

3 BWC/CONF.VI/6, 8 December 2006, http://www.opbw.org/rev_cons/6rc/docs/6/BWC_CONF.VI_6_EN.pdf

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

5 See http://articles.timesofindia.indiatimes.com/2003-09-18/india/27197960_1_ricin-castor-plant-toxin

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

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

8 During the October 2010 Commonwealth Games, at least 120 National Disaster Response Force (NDRF) personnel for a CBRN emergency were put on duty at venues. The plan to furnish the NDRF with prophylaxis was devised in December 2009, well ahead of the Games. See http://www.mid-day.com/news/2009/dec/221209-Commonwealth-Games-Pune-Terrorism.htm and http://ibnlive.in.com/generalnewsfeed/news/more-than-1000-ndrf-personnel-to-be-deployed-during-cwg/323582.html

9 On 5 October 2011, DRDO Chief Controller W. Selvamurthy delivered a talk on 'Indian Approach to CBRN Defence' to the XIV International CBRN Symposium at the Defence Academy at Shrivenham, Carnfield University (UK). See http://frontierindia.net/indiandefence/india-u-k-to-collaborate-chemical-biological-radiological-and-nuclear-protection-devices/

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, India has an important life science and biotechnology community. In absolute terms, India ranks thirteenth globally; in its geographical sub-region, Southern Asia, it ranks first. More specifically, globally, India ranks sixth in terms of publications and twenty-third in terms of patents.[10]

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 (INR 18,399.34 crore).[11] Of this, the biotech industry contributed INR 17,249.34 crore, while the life-science education market shares the remaining INR 1,150.00 crore. The biotech industry, without the life-sciences education component, recorded revenue growth of 21.5 per cent vis-à-vis 2009–10 revenues, amounting to INR 14,199 crore.[12]

India's biotech sector is the third largest in the Asia-Pacific region, after those of Australia and China.[13]

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 bioservices (21 per cent), bioagriulture (19 per cent), bioinformatics (14 per cent) and the bioindustrial sector (5 per cent).[14]

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.[15]

There is speculation that India's biopharma sector may only see a surge in R&D spending to about USD 25 billion in the next 15 years.[16] According to one assessment, some USD 700 million was spent during 2009–10 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

10 See the Annex to this report.

11 See http://biospectrumindia.ciol.com/content/CoverStory/11106091.asp

12 *Ibid.*

13 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

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

15 See http://biospectrumindia.ciol.com/content/bioEvents/11007071.asp

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

Medical Research (ICMR) in 2000–01.[17] In 2010, the Government of India announced plans to set up a 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 to at least 1973.[18]

The DRDO is spearheading biodefence R&D for civilian and military purposes. It has been working 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.[19]

In July 2010, India's Cabinet Committee on Security (CCS) approved a project under which the DRDO has been tasked with developing fast 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.[20] 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.[21] The Defence Acquisition Council has cleared orders for anti-NBC warfare products worth another INR 2,000 crore.[22]

In the life-science sphere, DRDO products under manufacture are valued at INR 600 crore. Technologies developed against NBC warfare agents include water-purification filters, nerve-agent detectors, and underground shelters.

The *BioWeapons Monitor 2011* 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

17 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.

18 India 1997 CBM.

19 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

20 See http://www.thehindu.com/news/national/article510906.ece

21 See http://articles.economictimes.indiatimes.com/2010-06-07/news/27576819_1_drdo-development-organisation-defence-research

22 See http://www.thehindu.com/news/national/article1076132.ece

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.[23]

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-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.[24] 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.[25]

Work at the facility focuses on countering biological weapons-related disease threats, such as anthrax, botulism, brucellosis, cholera, plague, smallpox and viral haemorrhagic fevers.[26] 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.[27]

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.[28] 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.[29] Collaborative projects receive funding from the Council for Scientific and Industrial Research, Department of Health, the All India

23 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

24 See http://articles.timesofindia.indiatimes.com/2009-07-04/india/28180829_1_nbc-recce-vehicle-drdo

25 See http://indiadefenceonline.com/956/nbc-reconnaissance-vehicle-inducted-into-army/

26 'A passage to India', CBRNE World, Summer 2010. (Interview with Dr. Rajagalopalan Vijayaraghavan, Director, DRDE.)

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

28 Information gathered during informal interactions with scientists involved in DRDO and university-level life-science projects in mid-2008.

29 India 1997 CBM.

Table 1. Contact information for government biodefence facilities in India

Biodefence facility	Contact 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
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	P. O. Box No. 9326, CV Raman Nagar, Bangalore (Karantaka) – PIN 560 093, India Tel.: +91 802-5280692/+91 802-5058425 E-mail: dirdebel@debel.drdo.in
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

Institute of Medical Sciences, and other life-science laboratories under the DRDO, as well as allocated funding from various life-science departments at universities.

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.[30]

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.[31]

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.[32]

The Defence Food Research Laboratory (DFRL) located in Mysore (Karantaka) under the aegis of the DRDO

30 *Ibid.*

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

Table 2. Contact information for private companies involved with the DRDO 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) – PIN 201 007, 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 – PIN 400 028, India Tel.: +91 222-4221880/1878 Fax: +91 222-4303705 E-mail: mumbai@lesliedraeger.com

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.[33]

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.[34]
- Dass Hitachi Ltd., a Gaziabad-based private company, has developed integrated NBC protection systems, IFS, NBC filtration systems, and ruggedised scooping devices. Dass Hitachi has successfully produced these technologies in bulk in a stipulated time frame for the Armed Forces. In 2010, the DRDO reportedly signed two Memorandums of Understanding with Dass Hitachi for CBRN protection systems. According to Executive Director Pradeep Dass, the CBRN products are being used in large numbers in the Army and Dass Hitachi is the only supplier at present.[35] The company also has invented an antigen-based diagnostic kit to aid diagnosis of anthrax, dengue, H1N1, leptospirosis, malaria, plague, typhoid, and other diseases.[36]
- Joseph Leslie Drager Mfg Pvt Ltd. has successfully developed items that provide troops with individual protection from toxic gases, radioactive

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

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

35 See http://www.indiastrategic.in/topstories576.htm

36 *Ibid.*

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.

Under the auspices of the National Disaster Management Authority (NDMA),[37] Ministry of Home 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.[38]

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.[39] Since 2002, the National Civil Defence College (NCDC) at Nagpur (Maharatsra) 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 multi-purpose 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.[40]

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.[41]

Another much touted BSL-4 facility is scheduled to be operational from November 2011 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 has undergone the highest bio-risk assessment to ensure that no virus escapes into the environment even during the most adverse conditions, such as an earthquake. He added that the

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

38 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

39 See http://cisf.nic.in/nisa/nisa.htm

40 See http://www.indiandefence.com/forums/f5/ndma-home-ministry-drdo-start-first-ever-nbc-institute-1070/

41 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/

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 http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp	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 http://www.jalma-icmr.org.in	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 411 021, India Tel.: +91 020-26006390 Fax: +91 020-25871895 E-mail: nivicl@pn3.vsnl.net.in http://www.niv.co.in	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, Beleghata, Kolkata (WB) – PIN 700 010, India Tel.: +91 33-23633373/+91 33-23537470 Fax: +91 33-23632398 http://www.niced.org.in	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	22, Sham Nath Marg New Delhi – PIN 110 054, India Tel.: +91 11-23913148/+91 11-23946893 E-mail: dirnicd@nic.in http://www.nicd.nic.in	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 (Kerela), Coonoor (Tamil Nadu), Jagdalpur (Chattisgarh), Patna (Bihar), Rajahmundry (Andhra Pradesh) and Varanasi (Uttar Pradesh).
Regional Medical Research Centre	P O Box No. 105, Dibrugarh (Assam) – PIN 786 001, India Tel.: +91 373-2381494 E-mail: icmrrcdi@hub.nic.in http://www.icmr.nic.in/rmrc.htm#dibrugarh	The Regional Medical Research Centre in Diburgarh 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 – PIN 110 029, India Tel.: +91 11-26588500/26588700 Fax: +91 11-26588663 E-mail: n/a http://www.aiims.edu/aiims/departments/medicine/labfacility.htm	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.

laboratory will be equipped to deal with bioterrorism in the country.[42] Similar concerns have been aired by NIV Director A.C. Mishra, who stated that '[v]iruses 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'.[43]

It was not possible to confirm the amount of funding involved in building the laboratory.[44]

The laboratory at NIV will handle both exotic and highly infectious pathogens, and will also be responsible for smallpox detection. At least 12 bio-safety suits have been imported from Italy for this purpose.[45]

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

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.[46]

42 See http://www.thehindu.com/news/national/article2305614.ece

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

44 According to available media reports, this BSL-4 Lab project was sanctioned in 2008 at a cost of INR 50 crore. However, one earlier report indicated that the Ministry of Health had approved an upgrade of the existing BSL-3 laboratory to BSL-4, costing approximately INR 30 crore. See http://www.indianexpress.com/news/pune-laboratory-upgrade-to-step-up-war-on-new-deadlier-virus/14964/ and http://www.indianexpress.com/news/niv-builds-hitech-virus-lab/825947/

45 See http://www.indianexpress.com/news/niv-builds-hitech-virus-lab/825947/

46 See http://www.indialawoffices.com/pdf/biotechnology.pdf

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.

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.[47] Although the WHO declared India a smallpox-free country in 1977, smallpox rumours continue to haunt Indian health agencies on occasion.

Disease outbreak data

With regard to particularly dangerous agents, the following disease outbreaks were recorded in 2010 and 2011:[48]

- **Anthrax:** the country is considered an endemic region for animal anthrax in general and south

47 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.)

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

Table 4. Government vaccine production facilities in India

Central Research Institute, Kasauli, Solan (Himachal Pradesh) – PIN 173 204, India Tel.: +91 179-2272060 http://www.mohfw.nic.in	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.
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 http://www.niv.co.in	Vaccines against Japanese encephalitis, Nipah virus, and influenza (H5N1).
Haffkine Institute for Training, Research and Testing, Acharya Donde Marg, Parel, Mumbai (Maharashtra) –PIN 400 012, India Tel.: +91 222-4160947/+91 222-4160961 http://haffkineinstitute.org	The Institute was tasked with the development and production of plague vaccine. Subsequently, vaccinology has been an active area of research at the Institute.
Pasteur Institute of India, Coonoor, Nilgiris (Tamil Nadu) – PIN 643 103, India Tel.: +91 423-2231250/+91 423-2232870 http://www.pasteurinstituteindia.com	Anti-rabies vaccine and diptheria-pertussis-tetanus group vaccines.
BCG Laboratory, Guindy, Chennai (Tamil Nadu) – PIN 600 032, India Tel.: +91 332-342976/+91 332-341745 http://mohfw.nic.in/dghs1.html	Manufactures and supplies BCG (bacille Calmette-Guerin) vaccine.

Table 5. Private sector vaccine production facilities in India

Serum Institute of India, Hadapsar, Off Soli Poonawalla Road, Pune (Maharashtra) – PIN 411 028, India Tel.: +91 202-6993900 http://www.seruminstitute.com	Nasal form of the 'Fluvac' vaccine for swine flu.
Shanta Biotechnics, Vasantha Chambers Road, Basheer Bagh, Hyderabad (Andhra Pradesh) – PIN 500 004, India Tel.: +91 402-3234136 http://www.shanthabiotech.com	Focuses on childhood infectious diseases. Shanvac-B (r-DNA hepatitis B vaccine) is India's first recombinant vaccine. Shanta Biotechnics also produces influenza vaccines.
Biological E. Ltd., Azamabad, Hyderabad (Andhra Pradesh) – PIN 500 020, India Tel.: +91 402-7603742 http://www.biologicale.com	Japanese encephalitis, dengue, rotavirus.
Bharat Biotech, Vamsi Sadan, Phase II, Kamalapuri Colony, Hyderabad (Andhra Pradesh) – PIN 500 073, India http://www.bharatbiotech.com	Swine flu vaccine—first indigenously developed cell-culture H1N1 swine flu vaccine under the brand name of HNVAC.
Sanofi Pasteur India Pvt Ltd. (the vaccines division of Sanofi-Aventis Group),[49] 54/A, Sir Mathuradas Vasanji Road, Andheri East, Mumbai (Maharashtra) – PIN 400 093, India http://www.sanofipasteur.in/	Seasonal and pandemic influenza, typhoid, yellow fever, dengue fever.

India is considered an endemic region for human anthrax.[50] Numerous cases were reported in livestock and wildlife as well as in human beings in 2010–11. There have been at least 140 reported cases of human and 57 reported cases of animal anthrax in the past two years.

- **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:[51]

- **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 transhipment of WMD (weapons of mass destruction) material, equipment, technology and the means of delivery. The Act is a major export 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.

49 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.

50 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.

51 For a comprehensive overview, see http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622EC1257777004DA382/$file/BWC_NID_Report.htm#in

Table 6. Number of Indian 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
Number of delegates	4	6	7	8	5	7	5	5	4	6

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

Codes of conduct, education and awareness-raising

While there are a number of general and specific ethical guidelines for life scientists, the *BioWeapons Monitor 2011* could not identify any codes of conduct that address specifically the misuse of life-science activities for biological weapons 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.[52]

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.

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 6).

Past biological weapons activities and accusations

In its 1997 CBM, India did not say anything about the existence or non-existence of past offensive biological weapons activities. In 2003, the United States Congressional Research Service asserted that there is a danger that India may develop a biological weapons programme. It claimed that 'India is believed to have an active biological defense research program as well as the necessary infrastructure to develop a variety of biological agents'.[53] However, there is no evidence in the public domain of India ever having pursued an offensive biological weapons programme. ■

52 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.

53 Cited in Feickert, A. and K.A. Kronstadt (2003) *Missile Proliferation and the Strategic Balance in South Asia,* CRS Report (RL 32115), 17 October.

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 Intersessional 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 Group of 8 (G8) and the Proliferation Security Initiative (PSI), as well as in relation to United Nations (UN).[1]

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 biological weapons development efforts of the religious group Aum Shinrikyo in the 1990s. At the Sixth Review Conference of the BWC in 2006, therefore, Japan assessed that 'bioterrorism appears to be a realistic threat . . . [alongside] the occurrence of pandemics, such as SARS [severe acute respiratory syndrome], the dramatic advancement in life sciences and the

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

rapid, global growth of biotechnology have brought about new challenges for the BWC'.[2]

Another notable development in 2006 was the formation of a new like-minded diplomatic group, 'JACKSNNZ', by Japan, Australia, Canada, (South) Korea, Switzerland, Norway and New Zealand, which rearranged the traditional Cold War groupings used in UN diplomacy, specifically the Western Group, the Eastern Group, and the Non-Aligned Movement (NAM). Based on the discussion at the ISP, JACKSNNZ reconfirmed in 2010 the importance of the role of public health sectors in biorisk reduction and the need to expand BWC cooperation with relevant international organisations, including INTERPOL, the Food and Agriculture Organization of the UN (FAO), the World Health Organization (WHO), and the World Organisation for Animal Health (OIE).[3] In addition, JACKSNNZ highlighted five key topics of specific interest for the Seventh Review Conference:

- enhancement of the Implementation Support Unit (ISU);
- confidence-building measures (CBMs);
- compliance and national implementation;
- review the current arrangement of meetings; and
- strengthen interaction with industry, academia and civil society.[4]

2 See http://www.unog.ch/80256EDD006B8954/(httpAssets)/B2AEB9E122CF40D4C125722C0041867A/$file/BWC-6RC-Statement-061120-Japan.pdf

3 See http://www.opbw.org/new_process/msp2010/BWC_MSP_2010_Statement_Canada-JACKSNNZ_E.pdf

4 *Ibid.*

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.[5] 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.[6] There are more than 30 different types of academic life-science societies.[7] For example, the Molecular Biology Society of Japan has increased its membership to about 15,000 since 1978 and some 8,000 participants attend its annual conventions.[8] Around 200 universities have life-science degree courses and conduct biotechnology research projects, often in cooperation with relevant public and private research institutions.[9] Since 1942, the Japan Bioindustry Association (JBA) has organised the World Business Forum, which is the longest-running inter-

5 See the Annex to this report.

6 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/

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

8 See http://www.mbsj.jp/en/index.html

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

national biotechnology event in Asia. In 2010, 15,175 participants from 25 countries attended 425 business exhibitions.[10]

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.[11] Importantly, efforts to strengthen NBC counter-measures were further enhanced in light of increasing international attention to the threat of proliferation of biological weapons 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 sought to allocate USD 65 million to the Ministry of Health, Labour and Welfare. For the same Fiscal Year, USD 24 million was earmarked for the Ministry of Defense for its counter NBC project.[12] 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 inter-departmental and inter-organisational collaboration and co-operation should be enhanced to maximise the limited resources in this field'.[13] Table 1 summarises these policy developments, and Table 2 lists the relevant units and facilities.

Japan declared in its 2005 CBM that the Test and Evaluation Command, Military Medicine Research Unit of the JGSDF conducted a biological defence research and development programme in Fiscal Year 2004.[14] Key details of the Unit are as follows:

- Highest containment level: BSL-2.
- Size of facility: approximately 42 square metres.
- Total number of personnel: six (all military)—four scientists and two technicians.

10 See http://expo.nikkeibp.co.jp/biojapan/2011/exhibitorsite/eng/report.html

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

12 *Ibid.*

13 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://biopreparedness.jp/index.php?plugin=attach&refer=MEXTPJ2007&openfile=G-SEC%20Biosecurity%20report_H19_3.pdf

14 Japan 2005 CBM.

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 *Report of the Council for Dealing with Biological Weapons*	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. Selected agencies, divisions and units in relation to biodefence in Japan as of 2011

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, 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

Table 3. Civil contractors for biodefence projects in 2004

Name	Content
Midori Anzen Co. Ltd	Surveillance and sample collection
Toyobo Co. Ltd	Analysis and extraction of DNA from cells
Shimadzu Co. Ltd	Identification by Time Of Flight-Mass Spectrometry (TOF-MS)
Toyobo Co. Ltd and TakaraBio Co.	Identification by polymerase chain reaction (PCR)

Total funding for this project was around USD 84,000, all from the Japan Defense Agency (replaced by the Ministry of Defense in December 2006).

The primary objectives of the programme were to:

- develop epidemiologic surveillance systems;
- research molecular biological diagnosis for biological agent casualties;
- research aerobiology; and
- evaluate medical equipment for sanitisation.[15]

No research publications or reports were produced in 2004.

Japan seems to conduct most of its biodefence research under contract. The latest available information indicates that, in 2004, Japan engaged in biodefence research activities funded by the Technical Research and Development Institute and the Japan Defense Agency under its 'Research for detection of biological agents' programme. Total funding for this project amounted to approximately USD 4 million. The contractors are listed in Table 3.[16]

15 *Ibid.*

16 *Ibid.*

Maximum and high biological containment laboratories

Japan has two BSL-4 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 lower biosafety level facilities.[17] Table 5 shows the pathogens classified as BSL-4 in Japan by the National Institute for Infectious Diseases (NIID). 'BSL-4 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.'[18] With a view to making BSL-4 facilities operational in Japan, discussions have taken place between academic and governmental experts.[19] 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 BSL-4 facilities

17 See http://www.ncbi.nlm.nih.gov/pubmed/19797849 and http://www.nature.com/nrmicro/journal/v3/n8/full/nrmicro1224.html

18 See http://www.fujipress.jp/JDR/DSSTR00040005.html, p. 352.

19 For example, an event organised by Keio University, see http://biopreparedness.sakura.ne.jp/blog/2008/07/bsl4_1.html

Table 4: BSL-4 facilities in Japan

Name	Location	Size of BSL-4 facility	Agents worked with	Comments
National Institute for Infectious Diseases (NIID)[20]	Tokyo	One BSL-4 unit (and one BSL-3 and its supporting laboratories) 2,270.36 sqm.	Laboratory diagnosis and virological studies include hemorrhagic fever viruses including Crimean-Congo, Ebola, Lassa, and Marburg	Although both institutions are technically equipped with BSL-4 facilities, they are not operated as BSL-4 facilities. Rather, they are limited to working on BSL-3 agents, due to the opposition of local residents.
Institute of Physical and Chemical Research (IPCR)[21]	Tsukuba	Two units 82 sqm. each	Risk assessment of recombinant DNA material using Retrovirus	

Table 5. Pathogens classified as BSL-4 by the NIID[22]

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

were introduced in 1981, and there is improved public understanding about the necessity.[23] However, financial constraints remain an issue for local governments looking to sustain such facilities.[24]

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 study of the measles virus and quality control of measles vaccines.[25]

The *BioWeapons Monitor 2011* could not identify the exact number of BSL-3 facilities in Japan. According

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

21 See http://www.riken.go.jp/engn/index.html

22 See http://www.fujipress.jp/JDR/DSSTR00040005.html

23 See http://scitation.aip.org/getabs/servlet/GetabsServlet?prog=normal&id=ASMECP002010049118000189000001&idtype=cvips&gifs=yes&ref=no

24 *Ibid.*

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

Table 6. Vaccine production facilities in Japan

Name	Location	Disease covered (not limited/among others)/additional information
Kitasato Institute[26]	5-9-1, Shirokane, Minatoku, Tokyo	● Vaccines for humans and animals ● Inactivated vaccines for diphtheria, pertussis, and tetanus ● Attenuated virus vaccines for measles and MMR (measles, mumps, and rubella) ● Animal vaccines for canine madness, infectious coryza, and swine erysipelas
Takeda Pharmaceutical Company, Ltd.[27]	4-1-1, Doshomachi, Chuo ku, Osaka City, Osaka	● Dried Live Attenuated Vaccines for MMR ● Japanese Encephalitis Vaccine ● Freeze-dried Live Attenuated Measles and Rubella Combined Vaccine ● Influenza hemagglutinin (HA) Vaccine
Denka Seiken Company, Ltd.[28]	3-4-2, Nihonbashi, Kayaba cho, Chuo ku, Tokyo	● 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
Sanofi-Aventis[29]	3-2-20, Nishi Shinjuku, Shinjuku ku, Tokyo	● As a Japanese section of Sanofi-Pasteur of France, Sanofi-Aventis ActHIB develops vaccine for haemophilus influenza type b (Hib)
Kaketsuken (Cherno Sero Therapeutic Research Institute)[30]	1-6-1, Okubo, Kumamoto City, Kumamoto	● Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine ● Adsorbed Diphtheria-Tetanus Combined Toxoid ● Freeze-dried, Cell Culture-Derived Japanese Encephalitis Vaccine (Inactivated) ● Vaccines for Smallpox
Research Foundation for Microbial Diseases of Osaka University[31]	3-1, Yamadaoka, Suita City, Osaka	● Iridovirus (injection vaccine for fish) ● Development of influenza vaccine
Japan BCG Laboratory[32]	4-2-6, Kohinata, Bunkyo ku, Tokyo	● Vaccines for Tuberculosis
Japan Polimyelitis Research Institute[33]	5-34-4, Kumegawa cho, Higahimurayama City, Tokyo	● Vaccines for Poliomyelitis
Meiji Dairies Co.[34]	1-2-10, Shinsuna, Kouto ku, Tokyo	● Vaccines for Heptitis B

26 See http://www.kitasato-u.ac.jp/research/gakubu/k117101101.html

27 See http://www.takeda.com/products/ethical-drugs/article_896.html#vaccine

28 See http://denka-seiken.jp/english/newsroom/n20060707.html

29 See http://www.sanofi-aventis.co.jp/l/jp/ja/index.jsp

30 See http://www.kaketsuken.or.jp/eng/prod/index.html

31 See http://www.biken.osaka-u.ac.jp/e/

32 See http://www.bcg.gr.jp/english/index.html

33 See http://www.jpri.or.jp/

34 See http://www.meiji.co.jp/english/

Table 7. Vaccine exports by Japan[35]

Vaccine	Importing countries	Amount
DDT Vaccine	Republic of Korea, Taiwan	110,000 bottles
DDT Undiluted Vaccine	Republic of Korea	460 litres
Pertussis Vaccine	US	2 million doses
Japanese Encephalitis Vaccine	Australia, Canada, Thailand, US	70,000 shots
Varicella 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	1,650 litres
Influenza Vaccine	Australia	9,500 bottles

to the National Institute of Health and Sciences (NIHS), however, there are approximately 200 BSL-3 facilities, of which 62 are located in institutes of health in local municipalities. The remaining BSL-3 facilities belong to hospitals, pharmaceutical industries and universities.[36]

Vaccine production facilities

Japan has a comparatively large number of vaccine production facilities (see Table 6).[37] Little information was found on production capacity; quantities of vaccine exports, listed in Table 7, though, illustrate the scale of vaccine production in Japan.[38]

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

36 See http://www.nihs.go.jp/aboutnihs/itenkeikaku/090403-2.pdf

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

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

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[39] is from 23 April 2011, official disease statistics are available only for the years up to 2009—no data could be found for 2010 and 2011. 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).
- Lassa: none.
- Plague: none.

39 See http://idsc.nih.go.jp/idwr/ydata/report-E.html

- 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.[40] 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.[41]

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 BTWC 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.

Codes of conduct, education and awareness-raising

To help mitigate biological weapon 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'.[42] On the issue of education, Japan, in consultation with JACKSNNZ, provided a Working Paper to the BWC Meeting of States Parties in 2008[43] and an Information Paper to the Preparatory Committee of the Seventh Review Conference in 2011.[44] In addition, the Japan

40 See http://www.mofa.go.jp/policy/un/disarmament/policy/pamph0404.html

41 See http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp10.pdf

42 See BWC/MSP2005/MX/WP.21, http://www.opbw.org/new_process/mx2005_wps.htm

43 *Ibid.*

44 See BWC/CONF.VII/PC/INF.4, http://www.opbw.org/rev_cons/prep_com/Prepcom2011_other.htm. 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/

Table 8. Ongoing projects on education, awareness raising and outreach in Japan[45]

Institution	Approaches and content
National Defense Medical College	● Compulsory biosecurity education courses: two days for undergraduate and five days for post-graduate levels (since 2008) ● Development of an online educational resource
Keio University[46]	● Biosecurity educational programmes for medical students (since 2010) ● Long series of interdisciplinary seminars on biopreparedness ● Biosecurity watch (blog)
Waseda University	● Educational courses on social responsibility of life scientists, including biosecurity topics at the master and doctoral levels (since 2009)
Jikei University[47]	● Tabletop counter-bioterrorism exercises with relevant ministries (2007)
Japan Association of Bioethics	● A panel focused on dual-use issues at the Association's conventions (2010 and 2011) ● Publication of a newsletter in April 2010 on dual-use issues
Research Institute of Science and Technology for Society (RISTEX)-JST[48]	● Establishment of a network on biosecurity issues, including officials from all relevant ministries and agencies, experts from universities and research institutions, and journalists ● Wide range of seminars on science, dual-use and international security issues

Bioindustry Association (JBA) has underscored its mandatory professional rules and guidelines, stating that such standards are important in ensuring both 'corporate compliance' and social responsibility of the industrial sector.[49]

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.[50] 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). The Biosecurity Code of Conduct, developed by the Royal Netherlands Academy of Arts and Science (KNAW), was translated into Japanese by the biosecurity section of the Global Security Project of Keio University. The Japanese version was distributed to relevant ministries and universities and is available on the Project's website.[51]

45 See http://epress.anu.edu.au/education_ethics/pdf_instructions.html

46 See http://biopreparedness.jp/index.php?MEXTPJ_en

47 See http://www.sussex.ac.uk/Units/spru/hsp/Reports%20from%20Geneva/HSP%20Reports%20from%20Geneva%20No.%2032.pdf

48 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.

49 See BWC/MSP2005/MX/WP.22, http://www.opbw.org/new_process/mx2005_wps.htm

50 See http://epress.anu.edu.au/education_ethics/pdf_instructions.html

51 See http://biosecurity.gsec.keio.ac.jp/blog/2010/02/post-210.html

Table 9. Number of Japanese 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
Number of delegates	9	6	7	7	6	7	8	8	5	6

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

The 2009 survey identified three specific biosecurity modules and some other instances of biosecurity-specific teaching. Although only 18 biosafety modules were identified, biosafety education has been provided in many universities by other means.[52] Moreover, while the term 'dual use' is unfamiliar on life-science degree courses in Japan, it is relatively well understood in relation to the role of science in society.[53]

CBM participation

Japan has submitted CBM declarations regularly since their establishment, except for 1987, 1989 and 1990.[54] It has not made its CBM declarations available to the public.

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 biological weapons programme since 1972. Japan's programme dates from the Second World War and is comparatively well documented.[55] 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.[56]

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

52 See http://epress.anu.edu.au/education_ethics/pdf_instructions.html

53 *Ibid.*

54 See http://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/9b7413664d854ea0c12572dd002b29dd?OpenDocument&ExpandSection=1%2C22#_Section1; See also http://www.biological-arms-control.org/projects_improvingtheconfid/ParticipationCBMs1987-2010-1103.pdf

55 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.

56 See http://www.archives.gov/iwg/japanese-war-crimes/

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'.[57] The Tokyo District Court 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.[58]

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.[59] Aum Shinrikyo attempted several biological attacks using botulinum toxin and anthrax from 1990–95.[60] 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. ■

57 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.anti731saikinsen.net/en/bassui-en.html.

58 *Ibid.*

59 See http://www.aktualnosci.pan.pl/images/stories/pliki/konferencje_inne/2007/dual_use/22_Furukawa.pdf.

60 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

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'.[1]

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

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

you could use an alien and invasive species to control cannabis, coca and so on, maybe tomorrow it 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'.[2]

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.[3]

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

3 See http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/51821B6A2457E047C12577F200353548/$file/BWC_MSP_2010-Kenya-101206.pdf

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, Kenya has a moderate life science and biotechnology community. Globally, Kenya ranks fifty-first; in its geographical sub-region, Eastern Africa, it ranks first. More specifically, globally, Kenya ranks forty-seventh in terms of publications; no data is available on EspaceNet on relevant patents.[4]

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.[5]

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

4 See the Annex to this report.

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

Table 1. BSL-3 laboratories in Kenya[6]

Name and location of the host institution	Name of the BSL-3 laboratory	Research focus
International Livestock Research Institute (ILRI), Naivasha Road, Nairobi	ILRI Laboratory[7]	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[8]	HIV (clinical virology and immunology); arboviruses
Kenya Medical Research Institute (KEMRI)[9]		
KEMRI headquarters, Mbagathi Road, Nairobi	KEMRI–Centers for Disease Control and Prevention (CDC) Laboratory[10]	Parasites; HIV
	KEMRI–US Army Medical Research Unit Kenya (USAMRU) Laboratory[11]	Parasites, HIV, influenza, haemorrhagic fevers
KEMRI Centre for Microbiology Research, Kenyatta National Hospital Complex, Nairobi	KEMRI–Nagasaki University Institute of Tropical Medicine (NUITM) Laboratory[12]	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[13]	Vector-borne diseases; malaria (clinical vaccine trials); other parasitic diseases; HIV and other STIs; paediatric pneumonia and rotavirus research

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

7 See http://www.ilri.org

8 See http://www.uonbi.ac.ke/faculties/?fac_code=44

9 See http://www.kemri.org

10 See http://www.cdc.gov/kenya

11 See http://www.usamrukenya.org

12 See http://www.nagasaki-u.ac.ip/index_en.html

13 See http://www.kemri-wellcome.org

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 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.[14]

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 is produced at the International Livestock Research Institute, Nairobi.

Table 2. Animal vaccines produced at the Kenya Veterinary Vaccines Production Institute[15]

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

All of the vaccines handled by the three facilities[15] 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 2011* could not discover any research activity in this area.

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

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

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.

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 in 2011 as of September):[16]

- **31 August 2010**
  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.

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.[17]

Relevant national laws, regulations and guidelines

The National Council for Science and Technology (NSCT) is the national focal point for all relevant information on WMD, including biological weapons. The Liaison Officer is Professor Shaukat Abdulrazak, Chief Executive Officer of NCST. Ms. Roselida Owuor acts as the alternative Laison officer. The NCST constituted a National Biological and Toxin Weapons Convention Committee in 2009, which draws repre-

16 Personal communication with KEMRI–CDC Laboratory in 2010, Nairobi; also see http://www.promedmail.org

17 Personal communication with a member of the Kenya National Committee for Eradication of Poliomyelitis.

sentation 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 has been drafted and is awaiting next steps.[18]

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 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.[19]

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 bio-

18 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.

19 See http://www.kenyalaw.org; also see http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622EC1257777004DA382/$file/BWC_NID_Report.htm#ke

Table 6. Number of Kenyan 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
Number of delegates	5	1	2	1	4	5	6	5	5	8

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

security for the safe handling, storage and transport of biological materials, particularly highly pathogenic avian influenza and other infectious diseases.[20]

Awareness-raising vis-à-vis biological weapon and biosecurity issues is non-existent. 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.[21]

CBM participation

Kenya submitted its first CBM (confidence-building measure) declaration in June 2010. This CBM has not been made publicly available. Kenya's 2011 CBM declaration, although reportedly submitted in September, had not been listed on the Implementation Support Unit (ISU) website as of 20 November 2011.

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 biological weapons has been levelled against Kenya. The only case of biological weapons 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.[22] ■

20 See http://www.bepstate.net/news.php?id=4

21 Statement by the representative of Kenya to the Preparatory Committee of the Seventh BWC Review Conference, 14 April 2011.

22 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: South Africa

1972 Biological Weapons Convention

Signed: 10 April 1972
Deposit of ratification: 3 November 1975

1925 Geneva Protocol

Acceded: 24 May 1930

South Africa acceded to the 1925 Geneva Protocol with a reservation but in October 1996, withdrew it.

National point of contact

Mr. Daan van Beek, The South African Council for the Non-Proliferation of Weapons of Mass Destruction, Non-Proliferation Secretariat, Private Bag X84, 0001, Pretoria, South Africa

Tel.: +27 12 394 3033
Fax: +27 12 394 4033 (direct)
E-mail: DJvBeek@thedti.gov.za

Since its inauguration in May 1994, South Africa's first democratic government has committed itself to a policy of non-proliferation, disarmament and arms control covering all weapons of mass destruction (WMD). This policy forms an integral part of its commitment to democracy, human rights, sustainable development, social justice and environmental protection.[1] To implement this policy, the South African Cabinet decided on 31 August 1994 that South Africa should:

- be an active participant in the various non-proliferation regimes and supplier groups;
- adopt positions publicly supporting the non-proliferation of WMD with the objective of promoting international peace and security; and
- use its membership of supplier regimes and of the Africa Group and the Non-Aligned Movement to promote the importance of non-proliferation and to ensure that these controls do not become

1 Abdul Samad Minty, 'Statement to the Conference on Disarmament', 1 September 2011.

the means whereby developing countries are denied access to advanced technologies.[2]

Since 1994, South Africa has consistently promoted the view that the continued existence of *all* WMD poses a threat to international peace and security.[3] In 2010, South Africa reiterated its commitment to the strengthening of the BWC 'to ensure that our common goal of eliminating the threat posed by biological weapons is achieved'.[4] At the same time, South Africa's primary national concern is the risk posed by naturally occurring infectious and other disease outbreaks and the public and private sector's ability to mitigate and respond to such events.

While being totally committed to ensuring the safety and security of biological (and nuclear and other radioactive and chemical) materials, South Africa stance is that this must be done without impeding the continued delivery of the developmental benefits that such materials and related applications provide or undermining international cooperation for the peaceful application of such material. Thus 'South Africa strongly believes, in line with Article X [of the BWC], that . . . implementation [of the Convention] should not hamper economic and technological development of the peaceful uses of biological agents, but allow the beneficial elements of these agents to be developed to aid humanity'.[5]

South Africa has prepared four working papers in anticipation of the Seventh BWC Review Conference in December 2011. They focus on: mechanisms to advance the implementation of Article X; future planning for the Implementation Support Unit; a new intersessional process; and, revising the confidence-building measures (CBMs).[6]

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, South Africa has an important life science and biotechnology community. Globally, South Africa ranks twenty-eighth; in its geographical sub-region, Southern Africa, it ranks first. More specifically, globally, South Africa ranks twenty-eighth in terms of publications and twenty-seventh in terms of patents.[7]

The central biotechnology policy instrument in South Africa is the National Biotechnology Strategy (NBS), which was officially adopted by the Cabinet in 2001 and which aims to create a 'vibrant culture of

2 Shelton, G. (2003) 'South Africa's nuclear weapons experience – an opportunity for leadership in advancing the global arms control agenda?', *Global Insight*, No. 25, http://www.igd.org.za/index.php?option=com_k2&view=item&id=87:south-africa%E2%80%99s-nuclear-weapons-experience-%E2%80%93-an-opportunity-for-leadership-in-advancing-the-global-arms-control-agenda?&Itemid=37

3 See various *note verbale* from the Permanent Mission of South Africa to the United Nations addressed to the Chairman of the 1540 Committee, http://www.un.org

4 South Africa (2010) 'Statement to the Meeting of States Parties to the Bacteriological (Biological) and Toxin Weapons Convention (BTWC)', 6 December.

5 *Ibid.*

6 http://www.unog.ch/__80256ee600585943.nsf/%28httpPages%29/f1cd974a1fde4794c125731a0037d96d?OpenDocument&ExpandSection=4#_Section4

7 See the Annex to this report.

innovation and entrepreneurship'.[8] The aim is to make South Africa one of the top three emerging economies in the biopesticide, flavour, fragrance, nutraceutical and pharmaceutical industry realm by 2018.[9]

As of February 2010, the Government of South Africa via the Department of Science and Technology (DST) had invested more than ZAR 900 million in biotechnology. Recent initiatives in the biotechnology industry have led to:

- the setting up of 78 active companies;
- the development and/or commercialisation of 1,542 products/services;
- the generation of and leveraged revenue greater than USD 100 million; and
- the creation of 2,051 specific jobs and 16 technology platforms—these platforms enable the establishment of products and processes that support present or future development.[10]

South Africa also is a leading player in the field of genetically-modified (GM) crops. It ranks eighth globally with a combined GM crop area of 1.8 million hectares.[11] It is classified as one of the 14 biotech-mega countries[12] in the world, and the only one in Africa.[13]

Publications produced by South African researchers address mostly microbiology and veterinary and animal health.[14] In 2010, South Africa produced 38 per cent of the biotechnology-related publications from Africa.[15] Three universities—University of Cape Town, University of Stellenbosch and University of the Witwatersrand—have produced more than 50 per cent of the country's publications over the past 10 years. The country's research councils[16]—including the Agricultural Research Council (ARC), the Centre for Scientific and Industrial Research (CSIR) and the Medical Research Council (MRC)—and industrial establishments also produce a number of publications on biotechnology.[17]

In terms of patents, South Africa has a comparatively low output. In a survey measuring the biotech patent

8 Jordaan, A. and D Jordaan (2010) 'Reality Bites: biotech innovation in South Africa', *Innovate,* 4, http://ebookbrowse.com/reality-bites-biotech-innovation-in-south-africa-1-pdf-d62351017

9 Statement by Derek Hannekom, Deputy Minister, Science and Technology, at the 'Launch of Biosafety South Africa', Somerset West, 18 February, http://www.dst.gov.za/speech-by-deputy-minister-derek-hanekom-at-the-launch-of-biosafety-south-africa

10 See http://blogs.nature.com/trade_secrets/blessed-okole/

11 Pouris, A. (2008) *The funding environment of South African biotechnology,* Institute for Technological Innovation, University of Pretoria, Pretoria.

12 A biotech-mega country is one that grows 50,000 hectares or more of biotech crops.

13 Derek Hannekom, Deputy Minister: Science & Technology, Speech at the launch of Biosafety South Africa, Somerset West, 18 February 2010, http://www.dst.gov.za/speech-by-deputy-minister-derek-hanekom-at-the-launch-of-biosafety-south-africa

14 Pouris, A. (2008) *The funding environment of South African biotechnology, op. cit.*

15 Gastrow, M. (2010) *Great expectations: The state of biotechnology research and development in South Africa*, 26 November, http://africabusiness.com/2010/11/26/great-expectations-the-state-of-biotechnology-research-and-development-in-south-africa

16 Research Councils are public sector, not-for-profit, research and development organisations, generally established by statutes and funded by the government.

17 Pouris, A. and A. Pouris (2009) *Biotechnology research in South Africa: A benchmarking exercise*, http://www.businesschemistry.org/article/?article=31

output of seven developing countries between 1991 and 2003, South Africa ranked second lowest in terms of biotech patents and their ownership.[18] A National Biotech Audit from 2007 shows that the core biotech companies have 45 existing patents, 23 of which are from South Africa. The active biotech companies have 287 patents, 140 of which are from South Africa.[19]

Biodefence activities and facilities

South Africa has sophisticated capabilities for the detection, protection, decontamination and treatment of biological threats. The South African Military Health Service (SAMHS), a sub-division of the South African National Defence Force (SANDF), is responsible for deploying troops in support of the Department of Health and the Department of Agriculture when dealing with situations with a distinct biological threat. The 7 Medical Battalion Group of the SAMHS provides medical support to the Special Forces and Airborne community and chemical, biological, radiological, and nuclear defence support to the South African Police Service (SAPS), the Departments of Health and International Relations and Co-operation (DIRCO), as well as, for example, the Nuclear Energy Regulator. A Chemical and Biological Defence Adviser works closely with the head of SAMHS, the Surgeon-General, and supports the work of the National Authority (The South African Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) hosted by the Department of Trade and Industry) and DIRCO with respect to the requirements of relevant national legislation and the meetings of the BWC.

Importantly, in 2006, the Department of Provincial and Local Government published standard operational procedures, drafted in collaboration with SAMHS, governing the joint management of incidents involving biological or chemical agents or radioactive material.[20]

The Department of Defence's Strategic Plan Fiscal Year 2010/11–2012/13 includes exercises over the next three years relating to the 'maintenance of the Provincial Chemical, Biological and Radiological Response Teams and interdepartmental co-operation for the management of Chemical, Biological and Radiological incidents'.[21]

According to the authoritative *DefenceWeb* website, South Africa has invested in biological and chemical defence equipment and research in recent times.[22] However most of this investment pertains to chemical

18 Quach, U. et al. (2006) 'Biotechnology patenting takes off in developing countries', *International Journal of Biotechnology*, Vol. 8, No. 1-2, pp. 43-59.

19 South Africa Department of Science and Technology (2007) *National Biotechnology Audit 2007: Biotechnology use and development in South Africa*, South Africa Department of Science and Technology, Pretoria, http://www.dst.gov.za/publications-policies/strategies-reports/National%20Biotech%20Audit

20 See Government Gazette Number 28437, 3 February 2006, and Government Notice 143/3, February 2006.

21 See http://www.defenceweb.co.za/index.php?option=com_content&view=article&id=7152:fact-file-upcoming-sandf-exercises&catid=79:fact-files&Itemid=159

22 See http://www.defenceweb.co.za/index.php?option=com_content&view=article&id=14303:samhs-buys-more-chemical-defence-&catid=47:Logistics&Itemid=110

defence equipment, such as detection hardware and decontamination systems.[23] Research activities in relation to biological agents focus primarily on *Bacillus anthracis* and the detection of *ricin* and have funds totalling some USD 222,000, emanating from the Department of Defence. 'Much of the research is undertaken at Protechnik Laboratories, which was established as a private company in 1986 to develop defensive equipment against chemical weapons and was later connected, together with Roodeplaat Research Laboratories and Delta G, to Project Coast – apartheid South Africa's chemical and biological warfare (CBW) programme'.[24] In 1996, Protechnik was acquired by the State agency, the Armaments Corporation of South Africa Ltd. (Armscor).

Biological activities at Protechnik Laboratories currently centre on:

- detection of biological warfare agents and other biological compounds;
- technical support for WMD non-proliferation treaties; and
- data collection and maintenance of an information database on biological weapons.[25]

Research activities include the genotyping of anthrax samples and the development of a strategic national knowledge base, with a special focus on anthrax lineages and identification.[26] Protechnik also provides chemical, biological and radiological incident management and detection training to various government authorities, including the SAPS and the Fire Department and Emergency Medical Services ahead of the 2010 World Cup.[27]

Maximum and high biological containment laboratories

South Africa has one BSL-4 facility, the Special Pathogens Unit (SPU) of the National Institute for Communicable Diseases (NICD) of the National Health Laboratory Service (NHLS). The original stimulus for the then Department of National Health and Population Development to build a BSL-4 laboratory in South Africa was an outbreak of Marburg disease in Johannesburg in 1975.[28] The SPU is located in Sandringham, Johannesburg, and was established in 1992, closed down in 2004 for upgrading, and reopened in May 2011. The laboratory is one of the world's largest containment facilities for dangerous biological specimens, covering some 195 square metres, and is recognised by the World Health

23 *Ibid.*

24 Burgess, S.F. and H.E. Purkitt (2001) *The Rollback of South Africa's Chemical and Biological Warfare Program*, USAF Counterproliferation Center, Montgomery, Alabama, http://www.au.af.mil/au/awc/awcgate/cpc-pubs/southafrica.pdf

25 See http://www.armscordi.com/SubSites/PROTECH/PROTECH01_landing.asp

26 Armaments Corporation of South Africa, *Annual Report 2009–10*, http://www.armscor.co.za/Downloads/Armscor%20Annual%20Report%202009-2010.pdf

27 See http://www.defenceweb.co.za/index.php?option=com_content&view=article&id=14303:samhs-buys-more-chemical-defence-&catid=47:Logistics&Itemid=110

28 Swanepoel, R. (1985) *Recognition and management of viral haemorrhagic fevers: A handbook and resource directory*, Special Pathogens Unit, National Institute for Virology, Department of National Health and Population Development, Sandringham. (Revised in November 1987.)

Table 1. BSL-3 facilities in South Africa

Name	Location	Agents handled and activities
National Institute for Communicable Diseases: 1. Influenza facility (under construction) 2. Special Bacterial Pathogens Reference Unit[29]	Sandringham, Johannesburg	The BSL-3 laboratory serves as the WHO networking laboratory for plague and anthrax in Africa and handles dangerous bacterial pathogens and Zoonotic diseases such as anthrax and plague. It stores historical and new B. anthracis isolates from the Kruger National Park as well as other isolates from the rest of South Africa and neighbouring countries.
Division of Medical Virology, Faculty of Health Sciences, Stellenbosch University[30]	Tygerberg, Cape Town	The Division delivers a comprehensive diagnostic virology service, which includes the detection and isolation of viruses as well as serological assays. Research areas are genomic diversity and molecular epidemiology of human immunodeficiency virus (HIV), immunological aspects of HIV infection relevant to the development of vaccines and other novel immunotherapeutic approaches, and antiretroviral drug resistance.
Department of Clinical Microbiology and Infectious Diseases (CMID), Faculty of Health Sciences, University of the Witwatersrand[31]	Johannesburg	The CMID has a state-of-the-art molecular laboratory, a BSL-3 facility for research on special pathogens and specialised infection control, and public health and oral microbiology laboratories.
Faculty of Health Sciences, University of Pretoria[32]	Pretoria	The Faculty facilitates research on arboviruses.
Molecular Mycobacteriology Research Unit (MMRU), University of the Witwatersrand[33]	Johannesburg	The MMRU undertakes tuberculosis and related organism research aimed at identifying and validating new drug and vaccine targets.
Mobile Diagnostic Laboratory Biosafety Level 3 (BSL-3)[34]	Western Cape Province (rural areas)	The mobile laboratory comprises, inter alia, a patient area, sample storage facility, and an onboard autoclave, power-supply, satellite-linked communications. Its primary function currently is HIV diagnosis (as well as tuberculosis and outbreaks such as H1N1).
Kwa-Zulu Natal Research Institute for Tuberculosis and HIV (K-RITH), Nelson R Mandela School of Medicine, University of KwaZulu-Natal[35]	Durban	K-RITH is expected to be completed in 2012. It will conduct research on tuberculosis and HIV/AIDS (acquired immune deficiency syndrome).
Transboundary Animal Diseases Programme (TADP), Onderstepoort Veterinary Institute[36]	Pretoria	The TADP works on African swine fever and foot-and-mouth disease.

29 See http://www.nicd.ac.za

30 See http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Departments/Pathology/Medical_Virology/General

31 See http://www.wits.ac.za/academic/health/pathology/cmid/ 9357/introduction_to_cmid.html

32 See http://web.up.ac.za/default.asp?ipkCategoryID=45

33 See http://www.wits.ac.za/academic/health/research/mmru/ 10260/research.html

34 See http://www.capegateway.gov.za/eng/pubs/news/2011/mar/214441

35 See http://www.k-rith.org/what-is-k-rith

36 See http://www.arc.agric.za/home.asp?pid=6938

Organization (WHO) as a leading global research centre for viral haemorrhagic fevers (VHF).

The status of the NICD as a WHO Reference Centre for VHF and Arboviral Disease is presently in the process of being reactivated.[37]

The SPU is tasked with laboratory confirmation and investigation (diagnosis) of diseases caused by biohazard class 3 and 4 viral agents, as well as arboviral disease. Biohazard class 3 and 4 viral agents include the viral haemorrhagic fevers caused by Crimean-Congo haemorrhagic fever (CCHF), Ebola, the Hantaviruses, Lassa fever, Marburg, and Rift Valley fever (RVF). Arboviral disease includes Chikungunya, dengue fever, Sindbis, West Nile fever, and yellow fever.[38]

The SPU is also the only laboratory in South Africa for rabies testing and operates a BSL-3 laboratory.

Table 1 lists the BSL-3 facilities in South Africa that the *BioWeapons Monitor 2011* could identify.

Vaccine production facilities

Human vaccines

South Africa stopped producing human vaccines in 2001 due to a lack of technology, funding and skills. Vaccines for current use are imported into South Africa.[39] In 2003, the Biological and Vaccines Institute of Southern Africa (Biovac) was established as a ZAR 500 million public–private partnership between the Government of South Africa and a group of health care companies.[40] Biovac is the only facility with the potential to manufacture human vaccines and all vaccines under development are currently in a pre-clinical phase. Vaccines against diphtheria, haemophillus influenza, hepatitis B, pneumococcal infections, tetanus, and whooping cough are currently under development.[41] The institute aims to complete testing and start production by 2013.[42] Biovac is presently mostly involved in the packaging of vaccines.

Animal vaccines

The ARC was established by legislation in 1990 and is the principal agricultural research institution in South Africa. Vaccine development for animals is undertaken at the Onderstepoort Veterinary Institute (OVI) of the ARC. The ARC-OVI is the collaborating centre for both the Office International des Epizooties (OIE) surveillance and control of animal diseases in Africa and the Food and Agriculture Organization (FAO) of the United Nations for the emergency preparedness for transboundary animal diseases for Africa. The

37 E-mail communication from Jacqueline Weyer, Senior Medical Scientist, Special Pathogens Unit, Center for Emerging and Zoonotic Diseases, National Institute for Communicable Diseases of the National Health, Laboratory Service, 8 September 2011.

38 See http://www.nicd.ac.za/?page=special_pathogens_unit&id=25 and http://www.nicd.ac.za/assets/files/Annual_report_2009.pdf

39 Telephone interviews with Professor J. Paweska, Head of Special Pathogens Unit, National Health Laboratory Service, National Institute for Communicable Diseases, 5 August 2011, and with Julian Jellin, Responsible Pharmacist, Biovac, Cape Town, 5 August 2011.

40 See http://www.biovac.co.za

41 See http://www.biovac.co.za/company-overview.html

42 Telephone interview with Julian Jellin, *op. cit.*

ARC-OVI hosts seven OIE reference laboratories for economically important viral diseases: African horse sickness, African swine fever, bluetongue, foot-and-mouth disease, lumpy skin disease, rabies, and RVF.[43]

Onderstepoort has developed unique vaccines for the prevention or control of several endemic diseases. These include African horse sickness, anaplasmosis, anthrax, babesiosis, bluetongue in sheep, botulism, ephemeral fever, heartwater, and lumpy skin disease.

Onderstepoort Biological Products (OBP) Ltd. currently manufactures vaccines in various volumes and pack/dose sizes. These are for 32 bacterial and protozoal diseases and 11 viral diseases, including: African horse sickness, anthrax, bluetongue, botulism, fowl pox, lumpy skin disease, Newcastle disease, RVF, and Rinderpest (export only).[44]

A second animal vaccine production company, Deltamune, was established in South Africa in 2005. It previously traded as Avimune, a poultry veterinary health service. It has a vaccine production unit capable of manufacturing bacterial and viral vaccines or combinations mainly for diseases affecting poultry such as Avian influenza, coryza and Newcastle disease.[45]

Research and policy issues regarding smallpox

South Africa's smallpox stocks were destroyed on 9 December 1983. South Africa holds a duplicate set of DNA clones of the non-infectious variola virus originally prepared in the United Kingdom. This duplicate set was transferred to South Africa following an agreement between the Government of South Africa and the WHO to allow the country's Department of Health to retain a set of clones in exchange for destroying its variola virus stocks.[46] They are currently in storage inside the BSL-4 facility at the NICD and have never been used.

South Africa recently decided that clones of recombinant plasmids potentially useful in producing diagnostic reagents, and constituting no more than 20 per cent of the genome of the virus, should be retained. The rest of the clones should be destroyed under the supervision of the WHO.[47] In 2005, South Africa called for research on the live virus to be stopped and proposed the establishment of a World Health Assembly 'task team' to evaluate the status of work with live smallpox viruses and its oversight. In 2007, the developing countries, led by South Africa, made specific requests to the WHO to prohibit genetic engineering of the smallpox virus, to have an annual substantive World Health Assembly review of the virus research, and for strengthened WHO oversight.[48]

43 See http://www.arc.agric.za/home.asp?pid=2564

44 See http://www.obpvaccines.co.za/vacc_about.htm

45 See http://www.deltamune.co.za/products.html

46 World Health Organization, Advisory Group of Independent Experts to review the smallpox research programme (AGIES), 'Comments on the Scientific Review of Variola Virus Research, 1999-2010', December 2010.

47 World Health Organization, Advisory Committee on Variola Virus Research, *Report of the Twelfth Meeting,* Geneva, Switzerland, 17–18 November 2010.

48 Hammond, E. and L.L. Ching (2005) 'At WHA, countries express concern over smallpox research', *TWN Info Service on Health Issues,* No. 6, 20 May.

Disease outbreak data

African viral haemorrhagic fevers include CCHF, Ebola, hantavirus infection with renal syndrome, Lassa fever, Marburg, RVF, and related arenaviral infections. Of these, CCHF and RVF are endemic to South Africa.[49] No endemic transmission of Ebola, Marburg or Lassa virus has occurred in South Africa. There have been no cases of Ebola or Marburg virus infections in South Africa since at least 2006 and 1975 respectively, and only one case of imported Lassa fever. In the first reported case of importation of Lassa fever into South Africa, in February 2007, a 46-year old public health physician from Nigeria was evacuated to South Africa for medical treatment. The SPU confirmed Lassa fever. The patient passed away five days after admission to the South African hospital.[50]

In October 2008, Lujo virus, the first hemorrhagic fever-associated arenavirus from the Old World discovered in three decades, was isolated in South Africa during an outbreak of human disease characterised by nosocomial transmission and an unprecedented high case fatality. Four of five confirmed patients died of the disease.[51]

While anthrax and plague are endemic in South Africa, there have been no recorded human cases of plague since at least 2004, and the last human cases of anthrax were recorded in 2004.[52] No human cases of tularaemia have been identified in South Africa to date,[53] and human cases of botulism seem to be extremely rare—the last cases were reported in 2002.[54]

No suspicious outbreaks were reported in South Africa in 2010–11.[55]

Relevant national laws, regulations and guidelines

South Africa, has comprehensive legislation aimed at preventing the misuse of biological (and chemical and nuclear) materials and to reinforce and promote its vision of being a responsible producer, possessor and trader of advanced technologies in the nuclear, biological, chemical and conventional arms fields.[56] South Africa thus prohibits:

- any person, whether for offensive or defensive purposes, to be or become involved in any activity or with goods that contribute to WMD programmes; and

49 Outbreak Response Unit and Special Pathogens Unit, National Institute for Communicable Diseases (2010) 'Viral Haemorrhagic Fever Outbreaks in South Africa, 2007–2009', *Communicable Diseases Surveillance Bulletin,* Vol. 8, No. 1.

50 *Ibid.*

51 See http://www.plospathogens.org/article/info:doi/10.1371/journal.ppat.1000455

52 South Africa CBM 2005; also see various issues of the *Communicable Diseases Surveillance Bulletin* at http://www.nicd.ac.za/?page=publications&id=48

53 E-mail communication from Jacqueline Weyer, *op. cit.*

54 Frean, J. et al. (2004) 'Fatal type A botulism in South Africa, 2002', *Transactions of the Royal Society of Tropical Medicine and Hygiene,* Vol. 98, No. 5, pp. 290–295.

55 Personal interviews with Captain Ben Nel and Colonel Eric Dewey, SAPS, 18 August 2011, as well as with Ben Steyn of the SAMHS, 24 August 2011.

56 See http://www.diplomacy.edu/books/mdiplomacy_book/muller/regular/default.html

- any person to be or become involved in any dual-use goods or activities that could contribute to WMD.[57]

South Africa has the most advanced export control laws and systems on the continent and belongs to all of the non-proliferation export control regimes, except for the Australia Group. The proliferation of biological dual-use items is controlled by the NPC, which is appointed in accordance with the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993).

The Council has a Non-Proliferation Secretariat (NPS) that provides administrative and secretarial services to the NPC and its technical committees, one of which is the Biological Weapons Working Committee (BWWC). The BWWC is composed of representatives of the various government stakeholders and expert bodies involved in biological-related controls, manufacturing, use and distribution, including the ARC, DIRCO, higher education institutes, the Industrial Biotechnology Association of South Africa, the NICD, Protechnik Laboratories, and the SAMHS. The Committee advises the NPC on issues related to the BWC and the implementation of biological controls.

In addition to biological pathogens being controlled under the Non-Proliferation of Weapons of Mass Destruction Act, 1993, various other pieces of legislation also are pertinent. These include the: Agricultural Pests Act, 1983 (Act No. 36 of 1983); Animal Health Act, 2002 (Act No. 7 of 2002); Defence Act, 2002 (Act No. 42 of 2002); Hazardous Substances Act, 1973 (Act No. 15 of 1973); Health Act, 2003 (Act No. 61 of 2003); and, importantly, the Protection of Constitutional Democracy against Terrorists and Related Activities Act (Act No. 33 of 2004).

These Acts cover a range of activities from measures to secure and account for the production, use, storage, and transport of such agents to the regulation of the physical protection of facilities/materials/transport. In addition, they contain penalties for violations and provisions for the licensing or registration of facilities and persons handling biological materials. Border controls are provided for under the Customs and Excise Act, 1964 (Act No. 91 as amended in 2009) whereas export controls are governed by, inter alia, the Non-Proliferation of Weapons of Mass Destruction Act, 1993, and various Government Notices and Regulations attached to the relevant Acts. Examples of the latter are the Government Notice, Department of Trade and Industry, No. 19 of 3 February 2010, and the Notice Under Section 13 of the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), Declaration of Certain Biological Goods and Technologies to be Controlled and Control Measures Applicable to such Goods.

(Bio)chemical non-lethal weapons

In 2006, the SANDF investigated the general issue of 'non-lethal weapons and weapons yielding reduced effects'. It concluded that, while it recognises the emergence of such technology and the need to take cognisance of their capability, funding allocations should remain with conventional capabilities. The

57 See http://www.thedti.gov.za/nonproliferation/policy.htm

SANDF has no intention of acquiring, developing or using biological non-lethal weapons.[58]

Codes of conduct, education and awareness-raising

Most, if not all, professional associations, scientific institutions, and universities in South Africa have codes of conduct and ethical committees that provide oversight mechanisms for research processes and to which scientists are required to adhere. In May 2007, for instance, the Health Professions Council of South Africa (HPCSA), which is a statutory body, established under the Health Professions Act (No. 56 of 1974), published its 'General Ethical Guidelines for Biotechnology Research'.

Education and awareness-raising activities with respect to biosafety in particular occur mainly at the laboratory level. However, South Africans also participate in regional meetings that bring together delegates from national public health and veterinary laboratories and are aimed at fostering the safe, efficient and secure use of pathogens for human and animal health. Non-governmental organisations such as the South African-based Institute for Security Studies have hosted workshops for African delegates on concerns about dual-use research and on the need to develop an educational module for life scientists in line with the *Final Document* of the 2006 Meeting of States Parties to the BWC. The latter urged States Parties to promote the development of training and educational programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as the obligations of States Parties under the BWC.

The African Biological Safety Association (AfBSA)[59] is due to host its third Annual Biological Safety Conference in South Africa in June 2012. This regional conference seeks to create 'a forum of exchange on various developments in biosafety, biosecurity and the unique emerging issues in the respective countries from the region'.[60]

CBM participation

South Africa submitted its first CBM declaration in 1993 and with the exception of 1994 has filed CBM declarations ever since.[61] South Africa has not made its CBMs publicly available—'Information provided under South Africa's Confidence Building Measure (CBM) declarations to the BTWC is confidential until a decision is taken to the contrary'.[62]

Participation in BWC meetings

South Africa participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth

58 Interview with an unnamed SANDF official, 23 August 2011.

59 The AfBSA Secretariat operates from the Office of Health, Safety and Environment of the Kenya Medical Research Institute (KEMRI), Nairobi, Kenya.

60 *AfBSA News*, Issue 1, March 2009.

61 E-mail communication with officials at the Department of International Relations and Cooperation (DIRCO) and South African Council for the Non-Proliferation of Weapons of Mass Destruction's Non-Proliferation Secretariat, 14 July 2011.

62 E-mail communication with Daan van Beek, Chief Director, Non-Proliferation, Department of Trade and Industry, 10 August 2011.

Table 2. Number of South African 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
Number of delegates	7	2	6	5	6	5	7	7	6	3

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

BWC Review Conference in 2006, South Africa has taken part in all relevant meetings (see Table 2).

Past biological weapons activities and accusations

During the 1980s, South Africa developed a chemical and biological warfare programme under the auspices of the then South African Defence Force (SADF), codenamed Project Coast. Some analysts allege that the programme was of an offensive nature while others argue that it was defensive.[63] Much of what is known about this programme derives from the trial in 1999–2002 of its head, Wouter Basson, and the South African Truth and Reconciliation Commission (TRC) public hearings in 1998.[64] It seems likely that at least some aspects of the programme were of an offensive nature in that unbeknown to most high-ranking politicians and diplomats, parliament and indeed the Surgeon-General (who ran the defensive part of the programme), an unofficial offensive project also was established with its own command-and-control channel. This project was closed in 1993.[65]

Allegations and hoaxes

Approximately 3,000 'white-powder' threats were reported in South Africa between 2001 and 2010, all of which turned out to be hoaxes. In June 2011, a South African—Brian Roach, a retired engineer—was jailed for five years for threatening to unleash foot-and-mouth disease in the UK and the US unless he was paid USD 4 million. Roach stated that the UK and the US failed to protect white property owners in Zimbabwe who lost their farms under a land-reform programme initiated by President Robert Mugabe.[66] Roach struck a plea deal with prosecutors that allowed him to escape charges of terrorism. Six months of investigation by the SAPS and US and UK law-enforcement officials, as well as a search of his home and other sites, showed that he had no means to carry out his threat. Given the destructive nature of the biological pathogen if released, officials regarded the threat as 'very serious'.[67] ■

63 See, for example, Gould, C. and P. Folb (2002) *Project Coast: Apartheid's Chemical and Biological Warfare Programme,* United Nations Institute for Disarmament Research, Geneva, and Truth and Reconciliation Commission (1998) *Special Investigation into Project Coast, Final Report,* Vol. 2, Ch. 6, 29 October.

64 Gould, C. and P. Folb (2000) 'The South African Chemical and Biological Warfare Program: An Overview', *The Nonproliferation Review,* Fall/Winter, pp. 10–23.

65 Burgess, S.F. and H.E. Purkitt (2001) *The Rollback of South Africa's Chemical and Biological Warfare Program, op. cit.*

66 Tinder, P. (2011) 'South African man jailed for bioterror threat', 24 June, http://www.bioprepwatch.com/news/250709-south-african-man-jailed-for-bioterror-threat

67 See http://www.zimbabwesituation.org/?p=29636

Country report: Switzerland

1972 Biological Weapons Convention

Signed: 10 April 1972
Deposit of ratification: 4 May 1976

Upon ratification of the BWC, Switzerland retained two formal reservations: 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).[1]

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 and Crisis Management, Section for Arms Control and Disarmament, Bernastrasse 28, 3003 Bern, Switzerland

Tel.: +41 31 32 41009

Switzerland considers the proliferation and potential use of biological weapons by states as well as non-state actors as a threat to international security. It actively supports relevant non-proliferation efforts as well as the complete and verifiable elimination of biological weapons under international law.[2] Switzerland is a long-standing proponent of the BWC and works towards making accession universal and strengthening the Convention.

Accordingly, as stated in the Federal Council's 2008 report on Switzerland's arms control and disarmament policy, it remains committed to the establishment of a credible verification mechanism within the framework of the BWC to ensure compliance.[3] '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

1 See http://unhq-appspub-01.un.org/UNODA/TreatyStatus.nsf

2 See http://www.vbs.admin.ch/internet/vbs/fr/home/documentation/bases/sicherheit.parsys.5013.downloadList.36678.DownloadFile.tmp/sipolbf.pdf

3 See http://www.eda.admin.ch/etc/medialib/downloads/edazen/topics/peasec/peac.Par.0210.File.tmp/7253fr.pdf

welcomes working towards a legally binding compliance framework'.[4]

However, Switzerland has repeatedly stated that such an endeavour seems not to be feasible at the moment and has suggested instead a discussion of alternative ways to ensure compliance. As interim steps towards a comprehensive verification system, Switzerland proposes:

- to review, strengthen, and broaden the BWC's confidence-building measures (CBMs);
- 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.[5]

More recently, in December 2010, Switzerland also suggested dedicating time at future annual meetings for sessions in which compliance with the Convention can be demonstrated, assessed, and discussed.[6]

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, Switzerland has an important life science and biotechnology community. In absolute terms, Switzerland ranks sixteenth globally; in its geographical sub-region, Western Europe, it ranks fourth. More specifically, globally, Switzerland ranks twenty-second in terms of publications and thirteenth with regard to patents.[7]

Switzerland is the country with the second highest number (after Sweden) of independent, dedicated biotechnology firms per capita in Europe, according to a 2002 survey of the European Commission.[8] The Swiss biotechnology industry is one of the strongest in Europe with high growth rates and high potential for innovation, which can be seen in the increasing number of patent applications and patent turnout.[9] 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.[10] In the 2011 Scientific American Worldview survey of 48 countries' capa-

4 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+MSP+2010+-+Switzerland+-+101206.pdf

5 Rapport 2008 du Conseil fédéral sur la politique de la Suisse en matière de maîtrise des armements et de désarmement, http://www.eda.admin.ch/etc/medialib/downloads/edazen/topics/peasec/peac.Par.0210.File.tmp/7253fr.pdf

6 Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, *op. cit.*

7 See the Annex to this report.

8 Allansdottir, A. et al. (2002) *Innovation and competitiveness in European biotechnology,* Enterprise Papers, No. 7, European Commission/DG Enterprise, Brussels, http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=1844

9 Cf. 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

10 Stadler, R. (2011) 'An innovative decade in Swiss biotech: evidence of patent statistics', in Ernst & Young et al., *Swiss Biotech Report 2011,* http://www.swissbiotech.org/swiss_biotech_report_2011

bilities to generate innovation in biotechnology, Switzerland ranks sixth.[11]

Looking at the strengths within the sector, Switzerland's biotechnology industry is most active in medical applications of biotechnology ('red biotech') and the least in the agricultural and food domains ('green biotech').[12]

The auditing company Ernst & Young, which has been collecting global data on the biotechnology industry for more than 20 years, cites 174 Swiss biotechnology companies in 2010 ('Developers') as well as 63 'Suppliers'.[13] The Swiss Life Sciences Database, a directory and information platform comprising data on life science and biotechnology companies and institutes in Switzerland, lists 1,712 such companies and institutes.[14] 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.[15]

The Swiss Biotech Association (SBA), the industry grouping of enterprises and institutions active in all areas of biotechnology, had 217 members as of August 2011.[16]

11 See http://www.saworldview.com/files/dmfile/SAWorldView2011june10.pdf

12 See http://www.oecd.org/dataoecd/17/9/39678950.pdf

13 Ernst & Young et al. (2011) *Swiss Biotech Report 2011, op. cit.*

14 See http://www.swisslifesciences.com/swisslifesciences/db/index.php

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

16 See http://www.swissbiotech.org/industry_association_sba/members

Biodefence activities and facilities

Biodefence programme

The Swiss biodefence programme was initiated in 1995.[17] According to Switzerland's 2011 CBM declaration, 12 facilities are involved in the Swiss biodefence programme. Aside from the special role of the Spiez Laboratory, they act as either National Reference Centres and/or are part of one of the six Regional Competence Centres within the framework of the Regional Laboratory Network (see below). These facilities are listed in Table 2.

At the centre of the Swiss biodefence programme is the Spiez Laboratory of the Federal Office for Civil Protection (FOCP) within the Federal Department of Defence, Civil Protection and Sports (DDPS). The Spiez Laboratory is the Swiss Centre of Expertise for NBC (nuclear, biological, chemical) Protection and is tasked with the development of the technical expertise needed for comprehensive protection from CBRN (chemical, biological, radiological, nuclear) incidents and to provide support to civilian and military stakeholders. Its Biology Section performs research and offers expertise and training in the areas of bacteriology, toxinology, and virology with the primary aim of maintaining and improving capacities in the fields of detection, identification and characterization of biological agents and toxins for rapid diagnosis.[18] Other tasks include the analysis of unknown samples, food and water evaluation for the Swiss Armed Forces, and research and devel-

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

18 Cf. http://www.labor-spiez.ch/en/the/bs/index.htm

Table 1. Contracted facilities and projects in 2010

Contractor	Project title
Research Station Agroscope Changins-Wädenswil	• Development of a DNA chip for the detection of biological warfare agents
University of Zurich, Institute of Social and Preventive Medicine	• Medical concept for the high-containment facility
University of Bern, Institute of Infectious Diseases	• Tick-borne encephalitis virus in Swiss ticks • Evaluation of siRNA for antiviral therapy of encephalitogenic viruses: studies in cell cultures and animal models
University of Bern, Institute of Parasitology	• Habitat of free-living pathogenic amoebae • Analysis of mechanisms of pathogenicity in Naegleria fowleri
University of Bern, Institute of Ecology and Evolution	• Hantaviruses in mice populations of Switzerland
Max Planck Institute of Colloids and Interfaces, Department for Biomolecular Systems, Potsdam, Germany	• Development of antibodies against Yersinia pestis
Miprolab GmbH / University of Göttingen, Germany	• Development of detection methods for Botulinum neurotoxins
Robert Koch Institute, Centre for Biological Security, Berlin, Germany	• Development of antibodies against B-toxins

Source: Switzerland 2011 CBM.

opment in coordination with various contractors (see Table 1).

In 2010, the Spiez Laboratory started to commission its new BSL-4 high containment facility, which will be fully operational by mid-2012, according to an informed source. Furthermore, the BSL-3 laboratory space will move to the new facility (and be enlarged) by the end of 2011 (initially with a glove box). Remarkably, the inauguration of the new containment facility in June 2010 was accompanied by an open day during which the facility was publicly accessible; in addition, the overall design of the new facility is freely available,[19] demonstrating a level of openness and transparency not common elsewhere.

Due to the opening of the new facility, total funding for the Swiss biodefence programme doubled in 2010 compared to the previous year, amounting to CHF 5 million (excluding the Regional Laboratory Network; see below).[20] It is expected to remain at a similar level for the foreseeable future.[21] Figure 1 shows the trend in funding for the Swiss biodefence programme between 2002 and 2010. The increase in total funding between 2007 and 2009 is due in part to the costs associated with the construction of the

19 Cf. http://www.labor-spiez.ch/en/the/sl/entheslpl.htm

20 Switzerland 2011 CBM.

21 *Ibid.*

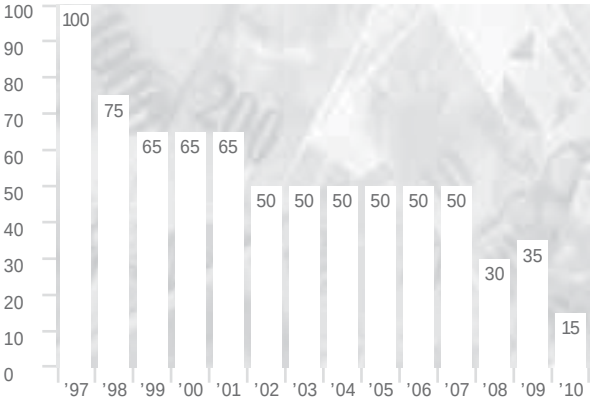
Figure 1. Declared funding for the Swiss biodefence programme, 2002–10

Funding in CHF millions

Source: Switzerland 2003–11 CBMs.

Figure 2. Percentage of total funds for contracted research, 1997–2010

Percentage of contracted research



Source: Switzerland 1998–2011 CBMs.

new facility; in addition, though, the programme's capacities in terms of employees and detection capabilities have been gradually expanded and upgraded.[22] The number of personnel at the Biology Section of the Spiez Laboratory has roughly doubled over the past 10 years (to 15 in 2010).[23]

Figure 2 shows the percentage of the total funds for the Swiss biodefence programme that went to contracted facilities between 1997 and 2010. In 2010, approximately 15 per cent of FOCP funding went to contracted facilities, which are supervised by the Spiez Laboratory. The 20 per cent decrease in contracted research as compared to 2009 is mostly due to the higher proportion of costs associated with the operation of the new containment facility, though it remained at a similar level in absolute terms.

The 2010 contracted facilities and their respective projects are summarised in Table 1. It is interesting to note that Switzerland is partially contracting research out to German institutions.

Regional Laboratory Network

In its 2010 CBM declaration, Switzerland started to declare the Regional Laboratory Network as part of its biodefence programme. The Regional Laboratory Network provides decentralised laboratory capacities for the initial diagnosis of pathogenic organisms in case of a natural, accidental, or deliberate biological emergency. It consists of a total of four National Reference Centres and six Regional Competence Centres that comprise one or more of the eight

22 Cf. Spiez Laboratory, *Annual Report 2008* and *Annual Report 2009*, http://www.labor-spiez.ch/en/dok/ge/index.htm

23 Switzerland 2003–11 CBMs.

Table 2. Facilities involved in the Swiss biodefence programme

Name	Role(s)	Source(s) of funding	Location	Number of staff	Highest containment level	Agents covered
Centre of Expertise for NBC Protection						
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	15 (all civilian)	BSL-4 (118 sqm. (square metres) of 727 sqm. overall laboratory space; in commissioning phase)	Various bacteria, viruses and toxins[24]
National Reference Centres						
Institute of Virology and Immunoprophylaxis	National Reference Centre for highly contagious epizootics and emerging viral diseases	Federal Veterinary Office (Federal Department of Economic Affairs)	Mittelhäusern	75 (all civilian)	BSL-3Ag (2,600 sqm. of 3,000 sqm. overall laboratory space)	Influenza virus, foot-and-mouth disease, classical and African swine fever, African horse sickness, porcine circovirus type 2, bluetongue, Rift Valley fever, lumpy skin disease, rinderpest, and others[25]
National Reference Centre for Emerging Viral Infections (Virological Laboratory, University Hospitals of Geneva)	National Reference Centre for emerging and re-emerging viruses	Federal Office of Public Health (Federal Department of Home Affairs)	Geneva	4 (all civilian)	BSL-4, approved for diagnostic purposes only (18 sqm. of 18 sqm. overall laboratory space)	Lassa, Ebola, Marburg, West Nile, Dengue, Chikungunya, Rift Valley, Crimean-Congo, yellow fever, rubella, SARS-CoV, influenza, enterovirus 71, tick-borne meningoencephalitis (FSME), orthopox viruses[26]
National Reference Centre for Anthrax (Institute of Veterinary Bacteriology, University of Bern)	National Reference Centre for bacteriological agents	Federal Office of Public Health (Federal Department of Home Affairs)	Bern	1 (civilian)	BSL-3 (22 sqm. of 22 sqm. overall laboratory space)	Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella sp[27]
Regional Competence Centres						
Bacteriological Laboratory (University Hospitals of Geneva)	Regional Laboratory West	Cantons of West Switzerland	Geneva	6 (all civilian)	BSL-3 (45 sqm. of 45 sqm. overall laboratory space)	Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella sp[28]

Virological Laboratory (University Hospitals of Geneva)	Regional Laboratory West	Cantons of West Switzerland	Geneva	Not specified (all civilian)	BSL-3 (not specified)	Viral samples; see also National Reference Centre for Emerging Viral Infections (above)
Diagnostic Laboratories of the Institute of Microbiology (University Hospital Centre of Vaud)	Regional Laboratory West	Cantons of West Switzerland	Lausanne	Not specified (all civilian)	BSL-3 (not specified)	Various[29]
Institute of Medical Microbiology (Cantonal Hospital of Lucerne)	Regional Laboratory East Central	Cantons of Central Switzerland	Lucerne	34 (all civilian)	BSL-3 (62 sqm. of 778 sqm. overall laboratory space)	Various[30]
Institute of Medical Microbiology (University of Zurich)	Regional Laboratory East	Cantons of East Switzerland; Principality of Liechtenstein	Zurich	2 (all civilian)	BSL-3 (20 sqm. of 20 sqm. overall laboratory space)	Various bacteriological samples[31]
Institute of Medical Virology (University of Zurich)	Regional Laboratory East	Cantons of East Switzerland; Principality of Liechtenstein	Zurich	2 (all civilian)	BSL-3 (25 sqm. of 25 sqm. overall laboratory space)	Various viral samples[32]
Cantonal Laboratory of Basel-Stadt	Regional Laboratory North	Cantons of North Switzerland	Basel	4 (all civilian)	BSL-3 (36 sqm. of 50 sqm. overall laboratory space)	Staphylococcus aureus, Pseudomonas aeruginosa, Bacillus anthracis, adenoviruses, lentiviruses, and others[33]
Cantonal Institute of Microbiology (Canton of Ticino)	Regional Laboratory South	Canton of Ticino	Bellinzona	66 (all civilian)	BSL-3 (40 sqm. of 840 sqm. overall laboratory space)	Various[34]

24 For a complete list of the agents that the Spiez Laboratory is able to analyse, see http://www.labor-spiez.ch/en/the/bs/enthebs01.htm

25 Cf. http://www.bvet.admin.ch/ivi/01736/index.html?lang=en&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCDeoR_gWym162epYbg2c_JjKbNoKSn6A--

26 Cf. http://virologie.hug-ge.ch/_library/pdf/Analyses_disponibles_CRIVE_fr.pdf

27 Cf. http://www.vbi.unibe.ch/content/nant/index_ger.html

28 Switzerland 2011 CBM.

29 For a complete list of the samples that the Diagnostic Laboratories is able to analyse, see http://www.chuv.ch/dml/dml_home/dml_analyse_home.htm

30 Cf. http://www.luks.ch/uploads/media/2011_Feb_Auftragsformular_IMM.pdf

31 Cf. http://www.imm.uzh.ch/services/eVademecum.html

32 Cf. http://www.virology.uzh.ch/services/VirusAnalysenID/71.09_2_eVADEMECUM_Analysenverzeichnis_Allg.Virologie.pdf

33 Switzerland 2011 CBM.

34 See http://www4.ti.ch/dss/dsp/icm/e-vademecum/analisi-cliniche/; and http://www4.ti.ch/dss/dsp/icm/cosa-facciamo/laboratorio-regionale-sud/

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 also provide some centralised services and support to the regional facilities.[35]

The network is based on previously existing laboratory capacities and was established by the Federal Office of Public Health in collaboration with the cantons in 2006. It is jointly funded by the federal state (reference centres) and all cantons (regional centres). The total amount of funding for the network is not available because it relies on infrastructure that is primarily used for other civil purposes.[36] A coordination committee composed of federal, cantonal, and scientific experts coordinates and supervises the activities of the network.

Apart from its role as the national Centre of Expertise for NBC Protection, the Spiez Laboratory also acts as a contractor to the Regional Laboratory West Central within the framework of the Regional Laboratory Network. In addition, it will be established as a National Reference Centre for various pathogens in the near future.

In the context of the Regional Laboratory Network, a list of select agents that are considered to pose significant potential danger to public health and could be used for terrorist or military purposes is provided.[37] These agents are: Bacillus anthracis, Francisella tularensis, Yersinia pestis, Clostridium botulinum, Burkholderia mallei and pseudomallei, Coxiella burnetii, Ebola, Marburg, Lassa, Variola major, Vaccinia, Influenza A H5N1, Ricin, and Staphylococcus enterotoxin B. Further (re-)evaluation is, however, ongoing.

Civil protection and crisis management

Procedural and organisational arrangements for the management of a deliberate or major natural release of biological agents affecting Switzerland are specified in detail in the 2007 strategy for 'NBC Protection Switzerland'[38] by the Federal Commission for NBC Protection (ComNBC).[39] Due to the federal tradition of the country and the far-reaching competencies of the cantons especially in the sphere of civil protection (but not in the area of infectious diseases), there exists also a Coordination Platform NBC of the Cantons (CpNBC) for the implementation and coordination of activities within the framework of the strategy.[40] Both the ComNBC and CpNBC are supported by a permanent secretariat, located at

35 Federal Office of Public Health (2006) *Bulletin,* 33/06, 14 August, http://www.bag.admin.ch/dokumentation/publikationen/01435/01795/index.html?lang=de&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCFfXx5g2ym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCUZ,s-, pp. 668-672.

36 Switzerland 2011 CBM.

37 See http://www4.ti.ch/fileadmin/DSS/DSP/ICM/PDF/CatalogoDellePrestazioni_RLN_d.pdf

38 See http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/strategie.parsysrelated1.30028.downloadList.60659.DownloadFile.tmp/strategieabcschutzch200706f.pdf

39 See http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/organisation/komabc.html

40 See http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/organisation/kpabc.html

the Spiez Laboratory.[41] Together, these are the central Swiss bodies that integrate the complex web of relevant national and sub-national actors in CBRN protection and advise federal institutions as well as the municipalities and cantons, which are primarily in charge of the deployment of first responders, on the preparation and coordination of CBRN-protection activities in Switzerland.

The B-section of ComNBC, which is led by the Federal Office of Public Health, is the competent national advisory body for the management of biological incidents and is composed of leading institutions and experts from the public and private sector. Within the framework of the aforementioned strategy, reference scenarios have been developed and are continuously reviewed to guide preparations. With regard to biological emergencies, the following scenarios have been established:

- Deliberate contamination of food with ricin;
- Terrorist attack involving poxviruses;
- Terrorist attack involving anthrax;
- Pandemic; and
- Accident in a BSL-3 laboratory with an unintentional release of pathogenic organisms.[42]

In the event of a CBRN emergency or a major natural disaster, leadership on the federal level is provided by the Federal NBCN[43] Crisis Management Board, comprising the heads of relevant federal offices and cantonal representatives, depending on the hazard.[44] The Board is supported by the permanent National Emergency Operations Centre (NEOC), which is the federal body of expertise on exceptional events and provides nation-wide information, coordination, notification, warning, and alert capabilities for all kinds of disasters and emergencies, including incidents involving CBRN substances.[45] Recently, it has been tasked by the Federal Council with acting as a permanent point of contact and a situation assessment centre for all federal and cantonal offices responsible for CBRN protection and with supporting the Federal NBCN Crisis Management Board in case of an incident.[46]

Armed Forces

The Swiss Armed Forces, which are based on a militia system, command CBRN defence forces. These are primarily devoted to the protection and training of troops—they are not engaged in science and research—and are dependent in part on support from, and research and expertise that is carried out and maintained in the biodefence programme (mainly through the Spiez Laboratory). All personnel receive basic training in CBRN protection and are equipped accordingly.

The NBC Centre of Competence of the Armed Forces, which is also located in Spiez, develops the CBRN defence doctrine, ensures the operational readiness

41 See http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/organisation/gestl.html

42 See http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/abcschutz/szenarien.html

43 That is, nuclear (N), biological (B) and chemical (C) incidents as well as natural disasters (N).

44 See http://www.admin.ch/ch/f/rs/520_17/index.html and https://www.naz.ch/en/naz/eor.html

45 See https://www.naz.ch/en/themen/abc_schutz.html

46 See http://www.admin.ch/ch/f/rs/520_17/index.html

of the military's CBRN resources, and maintains the NBC Defence School.[47] It is responsible for the ongoing establishment, maintenance and training of the NBC Defence Corps (also largely a militia force), which 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).[48] 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 also are offered in support of civil authorities and international operations. The NBC Defence Corps is largely staffed with civil experts who work in comparable professional fields.

The same applies to the Medical Service of the Armed Forces, which is responsible for the elaboration of an operational medicinal concept for CBRN protection and is in charge of the Coordinated Medical Service. The latter is a coordination instrument of the different partners in the Swiss health system for the provision of medical care in emergencies.[49]

47 See http://www.vtg.admin.ch/internet/vtg/en/home/schweizerarmee/organisation/fsta/abc.html and http://www.vtg.admin.ch/internet/vtg/en/home/schweizerarmee/organisation/fsta/abc.parsysrelated1.97017.downloadList.58864.DownloadFile.tmp/20110419broschrekompetenzzentrumabckamir2011ehpt.pdf

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

49 Cf. http://www.lba.admin.ch/internet/lba/de/home/themen/sanit/nationale_und_internationale.html and http://www.lba.admin.ch/internet/lba/fr/home/themen/sanit/koordinierter0.html

In addition, the Pharmacy of the Army, together with the Federal Office for National Economic Supply and the cantonal pharmacies, is responsible for acquiring and stocking biological-agent vaccines for military personnel and the general population. Among others, Switzerland holds stocks of a smallpox and anthrax vaccine, antibiotics against anthrax and plague, as well as botulism anti-toxins.[50] Distribution and vaccination plans exist to make these counteragents available rapidly.

Maximum and high biological containment laboratories

All of the laboratories in the Regional Laboratory Network have at least a BSL-3 containment facility at their disposal, while two of them, the National Reference Centre for Emerging Viral Infections (NAVI) in Geneva and the Spiez Laboratory, have BSL-4 capacities (cf. Table 2). The BSL-4 unit of NAVI, currently the only BSL-4 laboratory space in operation in Switzerland, is solely approved for diagnostic purposes and is not allowed to culture or manipulate viral agents of risk group 4.[51] The BSL-4 unit of the Spiez Laboratory is due to be operational by mid-2012. 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.[52]

50 http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch_id=20023781

51 http://www.hug-ge.ch/_library/pdf/Dossiers_presse/DPP4D.pdf

52 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, September 2011

Biosafety level of the activity	Number of activities (approved/awaiting approval)	Number of organisations
1	1,011	n/a
2	1,087	n/a
3	66/14	36
4	4/2	3

Table 4. Risk level 4 activities in the ECOGEN public register, September 2011

Title of notification[53]	Organisation[54]	Status
Analysis of viruses in clinical samples using molecular or serological methods	University Hospitals of Geneva	Approved
Quality control of immunobiological products for veterinary medicinal applications	Institute of Virology and Immunoprophylaxis	Approved
Establishment of a rapid cell-based test for the identification of immunisation protection against foot-and-mouth disease	Institute of Virology and Immunoprophylaxis	Approved
Opsonising antibodies against foot-and-mouth disease virus: characterisation and establishment of a quantitative cell-based test	Institute of Virology and Immunoprophylaxis	Approved
Veterinary virus diagnostics	Institute of Virology and Immunoprophylaxis	Undergoing assessment by authorities
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

An official register of BSL-1 to BSL-4 containment facilities in Switzerland does not exist. Biological containment facilities themselves are not subject to direct authorisation; instead, projected activities must satisfy the ordinances on the contained use of organisms as well as those on occupational safety in the area of biotechnology. Prior to approval of projects, however, the appropriateness of a facility's infrastructure for the planned activity is checked.

Risk level 3 and 4 activities are subject to approval, whereas only notification is required for risk level 1

53 Author's translation from French or German.

54 This shows the organisation 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 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[55]	Bern/Thoerishaus	Hepatitis A, influenza, cholera, enterotoxigenic E. coli, typhus abdominalis, measles, rubella, meningitis C (for Pfizer), tuberculosis (trial phase), yellow fever (licensing in process)[56] The former Berna Biotech AG, which was acquired by Crucell in 2006, also used to produce a smallpox vaccine (Lancy-Vaxina)
Cytos Biotechnology AG[57]	Schlieren	Development of therapeutic vaccines/immunotherapies mainly against chronic diseases for clinical trials: diabetes mellitus, melanoma, allergic rhinoconjunctivitis, allergic asthma, allergic diseases, nicotine addiction, hypertension, Alzheimer's disease, inflammation, multiple sclerosis/psoriasis, influenza, malaria[58]
Pevion Biotech Ltd.[59]	Ittigen	Development of virosome-based vaccines for clinical trials: Candidiasis/thrush, respiratory syncytial virus, breast cancer, malaria, human immunodeficiency virus (HIV)[60]

and 2 activities. An official register 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 September 2011.

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

55 See http://www.crucell.ch/

56 Cf. http://www.crucell.ch/fr/produits and http://hugin.info/132631/R/1401132/356214.pdf

57 See http://www.cytos.com/

58 Cf. http://www.cytos.com/userfiles/file/110217_ProductPipeline.pdf

59 See http://www.pevion.com/

60 See http://www.ecogen.admin.ch/ecogen/Forms/Register/RegisterSearch.aspx

Vaccine production facilities

There is one vaccine production facility in Switzerland, and two companies that produce vaccines for clinical trials (see Table 5).[61]

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. The total floor space is 45,000 square metres for the combined facilities, 33,000 square metres of which is GMP (Good Manufacturing Practice)-certified manufacturing space to produce viral and bacterial vaccines within BSL-1 and BSL-2 environments.[62]

61 Switzerland 2011 CBM. The lists of covered diseases may differ slightly depending on the sources, which include the companies' websites, annual reports and the Swiss 2010 and 2011 CBMs.

62 Crucell (2009) *Bringing Innovation to Global Health*, http://hugin.info/132631/R/1401132/356214.pdf

Cytos also has its own GMP-compliant infrastructure, including a pilot facility for the development of active pharmaceutical ingredients (API). The facility occupies an area of 380 square metres, including a cleanroom class C measuring 80 square metres. Cytos has implemented a 50 litre-scale fermentation process for the production of virus-like particles (VLPs) in bacterial cell culture with a process time of 28 hours. The total yield of correctly folded and assembled VLPs from *E.coli* culture is approximately 8 grams per litre.[63]

Pevion is commissioning Baccinex SA[64], located in Courroux, for the production of clinical trial material. Baccinex has qualified production units, including freeze-drying services and class A and B cleanroom facilities with approved GMP compliance status. For its Phase I/II studies, Pevion manufactures the vaccine batches GMP-compliant on its own.[65]

Disease outbreak data

In 2010, there were no outbreaks of infectious diseases or similar occurrences in Switzerland that seemed to deviate from the normal pattern.[66] The following outbreaks of particularly dangerous diseases were recorded in Switzerland in 2009 and 2010:[67]

- Anthrax: none.
- Botulism: one case in 2010.
- Ebola/Lassa/Machupo/Marburg: none.
- Plague: none.
- Smallpox: none.
- Tularaemia: four cases in 2009; 12 cases in 2010.

No cases of the listed diseases have been recorded in Switzerland in 2011 (as of September).[68]

Relevant national laws, regulations and guidelines

Switzerland has a broad range of legislation and regulations in place that cover biosecurity, biosafety, the transfer (export/import) of relevant goods, and the criminalisation of the deliberate use of diseases. Most of these legal instruments were adopted before the bioterrorism debate accelerated in 2001, but they provide the necessary means to cope adequately with such concerns as well.

The central pieces of legislation include:[69]

- The *Swiss Criminal Code* of 1937 (RS 311.0), which criminalises the endangerment of public health, including the deliberate spreading of human diseases, zoonoses, and pathogenic or genetically-modified organisms, as well as the contamination of drinking water. In addition, it foresees penal-

63 See http://www.cytos.com/userfiles/file/GMP_Facts_Final_Jan06.pdf.

64 See http://www.baccinex.ch/.

65 See http://www.pevion.com/images/content/Pevion_AnnualReport%202010-1.pdf

66 Switzerland 2011 CBM.

67 Sources: Switzerland 2011 CBM and http://www.bag.admin.ch/k_m_meldesystem/00733/00813/index.html?lang=de

68 See http://www.bag.admin.ch/k_m_meldesystem/00733/00813/index.html?lang=de

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

ties for criminal acts that endanger the lives of several persons or cause major damage. The penal code also outlaws the financing of terrorism and participation in terrorist organisations.

- The *Federal Act on War Material* of 1996 (RS 514.51), which prohibits 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 stipulates license requirements for the manufacture, import, export, or transit of war material.
- The *Federal Act on the Control of Goods Suitable for Civilian and Military Purposes and Specific Military Goods* of 1996 (RS 946.202), which regulates the development, export, import, and transit of dual-use and military goods. It specifically refers to goods that may be used to develop weapons of mass destruction, including microorganisms and toxins, as well as dedicated delivery systems.
- The *Federal Act on Epidemics* of 1970 (RS 818.101), which establishes a notification system on the occurrence of certain infectious diseases and requires an authorisation for laboratories and persons that handle pathogenic agents. It authorises the government to regulate the transport, trade, and transit of pathogens, to limit or ban the use of certain pathogens, and to set conditions for their use. In addition, it outlines provisions for vaccination, quarantine, and disease monitoring. Similar provisions are stipulated in the *Federal Act on Animal Epidemics* of 1966 (RS 916.40) for certain animal diseases as well as in the *Federal Act on Agriculture* of 1998 (RS 910.1) for communicable plant diseases.
- The *Federal Act on the Protection of the Environment* of 1983 (RS 814.01), which regulates the handling of pathogenic or genetically-modified organisms and the contained use or release of such organisms into the environment. In this context, the Federal Office for the Environment regularly issues a classification of microorganisms according to four risk groups as required under several federal ordinances, such as those on the contained use of organisms and on the protection of workers from risks related to exposure to microorganisms.[70]

There are a number of federal ordinances that specify the provisions envisaged in the Federal Acts mentioned above, which are not detailed further here. For a comprehensive list of these ordinances as well as additional acts, refer to the Swiss 2011 CBM.

(Bio)chemical non-lethal weapons

Comprehensive information on what kinds of (bio) chemical non-lethal weapons are being used by police forces in Switzerland is not available. Police forces are under the jurisdiction of the cantons and the types of non-lethal weapons at their disposal may differ from canton to canton.

However, most of them do employ tear gas for riot-control purposes, either Chloroacetophenone (CN), Chlorobenzalmalononitrile (CS) and/or Pelargonic acid vanillylamide (Pava), as well as

70 For the lists of organisms, see http://www.bafu.admin.ch/biotechnologie/01744/01753/index.html?lang=en

Capsaicin-based pepper sprays for police officer's personal protection.[71]

Furthermore, the Swiss Armed Forces have Pava-based pepper sprays at their disposal[72] and were armed with tear gas for riot-control purposes within the framework of Switzerland's contribution to the North Atlantic Treaty Organization (NATO)-led Kosovo Force (Swisscoy).[73] The latter is apparently no longer the case as Swisscoy's crowd and riot-control mandate was revoked in 2010–11.[74]

Codes of conduct, education and awareness-raising

Codes of conduct that explicitly address biosecurity issues and the dual-use problem in the life sciences are rare in Switzerland. In 2002, the Association of Swiss Pharmaceutical Research Companies, Interpharma, published its 'Biosafety and Biosecurity Industry Best Practices to Prevent Misuse of Biohazardous Material'. It contains a commitment to exploit the broad potential of biotechnology to improve human life, while respecting human rights and engaging in dialogue on cultural, religious and security implications and concerns.[75]

71 See http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch_id=20021087 and http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch_id=20033576

72 See http://www.lba.admin.ch/internet/lba/de/home/verbaende/logbr/anlaesse/archiv/archiv_2009/TKRSG.html

73 See http://www.parlament.ch/f/suche/pages/geschaefte.aspx?gesch_id=20043695

74 See http://www.admin.ch/ch/d/ff/2010/8425.pdf

75 Interpharma (2002) *Biosafety and Biosecurity — Industry Best Practices to Prevent Misuse of Biohazardous Material*.

The code briefly defines industry practices in the following categories:

- Adherence to risk management and safety standards;
- Registration of projects and inventories of biohazardous material;
- Transparent acquisition of biohazardous material (with an explicit commitment by industry not to store or use biohazardous material of the highest risk group 4);
- Safe transport of biological material; appropriate handling of biological waste;
- Biosecurity measures to prevent unauthorised access to facilities where risk group 2 and 3 biological material is handled; and
- Verification of compliance through internal biosafety audit programmes.

Interpharma's code of conduct also explicitly references the BWC and upholds its objectives. It acknowledges the dual-use problem and even states that 'we accept that a Compliance Protocol strengthening the BWC must include private industry'.

The current status and application of Interpharma's code of conduct is unclear, but its importance seems to be marginal. While the *BioWeapons Monitor 2011* possesses a copy of the three-page document, it is not available online on Interpharma's website (or anywhere else for that matter), and it has not been promoted in any way in recent years.

Regarding education in and awareness-raising of dual-use issues, several initiatives are currently being pursued in Switzerland. Preliminary surveys on the awareness of dual-use and security issues

Table 6. Number of Swiss 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
Number of delegates	10	10	6	8	4	12	9	9	8	6

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

among life scientists in Switzerland show that such knowledge is largely lacking. Most life scientists also are unaware of BWC obligations of relevance to their work.[76] In light of these findings, the Government of Switzerland began to sensitise researchers in 2008 using the 'Biology for Peace' brochure, which elaborates on the dual-use and misuse problem, explains the Swiss legal framework and the BWC and Geneva Protocol, and calls for broader engagement by the scientific community.[77] The issuance of the brochure was accompanied 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 in Switzerland in 2009 as well as by the Government of Switzerland itself in 2010.

These outreach efforts revealed an almost complete absence of educational modules on biosecurity on regular life-science curricula and a missing link between life science practitioners and the Swiss security community. It was concluded that awareness-raising efforts need to be sustained, preferably in the regular work environments of life scientists employing a bottom-up approach, and that incentives need to be generated to foster the integration of lectures on the dual-use issue into regular curricula, such as through the provision of teaching material.[78]

CBM participation

Switzerland has submitted CBM declarations regularly every year since 1988—only in the first year of their establishment, 1987, did it not do so. Since 2006, Switzerland has made its CBM declarations publicly available on the website of the BWC Implementation Support Unit (ISU).

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 BWC meetings.[79]

76 *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, http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/Educationand7thRevCon/Possible_Approaches_to_Education_and_Awareness-Raising_among_Life_Scientists.pdf

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

78 François Garraux (2010) 'Linking Life Sciences with Disarmament in Switzerland', in B. Rappert (ed.) *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons,* http://epress.anu.edu.au/apps/bookworm/view/Education+and+Ethics+in+the+Life+Sciences%3A+Strengthening+the+Prohibition+of+Biological+Weapons/202/upfront.xhtml

79 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. Also see F. Lentzos and R.A. Hamilton (2009) Compendium of Proposals to Improve the CBM Mechanism, http://www2.lse.ac.uk/BIOS/research/biosecurity/pdf/CBM%20Compendium.pdf

Participation in BWC meetings

Switzerland participates regularly in BWC-related meetings in Geneva. Since the Sixth BWC Review Conference in 2006, it has taken part in all relevant meetings (see Table 6).

Past biological weapons activities and accusations

Switzerland never maintained a biological weapons programme nor has it ever been accused of doing so.

There have been numerous white powder instances in Switzerland every year since 2001, all of which turned out to be hoaxes.[80] In the time between the anthrax attacks in the United States in 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.[81] ■

80 Cf., for instance, the Annual Reports of the Spiez Laboratory, http://www.labor-spiez.ch/en/dok/ge/index.htm. Also see 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, http://www.isn.ethz.ch/isn/Digital-Library/Publications/Detail/?lng=en&id=10449

81 See http://www.admin.ch/ch/d/ff/2003/1832.pdf, p. 1896.

Country report: United Kingdom

1972 Biological Weapons Convention

Signed: 10 April 1972[1]
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 its right to retaliate in kind following the use of biological weapons.[2] All remaining reservations were withdrawn on 20 December 2002.[3]

National point of contact

Valentine Madojemu, Desk Officer for BTWC and The Australia Group, CBW Team, Counter Proliferation Department, Foreign and Commonwealth Office, London SW1A 2AH, United Kingdom

E-mail: BTWC@fco.gov.uk

The UK is one of the three Depositary Governments for the BWC and a long-standing supporter of the international prohibition on biological weapons.[4] UK policy on biological weapons is influenced by, and influences,[5] a number of regional and like-minded

1 See http://disarmament.un.org/treatystatus.nsf

2 UK Parliament (1991) 'Biological and Toxin Weapons', Written Answers to Questions, 16 October 1991, http://www.publications.parliament.uk/pa/cm199091/cmhansrd/1991-10-16/Writtens-1.html

3 UN (United Nations) (2004) M*easures 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/67458ce237aeef6785256ebd004bfee8/6ae6ac038e09307c85256ef9004cfb93/$FILE/sg59.179.pdf

4 The UK first sought to reinforce the Geneva Protocol as early as 1933 through the submission of a draft Disarmament Convention, which was unanimously accepted as a basis for future discussions, however the rearmament of Europe in the build-up to the Second World War meant discussions did not proceed. Subsequently, the UK proposed reinforcing the ban on biological weapons embodied in the Geneva Protocol in the Eighteen Nation Disarmament Committee Meeting of 6 August 1968, when Ambassador Fred Mulley presented the British proposal for a convention to prohibit the 'use for hostile purposes of microbiological agents causing death or disease by infection in man, other animals or crops'. See Goldblatt, J. (1971) *CB disarmament Negotiations 1920–1970, The Problem of Chemical and Biological Warfare,* Vol. IV, Humanities Press, New York, NY.

5 See http://www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/428-xxxi/42814.htm

groups, such as the European Union (EU), the Group of Eight (G8), and the North Atlantic Treaty Organization (NATO). National perceptions of the threat of biological weapons have been articulated in several documents, including the 2010 *Strategic Defence and Security Review,* which states that 'Direct threats to the UK include an attack by a terrorist group, or a state, using chemical, biological, radiological or nuclear (CBRN) weapons'.[6] Similarly, the 2010 report, *A Strong Britain in an Age of Uncertainty: the National Security Strategy,* states 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'.[7]

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 securing and accounting for biological materials as part of Global Cooperative Threat Reduction work[8] to promoting the universality of the BWC alongside fellow EU Member States.[9] The BWC is identified as the 'keystone in the overall international architecture to defend against the threat posed by biological and toxin weapons'.[10] The UK's objectives for the future of the Convention have been outlined by the UK Minister for Disarmament, Alistair Burt, who has said that the 'over-arching objective is to strengthen the BTWC to help prevent the acquisition or retention of biological and toxin weapons and their ever being used by states or terrorists. It is in this spirit that we will approach the Review Conference'.[11] More specific priorities for 2011 include:

- 'A new substantive programme of annual intersessional meetings;
- Revised Confidence Building Measures (CBMs);
- A regular review process of scientific and technological developments;
- To strengthen and expand the mandate of the Implementation Support Unit (ISU);
- To strengthen further the UN Secretary General mechanism for investigating allegations of chemical or biological weapons Use;
- To put in place practical support for Article VII.'[12]

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, the UK is one of the world's leading countries in the field of

6 See http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_191634.pdf?CID=PDF&PLA=furl&CRE=sdsr

7 See http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_191639.pdf

8 See http://www.decc.gov.uk/assets/decc/What%20we%20do/UK%20energy%20supply/Energy%20mix/Nuclear/nonproliferation/global_threat/1361-gtrp-eighth-annual-report.pdf

9 See, for example, the reports at http://www.euja-btwc.eu/activities

10 See http://www.fco.gov.uk/en/global-issues/counter-proliferation/biological-and-toxin-weapons-convention/burt-message/

11 *Ibid.*

12 See http://www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/428-xxxi/42814.htm and http://www.fco.gov.uk/en/global-issues/counter-proliferation/biological-and-toxin-weapons-convention/role-of-the-uk-in-btwc/

the life sciences and biotechnology. Globally, the UK ranks third; in its geographical sub-region, Northern Europe, it ranks first. More specifically, globally, the UK ranks second in terms of publications and fourth in terms of patents.[13]

Moreover, there has been a concerted effort to promote biotechnology in the UK, and the Office for Life Sciences (OLS) has identified biotechnology as 'an important growth area'[14] and has undertaken a number of initiatives to foster life science research and development (R&D).[15] The Department for Business, Innovation and Skills claimed that, as of December 2010, the 'medical technology and diagnostics, medical biotechnology and industrial biotechnology landscape in the UK contains just over 4,000 companies, with a combined turnover of £19bn, employing 93,500 people across the UK'.[16] However, the 4,000+ figure appears to incorporate a significant number of small and medium enterprises (SMEs); estimates by other organisations are much smaller, for example *Beyond Borders: Global Biotechnology 2011* posits that the UK has a total of 41 *public* biotechnology companies, which generated a total of EUR 3,298 million in revenues over the course of 2010. [17]

13 See the Annex to this report.

14 See http://www.bis.gov.uk/ols

15 See http://www.bis.gov.uk/assets/biscore/business-sectors/docs/u/10-542-life-sciences-2010-delivering-the-blueprint.pdf

16 See http://www.bis.gov.uk/assets/biscore/business-sectors/docs/s/10-p90-strength-and-opportunity-bioscience-and-health-technology-sectors

17 Ernst & Young (2011) *Beyond Borders: Global Biotechnology Report 2011,* http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders--global-biotechnology-report-2011, p. A50.

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 under both programmes occurs primarily at the Defence Science and Technology Laboratory (Dstl) facilities in Porton Down. A number of laboratory facilities are included on the Dstl Porton Down site, including a total of 335 square metres (sqm.) of Biosafety Level (BSL)-4 facilities and 1,050 sqm. of BSL-3 facilities.[18]

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 (chemical, biological, radiological, nuclear) incident through building capabilities in the areas of, inter alia, detection, decontamination, hazard assessment and medical countermeasures. The relatively small amount of funding for the HO programme is used principally to fund Dstl activities and has decreased significantly over the past three years (see Table 1).

Ministry of Defence biological defence programme

The MoD's biodefence 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

18 UK 2011 CBM, p. 3.

Table 1. HO biological defence programme spending and contracted percentage[19]

Period	Total estimated spending	Percentage of the total funds contracted to 'industry, academic institutions, or in other non-defence facilities'
1 April 2006–31 March 2007	GBP 6.7 million	88
1 April 2007–31 March 2008	GBP 7.1 million	85
1 April 2008–31 March 2009	GBP 7.0 million	80
1 April 2009–31 March 2010	GBP 5.0 million	80
1 April 2010–31 March 2011	GBP 3.0 million	0.05[20]

military freedom of action despite the presence, threat or use of biological, chemical or radiological agents'.[21] In this regard five components have been identified:

- hazard assessment;
- detection and diagnostics;
- protection;
- medical countermeasures; and
- hazard management.

In addition to which Dstl staff provide 'technical advice on CBW non-proliferation' to inform UK arms control and non-proliferation policies.[22] MoD biodefence funding over the past five years has averaged roughly GBP 50 million per annum, of which a significant segment is earmarked for activities to support the procurement of 'armed forces biological defence equipment'.[23] A further percentage of this funding goes towards supporting extramural contracts for R&D conducted by industrial companies and academic institutions, which occurs, in part, through open calls for proposals in certain issues areas.[24] Table 2 shows estimated spending, personnel and the number of extramural contracts by year.

Compliance review and transparency

Until recently, there was no official structure in place to review MoD biodefence projects vis-à-vis compliance with arms control agreements, rather, 'Dstl research scientists generally consult[ed] with Dstl's own arms control and non-proliferation

19 See UK CBM submissions.

20 The difference in the percentage of funding contracted to industry, academic institutions, or in other non-defence facilities is a result of a reinterpretation of the question posed in CBM Form A, part 2(ii), not a significant change in the percentage contracted out, which has remained at similar levels. Personal correspondence with FCO representative, 20 October 2011.

21 UK 2011 CBM, p. 12.

22 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 and the UK 2011 CBM.

23 Data derived from UK 2007–11 CBMs, http://www.unog.ch/80256EDD006B8954/(httpAssets)/009540B24174AC38C12578930057FF00/$file/BWC_CBM_2011_United+Kingdom.pdf

24 See, for example, the recent Joint Synthetic Biology Initiative (JSBI), http://www.bbsrc.ac.uk/jointsyntheticbiology

Table 2. MoD biodefence programme costs, personnel and external contracts[25]

Period	Total estimated spending	Procurement of defence equipment	Personnel biodefence	Extramural contracts: universities/ academic institutions	Extramural contracts: government funded or industrial companies
1 April 2006–31 March 2007	GBP 43.5 million	GBP 5.4 million	207 civilians 10 military	35	45
1 April 2007–31 March 2008	GBP 55.4 million	GBP 13.5 million	220 civilians 7 military	35	46
1 April 2008–31 March 2009	GBP 57 million	GBP 10.1 million	221 civilians 4 military	45	55
1 April 2009–31 March 2010	GBP 47 million	GBP 12.9 million	216 civilians 10 military	36	40
1 April 2010–31 March 2011	GBP 51 million	GBP 10.25 million	216 civilians 4 military	22	49

advisor(s) as needed to obtain advice on whether a project is treaty compliant'.[26] In the past two years, though, the MoD has developed 'written guidelines for BWC compliance'.[27] These are not publicly available, although the objectives are identified as the following:

- to provide guidance on biodefence projects, including joint international projects;
- to ensure the work is consistent with UK interpretations of the BWC and associated treaties;
- to provide guidance on relevant domestic law that implements UK obligations; and
- to demonstrate that the MoD has appropriate guidance in place.[28]

Dstl personnel are actively encouraged to publish research when appropriate[29] and research is evident in a number of different scientific journals.[30] A simple search of the 'Web of Science' database identifies more than 35 life-science-related academic publications between 2009 and 2011, with one author affiliated with Dstl.[31] Table 3 outlines the subject areas of these publications, many of

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 and the UK 2011 CBM.

26 *Ibid.*

27 *Ibid.*

28 *Ibid.*

29 See http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/415/415ap59.htm

30 See the Web of Science, which identifies the Dstl as an institution, http://apps.webofknowledge.com/UA_GeneralSearch_input.do?product=UA&search_mode=GeneralSearch&SID=4EfmPl6Obkh6pogI7cI&preferencesSaved=

31 For further details on the search term used, please contact the author.

Table 3. Life-science subject areas dealt with by Dstl, Porton Down

Subject areas	Record count
Immunology	10
Biochemistry molecular biology	9
Toxicology	6
Biotechnology applied microbiology	5
Microbiology	4
Chemistry	3
Infectious diseases	3
Research experimental medicine	3
Genetics heredity	2
Pathology	2

which were produced in collaboration with other academic and industrial institutions.[32]

In addition to the academic publications produced by Dstl-affiliated authors, some unclassified research abstracts are also available in the Athena report collection.[33] However, the MoD has stated that: '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"'.[34]

32 See http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/415/415ap59.htm

33 See http://www.dstl.gov.uk/pages/85

34 See http://www.parliament.the-stationery-office.co.uk/pa/cm200203/cmselect/cmsctech/415/41515.htm#note226

Maximum and high biological containment laboratories

A Health and Safety Executive (HSE) audit in 2008 identified 10 sites working with Containment Level 4 (CL4) pathogens,[35] all except two of these sites were government-run—the two exceptions being private companies working on veterinary vaccines.[36] According to the report, 'these facilities vary in capacity and capability, ranging from single rooms to multiple suites of CL4 laboratories on a single site'.[37] Table 4 shows the number of UK laboratories at Containment levels 2, 3 and 4, and the break down by organisation or site type as of 2008.

Since the HSE audit in 2008, one government CL4 facility and one CL4 private vaccine manufacturing facility, ran by *Intervet Schering-Plough,* have been 'de-operationalised',[38] leaving eight high-containment sites covering both human pathogens and those agents identified as being level four under the Specified Animal Pathogens Order (SAPO).

35 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 World Health Organization (WHO) BSL-4 and the EU P-4 standards; the former being animal pathogens that vary in terms of their biosafety level.

36 The two companies were identified as private manufacturers of veterinary vaccines. See House of Commons, Innovation, Universities, Science and Skills Committee (2008) *Biosecurity in UK Research Laboratories,* Sixth Report of Session 2007–08, Volume I, http://www.publications.parliament.uk/pa/cm200708/cmselect/cmdius/360/360i.pdf

37 *Ibid.*

38 Many thanks to the HSE respondent for assistance with queries here.

Table 4. Number of UK laboratories by containment level and organisation or site type (2008)

	Organisation or site type			
Containment level	**Government**	**Private**	**Research council**	**University**
2	212	230	17	70
3	202	98	7	40
4	5	2	3	0

Table 5. UK CL4 facilities, location, funders, activities and size (2011)

Name	Address	Funder	Activities and agents	Number of units and size
Defence Science and Technology Laboratory (Dstl), Porton Down[39]	Porton Down, Salisbury, Wiltshire, SP4 0JQ	Primarily the Ministry of Defence	Broad range of research and development activities related to countering the threat posed biological agents[40] involving a range of different agents	2 units, 335 sqm. in total
Health Protection Agency, Colindale	61 Colindale Avenue, London, NW9 5HT	Department of Health	Diagnostic services for Herpes B; viral haemorrhagic fever infections: Lassa fever, Ebola, Marburg, Congo-Crimean haemorrhagic fever; avian influenza and SARS[41]	1 unit, 30 sqm.
Health Protection Agency, Centre for Emergency Preparedness and Response	Porton Down, Salisbury, Wiltshire, SP4 0JG	Department of Health	Provides 'diagnostic services for pathogenic Arboviruses, Haemorrhagic Fever viruses, Rickettsias and a number of Hazard Group 3 bacteria pathogens'[42]	2 units, 105 sqm. in total
National Institute for Biological Standards and Control (NIBSC)	Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG	Department of Health	'. . . activities are related to development and testing of modified strains of highly pathogenic influenza virus suitable as seeds for vaccine manufacturing'[43]	1 unit (SAPO level 4),[44] 118 sqm.

National Institute for Medical Research (NIMR), Containment 4 Building C	The Ridgeway, Mill Hill, London, NW7 1AA	Primarily the UK Medical Research Council (MRC)[45]	Research and diagnostics on highly pathogenic avian influenza virus	1 unit, 298 sqm.
Institute for Animal Health, Pirbright Laboratory	High Street, Compton Laboratory, Compton, Newbury, Berks, RG20 7NN	Approximately 25 per cent from the Biotechnology and Biological Sciences Research Council (BBSRC); around 50 per cent in research contracts; and the remainder from rents, royalties and sales[46]	Work on exotic animal virus diseases, including: African horse sickness; African swine fever; Bluetongue and related viruses; foot-and-mouth disease; Lumpy skin disease; Peste de petits ruminants and Rinderpest; Sheep- and goat-pox; Swine vesicular disease[47]	5,173.87 sqm. of SAPO level 4 in total
Veterinary Laboratories Agency	Ash Road, Pirbright, Woking, Surrey, GU24 0NF	Department for Environment, Food and Rural Affairs[48]	Diagnosis and applied research on the epidemiology and pathology of the disease of farmed, domesticated livestock	6 units (SAPO level 4), 160 sqm. in total; plus around 100 sqm. SAPO level 4 capable facilities
Merial Animal Health, Pirbright Laboratory.	Ash Road, Pirbright, Woking , Surrey, GU24 0NF	Privately financed[49]	'the manufacture of FMD viral vaccines; the manufacture of viral antigens of BTV and running the world's largest FMD (vaccine) antigen bank'[50]	1 facility (SAPO level 4)

39 See http://www.dstl.gov.uk/pages/169

40 See http://www.dstl.gov.uk/pages/126

41 UK 2011 CBM, p. 4.

42 Health Protection Agency (2010) 'Special Pathogens Reference Unit', http://www.hpa.org.uk/ProductsServices/InfectiousDiseases/SpecialPathogensReferenceUnit/

43 See http://www.nibsc.ac.uk/spotlight/influenza_resource_centre/pandemic_preparedness.aspx

44 One should note that the NIBSC facility operates at Specified Animal Pathogens Order level 4, but not to CL4 requirements.

45 See http://www.nimr.mrc.ac.uk/about/funding/

46 See http://www.iah.ac.uk/About/funding.aspx

47 See http://www.iah.ac.uk/About/Lab_p.aspx

48 See http://vla.defra.gov.uk/reports/docs/rep_accounts1011.pdf

49 See http://uk.merial.com/corporate_content/our_company/index.asp

50 See http://www.publications.parliament.uk/pa/cm200708/cmselect/cmdius/360/360we06.htm

Research and policy issues regarding smallpox

The 2003–04 *Annual Report* of the UK's National Biological Standards Board (NBSB) stipulates that one of the objectives of the National Institute for Biological Standards and Control (NIBSC) was to 'identify and validate suitable biological markers for assessment of consistency of production for new generation smallpox vaccines'.[51] This is consistent with earlier UK CBMs, which reported 'developing and testing reagents' for smallpox vaccines at the NIBSC facility.[52] 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 NIBSC Director, Dr Stephen Inglis reports that 'further development of such tests is not an area of active research at this time'.[53]

According to the Web of Science database, a small number of publications related to smallpox have been produced by academic institutions in the UK, which draw from a range of disciplinary groupings, including immunology, medical ethics, history of social science, and statistics.[54] There is, however, no evidence of research using the virus per se and there are no smallpox stockpiles in the UK. In 2011, the Parliamentary Under-Secretary of State, Earl Howe, said that 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'.[55] Such arrangements include the maintenance of anti-smallpox vaccine stockpiles, an operational planning framework for mass vaccination, and the pre-emptive vaccination[56] of a small number of front-line health workers against smallpox in 2005, 'to deal with any initial suspected or confirmed case of smallpox if one were to occur'.[57]

Vaccine production facilities

The UK hosts 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).* In the 2011 edition of the Register, there a small number of facilities seemingly licensed to produce vaccines for the protection of human beings. Correspondence with representatives of these companies and a

51 See http://www.nibsc.ac.uk/PDF/NBSB_annual_report_200304.pdf and UK CBM returns.

52 See UK CBM Returns 2007, 2008, 2008, 2009.

53 Personal correspondence with representative of the National Institute for Biological Standards and Control, 26 September. See also http://www.nibsc.ac.uk/PDF/NBSB_Annual_Report_07.pdf

54 For further details on the search, please contact the author.

55 See http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/110516w0001.htm#1105161000427

56 Department of Health (2005) *Smallpox mass vaccination: An operational planning framework,* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4114017

57 See http://www.publications.parliament.uk/pa/cm201011/cmhansrd/cm101108/text/101108w0006.htm

Table 6. Licensed manufacturing sites for human vaccines[58]

Name	Address	Vaccines or license
Health Protection Agency, Centre for Emergency Preparedness and Response	Porton Down, Salisbury, Wiltshire, SP4 0JG	'The HPA is the sole manufacturer of the UK's licensed anthrax vaccine'[59]
MedImmune UK Ltd.	Plot 6 Renaissance Way, Boulevard Industry Park, Speke, Liverpool, L24 9JW	Influenza Vaccine Live[60] — 'The egg-based process can produce up to 50 million monovalent vaccine doses per 12-month cycle'[61]
Novartis Vaccines and Diagnostics Ltd.	Gaskill Road, Speke, Liverpool, L24 9GR	Bulk manufacture of Influenza vaccine; Vaccines for meningococcus A, C, W and Y, rabies, Japanese encephalitis, typhoid and diptheria[62]

review of company websites, though, revealed that only three companies are actually involved in the production of human vaccines.[63]

In addition, a number of private facilities in the UK are licensed to work on laboratory-based vaccine R&D,[64] the 'filling of vaccines',[65] and the manufacture of, inter alia, active pharmaceutical ingredients.

Disease outbreak data

The following is based on a review of official data in the *Statutory Notifications of Infectious Diseases* from the four different agencies across the UK.

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 produced 47 cases of 'injectional' anthrax[66] in Scotland,[67] resulting in 13 reported deaths, and five cases caused four deaths in England.[68] A number of people have been arrested for dealing

58 All information derived from the Department of Health and the MHRA *Register of Licensed Manufacturing Sites (Human and Veterinary Sites) 2011.* See http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf

59 See http://www.hpa.org.uk/ProductsServices/BiopharmaceuticalManufacturingCapabilities/AnthraxVaccine/

60 See http://www.medimmune.com/about_us_facilities.aspx

61 *Ibid.*

62 See http://www.novartis.co.uk/our_business/vaccines_and_diagnostics.shtml

63 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 of them independently confirmed that they did not currently manufacture vaccines. A review of the available material and product lists on two remaining company websites suggested that they were not involved in vaccine production, but rather worked variously on pain management for cancer patients or drug transportation, logistics and storage.

64 See http://www.mhra.gov.uk/home/groups/es-foi/documents/foidisclosure/con2024017.pdf

65 A number of facilities are licensed for the 'filling of vaccines', all of which are identified in the MHRA report. See *ibid.*

66 The term 'injectional' is used specifically in some texts: see, for example, Holta Ringertz, C.N. (2000) 'Injectional anthrax in a heroin skin-popper', *The Lancet,* Vol. 356, No. 9241; and Ramsay, C.N (2010) 'An outbreak of infection with Bacillus anthracis in injecting drug users in Scotland', *Eurosurveillance,* Vol. 15, No. 2.

67 See http://www.scotland.gov.uk/Publications/2010/07/30140320/3

68 See http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1265637163487 and http://www.bbc.co.uk/news/uk-england-kent-11685984. Also see Booth, M.G. et al (2010) 'Anthrax infection in drug users', *The Lancet,* Vol. 375, No. 9723, pp. 1345–1346.

Table 7. Outbreaks of particularly dangerous diseases in the UK, 2007–10

	2007[69]	2008[70]	2009[71]	2010
Anthrax	0	1	1	52[72]
Botulism[73]	0	0	0	2[74]
Plague	0	0	0	0
Smallpox	0	0	0	0
Tularemia	0	0	0	0
Viral haemorrhagic fevers	1	3	5	3

the contaminated drugs, but they are not believed to have been responsible for, or aware of, the contamination.[75] Instead, it is thought that the drugs are likely to have been contaminated at the original point of production,[76] 'through contact with infected soil or animal skins', most likely in Afghanistan.[77] There have also been a small number of outbreaks of viral haemorrhagic fevers, such as Lassa Fever, brought into the country by infected travellers.[78]

Relevant national laws, regulations and guidelines

The UK has a number of regulatory and legislative measures, covering human, animal and plant agents, designed to prohibit and prevent the development, production, and stockpiling of biological weapons.

69 See http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1223622641711 and http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/EpidemiologicalData/botu010FoodborneBotulismLaboratoryreportedcases/

70 See http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1253205364859

71 See http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/ 1281952671504 and http://www.publichealthagency.org/directorate-public-health/health-protection/notifications-infectious-diseases

72 The Health Protection Agency confirmed five cases of anthrax in heroin users in England in 2010, in addition to the 47 confirmed cases in Scotland by 23 December 2010, making a total of 52 cases in total in 2010. This differs slightly from the CBM return due to the five cases in England being confirmed after the submission in March. See http://www.hps.scot.nhs.uk/anthrax/index.aspx and http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1265637163487

73 A small number of cases of infant botulism were recorded in 2009 and 2010 and a larger number of cases of wound botulism in injecting drug users. See http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/ and http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/GeneralInformation/botu020Woundbotulismcasesininjectingdrugusers/

74 See http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/NotificationsOfInfectiousDiseases/NOIDSReportsAndTables/NoidsPreviousNOIDsReports/Noids2010NOIDsReports/

75 See http://www.bioprepwatch.com/news/215090-five-men-arrested-in-connection-with-heroin-anthrax-death and http://www.bbc.co.uk/news/uk-scotland-south-scotland-11718683

76 Hoffman, B. (2010) 'Anthrax: In Scotland, Six Heroin Users Die of Anthrax Poisoning', 11 January.

77 See Christie, B. (2010) 'Heroin contaminated with anthrax has killed 11 people', *British Medical Journal,* 340:c937, http://www.bmj.com/content/340/bmj.c937.full; Karishma, S.K et al. (2010) 'Shooting up: the interface of microbial infections and drug abuse', *Journal of Medical Microbiology,* Vol. 60, No. 4, pp. 408–422; and the UK 2011 CBM.

78 See http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/LassaFever/GeneralInformation/lassa005HistoricalTableImportedConfirmedLassaCases/

While many of these measures date back to the 1970s, more recent concerns about bioterrorism in the post-11 September 2001 context, and following the 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. Key legislative measures include the Biological Weapons Act 1974, which applies to all UK persons and entities, including bodies corporate, and bans 'the development, production, acquisition and possession of certain biological agents and toxins and of biological weapons',[79] and the Anti-terrorism, Crime and Security Act (ATCSA) 2001.[80] Part 7 of the 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'.[81] The Act was extended in 2007 to cover some animal pathogens.[82]

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-1990s,[83] although export controls were updated more recently through the Export Control Act of 2002 (and the subsequent secondary legislation introduced under this Act[84]), which includes catch-all controls, end-user certification, and, notably, mechanisms to regulate intangible technology transfer.[85] 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,[86] and measures to manage health, safety and environmental issues, principally the Control of Substances Hazardous to Health Regulations (COSHH) 2002,[87] which places an obligation on employers 'to control substances that can harm workers' health'.[88]

Bio(chemical) non-lethal weapons

There has been some interest around the world in the potential development of certain biological agents as incapacitating weapons for law-enforcement

79 Biological Weapons Act 1974, http://www.legislation.gov.uk/ukpga/1974/6/contents

80 Anti-terrorism, Crime and Security Act 2001, http://www.publications.parliament.uk/pa/cm200102/cmbills/049/2002049.pdf

81 United Kingdom (2008) *Implementation of the UK Anti-terrorism Crime and Security Act (ATCSA) 2001: Biosecurity Aspects,* BWC/MSP/2008/MX/WP.6.

82 '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

83 Including the Export of Goods Order (1994), the Dual-Use and Related Goods (Export Control) Regulations 1996, and the Plant Health (Great Britain) Order 1993 See http://www.vertic.org/pages/homepage/databases/bwc-legislation-database/u.php

84 For instance, the 'Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003'.

85 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.

86 See http://www.fco.gov.uk/en/about-us/what-we-do/services-we-deliver/atas/

87 See http://www.vertic.org/media/National Legislation/United_Kingdom/GB_Control_Substances_Hazardous_Regulations_2002.pdf

88 See http://www.hse.gov.uk/coshh/

purposes.[89] The UK has stated that the 'development, production, retention, acquisition or use of "Incapacitating biochemical weapons" are prohibited by both Conventions'.[90] Although broader conceptual issues continue to surround the term 'weapons', in the context of the BWC, the Government of the UK has recalled language from the Fourth and Sixth Review Conferences and affirmed that the 'use in any way and under any circumstances of microbial or other biological agents or toxins that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the [BWC]'.[91] Herbicides and defoliants are 'more complex' under the BWC, being considered primarily as chemicals, however the Government of the UK has stated that '[a]nti-crop biological agents are already prohibited if held contrary to the provisions of the BTWC's Article I'.[92]

Codes of conduct, education and awareness-raising

The UK, which has made modest progress in this area, explicitly outlined its support for these measures in 2008, stating that such tools:

- heighten levels of awareness in the academic and research communities of the need for care;
- highlight the nature of the Convention's legal prohibitions; and
- promote the need to address issues such as technology governance on a continuing basis.[93]

The Government of the UK has recognised the challenges involved in convincing stakeholders in the academic community of the importance of these issues. Notable in this regard is that a seminar series on Chemical Weapons Convention (CWC) issues was 'abandoned in view of a lack of interest'.[94] Nonetheless, a small number of universities include discussion on security-related topics in life-science-related degrees and certainly there are 'four discernable 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'.[95] Furthermore, since 2005, major funders of scientific research in the UK have demanded that applicants take dual-use issues into consideration when submitting funding proposals.[96] Support for some form of code of conduct also has emerged from the Royal Society.[97] Yet, despite some evidence of progress in

89 Davison, N. (2009) *'Non-Lethal' Weapons (Global Issues),* first edition, Palgrave Macmillan, Basingstoke.

90 See http://www.publications.parliament.uk/pa/cm200809/cmselect/cmfaff/222/response.pdf

91 *Ibid.*, p. 22.

92 *Ibid.*

93 UK (2008) *Oversight, Education and AwarenessRaising: Report of a UK Seminar,* BWC/MSP/2008/MX/WP.10, 28 March, p. 6.

94 See http://www.nti.org/e_research/source_docs/uk/docs/08.pdf, p. 3.

95 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

96 See http://www.bbsrc.ac.uk/organisation/policies/position/public_interest/misuse_of_research_joint.pdf

97 See http://royalsociety.org/The-roles-of-codes-of-conduct-in-preventing-the-misuse-of-scientific-research-/

Table 8. Number of UK 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
Number of delegates	8	6	6	9	9	12	11	12	8	8

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

the UK, as with many countries around the globe, activity has been limited and dual-use and/bio-security-related issues continue to be considered as irrelevant or less relevant by many life-science educators and researchers.[98]

CBM participation

The UK is one of a small number of countries that have regularly submitted CBMs.[99] It was one of the first countries to make its CBMs publicly available, firstly though the Foreign and Commonwealth Office website, beginning in 2003,[100] and later, in 2006, through the United Nations Office at Geneva's BWC website.[101]

98 See Rappert, B., M. Chevrier and M. Dando (2006) *In-Depth Implementation of the BTWC: Education and Outreach,* Bradford Review Conference Papers, No. 18, http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_18.pdf; and Mancini, G. and J. Revill (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

99 With the exception of 2001, when records indicate a gap; see http://www.unog.ch/80256EDD006B8954/(httpAssets)/41BF3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf

100 Hunger, I. and N. Isla (2006) 'Confidence-building needs transparency: an analysis of the BTWC's confidence-building measures', *Disarmament Forum: Toward A Stronger BTWC,* http://www.unidir.org/pdf/articles/pdf-art2511.pdf, p. 30.

101 See http://www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument

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.[102]

Past biological weapons activities and accusations

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.[103] The UK's

102 *Ibid.*

103 The *SIPRI Yearbook 2010,* for example, reports allegations by Afghan farmers that UK and US forces used biological agent to cause leaf blight in opium poppies 'to hamper the opium production and trade that is essential for the continued Taliban insurgency in the region'. Stockholm International Peace Research Institute (2010) *SIPRI Yearbook 2010,* Oxford University Press, Oxford, p. 403.

offensive biological weapons programme is well documented as having concluded in the late 1950s[104] and such unofficial allegations remain unsubstantiated.

Allegations and hoaxes

Over the course of the past 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 the UK and the United States (see chapter on South Africa).[105]
- The incarceration in 2010 of Ian Davison of the White supremacist group, the Aryan Strike Force, who was jailed along with three others, including his son, for producing small quantities of Ricin.[106]

In addition, there have been a more significant number of hoax letters containing suspicious white powders being distributed to prominent individuals and organisations, including former Communities Minister Shahid Malik,[107] Prince William,[108] and personnel of the Barrett Homes company.[109] ■

104 Carter, G.B. and G.S. Pearson (1999) 'British biological warfare and biological defence, 1925–45', in E. Geissler and J.E.v.C. Moon, *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, Oxford University Press, Oxford, pp. 168–189.

105 See http://www.dailymail.co.uk/news/article-1356766/Man-threatened-biological-weapons-attack-Britain-U-S-arrested.html, http://gsn.nti.org/siteservices/print_friendly.php?ID=nw_20110214_7233, 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

106 See http://www.telegraph.co.uk/news/uknews/crime/7724848/White-supremacist-who-manufactured-ricin-jailed.html, http://www.guardian.co.uk/uk/2010/may/14/neo-nazi-ian-davison-jailed-chemical-weapon, and http://news.bbc.co.uk/1/hi/8682132.stm

107 See http://www.guardian.co.uk/politics/2009/dec/30/shahid-malik-white-powder-anthrax, 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

108 See http://www.guardian.co.uk/world/2001/oct/16/afghanistan.terrorism13

109 See http://www.nti.org/db/cbw/2006/cbw081606.htm

Country report: United States

1972 Biological Weapons Convention[1]

Signed: 10 April 1972
Deposit of ratification: 26 March 1975

1925 Geneva Protocol[2]

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'.[3]

National point of contact

Office of the Biological Policy Staff, Bureau of International Security and Nonproliferation, US Department of State, 2201 C Street, NW, Washington, DC 20520, USA

The US stated in August 2011 that: 'The United States is in compliance with all its obligations under arms control, nonproliferation, and disarmament agreements and commitments, and continues to make every effort to comply scrupulously with them. When U.S. treaty partners have raised compliance questions regarding U.S. implementation activities, the United States has carefully reviewed the matter to confirm that its actions were in compliance with its treaty obligations'.[4]

In 1969, US President Richard M. Nixon issued a 'Statement on Chemical and Biological Defense Policies and Programs' that renounced the use of offensive biological weapons and led to the adoption of the Biological Weapons Convention (BWC) in 1972:

> The United States shall renounce the use of lethal biological agents and weapons, and all other methods of biological warfare.

1 See http://disarmament.un.org/treatystatus.nsf

2 *Ibid.*

3 *Ibid.*

4 US Department of State (2011) 'Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments', U.S. Department of State, Washington, DC, p. 3.

> The United States will confine its biological research to defensive measures such as immunization and safety measures.[5]

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'.[6]

Most 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.[7]

However, as stated by Under Secretary of State Ellen Tauscher in her 2009 address to States Parties of the BWC, 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.[8]

Ambassador Kennedy reaffirmed the above statement in 2010 at the Annual Meeting of States Parties of the Biological and Toxic Weapons Convention:

> The United States remains convinced that a verification regime is no more feasible than it was in 2001, and perhaps even less so, given the evolution of technology and industry.[9]

US concern about biological weapons may be divided into two categories: the threat of bioterrorism; and the threat of state or state-sponsored attacks.

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 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

5 Miller, J., S. Engelberg and W. Broad (2001) *Germs: Biological Weapons and America's Secret War,* Simon and Schuster, New York, NY, p. 64.

6 See http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf, p. 8.

7 See http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/9F98E6515ACD48A7C12578770046DFD8/$file/BWC-7RC-PC-Statement-110413-USA.pdf

8 See http://geneva.usmission.gov/2009/12/09/tauscher-bwc/

9 See http://geneva.usmission.gov/2010/12/06/1206-bwc/

> 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.[10]

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.[11]

In an unclassified report to Congress, the US Deputy Director of National Intelligence for Analysis listed and commented on the states (Iran, North Korea and Syria) thought to have offensive biological weapons programmes: [12]

> **Iran** . . . probably has the capability to produce some biological warfare (BW) agents for offensive purposes, if it made the decision to do so. We assess that Iran has previously conducted offensive BW agent research and development. Iran continues to seek dual use technologies that could be used for BW . . .
>
> **North Korea** . . . North Korea has a biotechnology infrastructure that could support the production of various BW agents. We judge that North Korea possesses a conventional munitions production infrastructure that could be used to weaponize BW agents.
>
> **Syria** . . . Syria's biotechnical infrastructure is capable of supporting BW agent development.

The August 2011 US Department of State document on 'Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments' also contains findings on compliance or suspected non-compliance with the BWC.[13] This document adds Russia to the list of possible BWC violators:

> 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

10 See http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

11 See http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

12 See http://www.fas.org/irp/threat/wmd-acq2010.pdf

13 US Department of State (2011) 'Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments', *op. cit.*, pp. 5–14.

Table 1. United States biodefence funding, 2001–11[14]

Federal agency	Funding (USD millions)											
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010 (est.)	2011 (budget)	Totals
Department of Health and Human Services	271	2,940	3,738	3,819	4,148	4,132	4,069	3,993	4,369	4,519	4,719	40,718
Department of Defense	274	824	422	417	430	583	555	578	718	680	776	6,256
Department of Homeland Security	N/A	N/A	422	1,788	2,981	567	354	359	2,550	466	440	9,927
Other[15]	89	332	508	400	571	508	467	494	512	541	542	4,963
Total	**633**	**4,096**	**5,090**	**6,424**	**8,130**	**5,790**	**5,445**	**5,425**	**8,148**	**6,205**	**6,477**	**61,864**

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.[16]

Status of the life sciences and biotechnology industry

According to the 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.[17]

According to Ernst & Young[18], the US had 315 public biotechnology companies and 1,726 (public and private) companies in 2010. Worldwide, the number of public and private companies was 4,414 in 2008,[19] indicating that the US is home to approximately 39 per cent of the world's biotechnology companies.

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.

14 Franco, C. and T.K. Sell (2010) 'Federal Agency Biodefense 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

15 Other is the Environmental Protection Agency, National Science Foundation, and Departments of Agriculture, Commerce, and State.

16 *Ibid.*, p. 12.

17 See the Annex to this report.

18 Ernst & Young (2011) *Beyond Borders: Global Biotechnology Report 2011,* 25th anniversary edition, http://www.ey.com/Publication/vwLUAssets/Beyond_borders_global_biotechnology_report_2011/$FILE/Beyond_borders_global_biotechnology_report_2011.pdf

19 Ernst & Young (2008) *Beyond Borders: Global Biotechnology Report 2008,* which contains the worldwide data, is no longer online.

Table 2. Comparison of the CACNP and UPMC studies of US biodefence funding

Study	Funding (USD millions)							
	2001	2002	2003	2004	2005	2006**	2007**	Totals
Center for Arms Control*.**	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:

* 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.

** In the Center for Arms Control Study, 2006 funding is estimated and 2007 funding is requested.

The total amount of funding for biodefence between 2001 and 2011 is nearly USD 62 billion. Funding increased dramatically after 2001 due to the anthrax-containing letters posted to media representatives and elected officials. Annual funding remains high today. The Department of Health and Human Services (HHS) received the largest amount, close to USD 41 billion, for both in-house projects and private sector grants and contracts, much of it related to countermeasure research and development (see below).

Through 2007, the Center for Arms Control and Non-Proliferation (CACNP) also compiled biodefence funding.[20] The 2007 CACNP study pointed up significantly higher funding than the UPMC study.[21] 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 2001–11 is perhaps closer to USD 77 (1.24 x 62) billion.

Department of Health and Human Services funding

The bulk of HHS funding for biodefence research is in the Emergency Preparedness Budget. Relevant portions of the budget are listed in Table 3.

The National Institutes of Health (NIH) is slated to receive most of the requested funding, more than USD 1.7 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.[22]

Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is the recipient of most of the funding (see Table 4).

20 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

21 Franco, C. and T.K. Sell (2010) 'Federal Agency Biodefense Funding, FY2010–FY2011', *op. cit.*

22 Consolidated Appropriations Act, 2010 (P.L. 111-117)

Table 3. Selected items from the HHS Emergency Preparedness Budget (requested) for 2012[23]

Agency/programme	Funding (USD millions)	
Centers for Disease Control and Prevention (CDC)		775
Preparedness and response capability	183	
Strategic national stockpile	592	
National Institutes of Health		1,749
Biodefence research	1,749	
Food and Drug Administration		292
Food defence	217	
Vaccines/drugs/diagnostics	68	
Physical security	7	
Assistant Secretary for Preparedness and Response (ASPR)		1,054
National Disaster Medical System (NDMS)	57	
Hospital preparedness	426	
Biomedical Advanced Research and Development Authority (BARDA)	476	
Other	95	
Other		75
Project BioShield Fund from DHS to HHS		2,424

Table 4. NIAID extramural and intramural research budgets, 2010, 2011 and 2012 (requested)[24]

	Funding (USD millions)		
	2010	2011	2012
Extramural research			
HIV/AIDS	1,326	1,326	1,361
Biodefence and emerging infectious diseases	1,316	1,012	1,318
Infectious and immunological diseases	1,350	1,347	1,375
Intramural research	542	542	547
Research management and support	283	283	286

23 http://dhhs.gov/asfr/ob/docbudget/2011budgetinbrief.pdf

24 See http://www.niaid.nih.gov/about/whoWeAre/budget/Documents/fy2012cj.pdf

Table 5. DoD Chemical and Biological Defense Program (CBDP) funding, 2001–2012 (requested)

Budget category	Funding (USD millions)											
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
CBDP funding in the RTD&E budget	405	595	638	703	715	1,048	983	1,051	1,081	1,223	1,206	1,272
CBDP funding in the Procurement budget	470	512	658	545	707	713	522	519	456	356	350	254
Total	**875**	**1,107**	**1,296**	**1,248**	**1,422**	**1,761**	**1,505**	**1,570**	**1,537**	**1,578**	**1,555**	**1,526**

Notes:

CBDP stands for Chemical and Biological Weapons Defense Program.
RTD&E stands for Research, Development Test & Evaluation.

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 2012 (requested) is presented in Table 5.[25]

The CBDP programme was well funded prior to 2002,[26] in contrast to the HHS budget which increased substantially in 2002.

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 194-page detailed budget,[27] including transportable decontamination systems, general purpose masks, and protective clothing technology, shelters, and field hospitals, pertain to biological and chemical defence. Given that the DoD budget does not separate them, the *BioWeapons Monitor 2011* cannot estimate how much of the USD 1.526 billion for 2012 (requested funding) is for biodefence and how much is for chemical defence.

25 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 Procurement, respectively: http://comptroller.defense.gov/defbudget/fy2008/fy2008_r1.pdf

26 'Department of Defense Budget Fiscal Year 2001: RDT&E PROGRAMS (R-1)' (February 2000), http://comptroller.defense.gov/defbudget/fy2001/fy2001_r1.pdf

27 See http://comptroller.defense.gov/defbudget/fy2010/budget_justification/pdfs/02_Procurement/Vol_4_CBDP/CBDP_PDW_PB10.pdf

Table 6. Chemical and biological DoD funding

	Funding (USD millions)		
	2010	2011 (est.)	2012 (req.)
Chemical and Biological Weapons Defence Program			
Basic research CBW defence	64	49	53
Applied research CBW defence	233	169	220
RDT&E management support, CBW defence	113	121	93
RDT&E management support, SBIR grants	15	0	0
Operational systems development, CBW defence	6	7	16
Advanced technology development, CBW defence	305	177	229
Advanced component development and prototypes, CBW defence	248	277	261
System development and demonstration, CBW defence	238	406	401
Procurement installation force protection system cost	67	86	16
Procurement individual protection system cost	98	71	71
Procurement pecontamination system cost	29	20	7
Procurement joint bio defence programme – medical system cost	13	18	11
Procurement collective protection system cost	33	26	9
Procurement contamination avoidance system cost	117	129	140
Subtotal	1,578	1,555	1,526
Other (Army, Navy, DARPA, DTRA)			
SD&D medical materiel and defence equipment (Army)	38	38	27
Applied research biological warfare defence (DARPA)	41	33	30
Applied research materials and biological technology (DARPA)	256	312	238
Applied research WMD defeat technologies (DTRA)	219	212	197
SD&D WMD defeat technologies (DTRA)	9	7	6
ACD&P counterdrug RDT&E projects (Navy)	15	0	0
Procurement of support equipment CBRN soldier protection (Army)	180	156	12
Subtotal	758	758	510
Total	**2,336**	**2,313**	**2,037**

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.

Table 7. DHS biodefence programme funding in 2012 (requested)

DHS division/Programme	Funding (USD millions)	
Office of Health Affairs		
BioWatch		115
BioWatch Gen-1/2	90	
BioWatch Gen-3	25	
National Biosurveillance Integration Center		7
Science and Technology Directorate		
Laboratory facilites		277
National Bio and Agro Defense Facility (NBAF) construction	150	
Infrastructure upgrades	18	
Laboratory operations	77	
*NBACC operations**	31	
Research, Development & Innovation (RD&I)		147
Viable Bioparticle Capture Project	2	
Bioagent Threat Assessment	44	
Bioagent Detection	50	
Bioagent Attack Resiliency	50	
Federal Emergency Management Agency (FEMA)		
Regional Catastrophic Event Planning**		9
Total		**554**

Notes:

* NBACC stands for National Biodefense Analysis and Countermeasures Center.

** The focus is on plans for responding to biological events and earthquakes.

Department of Homeland Security funding

Biodefence programmes and funding requests are located in several DHS budget documents.[28] 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.

28 See http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012-overview.pdf, http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012.pdf and http://www.dhs.gov/ynews/testimony/testimony_1301519363336.shtm

Table 8. Summary of requested biodefence funding for 2012 for the HHS, DoD and DHS

Agency/programme	FY 2012 (USD millions)
HHS	
Centers for Disease Control and Prevention	775
National Institutes of Health (includes NIAID)	1,749
Food and Drug Administration	292
Assistant Secretary for Preparedness and Response	1,054
Other	75
DoD	
Chemical and Biological Weapons Defense Program	1,526
Other (Army, Navy, DARPA, and DTRA)	510
DHS	
Office of Health Affairs	115
Science and Technology Directorate	424
Federal Emergency Management Agency	9
Total	**6,529**

Of particular interest is the Science and Technology Directorate. Its total requested funding for 2012 is USD 1.18 billion (data not shown).[29] Almost half, USD 424 million (USD 277 + USD 147 million), is targeted at biodefence activities. Most biodefence funding is to be found in two programme areas: Laboratory facilities; and Research, Development & Innovation.

A summary of requested biodefence funding for 2012 for the HHS, DoD and DHS is provided in Table 8. Total requested funding of USD 6.5 billion is comparable to funding for 2011 in the UPMC study (see Table 2), 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 budget).

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 biological weapons.

29 See http://www.dhs.gov/ynews/testimony/testimony_1301519363336.shtm

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 biological weapons 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 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 . . .[30]

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 agents, advanced information technologies, medical biological defense research.[31]

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 biosurveillance system designed to detect the intentional release of aerosolized biological

30 See http://www.niaid.nih.gov/about/whoWeAre/budget/Documents/fy2012cj.pdf, p. 18.

31 See http://comptroller.defense.gov/defbudget/fy2011/budget_justification/pdfs/03_RDT_and_E/CBDP_RDT_E_PB11.pdf, p. 2.

agents in more than 30 cities'.[32] Gen-1/2 and Gen-3 describe the different generations of the system.

- The National Bio and Agro Defense Facility (NBAF) 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'.[33] 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'.[34] 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'[35]; 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'.[36]

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[37] 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 *Politics and the Life Sciences* journal, three arms control experts noted that, '[t]aken together, many of the activities . . . may constitute development (of bioweapons) in the guise of threat assessment, and they certainly will be interpreted that way'.[38] Development of biological weapons 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'.[39]

32 See http://www.dhs.gov/xlibrary/assets/budget-bib-fy2012-overview.pdf, p. 8.

33 *Ibid.*, p. 9.

34 See http://www.dhs.gov/files/labs/gc_1166211221830.shtm

35 *Ibid.*

36 *Ibid.*

37 Presentation by George Korch, 'Leading Edge of Biodefense — The National Biodefense Analysis and Countermeasures Center', Department of Defense Pest Management Workshop, February 2004.

38 Leitenberg, M., J. Leonard and R. Spertzel (2004) 'Biodefense crossing the line', *Politics and the Life Sciences,* Vol. 22, No. 2, p. 2.

39 See http://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-041-01-compliance-with-and-implementation-of-arms-control-agreements.pdf

As noted by the US Congressional Research Service, concern has not vanished:

> 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 inter-agency 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.[40]

Commercial sector biodefence activities

Fifty-seven biodefence biotechnology companies are listed on the Biodefense Stocks Directory website,[41] 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 biological weapon agents as well.

There are a number of companies with developed countermeasures that have been contracted by the Biomedical Advanced Research and Development Authority (BARDA) to supply the Strategic National Stockpile (SNS). The SNS warehouses countermeasures at multiple locations in the US, so they can be delivered quickly to victims of a biological weapon 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 (BSL-3)

The NIAID offers the following description of the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs):

> 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.[42]

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);

40 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.

41 See http://www.investorideas.com/BDS/Stock_List.asp

42 See http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx

Table 9. Biological weapon agents contracted for the Strategic National Stockpile[43]

Biodefence 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)	28,750	691
Human Genome Sciences	Raxibacumab (Abthrax)	Humanized Mab (*B. anthracis* infection — anthrax)	65	326
Cangene Corporation*	Anthrax Immune Globulin (AIG)	Passive immunization (*B. anthracis* infection — anthrax)	10	144
Cangene Corporation*	Botulism Antitoxin Heptavalent	Polyclonal antibody (botulinum toxin poisoning)	200	414
Bavarian Nordic**	IMVAMUNE®, MVA vaccine	Vaccine (Variola virus — smallpox)	10,000 or 20,000***	505
SIGA Technologies	ST-246	Oral proteinase inhibitor antiviral (Variola virus — smallpox)	1,700****	500

Notes:

* Cangene is a Canadian Company

** Bavarian Nordic is headquarted in Denmark, with a non-biodefence US facility in California

*** Two sources for the data report different doses (10 million vs. 20 million) for the smallpox vaccine

**** The number indicates treatment courses — each course consists of 14 daily doses.

- 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);
- 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);

43 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; 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

Table 10. US government biodefence facilities of special interest

Facility name	Location	Research laboratories (sqm.)	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 sqm. (BSL-2, -3)	A, B, other	Y	Y
Plum Island Animal Disease Center	Greenport, NY	17,643 sqm. (BSL-3)	No data available	No data available	No data available
Battelle Biomedical Research Center	West Jefferson, OH	8,032 sqm. (BSL-2, -3)	A, B, other	Y	N
US Army Medical Research Institute of Infectious Diseases	Fort Detrick, Frederick, MD	30,258 sqm. (BSL-2, -3, -4)	A, B, other	Y	N
Centers for Disease Control and Prevention, Office of Infectious Diseases	Atlanta, GA	3,458 sqm. (BSL-2, -3, -4)	A, B, other	N	N
Centers for Disease Control and Prevention, Division of Vector Borne Diseases	Fort Collins, CO	1,208 sqm. (BSL-2, -3)	A, B, other	N	N
Lawrence Livermore National Laboratory	Livermore, CA	1,321 m2 (BSL-2, -3)	A, B, other	Y	N

- 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).[44]

Size information is not readily available. Additional information is available on the NIAID website.[45]

Government biodefence laboratories/ facilities of special interest

In testimony to the US Congress, the General Accountability Office reported in 2007 that 1,356 BSL-3 labs in the US have registered under the Select Agent Regulations.[46] CDC (Centers for Disease Control and Prevention) and NIH represent-

44 See http://mrce.wustl.edu/index.php?page=resources&category=5

45 See http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx

46 '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 the Congressional hearing on 'Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States', *op. cit*.

atives testifying at the congressional hearing were unable to tell Congress what the labs were researching. All that the *BioWeapons Monitor 2011* 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 10. They are identified and described in some detail in the 'United States of America Confidence Building Measure Return covering 2010'[47] (hereafter called USA CBM 2011) 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.[48]

Agents studied include Category A and B biological weapon agents. The rural location of and outdoor aerosol experimentation at the Dugway facility are particularly noteworthy in the context of the *BioWeapons Monitor 2011*.

Plum Island Animal Disease Center (PIADC)

The PIADC in Greenport, New York, is a DHS-administered facility that researches animal diseases. It has three enhanced BSL-3 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.

> 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.[49]

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.

47 See http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/74ABF17BE7D317C6C1257893005657A6/$file/BWC_CBM_2011_United+States.pdf

48 *Ibid.*, pp. 74–76.

49 *Ibid.*

> Foot-and-mouth disease is an 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.[50]

The PIADC will be shut down and replaced by a BSL-3/BSL-4 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.[51]

Battelle Biomedical Research Center

The Battelle Biomedical Research Center in West Jefferson, Ohio, conducts experiments using its aerosol capabilities and BSL-3 containment facility. Battelle does not perform outdoor experiments.

Its research objective is to test and evaluate medical countermeasures against biological threats/terrorism agents,[52] which requires infecting animals with pathogens. According to its list of 2010 publications,[53] 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'.[54] Battelle also conducts aerosol experiments with Category A and B bacterial biological weapon 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 Fredrick, Maryland, is the leading military biodefence research institution. It has a number of BSL-4 (1,093 square metres) and BSL-3 (3,139 square metres) laboratories[55] for internal use and is constructing a new laboratory with a BSL-4 capability[56] 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.[57]

50 See http://www.ars.usda.gov/AboutUs/AboutUs.htm?modecode=19-40-00-00

51 See 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

52 USA CBM 2011, p. 73.

53 *Ibid.*, pp. 71–73.

54 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., p. 71.

55 USA CBM 2011, p. 109.

56 See http://gsn.nti.org/siteservices/print_friendly.php?ID=nw_20110722_1487

57 USA CBM 2011, p. 112.

The USAMRIID conducts research and countermeasure development with Category A and B biological weapon agents. It does not conduct outdoor experiments.

Centers for Disease Control and Prevention, Office of Infectious Diseases (CDC–OID)

The CDC–OID in Atlanta, Georgia, has BSL-4 (962 square metres) and BSL-3 (2,215 square metres) laboratories.[58] 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 biodefense 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. Biodefense activities include those with select agents."[59]

The CDC-OID facility is one of the two World Health Organization (WHO) 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 biodefense 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.[60]

The CDC–DVBD has BSL-3 (1,142 square metres) laboratories.[61] It does not conduct outdoor experiments.

Some Category A and B biological weapon agents are transmitted through insect vectors. Plague is transmitted by fleas and encephalitis is transmitted by mosquitoes. Although not mentioned in the USA CBM 2011, 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

58 *Ibid.*, p. 168.

59 *Ibid.*, p. 177.

60 *Ibid.*, p. 168.

61 *Ibid.*, p. 162.

are of little interest to the *BioWeapons Monitor 2011*. All are described in detail in the USA CBM 2011.

The LLNL conducts the most biodefence R&D of the four, but has minimal BSL-3 space (60 square metres)[62].

> 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.[63]

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.[64]

There are a few dozen lower-profile facilities fully described in the USA CBM 2011 that have biodefence activities. Some have only BSL-1 and BSL-2 biocontainment laboratories. For the most part, these facilities carry out research that is of little interest to the *BioWeapons Monitor 2011*—refer to the USA CBM 2011 for details.

Maximum and high biological containment laboratories

There are seven operational and four planned or under construction Biosafety Level 4 (BSL-4) laboratories in the US.[65] 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.[66] Table 11 lists the operational

62 *Ibid.*, p. 124.

63 *Ibid.*, p. 137.

64 See http://www.trivalleycares.org/comments/BWCstatementTVC.pdf

65 See http://www.fas.org/programs/bio/research.html and http://www.upmc-biosecurity.org/website/resources/publications/2007/2007-04-04-highcontainmentbioresearchlabtable1.html

66 '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 11. Operational BSL-4 laboratories in the US[67]

Institution	Location	Name of facility	Size of BSL-4 laboratories	Financing sources
Georgia State University	Atlanta, GA	Viral Immunology Center, National B Virus Resource Laboratory	60 sqm.	DoD, NIH, Georgia Research Alliance
Southwest Foundation for Biomedical Research	San Antonio, TX	Texas Biomedical Research Institute	114 sqm.	DoD, NIH, DHS, private companies and donors
US Army Medical Research Institute of Infectious Diseases	Fort Detrick, Frederick, MD	U.S. Army Medical Research and Materiel Command	1,093 sqm.	DHS
Centers for Disease Control and Prevention	Atlanta, GA	Office of Infectious Diseases (OID)	198 sqm., 221 sqm., four labs each 135 sqm.	DHS, HHS, EPA, other governmental agencies
Rocky Mountain Laboratories, Integrated Research Facility	Hamilton, MT	NIH, Integrated Research Facility (IRF), Rocky Mountain Laboratories (RML)	631 sqm.	HHS (NIAID)
The University of Texas, Medical Branch	Galveston, TX	Galveston National Laboratory (GNL)	186 sqm., 1,022 sqm.	NIH, DHS, DoD, DoE, USDA, universities, pharmaceutical industry, private foundations
Virginia Division of Consolidated Laboratory Services	Richmond, VA	Biotech Six	Information not available	CDC, USDA, EPA, others

Table 12. Planned or under construction BSL-4 laboratories in the US[68]

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
Department of Homeland Security	Fort Detrick, Frederick, MD	National Biodefense Analysis and Countermeasures Center

67 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://txbiomed.org/About/resources_3.aspx; and http://www2.gsu.edu/~wwwvir/Research/Index.html

68 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.

BSL-4 laboratories, along with descriptive information, and Table 12 lists the planned or under construction BSL-4 laboratories.

Vaccine production facilities

Human vaccines

The USA CBM 2011 itemises vaccine production facilities for human diseases only.[69] 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'.[70] The USA CBM 2011 does not itemise veterinary vaccine production facilities, but instead refers to the DoA document on veterinary vaccine and biological manufacturers.[71] 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 biological weapons viewpoint, the production facilities are the ones of interest. Correctly, the USA CBM 2011 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, the size of the facility by either area or number of employees, and other information.

The USA CBM 2011 lists MedImmune's FluMist® vaccine, which is produced in Speke in the United Kingdom. It is blended and packaged in the US (Philadelphia, PA),[72] so it should not be listed in the Return.

For one CBM-declared production facility, Organon Teknika, information is confusing. It appears not to have a website; and according to one business website,[73] it is a subsidiary of Schering-Plough and has very few employees. On another business website,[74] it is listed as a subsidiary of Merck. Is it really a vaccine production facility?

Two new large facilities dedicated to influenza vaccine are listed at the bottom of Table 13. The Novartis facility will produce vaccines whereas the GlaxoSimthKline 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 number of US vaccine production facilities is expected to increase over the next several years.

69 USA CBM 2011, pp. 275–284.

70 See http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

71 US Department of Agriculture (2011) *Veterinary Biological Products: Licensees and Permittees,* http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf, pp. 23–48.

72 See http://www.medimmune.com/about_us_facilities.aspx

73 See http://www.manta.com/c/mmjs6yr/organon-teknika-corp

74 See http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=116535033

Table 13. Human vaccine production facilities in the US

Facility (location)	Website	Size (area or employees)	Biodefence vaccines (Y or N)	Example vaccine targets
From USA CBM 2011 submission				
Emergent BioDefense Operations (Lansing, MI)	http://www.emergentbiosolutions.com/	214,000 square feet	Y	Anthrax
MassBiologics (Boston, MA)	http://www.umassmed.edu/massbiolabs/index.aspx	Not readily available	N	Diphtheria, tetanus
MedImmune (Vaccine manufacturing in Speke, UK, packaging in Philadelphia, PA)	http://medimmune.com/	Not readily available	N	Influenza
Merck & Co. (Vaccines and drugs, West Point, PA (70% of vaccine manufacturing will move to new facility in Durham, NC, which opens in 2011)	http://www.merck.com/index.html	8,500 employees (West Point), 272,000 square feet (Durham)	N	Cervical cancer, hepititis, measles, mumps
Organon Teknika Corporation (Durham, NC)	No website	10–19 employees	N	Tuberculosis
Sanofi Pasteur Biologics/Acambis (Cambridge, MA)	http://www.sanofipasteur.us/sanofi-pasteur2/front/ index.jsp?codeRubrique=73&siteCode=SP_US	100–250 employees	Y	Smallpox
Sanofi Pasteur (Swiftwater, PA)	http://www.sanofipasteur.us	3,200 employees	N	Diphtheria, influenza, tetanus, yellow fever
Wyeth Pharmaceuticals (now Pfizer) (New York, NY – main office)	http://www.pfizer.com/welcome/	115,000–345,000 square feet	N	Streptococcus pneumoniae
From CDC and FDA list of vaccines				
GlaxoSmithKline (Marietta, PA, influenza vaccine) (now only packaging and filling)	http://www.gsk.com/products/vaccines/index.htm	656,000 square feet	N	Influenza
Novartis Vaccines and Diagnostics (Holly Springs, NC)	http://www.novartis.com/products/vaccines.shtml	300,000 square feet (operational 2013)	N	Influenza, meningitis, rabies

Veterinary vaccines

In the DoA document on veterinary vaccine and biological manufacturers,[75] the table listing veterinary vaccines takes up 26 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 animal or human biological weapons.

To illustrate the biological weapons potential, Table 14 lists companies and other organisations that produce vaccines and biologics for Category A & B biological weapon agents for animal health purposes. The producers are listed by their DoA license number to identify them concisely. In Table 15, the license number is correlated with the companies and their location.

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.[76]

With the development of a new smallpox vaccine and an effective antiviral,[77] calls for the destruction of these two remaining smallpox stocks intensified in 2011. 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.[78]

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.[79]

75 US Department of Agriculture (2011) *Veterinary Biological Products: Licensees and Permittees, op. cit.*

76 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

77 See http://www.gazettetimes.com/news/local/article_3bae4488-a120-11e0-8793-001cc4c03286.html

78 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

79 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 biological weapon agents and other pathogens of interest

License number of producer	Vaccine target/ biological product	Type of vaccine	Type of agent
Category A and B biological weapon agents			
188	*Bacillus anthracis*	Live culture	Category A biological weapons agent
188	*Brucella abortus*	Live culture	Category B biological weapons agent
112, 188, 597	Eastern, Western and Venezuelan encephalomyelitis	Killed virus	Category B biological weapons agent
165A, 245	*Clostridium botulinum* poisoning	Botulinum type C bacterin-toxoid	Category A toxin
165A,112 ,124	*Chlamydia psittaci*	Modified live and killed virus	Category B biological weapons agent
124, 165A, 303, 337, 189, 196, 368	*Salmonella sp.*	Avirulent live and live culture	Category B biological weapons agent
455	*Brucella suis* Bacterin	n/a	Category B biological weapons agent
Other pathogens of interest			
368, 196, 112, 189, 279	Avian influenza (14 HxNy subtypes, no H5N1)	Killed virus	Strains of H5N1 deadly in humans
165A, 189, 303	Swine influenza (H1N1, H1N2, H3N2 subtypes)	Killed virus	Strains of H1N1 and H3N2 infect humans
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
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 discoveries in molecular biology have dual-use potential, and there may be dozens of experiments under way in the US and elsewhere that are of concern as identified in the Fink Report.[80] 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.

About six years ago, the 1918 flu virus was reconstructed from old pathology samples from victims and resurrected tissue from victims' graves. Pathogenicity experiments with the live reconstructed virus then began.[81] A 2009 publication reviews the animal pathogenicity experiments conducted with the live 1918 flu virus in Canada and the US.[82] 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,[83] and the NIAID.[84]

Experiments with viruses that increase their pathogenicity are included in the Fink Report 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.[85] In another experiment at Kawaoka's laboratory,[86] all possible reassortments between avian H5N1 and human H3N2 influenza viruses were made and tested in mice. Some highly pathogenic reassortments were found.

Disease outbreak data

The USA CBM 2011 lists reportable diseases,[87] which make up a much longer list than unusual disease

80 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

81 Tumpey, T.M. 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.

82 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.

83 See http://vir.sgmjournals.org/content/91/2/339.full

84 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.

85 Devitt, T. (2004) 'Gene From 1918 Virus Proves Key To Virulent Influenza', 6 October, http://www.wisconline.com/feature/flu.html

86 Li, C. 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.

87 USA CBM 2011, pp. 228–235.

outbreaks. The CBM list reports but does not highlight two Category A biological weapon agent outbreaks in 2010. There were 101 cases of botulinum toxin poisoning, which is not unusual for a single year. There was one victim of Lassa fever, a Category A biological weapons agent. Only one Lassa infection in the US is unusual, as the geographic area is limited to four West African countries.[88] The victim was a 'US traveler who visited rural Liberia, became ill while in country, sought medical care upon return to the United States, and subsequently had his illness laboratory confirmed. The patient recovered with supportive therapy. No secondary cases occurred'.[89]

National legislation and regulations

The 'Patriot Act' of 2001[90] was enacted to 'intercept and obstruct terrorism'. It contains one section, Section 817, that is relevant to the *BioWeapons Monitor 2011*:

> 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 prophylactic, protective, *bona fide* research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both.[91]

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',[92] 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'.[93] The Office of Inspector General can levy civil or criminal penalties for a violation of the Select Agent Regulations. Category A and B biological weapon agents[94] are among the pathogens on the list.

The Select Agent list was revised in 2008[95]—recommendations issued in 2011 by the Federal Experts Security Advisory Panel propose radical alterations

88 See http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/lassaf.htm

89 Amorosa, V. et al. (2010) 'Imported Lassa Fever, Pennsylvania, USA, 2010', *Emerging Infectious Diseases,* Vol. 16, No. 10, http://www.cdc.gov/eid/content/16/10/1598.htm

90 See http://www.gpo.gov/fdsys/pkg/PLAW-107publ56/pdf/PLAW-107publ56.pdf

91 *Ibid.* SEC. 817: Expansion of the Biological Weapons Statute.

92 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

93 *Ibid.*, p. 13297.

94 See http://www.bt.cdc.gov/agent/agentlist-category.asp

95 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

to the list.[96] The revised list identifies 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':[97]

> 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 . . .* [98]

Botulinum toxin and/or toxin-producing strains of *Clostridium botulinum* were added later to the list.

It is noteworthy that one Category A biological weapons 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 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[99] describes other legislation and regulations:

> **Export Administration Regulations — Regulation Change**
>
> A regulation change was published in the March 23, 2010 Federal Register . . . to amend the Export Administration Regulations by removing 'white pox' virus . . . from the Commerce Control List of biological agents . . .
>
> **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 . . .

96 Federal Experts Security Advisory Panel (2010) ' Recommendations 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

97 *Ibid.*, p. 3.

98 *Ibid.*

99 USA CBM 2011, pp. 266–272.

> 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 . . .
>
> **Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus**
>
> . . . The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS [Health and Human Services] Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety . . . Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus . . .[100]

Nine additional measures are reported in this section of the USA CBM 2011 that were either adopted or are near adoption. These are less relevant to the *BioWeapons Monitor 2011,* or are discussed elsewhere in this report.

(Bio)chemical non-lethal weapons

There was considerable discussion within the US military a decade ago about non-lethal chemical and biochemical weapons—also called calmatives or less-than-lethal weapons. Today, there is no mention of chemical, biochemical, or biological weapons on the DoD's Central Resource for Information on Non-Lethal Weapons.[101] The non-lethal weapons programme is called the Joint Non-Lethal Weapons Program (JNLWP).

Regarding current capabilities, the DoD describes only 'physical' non-lethal weapons such as acoustic devices.[102]

Of the nine non-lethal weapon development projects, none are chemical, biochemical, or biological weapons. Only one, the FN-303 Less Lethal Launching System, could perhaps be employed as a launch vehicle for chemical, biochemical, or biological non-lethal weapons.[103]

Furthermore, none of the four listed desired future capabilities[104] are chemical, biochemical, or biological non-lethal weapons.

In 1997, Penn State University established The Institute for Non-Lethal Defense Technologies (INLDT).[105]

100 *Ibid.*

101 See http://jnlwp.defense.gov/

102 See http://jnlwp.defense.gov/current.html

103 See http://jnlwp.defense.gov/developing_capabilities/default.html

104 See http://jnlwp.defense.gov/future_capabilities/default.html

105 See http://nldt2.arl.psu.edu/

In its early years, it had a major focus on chemical, biochemical, and biological (bioregulator) non-lethal weapons. In a 2000 INLDT report entitled *The Advantages and Limitations of Calmatives for Use as a Non-lethal Technique,*[106] the authors identify some three dozen specific chemical or biological compounds that might be employed as calmatives.[107]

The Institute's present-day website contains no references to chemical, biochemical, or biological non-lethal weapons. Since it works with the police,[108] who may utilise non-lethal calmatives in some circumstances that do not contravene the 1997 Chemical Weapons Convention, it is perhaps surprising that there is no mention of calmatives R&D.

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.[109]

106 Lakoski, J.M., W.B. Murray and J.M. Kenny (2000) *The Advantages and Limitations of Calmatives for Use as a Non-lethal Technique,* College of Medicine, Penn State University, Hershey, PA, http://nldt2.arl.psu.edu/documents/calamative_report.pdf

107 *Ibid.,* pp. 15–16.

108 See, for example, http://nldt2.arl.psu.edu/documents/2008_ILEF_Report_FINAL.pdf

109 National Security Council (2009) *National Strategy for Countering Biological Threats,* http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf, p. 8.

An internet search did not find evidence of implementation of any of these ideas by the government. In particular, there appear to be no US government agencies that have programmes dealing explicitly with hostile exploitation of life sciences, such as the development of offensive biological weapons. There are, however, a number of agencies that deal with research misconduct, whistle-blowing, and bioethics.[110] Hostile exploitation would fall under misconduct.

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,[111] whereas the CACNP offering[112] 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 biological weapons:[113]

> 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."[114]

The Organization does not provide any materials, though, for training or awareness-raising.

No material relevant to the *BioWeapons Monitor 2011* 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'.[115]

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 States Parties.[116] In 2011, the US submitted a public version of its CBM declaration and placed an additional 18 pages on the restricted CBM website.[117]

110 See http://ori.hhs.gov; See 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

111 See http://www.fas.org/biosecurity/education/dualuse/index.html

112 See http://www.politicsandthelifesciences.org/Biosecurity_course_folder/base.html

113 See http://bio.org/content/bio-statement-ethical-principles

114 See http://bio.org/content/bio-statement-ethical-principles?page=3

115 See http://www.phrma.org/

116 See http://www.biological-arms-control.org/publications/CBM-Reader2010-finalannex.pdf

117 Telephone interview by Iris Hunger with a governmental representative, August 2011.

Table 16. Number of US 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
Number of delegates	14	10	12	12	15	14	12	17	16	8

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

Participation in BWC meetings

The US participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, the US has taken part in all relevant meetings (see Table 16).

Past biological weapons activities and accusations

The past offensive biological weapons programme of the US is well documented.[118] It was dismantled in 1969 following the US decision to abandon offensive biological weapons.

Accusations of US biological weapons use or BWC violations

The listings here of accusations of US biological weapons 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 biological weapons use and offensive biological weapons research, some of which have proven to be false and some of which have been 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.[119]

A 1997 paper describes Soviet allegations of US offensive biological weapons research and use in the 1970s and 1980s.[120] 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;

118 Christopher, G.W. 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

119 *Ibid.* The quote was made in reference to the history of biological warfare, but is equally applicable to accusations of bioweapons use.

120 Leitenberg. M. (1997) 'Biological Weapons, International Sanctions and Proliferation', *Asian Perspective,* Vol. 21, No. 3, pp. 22-31.

- the US used biological weapons during the Korean War of 1950–53.[121] These allegations had been dismissed years before; and
- 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:[122]

- [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 biological weapon attacks against people, animals and crops, including a 1981 outbreak of dengue fever that sickened more than 300,000.[123] None of the allegations were ever proved, and the disease episodes probably were due to natural causes.

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.[124] 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.[125]

The two allegations of US BWC violations from 1998 to the present summarised below were gleaned from a secondary source: *The CBW Conventions Bulletin.*[126]

- In 2008, Indonesian Minister of Health, Siti Fadilah Supari, alleged that the US and the WHO had conspired against developing countries by seizing

121 'New Evidence on the Korean War', *Cold War International History Project Bulletin,* No. 11, pp. 176–199; Leitenberg, M. (forthcoming) 'False Allegations of U.S. Biological Weapons Use during the Korean War', in A.L. Clunan et al. (eds.) *Terrorism, War, or Disease? Unraveling the Use of Biological Weapons,* Stanford University Press, Palo Alto, CA, Chapter 6); Leitenberg, M. (2000) 'The Korean War Biological Weapons Allegations: Additional Information and Disclosures', *Asian Perspective,* Vol. 24, No. 3, pp. 159–172.

122 *Ibid.* Also see http://www.fas.org/bwc/papers/review/under.htm

123 Zilinskas, R. (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 Leitenberg, M. (1997) 'Biological Weapons, International Sanctions and Proliferation', *op. cit.*

124 See http://entomology.ifas.ufl.edu/creatures/veg/melon_thrips.htm

125 See http://www.globalsecurity.org/wmd/world/cuba/bw.htm

126 See http://www.sussex.ac.uk/Units/spru/hsp/pdfbulletin.html

control of samples of the H5N1 bird flu virus, in order to use the material for vaccines or biological weapons development.[127]

- In 2001, Iranian parliamentary deputies accused the US of being the producer of the world's most dangerous biological weapons.[128]

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:[129]

- **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.[130]
- **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 produced a benign, simulated biological weapons 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.

127 See http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb80.pdf, p. 24.

128 See http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb53.pdf, p. 50.

129 Crowley, M. (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

130 *Ibid.,* p. 50 and Scherer, M. (2004) 'The Next Worst Thing', March/April, http://motherjones.com/politics/2004/03/next-worst-thing

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.[131] ■

131 Drogin, B. (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

Annex: ranking of states in terms of their biotechnological capabilities

When discussing arms control and non-proliferation efforts in the biological weapons area, a key question relates to the biotechnological capabilities of countries. This data is vital in assessing which states possess the capability (although not necessarily the will) to develop biological weapons. The problem is, however, that no widely accepted global ranking of the biotechnological capabilities of states exists. While abundant data are available on biotechnology research, development and production capabilities in individual countries, global comparative overviews based on a common methodology are extremely rare. One effort to develop such a ranking system was published in 2005.[1] The *BioWeapons Monitor* has used the methodology suggested in that publication and updated the ranking.

The original survey used three criteria to judge the biotechnological capability of a state:

- the number of relevant publications for that state in the online database PubMed;
- the number of relevant patents for that state in the online database EspaceNet; and
- the number of biotechnology companies in that state as stipulated in Ernst & Young's *Global Biotechnology* reports.

For the updated ranking below, the terms of the PubMed search were: Country [Affiliation] AND (biotechnol* OR ferment* OR vaccine*); publication date 1 January 2006 to 31 December 2010. The search was conducted on 14 April 2011. The terms for the EspaceNet search were: IPC = C12; priority number = two-digit country code; EspaceNet does not allow a date restriction. The search also was conducted on 14 April 2011. The third criterion, number of biotechnology companies, could not be applied as Ernst & Young's *Global Biotechnology* reports no longer provide comprehensive data on the number of companies in individual countries.

Detailed information on the justification for the criteria selected, on how the searches were conducted, and on the limitations and shortcomings of the methodology are available in the original 2005 publication. ■

1 See http://www.biological-arms-control.org/publications/hunger_CBM.pdf, pp. 46–51.

2011 ranking	2005 ranking	Ranking change	Country	2005 rank in sub-region	2011 rank in sub-region	Hits in PubMed	PubMed ranking	Hits in Espacenet	Espacenet ranking	Combined ranking (1+2)/2 (or 1)
1	1	0	US	N. America 1	N. America 1	22,829	1	>100,000	1	1
2	5	3	Japan	E. Asia 1	E. Asia 1	6030	4	>100,000	1	2.5
3	3	0	UK	N. Europe 1	N. Europe 1	14,349	2	70,094	4	3
4	6	2	China	E. Asia 2	E. Asia 2	11,228	3	54,158	5	4
5	2	-3	Germany	W. Europe 1	W. Europe 1	4,699	7	77,281	3	5
6	11	5	Rep. of Korea	E. Asia 3	E. Asia 3	5,640	5	21,559	7	6
7	4	-3	France	W. Europe 2	W. Europe 2	2908	9	43,152	6	7.5
8	8	0	Australia	Australia/NZ 1	Australia/NZ 1	2,742	10	17,952	8	9
9	9	0	Italy	S. Europe 1	S. Europe 1	3,792	8	9,708	12	10
10	7	-3	Canada	N. America 2	N. America 2	2,440	11	7,538	14	12.5
11	17	6	Spain	S. Europe 2	S. Europe 2	2,393	12	5,014	15	13.5
12	9	-3	Sweden	N. Europe 2	N. Europe 2	1,270	17	9,841	11	14
13	13	0	Denmark	N. Europe 3	N. Europe 3	1,078	20	14,703	9	14.5
13	18	5	India	S. Asia 1	S. Asia 1	5,068	6	1,950	23	14.5
15	13	-2	Netherlands	W. Europe 4	W. Europe 3	2,021	14	4,435	18	16
16	12	-4	Switzerland	W. Europe 3	W. Europe 4	1,027	22	7,920	13	17.5
16	15	-1	Israel	W. Asia 1	W. Asia 1	1,105	18	4,486	17	17.5
18	19	1	Finland	N. Europe 4	N. Europe 4	1,104	19	4,102	19	19
19	21	2	Austria	W. Europe 6	W. Europe 5	904	23	4,501	16	19.5
20	22	2	Brazil	S. America 1	S. America 1	1,434	16	1,850	24	20
21	20	-1	Belgium	W. Europe 5	W. Europe 6	1,454	15	1,328	26	20.5
22	25	3	China (Taiwan)	E. Asia 4	E. Asia 4	2,161	13	1,012	31	22
23	23	0	Poland	E. Europe 2	E. Europe 1	1,068	21	1,635	25	23
24	51	27	Iran	S. Asia 2	S. Asia 2	786	24	Not available		24
25	16	-9	Russia	E. Europe 1	E. Europe 2	262	41	13,770	10	25.5
26	40	14	Thailand	SE. Asia 2	SE. Asia 1	741	26	Not available		26
27	24	-3	Ireland	N. Europe 5	N. Europe 5	526	31	2,059	22	26.5
28	28	0	South Africa	S. Africa 1	S. Africa 1	678	28	1,323	27	27.5
29	26	-3	Hungary	E. Europe 3	E. Europe 3	317	38	2,662	20	29
30	27	-3	Norway	N. Europe 6	N. Europe 6	574	30	1,046	29	29.5

2011 ranking	2005 ranking	Ranking change	Country	2005 rank in sub-region	2011 rank in sub-region	Hits in PubMed	PubMed ranking	Hits in Espacenet	Espacenet ranking	Combined ranking (1+2)/2 (or 1)
31	29	-2	New Zealand	Australia/NZ 2	Australia/NZ 2	308	39	2,299	21	30
32	35	3	Portugal	S. Europe 4	S. Europe 3	680	27	412	37	32
33	30	-3	Mexico	C. America 1	C. America 1	606	29	454	36	32.5
33	31	-2	Greece	S. Europe 3	S. Europe 4	748	25	250	40	32.5
35	48	13	Columbia	S. America 4	S. America 2	476	33	Not available		33
36	34	-2	Argentina	S. America 2	S. America 3	445	34	523	35	34.5
37	54	17	Tunisia	N. Africa 2	N. Africa 1	403	35	Not available		35
38	33	-5	Cuba	Carribean 1	Carribean 1	303	40	966	32	36
39	38	-1	Singapore	SE. Asia 1	SE. Asia 2	325	36	340	38	37
40	31	-9	Czech Rep.	E. Europe 4	E. Europe 4	249	43	867	33	38
41	36	-5	Turkey	W. Asia 2	W. Asia 2	523	32	68	47	39.5
42	41	-1	Bulgaria	E. Europe 5	E. Europe 5	79	51	1,023	30	40.5
42	42	0	Malaysia	SE. Asia 3	SE. Asia 3	321	37	165	44	40.5
44	44	0	Ukraine	E. Europe 6	E. Europe 6	52	54	1,277	28	41
45	58	13	Pakistan	S. Asia 3	S. Asia 3	258	42	Not available		42
46	43	-3	Slovenia	S. Europe 5	S. Europe 5	135	46	284	39	42.5
47	45	-2	Chile	S. America 3	S. America 4	200	45	204	41	43
48	52	4	Romania	E. Europe 8	E. Europe 7	36	57	655	34	45.5
49	37	-12	Lithuania	N. Europe 7	N. Europe 7	92	50	185	42	46
49	38	-11	Egypt	N. Africa 1	N. Africa 2	235	44	67	48	46
51	54	3	Kenya	E. Africa 1	E. Africa 1	132	47	Not available		47
52	48	-3	Nigeria	W. Africa 1	W. Africa 1	119	48	Not available		48
53	46	-6	Croatia	S. Europe 6	S. Europe 6	113	49	57	49	49
54	48	-5	Philippines	SE. Asia 4	SE. Asia 4	69	53	82	46	49.5
55	46	-9	Slovakia	E. Europe 7	E. Europe 8	41	56	90	45	50.5
56	53	-3	Latvia	N. Europe 8	N. Europe 8	18	60	173	43	51.5
57	56	-1	Saudi Arabia	W. Asia 3	W. Asia 3	70	52	Not available		52
58	59	1	Indonesia	SE. Asia 5	SE. Asia 5	47	55	35	50	52.5
59	59	0	Morocco	N. Africa 3	N. Africa 3	36	57	13	51	54
60	57	-3	Venezuela	S. America 5	S. America 5	32	59	Not available		59